6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

**40 CFR Part 50**

**[EPA-HQ-OAR-2015-0072; FRL-8635-01-OAR]**

**RIN 2060-AV52**

# Reconsideration of the National Ambient Air Quality Standards for Particulate Matter

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** Based on the Environmental Protection Agency's (EPA's) reconsideration of the air quality criteria and the national ambient air quality standards (NAAQS) for particulate matter (PM), the Environmental Protection Agency (EPA) proposes to revise the primary annual $PM_{2.5}$ standard by lowering the level. The Agency proposes to retain the current primary 24-hour $PM_{2.5}$ standard and the primary 24-hour $PM_{10}$ standard. The Agency also proposes not to change the secondary 24-hour $PM_{2.5}$ standard, secondary annual $PM_{2.5}$ standard, and secondary 24-hour $PM_{10}$ standard at this time. The EPA also proposes revisions to other key aspects related to the PM NAAQS, including revisions to the Air Quality Index (AQI) and monitoring requirements for the PM NAAQS.

**DATES:** Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

*Public Hearings:* The EPA will hold a virtual public hearing on this proposed rule. This hearing

will be announced in a separate *Federal Register* notice that provides details, including specific dates, times, and contact information for these hearings.

**ADDRESSES:** You may submit comments, identified by Docket ID No. EPA-HQ-OAR-2015-0072, by any of the following means:

- Federal eRulemaking Portal: *https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- Email: *a-and-r-Docket@epa.gov*. Include the Docket ID No. EPA-HQ-OAR-2015-0072 in the subject line of the message.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center, Air and Radiation Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- Hand Delivery or Courier (by scheduled appointment only): EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m. – 4:30 p.m., Monday – Friday (except Federal Holidays).

*Instructions*: All submissions received must include the Docket ID No. for this notice. Comments received may be posted without change to *https://www.regulations.gov*, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Dr. Lars Perlmutt, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C539-04, Research Triangle Park, NC 27711; telephone: (919) 541-3037;

fax: (919) 541-5315; email: *perlmutt.lars@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**General Information**

*Preparing Comments for the EPA*

Follow the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written submission. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, the cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

When submitting comments, remember to:

- Identify the action by docket number and other identifying information (subject heading, *Federal Register* date and page number).
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- Provide specific examples to illustrate your concerns and suggest alternatives.

- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

*Availability of Information Related to this Action*

All documents in the dockets pertaining to this action are listed on the *www.regulations.gov* website. This includes documents in the docket for the proposed decision (Docket ID No. EPA-HQ-OAR-2015-0072) and a separate docket, established for the Integrated Science Assessment (ISA) (Docket ID No. EPA-HQ-ORD-2014-0859) that has been incorporated by reference into the docket for this proposed decision. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and may be viewed with prior arrangement with the EPA Docket Center. Additionally, a number of the documents that are relevant to this proposed decision are available through the EPA's website at *https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards*. These documents include the Integrated Science Assessment for Particulate Matter (U.S. EPA, 2019a), available at *https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=347534*, the Supplement to the 2019 Integrated Science Assessment for Particulate Matter (U.S. EPA, 2022a), available at *https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=354490*, and the Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (U.S. EPA, 2022b), available at *https://www.epa.gov/naaqs/particulate-matter-pm-standards-integrated-science-assessments-current-review*.

**Table of Contents**

The following topics are discussed in this preamble:

**Executive Summary**

This document presents the Administrator's proposed decisions for the reconsideration of the 2020 final decision on the primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM). More specifically this document summarizes the background and rationale for the Administrator's proposed decisions to revise the primary annual $PM_{2.5}$ standard by lowering the level from 12.0 $\mu g/m^3$ to within the range of 9.0 to 10.0 $\mu g/m^3$ while taking comment on alternative annual standard levels down to 8.0 $\mu g/m^3$ and up to 11.0 $\mu g/m^3$; to retain the current primary 24-hour $PM_{2.5}$ standard (at a level of 35 $\mu g/m^3$) while taking comment on revising the level as low as 25 $\mu g/m^3$; to retain the

primary 24-hour $PM_{10}$ standard, without revision; and, not to change the secondary PM standards at this time, while taking comment on revising the level of the secondary 24-hour $PM_{2.5}$ standard as low as 25 $\mu g/m^3$. In reaching his proposed decisions, the Administrator has considered the currently available scientific evidence in the 2019 Integrated Science Assessment (2019 ISA) and the Supplement to the 2019 ISA (ISA Supplement), quantitative and policy analyses presented in the Policy Assessment (PA), and advice from the Clean Air Scientific Advisory Committee (CASAC). The EPA solicits comment on the proposed decisions described here and on the array of issues associated with the reconsideration of these standards, including the judgments of public health, public welfare and science policy inherent in the proposed decisions, and requests commenters also provide the rationales upon which views articulated in submitted comments are based.

The EPA has established primary and secondary standards for $PM_{2.5}$, which includes particles with diameters generally less than or equal to 2.5 μm, and $PM_{10}$, which includes particles with diameters generally less than or equal to 10 μm. The standards include two primary $PM_{2.5}$ standards, an annual average standard, averaged over three years, with a level of 12.0 $\mu g/m^3$ and a 24-hour standard with a $98^{th}$ percentile form, averaged over three years, and a level of 35 $\mu g/m^3$. It also includes a primary $PM_{10}$ standard with a 24-hour averaging time, and a level of 150 $\mu g/m^3$, not to be exceeded more than once per year on average over three years. Secondary PM standards are set equal to the primary standards, except that the level of the secondary annual $PM_{2.5}$ standard is 15.0 $\mu g/m^3$.

The last review of the PM NAAQS was completed in December 2020. In that review, the EPA retained the primary and secondary NAAQS, without revision (85 FR 82684, December 18, 2020). Following publication of the 2020 final action, several parties filed petitions for review

and petitions for reconsideration of the EPA's final decision.

In June 2021, the Agency announced its decision to reconsider the 2020 PM NAAQS final action.[1] The EPA is reconsidering the December 2020 decision because the available scientific evidence and technical information indicate that the current standards may not be adequate to protect public health and welfare, as required by the Clean Air Act. The EPA noted that the 2020 PA concluded that the scientific evidence and information called into question the adequacy of the primary $PM_{2.5}$ standards and supported consideration of revising the level of the primary annual $PM_{2.5}$ standard to below the current level of 12.0 $\mu g/m^3$ while retaining the primary 24-hour $PM_{2.5}$ standard (U.S. EPA, 2020a). The EPA also noted that the 2020 PA concluded that the available scientific evidence and information did not call into question the adequacy of the primary $PM_{10}$ or secondary PM standards and supported consideration of retaining the primary $PM_{10}$ standard and secondary PM standards without revision (U.S. EPA, 2020a).

The proposed decisions presented in this notice on the primary $PM_{2.5}$ standards have been informed by key aspects of the available health effects evidence and conclusions contained in the 2019 ISA and ISA Supplement, quantitative exposure/risk analyses and policy evaluations presented in the PA, advice from the CASAC[2] and public comment received as part of this

[1] The press release for this announcement is available at: *https://www.epa.gov/newsreleases/epa-reexamine-health-standards-harmful-soot-previous-administration-left-unchanged*

[2] In 2021, the Administrator announced his decision to reestablish the membership of the CASAC. The Administrator selected seven members to serve on the chartered CASAC, and appointed a PM CASAC panel to support the chartered CASAC's review of the draft ISA Supplement and the draft PA as a part of this reconsideration (see section I.C.6.b below for more information).

reconsideration.[3] The health effects evidence available in this reconsideration, in conjunction with the full body of evidence critically evaluated in the 2019 ISA, supports a causal relationship between long- and short-term exposures and mortality and cardiovascular effects, and the evidence supports a likely to be a causal relationship between long-term exposures and respiratory effects, nervous system effects, and cancer. The longstanding evidence base, including animal toxicological studies, controlled human exposure studies, and epidemiologic studies, reaffirms, and in some cases strengthens, the conclusions from past reviews regarding the health effects of $PM_{2.5}$ exposures. Epidemiologic studies available in this reconsideration demonstrate generally positive, and often statistically significant, $PM_{2.5}$ health effect associations. Such studies report associations between estimated $PM_{2.5}$ exposures and non-accidental, cardiovascular, or respiratory mortality; cardiovascular or respiratory hospitalizations or emergency room visits; and other mortality/morbidity outcomes (e.g., lung cancer mortality or incidence, asthma development). The scientific evidence available in this reconsideration, as evaluated in the 2019 ISA and ISA Supplement, includes a number of epidemiologic studies that use various methods to characterize exposure to $PM_{2.5}$ (e.g., ground-based monitors and hybrid modeling approaches) and to evaluate associations between health effects and lower ambient $PM_{2.5}$ concentrations. There are a number of recent epidemiologic studies that use varying study designs that reduce uncertainties related to confounding and exposure measurement error. The results of these analyses provide further support for the robustness of associations between $PM_{2.5}$ exposures and mortality and morbidity. Moreover, the Administrator notes that recent

[3] More information regarding the CASAC review of the draft ISA Supplement and the draft PA, including opportunities for public comment, can be found in the following *Federal Register* notices: 86 FR 54186, September 30, 2021; 86 FR 52673, September 22, 2021; 86 FR 56263, October 8, 2021; 87 FR 958, January 7, 2022.

epidemiologic studies strengthen support for health effect associations at lower $PM_{2.5}$ concentrations, with these new studies finding positive and significant associations when assessing exposure in locations and time periods with lower mean and 25$^{th}$ percentile concentrations than those evaluated in epidemiologic studies available at the time of previous reviews. Additionally, the experimental evidence (i.e., animal toxicological and controlled human exposure studies) strengthens the coherence of effects across scientific disciplines and provides additional support for potential biological pathways through which $PM_{2.5}$ exposures could lead to the overt population-level outcomes reported in epidemiologic studies for the health effect categories for which a causal relationship (i.e., short- and long-term $PM_{2.5}$ exposure and mortality and cardiovascular effects) or likely to be causal relationship (i.e., short- and long-term $PM_{2.5}$ exposure and respiratory effects; and long-term $PM_{2.5}$ exposure and nervous system effects and cancer) was concluded.

The available evidence in the 2019 ISA continues to provide support for factors that may contribute to increased risk of $PM_{2.5}$-related health effects including lifestage (children and older adults), pre-existing diseases (cardiovascular disease and respiratory disease), race/ethnicity, and socioeconomic status. For example, the 2019 ISA and ISA Supplement conclude that there is strong evidence that Black and Hispanic populations, on average, experience higher $PM_{2.5}$ exposures and $PM_{2.5}$-related health risk than non-Hispanic White populations. In addition, studies evaluated in the 2019 ISA and ISA Supplement also provide evidence indicating that communities with lower socioeconomic status (SES), as assessed in epidemiologic studies using indicators of SES including income and educational attainment are, on average, exposed to higher concentrations of $PM_{2.5}$ compared to higher SES communities.

The quantitative risk assessment, as well as policy considerations in the PA, also inform

the proposed decisions on the primary $PM_{2.5}$ standards. The risk assessment in this consideration focuses on all-cause or nonaccidental mortality associated with long- and short-term $PM_{2.5}$ exposures. The primary analyses focus on exposure and risk associated with air quality that might occur in an area under air quality conditions that just meet the current and potential alternative standards. The risk assessment estimates that the current primary $PM_{2.5}$ standards could allow a substantial number of $PM_{2.5}$-associated premature deaths in the United States, and that public health improvements would be associated with just meeting all of the alternative (more stringent) annual and 24-hour standard levels modeled. Additionally, the results of the risk assessment suggest that for most of the U.S., the annual standard is the controlling standard and that revision to that standard has the most potential to reduce $PM_{2.5}$ exposure related risk. Further analyses comparing the reductions in average national $PM_{2.5}$ concentrations and risk rates within each demographic population estimate that the average percent $PM_{2.5}$ concentrations and risk reductions are slightly greater in the Black population than in the White population when meeting a revised annual standard with a lower level. The analyses are summarized in this document and described in detail in the PA.

In its advice to the Administrator, the CASAC concurred with the draft PA that the currently available health effects evidence calls into question the adequacy of the primary annual $PM_{2.5}$ standard. With regard to the primary annual $PM_{2.5}$ standard, the majority of the CASAC concluded that the level of the standard should be revised within the range of 8.0 to 10.0 $\mu g/m^3$, while the minority of the CASAC concluded that the primary annual $PM_{2.5}$ standard should be revised to a level of 10.0 to 11.0 $\mu g/m^3$. With regard to the primary 24-hour $PM_{2.5}$ standard, the majority of the CASAC concluded that the primary 24-hour $PM_{2.5}$ was not adequate and that the level of the standard should be revised to within the range of 25 to 30 $\mu g/m^3$, while the minority

of the CASAC concluded that the primary 24-hour $PM_{2.5}$ standard was adequate and should be retained, without revision.

In considering how to revise the suite of standards to provide the requisite degree of protection, the Administrator recognizes that the current annual standard and 24-hour standard, together, are intended to provide public health protection against the full distribution of short- and long-term $PM_{2.5}$ exposures. Further, he recognizes that changes in $PM_{2.5}$ air quality designed to meet either the annual or the 24-hour standard would likely result in changes to both long-term average and short-term peak $PM_{2.5}$ concentrations. Based on the current evidence and quantitative information, as well as consideration of CASAC advice and public comment thus far in this reconsideration, the Administrator proposes to conclude that the current primary $PM_{2.5}$ standards are not adequate to protect public health with an adequate margin of safety.

The Administrator also notes that the CASAC was unanimous in its advice regarding the need to revise the annual standard. In considering the appropriate level for a revised annual standard, the Administrator provisionally concludes that a standard set within the range of 9.0 to 10.0 $\mu g/m^3$ would reflect his placing the most weight on the strongest available evidence while appropriately weighing the uncertainties. In addition, the Administrator recognizes that some members of CASAC advised, and the PA concluded, that the available scientific information provides support for considering a range that extends up to 11.0 $\mu g/m^3$ and down to 8.0 $\mu g/m^3$.

With regard to the primary 24-hour $PM_{2.5}$ standard, the Administrator finds it is less clear whether the available scientific evidence and quantitative information calls into question the adequacy of the public health protection afforded by the current 24-hour standard. He notes that a more stringent annual standard is expected to reduce both average (annual) concentrations and peak (daily) concentrations. Furthermore, he notes that the CASAC did not reach consensus on

whether revisions to the primary 24-hour $PM_{2.5}$ standard were warranted at this time. The majority of the CASAC recommended that the level of the current primary 24-hour $PM_{2.5}$ should be revised to within the range of 25 to 30 $\mu g/m^3$, while the minority of the CASAC recommended retaining the current standard. The Administrator proposes to conclude that the 24-hour standard should be retained, particularly when considered in conjunction with the protection provided by the suite of standards and the proposed decision to revise the annual standard to a level of 9.0 to 10.0 $\mu g/m^3$.

The EPA solicits comment on the Administrator's proposed conclusions, and on the proposed decision to revise the primary annual $PM_{2.5}$ standard and retain the primary 24-hour $PM_{2.5}$ standard, without revision. The Administrator is conscious of his obligation to set primary standards with an adequate margin of safety and preliminarily determines that the proposed decision balances the need to provide protection against uncertain risks with the obligation to not set standards that are more stringent than necessary. The requirement to provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information and to provide a reasonable degree of protection against hazards that research has not yet identified. Reaching decisions on what standards are appropriate necessarily requires judgments of the Administrator about how to consider the information available from the epidemiologic studies and other relevant evidence. In the Administrator's judgment, the proposed suite of primary $PM_{2.5}$ standards reflects the appropriate consideration of the strength of the available evidence and other information and their associated uncertainties and the advice of the CASAC. The final rulemaking will reflect the Administrator's ultimate judgments as to the suite of primary $PM_{2.5}$ standards that are requisite to protect the public health with an adequate margin of safety. Consistent with these principles, the EPA also solicits public

comment on alternative annual standard levels down to 8.0 $\mu g/m^3$ and up to 11.0 $\mu g/m^3$, on an alternative 24-hour standard level as low as 25 $\mu g/m^3$ and on the combination of annual and 24-hour standards that commenters may believe is appropriate, along with the approaches and scientific rationales used to support such levels. For example, the EPA solicits comments on the uncertainties in the reported associations between daily or annual average $PM_{2.5}$ exposures and mortality or morbidity in the epidemiologic studies, the significance of the 25$^{th}$ percentile of ambient concentrations reported in studies, the relevance and limitations of international studies, and other topics discussed in section II.D.3.b.

The primary $PM_{10}$ standard is intended to provide public health protection against health effects related to exposures to $PM_{10-2.5}$, which are particles with a diameter between 10 μm and 2.5 μm. The proposed decision to retain the current 24-hour $PM_{10}$ standard has been informed by key aspects of the available health effects evidence and conclusions contained in the 2019 ISA, the policy evaluations presented in the PA, advice from the CASAC and public comment received as part of this reconsideration. Specifically, the health effects evidence for $PM_{10-2.5}$ exposures is somewhat strengthened since past reviews, although the strongest evidence still only provides support for a suggestive of, but not sufficient to infer, causal relationship with long- and short-term exposures and mortality and cardiovascular effects, short-term exposures and respiratory effects, and long-term exposures and cancer, nervous system effects, and metabolic effects. In reaching his proposed decision, the Administrator recognizes that, while the available health effects evidence has expanded, recent studies are subjected to the same types of uncertainties that were judged to be important in previous reviews. He also recognizes that the CASAC generally agreed with the draft PA that it was reasonable to retain the primary 24-hour $PM_{10}$ standard given the available scientific evidence, including $PM_{10}$ as an appropriate

indicator. He proposes to conclude that the newly available evidence does not call into question the adequacy of the current primary $PM_{10}$ standard, and he proposes to retain that standard, without revision.

This reconsideration of the secondary PM standards focuses on visibility, climate, and materials effects.[4] The Administrator's proposed decision to not change the current secondary standards at this time has been informed by key aspects of the currently available welfare effects evidence as well as the conclusions contained in the 2019 ISA and ISA Supplement; quantitative analyses of visibility impairment; policy evaluations presented in the PA; advice from the CASAC; and public comment received as part of this reconsideration. Specifically, the welfare effects evidence available in this reconsideration is consistent with the evidence available in previous reviews and supports a causal relationship between PM and visibility, climate, and materials effects. With regard to climate and materials effects, while the evidence has expanded since previous reviews, uncertainties remain in the evidence and there are still significant limitations in quantifying potential adverse effects from PM on climate and materials for purposes of setting a standard. With regard to visibility effects, the results of quantitative analyses of visibility impairment are similar to those in previous reviews, and suggest that in areas that meet the current secondary 24-hour $PM_{2.5}$ standard that estimated light extinction in

[4] Consistent with the 2016 Integrated Review Plan (U.S. EPA, 2016), other welfare effects of PM, such as ecological effects, are being considered in the separate, on-going review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM. Accordingly, the public welfare protection provided by the secondary PM standards against ecological effects such as those related to deposition of nitrogen- and sulfur-containing compounds in vulnerable ecosystems is being considered in that separate review. Thus, the Administrator's conclusion in this reconsideration of the 2020 final decision will be focused only and specifically on the adequacy of public welfare protection provided by the secondary PM standards from effects related to visibility, climate, and materials and hereafter "welfare effects" refers to those welfare effects.

terms of a 3-year visibility metric would be at or well below the upper end of the range for the target level of protection (i.e., 30 deciviews (dv)). The CASAC generally agreed with the draft PA that substantial uncertainties remain in the scientific evidence for climate and materials effects. In considering the available scientific evidence for climate and materials effects, along with CASAC advice, the Administrator proposes to conclude that it is appropriate to retain the existing secondary standards and that it is not appropriate to establish any distinct secondary PM standards to address non-visibility PM-related welfare effects. With regard to visibility effects, while the Administrator notes that the CASAC did not recommend revising either the target level of protection for the visibility index or the level of the current secondary 24-hour $PM_{2.5}$ standard, the Administrator recognizes that, should an alternative level be considered for the visibility index, that the CASAC recommends also considering revisions to the secondary 24-hour $PM_{2.5}$ standard. In considering the available evidence and quantitative information, with its inherent uncertainties and limitations, the Administrator proposes not to change the secondary PM standards at this time, and solicits comment on this proposed decision. In addition, the Administrator additionally solicits comment on the appropriateness of a target level of protection for visibility below 30 dv and down as low as 25 dv, and of revising the level of the current secondary 24-hour $PM_{2.5}$ standard to a level as low as 25 $\mu g/m^3$.

Any proposed revisions to the PM NAAQS, if finalized, would trigger a process under which states (and tribes, if they choose) make recommendations to the Administrator regarding designations, identifying areas of the country that either meet or do not meet the new or revised PM NAAQS. Those areas that do not meet the PM NAAQS will need to develop plans that demonstrate how they will meet the standards. As part of these plans, states have the opportunity to use tools to advance environmental justice, in this case for overburdened communities in areas

with high PM concentrations above the NAAQS, as provided in current PM NAAQS implementation guidance to meet requirements (80 FR 58010, 58136, August 25, 2016). The EPA is not proposing changes to any of the current PM NAAQS implementation programs in this proposed rulemaking, and therefore is not requesting comment on any specific proposals related to implementation or designations.

On other topics, the EPA proposes to make two sets of changes to the $PM_{2.5}$ sub-index of the AQI. First, the EPA proposes to continue to use the approach used in the revisions to the AQI in 2012 (77 FR 38890, June 29, 2012) of setting the lower breakpoints (50, 100 and 150) to be consistent with the levels of the primary $PM_{2.5}$ annual and 24-hour standards and proposes to revise the lower breakpoints to be consistent with any changes to the primary $PM_{2.5}$ standards that are part of this reconsideration. In so doing, the EPA proposes to revise the AQI value of 50 within the range of 9.0 and 10.0 $\mu g/m^3$ and proposes to retain the AQI values of 100 and 150 at 35.4 $\mu g/m^3$ and 55.4 $\mu g/m^3$, respectively. Second, the EPA proposes to revise the upper AQI breakpoints (200 and above) and to replace the linear-relationship approach used in 1999 (64 FR 42530, August 4, 1999) to set these breakpoints, with an approach that more fully considers the $PM_{2.5}$ health effects evidence from controlled human exposure and epidemiologic studies that has become available in the last 20 years. The EPA also proposes to revise the AQI values of 200, 300 and 500 to 125.4 $\mu g/m^3$, 225.4 $\mu g/m^3$, and 325.4 $\mu g/m^3$, respectively. The EPA proposes to finalize these changes to the $PM_{2.5}$ AQI in conjunction with the Agency's final decisions on the primary annual and 24-hour $PM_{2.5}$ standards, if proposed revisions to such standards are promulgated. The EPA is soliciting comment on the proposed revisions to the AQI. In addition, the EPA also proposes to revise the daily reporting requirement from 5 days per week to 7 days per week, while also reformatting Appendix G and providing clarifications.

With regard to monitoring-related activities, the EPA proposes revisions to data calculations and ambient air monitoring requirements for PM to improve the usefulness of and appropriateness of data used in regulatory decision making and to better characterize air quality in communities that are at increased risk of $PM_{2.5}$ exposure and health risk. These proposed changes are found in 40 CFR part 50 (Appendices K, L, and N), part 53, and part 58 with associated appendices (A, B, C, D, and E). These proposed changes include addressing updates in data calculations, approval of reference and equivalent methods, updates in quality assurance statistical calculations to account for lower concentration measurements, updates to support improvements in PM methods, a revision to the $PM_{2.5}$ network design to account for at-risk populations, and updates to the Probe and Monitoring Path Siting Criteria for NAAQS pollutants.

In setting the NAAQS, the EPA may not consider the costs of implementing the standards. This was confirmed by the Supreme Court in *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001), as discussed in section II.A of this notice. As has traditionally been done in NAAQS rulemaking, the EPA prepared a Regulatory Impact Analysis (RIA) to provide the public with information on the potential costs and benefits of attaining several alternative $PM_{2.5}$ standard levels. In NAAQS rulemaking, the RIA is done for informational purposes only, and the proposed decisions on the NAAQS in this rulemaking are not based on consideration of the information or analyses in the RIA. The RIA fulfills the requirements of Executive Orders 13563 and 12866. The RIA estimates the costs and monetized human health benefits of attaining three alternative annual $PM_{2.5}$ standard levels and one alternative 24-hour $PM_{2.5}$ standard level. Specifically, the RIA examines the proposed annual and 24-hour alternative standard levels of 10/35 $\mu g/m^3$ and 9/35 $\mu g/m^3$, as well as the following two

more stringent alternative standard levels: (1) An alternative annual standard level of 8 μg/m$^3$ in combination with the current 24-hour standard (i.e., 8/35 μg/m$^3$), and (2) an alternative 24-hour standard level of 30 μg/m$^3$ in combination with the proposed annual standard level of 10 μg/m$^3$ (i.e., 10/30 μg/m$^3$). The RIA presents estimates of the costs and benefits of applying illustrative national control strategies in 2032 after implementing existing and expected regulations and assessing emissions reductions to meet the current annual and 24-hour particulate matter NAAQS (12/35 μg/m$^3$).

## I. Background

### *A. Legislative Requirements*

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those pollutants "emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare"; "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources"; and for which he "plans to issue air quality criteria…." (42 U.S.C. 7408(a)(1)). Air quality criteria are intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air…." (42 U.S.C. 7408(a)(2)).

Section 109 [42 U.S.C. 7409] directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants for which air quality criteria are issued [42 U.S.C. 7409(a)]. Section 109(b)(1) defines primary standards as ones "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing

an adequate margin of safety, are requisite to protect the public health."[5] Under section 109(b)(2), a secondary standard must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."[6]

In setting primary and secondary standards that are "requisite" to protect public health and welfare, respectively, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary. In so doing, the EPA may not consider the costs of implementing the standards. See generally *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001). Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards." *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); *accord Murray Energy Corporation v. EPA,* 936 F.3d 597, 623-24 (D.C. Cir. 2019).

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *Lead Industries*

[5] The legislative history of section 109 indicates that a primary standard is to be set at "the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population," and that for this purpose "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group." S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970).

[6] Under CAA section 302(h) (42 U.S.C. 7602(h)), effects on welfare include, but are not limited to, "effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

*Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980); *American Petroleum Institute v. Costle*, 665 F.2d at 1186; *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 617-18 (D.C. Cir. 2010); *Mississippi v. EPA*, 744 F.3d 1334, 1353 (D.C. Cir. 2013). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead Industries Ass'n v. EPA*, 647 F.2d at 1156 n.51, *Mississippi v. EPA*, 744 F.3d at 1351, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s), and the kind and degree of uncertainties. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Ass'n v. EPA*, 647 F.2d at 1161-62; *Mississippi v. EPA*, 744 F.3d at 1353.

Section 109(d)(1) of the Act requires the review every five years of existing air quality criteria and, if appropriate, the revision of those criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health and welfare. Under the same provision, the EPA is also to review every five years and, if appropriate, revise the NAAQS,

based on the revised air quality criteria.

Section 109(d)(2) addresses the appointment and advisory functions of an independent scientific review committee. Section 109(d)(2)(A) requires the Administrator to appoint this committee, which is to be composed of "seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies." Section 109(d)(2)(B) provides that the independent scientific review committee "shall complete a review of the criteria…and the national primary and secondary ambient air quality standards…and shall recommend to the Administrator any new…standards and revisions of existing criteria and standards as may be appropriate…." Since the early 1980s, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of the EPA's Science Advisory Board. A number of other advisory functions are also identified for the committee by section 109(d)(2)(C), which reads:

> Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

As previously noted, the Supreme Court has held that section 109(b) "unambiguously bars cost considerations from the NAAQS-setting process." *Whitman v. Am. Trucking Associations,* 531 U.S. 457, 471 (2001). Accordingly, while some of these issues regarding which Congress has directed the CASAC to advise the Administrator are ones that are relevant to the standard setting process, others are not. Issues that are not relevant to standard setting may be

relevant to implementation of the NAAQS once they are established.[7]

*B. Related PM Control Programs*

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under section 110 and Part D, Subparts 1, 4 and 6 of the CAA, and related provisions and regulations, states are to submit, for the EPA's approval, state implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The states, in conjunction with the EPA, also administer the prevention of significant deterioration of air quality program that covers these pollutants (see 42 U.S.C. 7470-7479). In addition, federal programs provide for or result in nationwide reductions in emissions of PM and its precursors under Title II of the Act, 42 U.S.C. 7521-7574, which involves controls for motor vehicles and nonroad engines and equipment; the new source performance standards under section 111 of the Act, 42 U.S.C. 7411; and the national emissions standards for hazardous pollutants under section 112 of the Act, 42 U.S.C. 7412.

*C. Review of the Air Quality Criteria and Standards for Particulate Matter*

[7] Some aspects of the CASAC's advice may not be relevant to the EPA's process of setting primary and secondary standards that are requisite to protect public health and welfare. Indeed, were the EPA to consider costs of implementation when reviewing and revising the standards "it would be grounds for vacating the NAAQS." Whitman, 531 U.S. at 471 n.4. At the same time, the CAA directs the CASAC to provide advice on "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance" of the NAAQS to the Administrator under section 109(d)(2)(C)(iv). In *Whitman*, the Court clarified that most of that advice would be relevant to implementation but not standard setting, as it "enable[s] the Administrator to assist the States in carrying out their statutory role as primary *implementers* of the NAAQS." *Id*. at 470 (emphasis in original). However, the Court also noted that the CASAC's "advice concerning certain aspects of 'adverse public health … effects' from various attainment strategies is unquestionably pertinent" to the NAAQS rulemaking record and relevant to the standard setting process. *Id.* at 470 n.2.

1. Reviews Completed in 1971 and 1987

The EPA first established NAAQS for PM in 1971 (36 FR 8186, April 30, 1971), based on the original Air Quality Criteria Document (AQCD) (DHEW, 1969).[8] The federal reference method (FRM) specified for determining attainment of the original standards was the high-volume sampler, which collects PM up to a nominal size of 25 to 45 μm (referred to as total suspended particulates or TSP). The primary standards were set at 260 $\mu g/m^3$, 24-hour average, not to be exceeded more than once per year, and 75 $\mu g/m^3$, annual geometric mean. The secondary standards were set at 150 $\mu g/m^3$, 24-hour average, not to be exceeded more than once per year, and 60 $\mu g/m^3$, annual geometric mean.

In October 1979 (44 FR 56730, October 2, 1979), the EPA announced the first periodic review of the air quality criteria and NAAQS for PM. Revised primary and secondary standards were promulgated in 1987 (52 FR 24634, July 1, 1987). In the 1987 decision, the EPA changed the indicator for particles from TSP to $PM_{10}$, in order to focus on the subset of inhalable particles small enough to penetrate to the thoracic region of the respiratory tract (including the tracheobronchial and alveolar regions), referred to as thoracic particles.[9] The level of the 24-hour standards (primary and secondary) was set at 150 $\mu g/m^3$, and the form was one expected exceedance per year, on average over three years. The level of the annual standards (primary and secondary) was set at 50 $\mu g/m^3$, and the form was annual arithmetic mean, averaged over three years.

[8] Prior to the review initiated in 2007 (see below), the AQCD provided the scientific foundation (i.e., the air quality criteria) for the NAAQS. Beginning in that review, the Integrated Science Assessment (ISA) has replaced the AQCD.

[9] $PM_{10}$ refers to particles with a nominal mean aerodynamic diameter less than or equal to 10 μm. More specifically, 10 μm is the aerodynamic diameter for which the efficiency of particle collection is 50 percent.

2. Review Completed in 1997

In April 1994, the EPA announced its plans for the second periodic review of the air quality criteria and NAAQS for PM, and in 1997 the EPA promulgated revisions to the NAAQS (62 FR 38652, July 18, 1997). In the 1997 decision, the EPA determined that the fine and coarse fractions of $PM_{10}$ should be considered separately. This determination was based on evidence that serious health effects were associated with short- and long-term exposures to fine particles in areas that met the existing $PM_{10}$ standards. The EPA added new standards, using $PM_{2.5}$ as the indicator for fine particles (with $PM_{2.5}$ referring to particles with a nominal mean aerodynamic diameter less than or equal to 2.5 μm). The new primary standards were as follows: (1) an annual standard with a level of 15.0 $\mu g/m^3$, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors;[10] and (2) a 24-hour standard with a level of 65 $\mu g/m^3$, based on the 3-year average of the 98$^{th}$ percentile of 24-hour $PM_{2.5}$ concentrations at each monitor within an area. Also, the EPA established a new reference method for the measurement of $PM_{2.5}$ in the ambient air and adopted rules for determining attainment of the new standards. To continue to address the health effects of the coarse fraction of $PM_{10}$ (referred to as thoracic coarse particles or $PM_{10-2.5}$; generally including particles with a nominal mean aerodynamic diameter greater than 2.5 μm and less than or equal to 10 μm), the EPA retained the primary annual $PM_{10}$ standard and revised the form of the primary 24-hour

[10] The 1997 annual $PM_{2.5}$ standard was compared with measurements made at the community-oriented monitoring site recording the highest concentration or, if specific constraints were met, measurements from multiple community-oriented monitoring sites could be averaged (i.e., "spatial averaging"). In the last review (completed in 2012) the EPA replaced the term "community-oriented" monitor with the term "area-wide" monitor. Area-wide monitors are those sited at the neighborhood scale or larger, as well as those monitors sited at micro- or middle-scales that are representative of many such locations in the same core-based statistical area (CBSA) (78 FR 3236, January 15, 2013).

$PM_{10}$ standard to be based on the 99th percentile of 24-hour $PM_{10}$ concentrations at each monitor in an area. The EPA revised the secondary standards by setting them equal in all respects to the primary standards.

Following promulgation of the 1997 PM NAAQS, petitions for review were filed by several parties, addressing a broad range of issues. In May 1999, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) upheld the EPA's decision to establish fine particle standards, holding that "the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particle standards." *American Trucking Associations, Inc. v. EPA*, 175 F. 3d 1027, 1055-56 (D.C. Cir. 1999). The D.C. Circuit also found "ample support" for the EPA's decision to regulate coarse particle pollution, but vacated the 1997 $PM_{10}$ standards, concluding that the EPA had not provided a reasonable explanation justifying use of $PM_{10}$ as an indicator for coarse particles. *American Trucking Associations v. EPA*, 175 F. 3d at 1054-55. Pursuant to the D.C. Circuit's decision, the EPA removed the vacated 1997 $PM_{10}$ standards, and the pre-existing 1987 $PM_{10}$ standards remained in place (65 FR 80776, December 22, 2000). The D.C. Circuit also upheld the EPA's determination not to establish more stringent secondary standards for fine particles to address effects on visibility. *American Trucking Associations v. EPA*, 175 F. 3d at 1027.

The D.C. Circuit also addressed more general issues related to the NAAQS, including issues related to the consideration of costs in setting NAAQS and the EPA's approach to establishing the levels of NAAQS. Regarding the cost issue, the court reaffirmed prior rulings holding that in setting NAAQS the EPA is "not permitted to consider the cost of implementing those standards." *American Trucking Associations v. EPA*, 175 F. 3d at 1040-41. Regarding the levels of NAAQS, the court held that the EPA's approach to establishing the level of the

standards in 1997 (i.e., both for PM and for the ozone NAAQS promulgated on the same day) effected "an unconstitutional delegation of legislative authority." *American Trucking Associations v. EPA*, 175 F. 3d at 1034-40. Although the court stated that "the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and PM are reasonable," it remanded the rule to the EPA, stating that when the EPA considers these factors for potential non-threshold pollutants "what EPA lacks is any determinate criterion for drawing lines" to determine where the standards should be set.

The D.C. Circuit's holding on the cost and constitutional issues were appealed to the United States Supreme Court. In February 2001, the Supreme Court issued a unanimous decision upholding the EPA's position on both the cost and constitutional issues. *Whitman v. American Trucking Associations*, 531 U.S. 457, 464, 475-76. On the constitutional issue, the Court held that the statutory requirement that NAAQS be "requisite" to protect public health with an adequate margin of safety sufficiently guided the EPA's discretion, affirming the EPA's approach of setting standards that are neither more nor less stringent than necessary.

The Supreme Court remanded the case to the D.C. Circuit for resolution of any remaining issues that had not been addressed in that court's earlier rulings. Id. at 475-76. In a March 2002 decision, the D.C. Circuit rejected all remaining challenges to the standards, holding that the EPA's $PM_{2.5}$ standards were reasonably supported by the administrative record and were not "arbitrary and capricious." *American Trucking Associations v. EPA*, 283 F. 3d 355, 369-72 (D.C. Cir. 2002).

3. Review Completed in 2006

In October 1997, the EPA published its plans for the third periodic review of the air quality criteria and NAAQS for PM (62 FR 55201, October 23, 1997). After the CASAC and

public review of several drafts, the EPA's National Center for Environmental Assessment (NCEA) finalized the AQCD in October 2004 (U.S. EPA, 2004a). The EPA's Office of Air Quality Planning and Standards (OAQPS) finalized a Risk Assessment and Staff Paper in December 2005 (Abt Associates, 2005; U.S. EPA, 2005).[11] On December 20, 2005, the EPA announced its proposed decision to revise the NAAQS for PM and solicited public comment on a broad range of options (71 FR 2620, January 17, 2006). On September 21, 2006, the EPA announced its final decisions to revise the primary and secondary NAAQS for PM to provide increased protection of public health and welfare, respectively (71 FR 61144, October 17, 2006). With regard to the primary and secondary standards for fine particles, the EPA revised the level of the 24-hour $PM_{2.5}$ standards to 35 $\mu g/m^3$, retained the level of the annual $PM_{2.5}$ standards at 15.0 $\mu g/m^3$, and revised the form of the annual $PM_{2.5}$ standards by narrowing the constraints on the optional use of spatial averaging. With regard to the primary and secondary standards for $PM_{10}$, the EPA retained the 24-hour standards, with levels at 150 $\mu g/m^3$, and revoked the annual standards.[12] The Administrator judged that the available evidence generally did not suggest a link between long-term exposure to existing ambient levels of coarse particles and health or

[11] Prior to the review initiated in 2007, the Staff Paper presented the EPA staff's considerations and conclusions regarding the adequacy of existing NAAQS and, when appropriate, the potential alternative standards that could be supported by the evidence and information. More recent reviews present this information in the Policy Assessment.

[12] In the 2006 proposal, the EPA proposed to revise the 24-hour $PM_{10}$ standard in part by establishing a new $PM_{10-2.5}$ indicator for thoracic coarse particles (i.e., particles generally between 2.5 and 10 μm in diameter). The EPA proposed to include any ambient mix of $PM_{10-2.5}$ that was dominated by resuspended dust from high density traffic on paved roads and by PM from industrial sources and construction sources. The EPA proposed to exclude any ambient mix of $PM_{10-2.5}$ that was dominated by rural windblown dust and soils and by PM generated from agricultural and mining sources. In the final decision, the existing $PM_{10}$ standard was retained, in part due to an "inability…to effectively and precisely identify which ambient mixes are included in the [$PM_{10-2.5}$] indicator and which are not" (71 FR 61197, October 17, 2006).

welfare effects. In addition, a new reference method was added for the measurement of $PM_{10-2.5}$ in the ambient air in order to provide a basis for approving federal equivalent methods (FEMs) and to promote the gathering of scientific data to support future reviews of the PM NAAQS.

Several parties filed petitions for review following promulgation of the revised PM NAAQS in 2006. These petitions addressed the following issues: (1) Selecting the level of the primary annual $PM_{2.5}$ standard; (2) retaining $PM_{10}$ as the indicator of a standard for thoracic coarse particles, retaining the level and form of the 24-hour $PM_{10}$ standard, and revoking the $PM_{10}$ annual standard; and (3) setting the secondary $PM_{2.5}$ standards identical to the primary standards. On February 24, 2009, the D.C. Circuit issued its opinion in the case *American Farm Bureau Federation v. EPA*, 559 F. 3d 512 (D.C. Cir. 2009). The court remanded the primary annual $PM_{2.5}$ NAAQS to the EPA because the Agency had failed to adequately explain why the standards provided the requisite protection from both short- and long-term exposures to fine particles, including protection for at-risk populations. *Id. at* 520-27. With regard to the standards for $PM_{10}$, the court upheld the EPA's decisions to retain the 24-hour $PM_{10}$ standard to provide protection from thoracic coarse particle exposures and to revoke the annual $PM_{10}$ standard. *Id.* at 533-38. With regard to the secondary $PM_{2.5}$ standards, the court remanded the standards to the EPA because the Agency failed to adequately explain why setting the secondary PM standards identical to the primary standards provided the required protection for public welfare, including protection from visibility impairment. *Id.* at 528-32. The EPA responded to the court's remands as part of the next review of the PM NAAQS, which was initiated in 2007 (discussed below).

4. Review Completed in 2012

In June 2007, the EPA initiated the fourth periodic review of the air quality criteria and the PM NAAQS by issuing a call for information (72 FR 35462, June 28, 2007). Based on the

NAAQS review process, as revised in 2008 and again in 2009,[13] the EPA held science/policy issue workshops on the primary and secondary PM NAAQS (72 FR 34003, June 20, 2007; 72 FR 34005, June 20, 2007), and prepared and released the planning and assessment documents that comprise the review process (i.e., IRP (U.S. EPA, 2008), ISA (U.S. EPA, 2009a), REA planning documents for health and welfare (U.S. EPA, 2009a, U.S. EPA, 2009c), a quantitative health risk assessment (U.S. EPA, 2009a, U.S. EPA, 2009c), a quantitative health risk assessment (U.S. EPA, 2010b) and an urban-focused visibility assessment (U.S. EPA, 2010a), and PA (U.S. EPA, 2011). In June 2012, the EPA announced its proposed decision to revise the NAAQS for PM (77 FR 38890, June 29, 2012).

In December 2012, the EPA announced its final decisions to revise the primary NAAQS for PM to provide increased protection of public health (78 FR 3086, January 15, 2013). With regard to primary standards for $PM_{2.5}$, the EPA revised the level of the annual $PM_{2.5}$ standard[14] to 12.0 $\mu g/m^3$ and retained the 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$. For the primary $PM_{10}$ standard, the EPA retained the 24-hour standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (i.e., $PM_{10-2.5}$). With regard to the secondary PM standards, the EPA generally retained the 24-hour and annual $PM_{2.5}$ standards[15] and the 24-hour $PM_{10}$ standard to address visibility and non-visibility welfare effects.

As with previous reviews, petitioners challenged the EPA's final rule. Petitioners argued

[13] The history of the NAAQS review process, including revisions to the process, is discussed at *https://www.epa.gov/naaqs/historical-information-naaqs-review-process*.
[14] The EPA also eliminated the option for spatial averaging.
[15] Consistent with the primary standard, the EPA eliminated the option for spatial averaging with the annual standard.

that the EPA acted unreasonably in revising the level and form of the annual standard and in amending the monitoring network provisions. On judicial review, the revised standards and monitoring requirements were upheld in all respects. *NAM v EPA*, 750 F.3d 921 (D.C. Cir. 2014).

5. Review Completed in 2020

In December 2014, the EPA announced the initiation of the current periodic review of the air quality criteria for PM and of the $PM_{2.5}$ and $PM_{10}$ NAAQS and issued a call for information (79 FR 71764, December 3, 2014). On February 9 to 11, 2015, the EPA's NCEA and OAQPS held a public workshop to inform the planning for the review of the PM NAAQS (announced in 79 FR 71764, December 3, 2014). Workshop participants, including a wide range of external experts as well as the EPA staff representing a variety of areas of expertise (e.g., epidemiology, human and animal toxicology, risk/exposure analysis, atmospheric science, visibility impairment, climate effects), were asked to highlight significant new and emerging PM research, and to make recommendations to the Agency regarding the design and scope of the review. This workshop provided for a public discussion of the key science and policy-relevant issues around which the EPA structured the review of the PM NAAQS and of the most meaningful new scientific information that would be available in the review to inform understanding of these issues.

The input received at the workshop guided the EPA staff in developing a draft IRP, which was reviewed by the CASAC Particulate Matter Panel and discussed on public teleconferences held in May 2016 (81 FR 13362, March 14, 2016) and August 2016 (81 FR 39043, June 15, 2016). Advice from the CASAC, supplemented by the Particulate Matter Panel, and input from the public were considered in developing the final IRP (U.S. EPA, 2016). The

final IRP discusses the approaches to be taken in developing key scientific, technical, and policy documents in the review and the key policy-relevant issues that frame the EPA's consideration of whether the primary and/or secondary NAAQS for PM should be retained or revised.

In May 2018, the Administrator issued a memorandum describing a "back-to-basics" process for reviewing the NAAQS (Pruitt, 2018). This memo announced the Agency's intention to conduct the review of the PM NAAQS in such a manner as to ensure that any necessary revisions were finalized by December 2020. Following this memo, on October 10, 2018, the Administrator additionally announced that the role of reviewing the key assessments developed as part of the ongoing review of the PM NAAQS (i.e., drafts of the ISA and PA) would be performed by the seven-member chartered CASAC (i.e., rather than the CASAC Particulate Matter Panel that reviewed the draft IRP).[16]

The EPA released the draft ISA in October 2018 (83 FR 53471, October 23, 2018). The draft ISA was reviewed by the chartered CASAC at a public meeting held in Arlington, VA in December 2018 (83 FR 55529, November 6, 2018) and was discussed on a public teleconference in March 2019 (84 FR 8523, March 8, 2019). The CASAC provided its advice on the draft ISA in a letter to the EPA Administrator dated April 11, 2019 (Cox, 2019a). The EPA took steps to address these comments in the final ISA, which was released in December 2019 (U.S. EPA, 2019a).

The EPA released the draft PA in September 2019 (84 FR 47944, September 11, 2019). The draft PA was reviewed by the chartered CASAC and discussed in October 2019 at a public meeting held in Cary, NC. Public comments were received via a separate public teleconference

[16] Announcement available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2015-0072-0223.*

(84 FR 51555, September 30, 2019). A public meeting to discuss the chartered CASAC letter and response to charge questions on the draft PA was held in Cary, NC in December 2019 (84 FR 58713, November 1, 2019), and the CASAC provided its advice on the draft PA, including its advice on the current primary and secondary PM standards, in a letter to the EPA Administrator dated December 16, 2019 (Cox, 2019b). With regard to the primary standards, the CASAC recommended retaining the current 24-hour $PM_{2.5}$ and $PM_{10}$ standards but did not reach consensus on the adequacy of the current annual $PM_{2.5}$ standard. With regard to the secondary standards, the CASAC recommended retaining the current standards. In response to the CASAC's comments, the 2020 final PA incorporated a number of changes (U.S. EPA, 2020a), as described in detail in section I.C.5 of the 2020 proposal notice (85 FR 24100, April 30, 2020).

On April 14, 2020, the EPA proposed to retain all of the primary and secondary PM standards, without revision. These proposed decisions were published in the *Federal Register* on April 30, 2020 (85 FR 24094, April 30, 2020). The EPA's final decision on the PM NAAQS was published in the *Federal Register* on December 18, 2020 (85 FR 82684, December 18, 2020). In the 2020 rulemaking, the EPA retained the primary and secondary $PM_{2.5}$ and $PM_{10}$ standards, without revision.

Following publication of the 2020 final action, several parties filed petitions for review and petitions for reconsideration of the EPA's final decision. The petitions for review were filed in the D.C. Circuit and the Court consolidated the cases. In order to consider whether reconsideration of the 2020 final action was warranted, the EPA moved for two 90-day abeyances in these consolidated cases, which the Court granted. After the EPA announced that it is reconsidering the 2020 final decision, the EPA filed a motion with the Court to hold the consolidated cases in abeyance until March 1, 2023, which the court granted on October 1, 2021.

6. Reconsideration of the 2020 PM NAAQS Final Action

On January 20, 2021, President Biden issued an "Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis," (Executive Order 13990; 86 FR 7037, January 25, 2021)[17] which directed review of certain agency actions. An accompanying fact sheet provided a non-exclusive list of agency actions that agency heads should review in accordance with that order, including the 2020 Particulate Matter NAAQS Decision.[18]

a. Decision to Initiate a Reconsideration

On June 10, 2021, the Agency announced its decision to reconsider the 2020 PM NAAQS final action.[19] The EPA is reconsidering the December 2020 decision because the available scientific evidence and technical information indicate that the current standards may not be adequate to protect public health and welfare, as required by the Clean Air Act. The EPA noted that the 2020 PA concluded that the scientific evidence and information supported revising the level of the primary annual $PM_{2.5}$ standard to below the current level of 12.0 $\mu g/m^3$ while retaining the primary 24-hour $PM_{2.5}$ standard (U.S. EPA, 2020a). The EPA also noted that the 2020 PA concluded that the available scientific evidence and information supported retaining the primary $PM_{10}$ standard and secondary PM standards without revision (U.S. EPA, 2020a).

b. Process for Reconsideration of the 2020 PM NAAQS Decision

[17] See https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/

[18] See *https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/*

[19] The press release for this announcement is available at: *https://www.epa.gov/newsreleases/epa-reexamine-health-standards-harmful-soot-previous-administration-left-unchanged*

In its announcement of the reconsideration of the PM NAAQS, the Agency explained that, in support of the reconsideration, it would develop a supplement to the 2019 ISA and a revised PA. The EPA also explained that the draft ISA Supplement and draft PA would be reviewed at a public meeting by the CASAC, and the public would have opportunities to comment on these documents during the CASAC review process, as well as to provide input during the rulemaking through the public comment process and public hearings on the proposed rulemaking.

On March 31, 2021, the Administrator announced his decision to reestablish the membership of the CASAC to "ensure the agency received the best possible scientific insight to support our work to protect human health and the environment."[20] Consistent with this memorandum, a call for nominations of candidates to the EPA's chartered CASAC was published in the *Federal Register* (86 FR 17146, April 1, 2021). On June 17, 2021, the Administrator announced his selection of the seven members to serve on the chartered CASAC.[21] [22] Additionally, a call for nominations of candidates to a PM-specific panel was published in the *Federal Register* (86 FR 33703, June 25, 2021). The members of the PM CASAC panel were announced on August 30, 2021.[23]

[20] The press release for this announcement is available at: *https://www.epa.gov/newsreleases/administrator-regan-directs-epa-reset-critical-science-focused-federal-advisory*

[21] The press release for this announcement is available at: *https://www.epa.gov/newsreleases/epa-announces-selections-charter-members-clean-air-scientific-advisory-committee*

[22] The list of members of the chartered CASAC and their biosketches are available at: *https://casac.epa.gov/ords/sab/f?p=113:29:1706195567016:::RP,29:P29_COMMITTEEON:CASAC*

[23] The list of members of the PM CASAC panel and their biosketches are available at: *https://casac.epa.gov/ords/sab/f?p=105:14:9979229564047:::14:P14_COMMITTEEON:2021%20CASAC%20PM%20Panel*

The draft ISA Supplement was released in September 2021 (U.S. EPA, 2021a; 86 FR 54186, September 30, 2021). The CASAC PM panel met at a virtual public meeting in November 2021 to review the draft ISA Supplement (86 FR 52673, September 22, 2021). A virtual public meeting was then held in February 2022, and during this meeting the chartered CASAC considered the CASAC PM panel's draft letter to the Administrator on the draft ISA Supplement (87 FR 958, January 7, 2022). The chartered CASAC provided its advice on the draft ISA Supplement in a letter to the EPA Administrator dated March 18, 2022 (Sheppard, 2022b). The EPA took steps to address these comments in the final ISA Supplement, which was released in May 2022 (U.S. EPA, 2022a; hereafter referred to as the ISA Supplement throughout this notice).

The evidence presented within the 2019 ISA, along with the targeted identification and evaluation of new scientific information in the ISA Supplement, provides the scientific basis for the reconsideration of the 2020 PM NAAQS final decision. The ISA Supplement focuses on a thorough evaluation of some studies that became available after the literature cutoff date of the 2019 ISA that could either further inform the adequacy of the current PM NAAQS or address key scientific topics that have evolved since the literature cutoff date for the 2019 ISA. In selecting the health effects to evaluate within the ISA Supplement, the EPA focused on health effects for which the evidence supported a "causal relationship" because those were the health effects that were most useful in informing conclusions in the 2020 PA (U.S. EPA, 2022a, section

1.2.1).[24] Consistent with the rationale for the focus on certain health effects, in selecting the non-ecological welfare effects to evaluate within the ISA supplement, the EPA focused on the non-ecological welfare effects for which the evidence supported a "causal relationship" and for which quantitative analyses could be supported by the evidence because those were the welfare effects that were most useful in informing conclusions in the 2020 PA.[25] Specifically, for non-ecological welfare effects, the focus within the ISA Supplement is on visibility effects. The ISA Supplement also considers recent health effects evidence that addresses key scientific topics where the literature has evolved since the 2020 review was completed, specifically since the

[24] As described in section 1.2.1 of the ISA Supplement: "In considering the public health protection provided by the current primary $PM_{2.5}$ standards, and the protection that could be provided by alternatives, [the U.S. EPA, within the 2020 PM PA] emphasized health outcomes for which the ISA determined that the evidence supports either a '*causal'* or a '*likely to be causal'* relationship with $PM_{2.5}$ exposures" (U.S. EPA, 2020a). Although the 2020 PA initially focused on this broader set of evidence, the basis of the discussion on potential alternative standards primarily focused on health effect categories where the 2019 PM ISA concluded a '*causal relationship*' (i.e., short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality) as reflected in Figures 3-7 and 3-8 of the 2020 PA (U.S. EPA, 2020a)." As described in section 1.2.1 of the ISA Supplement: "In considering the public health protection provided by the current primary $PM_{2.5}$ standards, and the protection that could be provided by alternatives, [the U.S. EPA, within the 2020 PM PA] emphasized health outcomes for which the ISA determined that the evidence supports either a '*causal'* or a '*likely to be causal'* relationship with $PM_{2.5}$ exposures" (U.S. EPA, 2020a). Although the 2020 PA initially focused on this broader set of evidence, the basis of the discussion on potential alternative standards primarily focused on health effect categories where the 2019 PM ISA concluded a '*causal relationship*' (i.e., short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality) as reflected in Figures 3-7 and 3-8 of the 2020 PA (U.S. EPA, 2020a)."

[25] As described in section 1.2.1 of the ISA Supplement: "The 2019 PM ISA concluded a '*causal relationship*' for each of the welfare effects categories evaluated (i.e., visibility, climate effects and materials effects). While the 2020 PA considered the broader set of evidence for these effects, for climate effects and material effects, it concluded that there remained 'substantial uncertainties with regard to the quantitative relationships with PM concentrations and concentration patterns that limit[ed] [the] ability to quantitatively assess the public welfare protection provided by the standards from these effects' (U.S. EPA, 2020a)."

literature cutoff date for the 2019 ISA.[26]

Building on the rationale presented in section 1.2.1, the ISA Supplement considers peer-reviewed studies published from approximately January 2018 through March 2021 that meet the following criteria:

- Health effects:
    - U.S. and Canadian epidemiologic studies for health effect categories where the 2019 ISA concluded a "*causal relationship*" (i.e., short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality).
        - U.S. and Canadian epidemiologic studies that employed alternative methods for confounder control or conducted accountability analyses (i.e., examined the effect of a policy on reducing $PM_{2.5}$ concentrations)
- Welfare Effects:
    - U.S. and Canadian studies that provide new information on public preferences for visibility impairment and/or developed methodologies or conducted quantitative analyses of light extinction
- Key Scientific Topics
    - Experimental studies (i.e., controlled human exposure and animal

[26] These key scientific topics include experimental studies conducted at near-ambient concentrations, epidemiologic studies that employed alternative methods for confounder control or conducted accountability analyses, studies that assess the relationship between $PM_{2.5}$ exposure and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and coronavirus disease 2019 (COVID-19) death; and in accordance with recent EPA goals on addressing environmental justice, studies that examine disparities in $PM_{2.5}$ exposure and the risk of health effects by race/ethnicity or socioeconomic status (SES) (U.S. EPA, 2022a, section 1.2.1).

toxicological) conducted at near-ambient $PM_{2.5}$ concentrations experienced in the U.S.

- U.S.- and Canadian-based epidemiologic studies that examined the relationship between $PM_{2.5}$ exposures and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and coronavirus disease 2019 (COVID-19) death
- At-Risk Populations
  - U.S.- and Canadian-based epidemiologic or exposure studies examining potential disparities in either $PM_{2.5}$ exposures or the risk of health effects by race/ethnicity or socioeconomic status (SES)

Given the narrow scope of the ISA Supplement, it is important to recognize that the evaluation does not encompass the full multidisciplinary evaluation presented within the 2019 ISA that would result in weight-of-evidence conclusions on causality (i.e., causality determinations). The ISA Supplement critically evaluates and provides key study specific information for those recent studies deemed to be of greatest significance for informing preliminary conclusions on the PM NAAQS in the context of the body of evidence and scientific conclusions presented in the 2019 ISA. In its review of the draft ISA Supplement, the CASAC noted that they found "the Draft ISA Supplement to be a well-written, comprehensive evaluation of the new scientific information published since the 2019 PM ISA" (Sheppard, 2022b, p. 2 of letter). Furthermore, the CASAC stated that "the final Integrated Science Assessment (ISA) Supplement… deserve[s] the Administrator's full consideration and [is] adequate for rulemaking" (Sheppard, 2022b, p. 2 of letter). However, recognizing the limited scope of the draft ISA Supplement, the CASAC stated that "[a]lthough this limitation is appropriate for the

targeted purpose of the Draft ISA Supplement…this limiting of scope applies only to this document and is not intended to establish a precedent for future ISAs" (Sheppard, 2022b, p. 2 of letter).

The draft PA was released in October 2021 (86 FR 56263, October 8, 2021). The CASAC PM panel met at a virtual public meeting in December 2021 to review the draft PA (86 FR 52673, September 22, 2021). A virtual public meeting was then held in February 2022 and March 2022, and during this meeting the chartered CASAC considered the CASAC PM panel's draft letter to the Administrator on the draft PA (87 FR 958, January 7, 2022). The chartered CASAC provided its advice on the draft PA in a letter to the EPA Administrator dated March 18, 2022 (Sheppard, 2022a). The EPA took steps to address these comments in revising and finalizing the PA. The PA considers the scientific evidence presented in the 2019 ISA and ISA Supplement and considers the quantitative and technical information presented in the 2020 PA, along with updated and newly available analyses since the completion of the 2020 review. For those health and welfare effects for which the ISA Supplement evaluated recently available evidence and for which updated quantitative analyses were supported (i.e., $PM_{2.5}$-related health effects and visibility effects), the PA includes consideration of this newly available scientific and technical information in reaching preliminary conclusions. For those health and welfare effects for which newly available scientific and technical information were not evaluated (i.e., $PM_{10-2.5}$-related health effects and non-visibility effects), the conclusions presented in the PA rely heavily on the information that supported the conclusions in the 2020 PA. The final PA was released in May 2022 (U.S. EPA, 2022b; hereafter referred to as the PA throughout this notice).

*D. Air Quality Information*

This section provides a summary of basic information related to PM ambient air quality.

It summarizes information on the distribution of particle size in ambient air (section I.D.1), sources and emissions contributing to PM in the ambient air (section I.D.2), monitoring ambient PM in the U.S. (section I.D.3), ambient PM concentrations and trends in the U.S. (I.D.4), characterizing ambient $PM_{2.5}$ concentrations for exposure (section I.D.5), and background PM (section I.D.6). Additional detail on PM air quality can be found in Chapter 2 of the PA (U.S. EPA, 2022b).

1. Distribution of Particle Size in Ambient Air

In ambient air, PM is a mixture of substances suspended as small liquid and/or solid particles (U.S. EPA, 2019a, section 2.2) and distinct health and welfare effects have been linked with exposures to particles of different sizes. Particles in the atmosphere range in size from less than 0.01 to more than 10 μm in diameter (U.S. EPA, 2019a, section 2.2). The EPA defines $PM_{2.5}$, also referred to as fine particles, as particles with aerodynamic diameters generally less than or equal to 2.5 μm. The size range for $PM_{10\text{-}2.5}$, also called coarse or thoracic coarse particles, includes those particles with aerodynamic diameters generally greater than 2.5 μm and less than or equal to 10 μm. $PM_{10}$, which is comprised of both fine and coarse fractions, includes those particles with aerodynamic diameters generally less than or equal to 10 μm. In addition, UFP are often defined as particles with a diameter of less than 0.1 μm based on physical size, thermal diffusivity or electrical mobility (U.S. EPA, 2019a, section 2.2). Atmospheric lifetimes are generally longest for $PM_{2.5}$, which often remains in the atmosphere for days to weeks (U.S. EPA, 2019a, Table 2-1) before being removed by wet or dry deposition, while atmospheric lifetimes for UFP and $PM_{10–2.5}$ are shorter and are generally removed from the atmosphere within hours, through wet or dry deposition (U.S. EPA, 2019a, Table 2-1; U.S. EPA, 2022b, section 2.1).

2. Sources and Emissions Contributing to PM in the Ambient Air

PM is composed of both primary (directly emitted particles) and secondary particles. Primary PM is derived from direct particle emissions from specific PM sources while secondary PM originates from gas-phase precursor chemical compounds present in the atmosphere that have participated in new particle formation or condensed onto existing particles (U.S. EPA, 2019a, section 2.3). As discussed further in the 2019 ISA (U.S. EPA, 2019a, section 2.3.2.1), secondary PM is formed in the atmosphere by photochemical oxidation reactions of both inorganic and organic gas-phase precursors. Precursor gases include sulfur dioxide ($SO_2$), nitrogen oxides ($NO_X$), and volatile organic compounds (VOC) (U.S. EPA, 2019a, section 2.3.2.1). Ammonia also plays an important role in the formation of nitrate PM by neutralizing sulfuric acid and nitric acid. Sources and emissions of PM are discussed in more detail the PA (U.S. EPA, 2022b, section 2.1.1). Briefly, anthropogenic sources of PM include both stationary (e.g., fuel combustion for electricity production and other purposes, industrial processes, agricultural activities) and mobile (e.g., diesel- and gasoline-powered highway vehicles and other engine-driven sources) sources. Natural sources of PM include dust from the wind erosion of natural surfaces, sea salt, wildfires, primary biological aerosol particles (PBAP) such as bacteria and pollen, oxidation of biogenic hydrocarbons, such as isoprene and terpenes to produce secondary organic aerosol (SOA), and geogenic sources, such as sulfate formed from volcanic production of $SO_2$. Wildland fire, which encompass both wildfire and prescribed fire, accounts for over 30% of emissions of primary $PM_{2.5}$ emissions (U.S. EPA, 2021).

In recent years, the frequency and magnitude of wildfires have increased (U.S. EPA, 2019a). The magnitude of the public health impact of wildfires is substantial both because of the increase in $PM_{2.5}$ concentrations as well as the duration of the wildfire smoke season, which is

considered to range from May to November. Wildfire can make a large contribution to air pollution (including $PM_{2.5}$), and wildfire events can threaten public safety and life. The impacts of wildfire events can be mitigated through management of wildland vegetation, including through prescribed fire. Prescribed fire (and some wildfires) can mimic the natural processes necessary to maintain fire dependent ecosystems, minimizing catastrophic wildfires and the risks they pose to safety, property and air quality (see, e.g., 81 FR 58010, 58038, August 24, 2016). Landowners, land managers and government public safety agencies are strongly motivated to reduce the frequency and severity of human caused wildfires. Additionally, land managers, landowners, air agencies and communities may be able to lessen the impacts of wildfires by working collaboratively to take steps to minimize fuel loading in areas vulnerable to fire. Fuel load minimization steps can consist of both prescribed fire and mechanical treatments, such as using mechanical equipment to reduce accumulated understory (81 FR 68249, October 3, 2016). There are specific federal plans of the Department of the Interior[27] and United States Forest Service[28] to increase fuel load minimization efforts in areas at high risk of wildfire. The recently passed Bipartisan Infrastructure Law[29] and Inflation Reduction Act[30] further direct agencies and

[27] See U.S. Department of the Interior, "Infrastructure Investment and Jobs Act Wildfire Risk Five-Year Monitoring, Maintenance, and Treatment Plan" (April 2022), available at: *https://www.doi.gov/sites/doi.gov/files/bil-5-year-wildfire-risk-mmt-plan.04.2022.owf_.final_.pdf*.

[28] See U.S. Department of Agriculture, Forest Service, "Confronting the Wildfire Crisis: A Strategy for Protecting Communities and Improving Resilience in America's Forests", FS-1187d (April 2022) available at: *https://www.fs.usda.gov/sites/default/files/Confronting-Wildfire-Crisis.pdf*.

[29] Inflation Reduction Act, Pub. L. No. 117-169 available at *https://www.congress.gov/bill/117th-congress/house-bill/5376/text*.

[30] Infrastructure Investment and Jobs Act, Pub. L. 117-58, available at *https://www.congress.gov/117/plaws/publ58/PLAW-117publ58.pdf*.

provide funding for such efforts at the federal level as well as at state, Tribal, local and private landowner levels.[31]

Wildfire events produce high PM emissions that impact the PM concentrations in ambient air to the extent that such days with high PM concentrations from wildfire smoke events may affect the design values in a given area. The annual and daily design values affected by potential exceptional events associated with wildfire smoke may qualify to be excluded from design value calculations used for comparison to the NAAQS. The EPA's Exceptional Events Rule (81 FR 68216, October 3, 2016) describes the process by which exceedances caused by fire events, including certain prescribed fires, can be excluded from the design values. It should be noted that potential exceptional events associated with prescribed fires on wildland may also qualify to be excluded from design value calculations used for comparison to the NAAQS under the Exceptional Events Rule (as described in more detail in section VIII below).

While the EPA is not proposing changes to implementation as a part of this proposal (as described in more detail in section VIII below), the EPA acknowledges that increases in $PM_{2.5}$ emissions due to increases in wildfire and prescribed fire on wildland present a number of challenges relevant to the implementation of the PM NAAQS, particularly if one or more standards are strengthened. Stakeholders have expressed concern about the growing health challenges associated with such emissions, the importance of prescribed fire for managing fire-dependent ecosystems and reducing fuel loads, and the potential for further increases in the frequency and magnitude of wildfires due to climate change. Though such issues are outside the scope of this proposal, the EPA acknowledges that these topics may arise in the context of

[31] Inflation Reduction Act, Pub. L. No. 117-169 available at *https://www.congress.gov/bill/117th-congress/house-bill/5376/text*.

implementation of any revised $PM_{2.5}$ NAAQS and intends to work with stakeholders to address these issues.

3. Monitoring of Ambient PM

To promote uniform enforcement of the air quality standards set forth under the CAA and to achieve the degree of public health and welfare protection intended for the NAAQS, the EPA established PM Federal Reference Methods (FRMs) for both $PM_{10}$ and $PM_{2.5}$ (40 CFR Appendices J and L to Part 50). Amended following the 2006 and 2012 PM NAAQS reviews, the current PM monitoring network relies on FRMs and automated continuous Federal Equivalent Methods (FEMs), in part to support changes necessary for implementation of the revised PM standards. The requirement for measuring ambient air quality and reporting ambient air quality data and related information are the basis for 40 CFR Appendices A through E to Part 58. More information on PM ambient monitoring networks is available in section 2.2 of the PA (U.S. EPA, 2022b).

The $PM_{2.5}$ monitoring program is one of the major ambient air monitoring programs with a robust, nationally consistent network of ambient air monitoring sites providing mass and/or chemical speciation measurements. For most urban locations, $PM_{2.5}$ monitors are sited at the

neighborhood scale,[32] where $PM_{2.5}$ concentrations are reasonably homogeneous throughout an entire urban sub-region. In each CBSA with a monitoring requirement, at least one $PM_{2.5}$ monitoring station representing area-wide air quality is sited in an area of expected maximum concentration. By ensuring the area of expected maximum concentration in a CBSA has a site compared to both the annual and 24-hour NAAQS, all other similar locations are thus protected. Sites that represent relatively unique microscale, localized hot-spot, or unique middle scale impact sites are only eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS.

There are three main methods components of the $PM_{2.5}$ monitoring program: filter-based FRMs measuring $PM_{2.5}$ mass, FEMs measuring $PM_{2.5}$ mass, and other samplers used to collect the aerosol used in subsequent laboratory analysis for measuring $PM_{2.5}$ chemical speciation. The FRMs are primarily used for comparison to the NAAQS, but also serve other important purposes, such as developing trends and evaluating the performance of FEMs. $PM_{2.5}$ FEMs are typically continuous methods used to support forecasting and reporting of the Air Quality Index (AQI) but are also used for comparison to the NAAQS. Samplers that are part of the Chemical Speciation Network (CSN) and Interagency Monitoring of Protected Visual Environments (IMPROVE) network are used to provide chemical composition of the aerosol and serve a

[32] For $PM_{2.5}$, neighborhood scale is defined as follows: Measurements in this category would represent conditions throughout some reasonably homogeneous urban sub-region with dimensions of a few kilometers and of generally more regular shape than the middle scale. Homogeneity refers to the particulate matter concentrations, as well as the land use and land surface characteristics. Much of the $PM_{2.5}$ exposures are expected to be associated with this scale of measurement. In some cases, a location carefully chosen to provide neighborhood scale data would represent the immediate neighborhood as well as neighborhoods of the same type in other parts of the city. $PM_{2.5}$ sites of this kind provide good information about trends and compliance with standards because they often represent conditions in areas where people commonly live and work for periods comparable to those specified in the NAAQS. In general, most $PM_{2.5}$ monitoring in urban areas should have this scale.

variety of objectives. More detail on of each of these components of the $PM_{2.5}$ monitoring program and of recent changes to $PM_{2.5}$ monitoring requirements are described in detail in the PA (U.S. EPA, 2022b, section 2.2.3).

4. Ambient Concentrations and Trends

This section summarizes available information on recent ambient PM concentrations in the U.S. and on trends in PM air quality. Sections I.D.4.a and I.D.4.b summarize information on $PM_{2.5}$ mass and components, respectively. Section I.D.4.c summarizes information on $PM_{10}$. Sections I.D.4.d and I.D.4.e summarize the more limited information on $PM_{10-2.5}$ and UFP, respectively. Additional detail on PM air quality and trends can be found in the PA (U.S. EPA, 2022b, section 2.3).

a. $PM_{2.5}$ mass

At monitoring sites in the U.S., annual $PM_{2.5}$ concentrations from 2017 to 2019 averaged 8.0 $\mu g/m^3$ (with the $10^{th}$ and $90^{th}$ percentiles at 5.9 and 10.0 $\mu g/m^3$, respectively) and the $98^{th}$ percentiles of 24-hour concentrations averaged 21.3 $\mu g/m^3$ (with the $10^{th}$ and $90^{th}$ percentiles at 14.0 and 29.7 $\mu g/m^3$, respectively) (U.S. EPA, 2022b, section 2.3.2.1). The highest ambient $PM_{2.5}$ concentrations occur in the western U.S., particularly in California and the Pacific Northwest (U.S. EPA, 2022b, Figure 2-15). Much of the eastern U.S. has lower ambient concentrations, with annual average concentrations generally at or below 12.0 $\mu g/m^3$ and $98^{th}$ percentiles of 24-hour concentrations generally at or below 30 $\mu g/m^3$ (U.S. EPA, 2022b, section 2.3.2.1).

Recent ambient $PM_{2.5}$ concentrations reflect the substantial reductions that have occurred across much of the U.S. (U.S. EPA, 2022b, section 2.3.2.1). From 2000 to 2019, national annual average $PM_{2.5}$ concentrations declined from 13.5 $\mu g/m^3$ to 7.6 $\mu g/m^3$, a 43% decrease (U.S. EPA,

2022b, section 2.3.2.1).[33] These declines have occurred at urban and rural monitoring sites, although urban $PM_{2.5}$ concentrations remain consistently higher than those in rural areas (Chan et al., 2018) due to the impact of local sources in urban areas. Analyses at individual monitoring sites indicate that declines in ambient $PM_{2.5}$ concentrations have been most consistent across the eastern U.S. and in parts of coastal California, where both annual average and 98$^{th}$ percentiles of 24-hour concentrations declined significantly (U.S. EPA, 2022b, section 2.3.2.1). In contrast, trends in ambient $PM_{2.5}$ concentrations have been less consistent over much of the western U.S., with no significant changes since 2000 observed at some sites in the Pacific Northwest, the northern Rockies and plains, and the southwest, particularly for 98$^{th}$ percentiles of 24-hour concentrations (U.S. EPA, 2022b, section 2.3.2.1). As noted below, some sites in the northwestern U.S. and California, where wildfire have been relatively common in recent years, have experienced high concentrations over shorter periods (i.e., 2-hour averages).

The recent deployment of $PM_{2.5}$ monitors near major roads in large urban areas provides information on $PM_{2.5}$ concentrations near an important emissions source. For 2016-2018, Gantt et al. (2021) reported that 52% and 24% of the time near-road sites reported the highest annual and 24-hour $PM_{2.5}$ design value[34] in the CBSA, respectively. Of the CBSAs with the highest annual design values at near-road sites reported by Gantt et al. (2021), those design values were, on average, 0.8 $\mu g/m^3$ higher than at the highest measuring non-near-road sites (range is 0.1 to 2.1 $\mu g/m^3$ higher at near-road sites). Although most near-road monitoring sites do not have sufficient data to evaluate long-term trends in near-road $PM_{2.5}$ concentrations, analyses of the

[33] See *https://www.epa.gov/air-trends/particulate-matter-pm25-trends* for up-to-date $PM_{2.5}$ trends information.

[34] A design value is considered valid if it meets the data handling requirements given in 40 CFR Appendix N to Part 50.

data at one near-road-like site in Elizabeth, NJ, [35] show that the annual average near-road increment has generally decreased between 1999 and 2017 from about 2.0 $\mu g/m^3$ to about 1.3 $\mu g/m^3$ (U.S. EPA, 2022b, section 2.3.2.1).

Ambient $PM_{2.5}$ concentrations can exhibit a diurnal cycle that varies due to impacts from intermittent emission sources, meteorology, and atmospheric chemistry. The $PM_{2.5}$ monitoring network in the U.S. has an increasing number of continuous FEM monitors reporting hourly $PM_{2.5}$ mass concentrations that reflect this diurnal variation. The 2019 ISA describes a two-peaked diurnal pattern in urban areas, with morning peaks attributed to rush-hour traffic and afternoon peaks attributed to a combination of rush hour traffic, decreasing atmospheric dilution, and nucleation (U.S. EPA, 2019a, section 2.5.2.3, Figure 2-32). Because a focus on annual average and 24-hour average $PM_{2.5}$ concentrations could mask sub-daily patterns, and because some health studies examine PM exposure durations shorter than 24-hours, it is useful to understand the broader distribution of sub-daily $PM_{2.5}$ concentrations across the U.S. The PA presents information on the frequency distribution of 2-hour average $PM_{2.5}$ mass concentrations from all FEM $PM_{2.5}$ monitors in the U.S. for 2017-2019. At sites meeting the current primary $PM_{2.5}$ standards, these 2-hour concentrations generally remain below 10 $\mu g/m^3$, and rarely exceed 30 $\mu g/m^3$. Two-hour concentrations are higher at sites violating the current standards, generally remaining below 16 $\mu g/m^3$ and rarely exceeding 80 $\mu g/m^3$ (U.S. EPA, 2022b, section 2.3.2.2.3). The extreme upper end of the distribution of 2-hour $PM_{2.5}$ concentrations is shifted higher during the warmer months, generally corresponding to the period of peak wildfire

[35] The Elizabeth Lab site in Elizabeth, NJ is situated approximately 30 meters from travel lanes of the Interchange 13 toll plaza of the New Jersey Turnpike and within 200 meters of travel lanes for Interstate 278 and the New Jersey Turnpike.

frequency (April to September) in the U.S. At sites meeting the current primary standards, the highest 2-hour concentrations measured rarely occur outside of the period of peak wildfire frequency. Most of the sites measuring these very high concentrations are in the northwestern U.S. and California, where wildfires have been relatively common in recent years (see U.S. EPA, 2022b, Appendix A, Figure A-1). When the period of peak wildfire frequency is excluded from the analysis, the extreme upper end of the distribution is reduced (U.S. EPA, 2022b, section 2.3.2.2.3).

b. $PM_{2.5}$ components

Based on recent air quality data, the major chemical components of $PM_{2.5}$ have distinct spatial distributions. Sulfate concentrations tend to be highest in the eastern U.S., while in the Ohio Valley, Salt Lake Valley, and California nitrate concentrations are highest, and relatively high concentrations of organic carbon are widespread across most of the continental U.S. (U.S. EPA, 2022b, section 2.3.2.3). Elemental carbon, crustal material, and sea salt are found to have the highest concentrations in the northeast U.S., southwest U.S., and coastal areas, respectively.

An examination of $PM_{2.5}$ composition trends can provide insight into the factors contributing to overall reductions in ambient $PM_{2.5}$ concentrations. The biggest change in $PM_{2.5}$ composition that has occurred in recent years is the reduction in sulfate concentrations due to reductions in $SO_2$ emissions. Between 2000 and 2015, the nationwide annual average sulfate concentration decreased by 17% at urban sites and 20% at rural sites. This change in sulfate concentrations is most evident in the eastern U.S. and has resulted in organic matter or nitrate now being the greatest contributor to $PM_{2.5}$ mass in many locations (U.S. EPA, 2019a, Figure 2-19). The overall reduction in sulfate concentrations has contributed substantially to the decrease in national average $PM_{2.5}$ concentrations as well as the decline in the fraction of $PM_{10}$ mass

accounted for by $PM_{2.5}$ (U.S. EPA, 2019a, section 2.5.1.1.6; U.S. EPA, 2022b, section 2.3.1).

c. $PM_{10}$

At long-term monitoring sites in the U.S., the 2017-2019 average of 2nd highest 24-hour $PM_{10}$ concentration was 68 $\mu g/m^3$ (with 10th and 90th percentiles at 28 and 124 $\mu g/m^3$, respectively) (U.S. EPA, 2022b, section 2.3.2.4).[36] The highest $PM_{10}$ concentrations tend to occur in the western U.S. Seasonal analyses indicate that ambient $PM_{10}$ concentrations are generally higher in the summer months than at other times of year, though the most extreme high concentration events are more likely in the spring (U.S. EPA, 2019a, Table 2-5). This is due to fact that the major $PM_{10}$ emission sources, dust and agriculture, are more active during the warmer and drier periods of the year.

Recent ambient $PM_{10}$ concentrations reflect reductions that have occurred across much of the U.S. (U.S. EPA, 2022b, section 2.3.2.4). From 2000 to 2019, 2nd highest 24-hour $PM_{10}$ concentrations have declined by about 46% (U.S. EPA, 2022b, section 2.3.2.4).[37] Analyses at individual monitoring sites indicate that annual average $PM_{10}$ concentrations have generally declined at most sites across the U.S., with much of the decrease in the eastern U.S. associated with reductions in $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section 2.3.2.4). Annual 2nd highest 24-hour $PM_{10}$ concentrations have generally declined in the eastern U.S., while concentrations in much of the midwest and western U.S. have remained unchanged or increased since 2000 (U.S. EPA, 2022b, section 2.3.2.4).

Compared to previous reviews, data available from the NCore monitoring network in the

[36] The form of the current 24-hour $PM_{10}$ standard is one-expected-exceedance, averaged over three years.

[37] For more information, see *https://www.epa.gov/air-trends/particulate-matter-pm10-trends#pmnat.*

current reconsideration allows a more comprehensive analysis of the relative contributions of $PM_{2.5}$ and $PM_{10-2.5}$ to $PM_{10}$ mass. $PM_{2.5}$ generally contributes more to annual average $PM_{10}$ mass in the eastern U.S. than the western U.S. (U.S. EPA, 2022b, Figure 2-23). At most sites in the eastern U.S., the majority of $PM_{10}$ mass is comprised of $PM_{2.5}$. As ambient $PM_{2.5}$ concentrations have declined in the eastern U.S. (U.S. EPA, 2022b, section 2.3.2.2), the ratios of $PM_{2.5}$ to $PM_{10}$ have also declined. For sites with days having concurrently very high $PM_{2.5}$ and $PM_{10}$ concentrations (U.S. EPA, 2022b, Figure 2-24), the $PM_{2.5}/PM_{10}$ ratios are typically higher than the annual average ratios. This is particularly true in the northwestern U.S. where the high $PM_{10}$ concentrations can occur during wildfires with high $PM_{2.5}$ (U.S. EPA, 2022b, section 2.3.2.4).

d. $PM_{10-2.5}$

Since the 2012 review, the availability of $PM_{10-2.5}$ ambient concentration data has greatly increased because of additions to the $PM_{10-2.5}$ monitoring capabilities to the national monitoring network. As illustrated in the PA (U.S. EPA, 2022b, section 2.3.2.5), annual average and $98^{th}$ percentile $PM_{10-2.5}$ concentrations exhibit less distinct differences between the eastern and western U.S. than for either $PM_{2.5}$ or $PM_{10}$.

Due to the short atmospheric lifetime of $PM_{10-2.5}$ relative to $PM_{2.5}$, many of the high concentration sites are isolated and likely near emission sources associated with wind-blown and fugitive dust. The spatial distributions of annual average and $98^{th}$ percentile concentrations of $PM_{10-2.5}$ are more similar than that of $PM_{2.5}$, suggesting that the same dust-related emission sources are affecting both long-term and episodic concentrations (U.S. EPA, 2022b, Figure 2-25). The highest concentrations of $PM_{10-2.5}$ are in the southwest U.S. where widespread dry and windy conditions contribute to wind-blown dust emissions. Additionally, compared to $PM_{2.5}$ and $PM_{10}$, changes in $PM_{10-2.5}$ concentrations have been small in magnitude and inconsistent in

direction (U.S. EPA, 2022b, Figure 2-25). The majority of $PM_{10-2.5}$ sites in the U.S. do not have a concentration trend from 2000-2019, reflecting the relatively consistent level of dust emissions across the U.S. during the same time period (U.S. EPA, 2022b, section 2.3.2.5).[38]

e. UFP

Compared to $PM_{2.5}$ mass, there is relatively little data on U.S. particle number concentrations, which are dominated by UFP. In the published literature, annual average particle number concentrations reaching about 20,000 to 30,000 $cm^3$ have been reported in U.S. cities (U.S. EPA, 2019a). In addition, based on UFP measurements in two urban areas (New York City, Buffalo) and at a background site (Steuben County) in New York, there is a pronounced difference in particle number concentration between different types of locations (U.S. EPA, 2022b, Figure 2-26; U.S. EPA, 2019a, Figure 2-18). Urban particle number counts were several times higher than at the background site, and the highest particle number counts in an urban area with multiple sites (Buffalo) were observed at a near-road location (U.S. EPA, 2022b, section 2.3.2.6).

Long-term trends in UFP are not routinely available at U.S. monitoring sites. At one background site in Illinois with long-term data available, the annual average particle number concentration declined between 2000 and 2019, closely matching the reductions in annual $PM_{2.5}$ mass over that same period (U.S. EPA, 2022b, section 2.3.2.6). In addition, a small number of

[38] PM from dust emissions in the NEI remain fairly consistent from year-to-year, except when there are severe weather incursions or there is a dust event that transports or causes major local dust storms to occur (particularly in the western U.S.). These dust events and weather incursions needed to effect dust emissions on a national level are not common and only seldomly occur. In the emissions trends analysis presented in the PA (U.S. EPA, 2022b, section 2.1.1), dust is included in the NEI sector labeled "miscellaneous."

published studies have examined UFP trends over time. While limited, these studies also suggest that UFP number concentrations have declined over time along with decreases in $PM_{2.5}$ (U.S. EPA, 2022b, section 2.3.2.6). However, the relationship between changes in ambient $PM_{2.5}$ and UFPs cannot be comprehensively characterized due to the high variability and limited monitoring of UFPs (U.S. EPA, 2022b, section 2.3.2.6).

5. Characterizing Ambient $PM_{2.5}$ Concentrations for Exposure

Epidemiologic studies use various methods to characterize exposure to ambient $PM_{2.5}$. The methods used to estimate $PM_{2.5}$ concentrations can vary from traditional methods using monitoring data from ground-based monitors to newer methods using more complex hybrid modeling approaches. Studies using hybrid modeling approaches aim to broaden the spatial coverage, as well as estimate more spatially-resolved ambient $PM_{2.5}$ concentrations, by expanding beyond just those areas with monitors and providing estimates in areas that do not have ground-based monitors (i.e., areas that are generally less densely populated and tend to have lower $PM_{2.5}$ concentrations) and at finer spatial resolutions (e.g., 1 km x 1 km grid cells). As such, the hybrid modeling approaches tend to broaden the areas captured in the exposure assessment, and in doing so, the studies that utilize these methods tend to report lower mean $PM_{2.5}$ concentrations than monitor-based approaches. Further, other aspects of the approaches applied in the various epidemiologic studies to estimate $PM_{2.5}$ exposure and/or to calculate the related study-reported mean concentration (i.e., population weighting, trim mean approaches) can affect those data values. More detail related to hybrid modeling methods, performance of the methods, and how the reported mean concentrations compare across approaches is provided in section 2.3.3.2 of the PA (U.S. EPA, 2022b). The subsections below discuss the characterization of $PM_{2.5}$ concentrations based on monitoring data (I.D.5.a) and using

hybrid modeling approaches (I.D.5.b).

a. Predicted Ambient $PM_{2.5}$ and Exposure Based on Monitored Data

Ambient concentrations of $PM_{2.5}$ are often characterized using measurements from national monitoring networks due to the accuracy and precision of the measurements and the public availability of data. For applications requiring $PM_{2.5}$ characterizations across large areas or provide complete coverage from the site measurements, data interpolation and averaging techniques (such as Average Nearest Neighbor tools, and area-wide or population-weighted averaging of monitors) are sometimes used (U.S. EPA, 2019a, chapter 3).

For an area to meet the NAAQS, all valid design values[39] in that area, including the highest annual and 24-hour values, must be at or below the levels of the standards. Because the monitoring network siting requirements are specified to capture the high $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section 2.2.3), areas meeting an annual $PM_{2.5}$ standard with a particular level would be expected to have long-term average monitored $PM_{2.5}$ concentrations (i.e., averaged across space and over time in the area) somewhat below that standard level. Analyses in the PA indicate that, based on recent air quality in U.S. CBSAs, maximum annual $PM_{2.5}$ design values are often 10% to 20% higher than annual average concentrations (i.e., averaged across multiple monitors in the same CBSA) (U.S. EPA, 2022b, section 2.3.3.1, Figures 2-28 and 2-29). This means that the $PM_{2.5}$ design value in an area is associated with a distribution of $PM_{2.5}$ concentrations in that area, and based on monitoring siting requirements, should represent the highest concentration location applicable to be monitored under the $PM_{2.5}$ NAAQS. This

[39] For the annual $PM_{2.5}$ standard, design values are calculated as the annual arithmetic mean $PM_{2.5}$ concentration, averaged over 3 years. For the 24-hour standard, design values are calculated as the 98$^{th}$ percentile of the annual distribution of 24-hour $PM_{2.5}$ concentrations, averaged over three years (Appendix N of 40 CFR Part 50).

difference between the maximum annual design value and the average concentration in an area can vary, depending on factors such as the number of monitors, monitor siting characteristics, and the distribution of ambient $PM_{2.5}$ concentrations. Given that higher $PM_{2.5}$ concentrations have been reported at some near-road monitoring sites relative to the surrounding area (U.S. EPA, 2022b, section 2.3.2.2.2), recent requirements for $PM_{2.5}$ monitoring at near-road locations in large urban areas (U.S. EPA, 2022b, section 2.2.3.3) may increase the ratios of maximum design values to average annual design values in some areas. Such ratios may also depend on how the averages are calculated (i.e., averaged across monitors versus across modeled grid cells, as described below in section I.5.b). Compared to annual design values, the analysis in the PA indicates a more variable relationship between maximum 24-hour $PM_{2.5}$ design values and annual average concentrations (U.S. EPA, 2022b, section 2.3.3.1, Figure 2-29).

b. Comparison of $PM_{2.5}$ Fields in Estimating Exposure and Relative to Design Values

Two types of hybrid approaches that have been utilized in several key $PM_{2.5}$ epidemiologic studies in the 2019 ISA and ISA Supplement include neural network approaches and a satellite-based method with regression of residual $PM_{2.5}$ with land-use and other variables to improve estimates of $PM_{2.5}$ concentration in the US. As such, the PA further compares these two types of approaches across various scales (e.g., CBSA versus nationwide), taking into account population weighting approaches utilized in epidemiologic studies when estimating $PM_{2.5}$ exposure (U.S. EPA, 2022b, section 2.3.3.2.4). Additionally, the PA assesses how average $PM_{2.5}$ concentrations computed in epidemiologic studies using these hybrid surfaces compare to the maximum design values measured at ground-based monitors. For this assessment, the PA

evaluates the DI2019[40] and HA2020[41] hybrid surfaces, surfaces that are used in several of the key epidemiologic studies in the PA. This analysis is intended to help inform how the magnitude of the overall study reported mean $PM_{2.5}$ concentrations in epidemiologic studies may be influenced by the approach used to compute that mean and how that value might compare to monitor reported concentrations.

In estimating exposure, some studies focus on estimating concentrations in urban areas, while others examine the entire U.S. or large portions of the country. In general, the areas that are not included in the CBSA-only analysis tend to be more rural or less densely populated areas, tend to have lower $PM_{2.5}$ concentrations, and likely correspond to those locations where monitoring data availability is limited or nonexistent (U.S. EPA, 2022b, section 2.3.3.2.4, Figure 2-37). To evaluate the differences in mean $PM_{2.5}$ concentrations across different spatial scales, the PA analysis compares the DI2019 and HA2020 surfaces. At the national scale, the two surfaces generally produce similar average annual $PM_{2.5}$ concentrations, with the DI2019 surface being slightly higher compared to the HA2020 surface. The average annual $PM_{2.5}$ concentrations are also slightly higher using the DI2019 surface compared to the HA2020 surface when the analyses are conducted for CBSAs. Also, regardless of which surface is used, the average annual

[40] This analysis includes an updated version of the surface used in Di et al. (2016). Predictions in Di et al. (2016) were for 2000 to 2012 using a neural network model. The Di et al. (2019) study improved on that effort in several ways. First, a generalized additive model was used that accounted for geographic variations in performance to combine predictions from three models (neural network, random forest, and gradient boosting) to make the final optimal $PM_{2.5}$ predictions. Second, the datasets were updated that were used in model training and included additional variables such as 12-km CMAQ modeling as predictors. Finally, more recent years were included in the Di et al. (2019) study.

[41] The HA2020 field is based on the V4.NA.03 product available at: *https://sites.wustl.edu/acag/datasets/surface-pm2-5/*. The name "HA2020" comes from the references for this product (Hammer et al., 2020; van Donkelaar et al., 2019).

and 3-year average of the average annual $PM_{2.5}$ concentrations for the CBSA-only analyses are somewhat higher than for the nationwide analyses (4-8% higher) (U.S. EPA, 2022b, section 2.3.3.2.4, Table 2-5).[42] Overall, these analyses suggest that there are only slight differences in the average $PM_{2.5}$ concentrations depending on the hybrid modeling method employed, though including other hybrid modeling methods in this comparison could result in larger differences.

The PA next evaluates how the averages of the hybrid model surfaces compare to regulatory design values using both the DI2019 and HA2020 surfaces and how population weighting influences the mean $PM_{2.5}$ concentration.[43] As presented in the PA, the results using the DI2019 and HA2020 surfaces are similar for the average annual $PM_{2.5}$ concentrations, for each 3-year period. When population weighting is not applied, the average annual $PM_{2.5}$ concentrations generally range from 7.0 to 8.6 $\mu g/m^3$. When population weighting is applied, the average annual $PM_{2.5}$ concentrations are slightly higher, ranging from 8.2 to 10.2 $\mu g/m^3$. As with CBSAs versus the national comparison above, population weighting results in a higher average $PM_{2.5}$ concentration than when population weighting is not applied (U.S. EPA, 2022b, section 2.3.3.2.4, Table 2-7). For the CBSAs included in the population weighted analyses, the average maximum annual design values generally range from 9.5 to 11.7 $\mu g/m^3$. The results are similar for both the DI2019 and HA2020 surfaces and the maximum annual $PM_{2.5}$ design values

[42] For the national scale, 3-year averages of the average annual $PM_{2.5}$ concentrations generally range from about 5.3 $\mu g/m^3$ to 8.1 $\mu g/m^3$, compared to the CBSA scale, which ranges from 5.7 $\mu g/m^3$ to 8.7 $\mu g/m^3$. (U.S. EPA, 2022b, section 2.3.3.2.4, Table 2-6).

[43] For this analysis, the PA includes CBSAs with three or more valid design values for the 3-year period. The regulatory design values for the CBSAs were calculated for each 3-year period for the CBSAs with 3 or more design values in each of the 3-year periods. Using the maximum design value for each CBSA and by each 3-year period, the ratio of maximum design values to modeled average annual $PM_{2.5}$ concentrations were calculated, for each 3-year period. More details about the analytical methods used for this analysis are described in section A.6 of Appendix A in the PA (U.S. EPA, 2022b).

measured at the monitors are often 40% to 50% higher than average annual $PM_{2.5}$ concentrations predicted by hybrid modeling methods when population weighting is not applied. However, when population weighting is applied, the ratio of the maximum annual $PM_{2.5}$ design values to the predicted average annual $PM_{2.5}$ concentrations are lower than when population weighting is not applied, with monitored design values generally 15% to 18% higher than population-weighted hybrid modeling average annual $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section 2.3.3.2.4, Table 2-7).

6. Background PM

In this reconsideration, background PM is defined as all particles that are formed by sources or processes that cannot be influenced by actions within the jurisdiction of concern. U.S. background PM is defined as any PM formed from emissions other than U.S. anthropogenic (i.e., manmade) emissions. Potential sources of U.S. background PM include both natural sources (i.e., PM that would exist in the absence of any anthropogenic emissions of PM or PM precursors) and transboundary sources originating outside U.S. borders. Background PM is discussed in more detail in the PA (U.S. EPA, 2022b, section 2.4). At annual and national scales, estimated background PM concentrations in the U.S. are small compared to contributions from domestic anthropogenic sources.[44] For example, based on zero-out modeling in the last review of

[44] Sources that contribute to natural background PM include dust from the wind erosion of natural surfaces, sea salt, wildland fires, primary biological aerosol particles such as bacteria and pollen, oxidation of biogenic hydrocarbons such as isoprene and terpenes to produce secondary organic aerosols (SOA), and geogenic sources such as sulfate formed from volcanic production of $SO_2$ and oceanic production of dimethyl-sulfide (U.S. EPA, 2022b, section 2.4). While most of these sources release or contribute predominantly to fine aerosol, some sources including windblown dust, and sea salt also produce particles in the coarse size range (U.S. EPA, 2019a, section 2.3.3).

the PM NAAQS, annual background $PM_{2.5}$ concentrations were estimated to range from 0.5-3 $\mu g/m^3$ across the sites examined. In addition, speciated monitoring data from IMPROVE sites can provide some insights into how contributions from different sources, including sources of background PM, may have changed over time. Such data suggests the estimates of background concentrations using speciated monitoring data from IMPROVE monitors are around 1-3 $\mu g/m^3$ and have not changed significantly since the 2012 review. Contributions to background PM in the U.S. result mainly from sources within North America. Contributions from intercontinental events have also been documented (e.g., transport from dust storms occurring in deserts in North Africa and Asia), but these events are less frequent and represent a relatively small fraction of background PM in most of the U.S. (U.S. EPA, 2022b, section 2.4).

## II. Rationale for Proposed Decisions on the Primary $PM_{2.5}$ Standards

This section presents the rationale for the Administrator's proposed decision to revise the primary annual $PM_{2.5}$ standard and retain the primary 24-hour $PM_{2.5}$ standard. This rationale is based on a thorough review of the scientific evidence generally published through January 2018,[45] as presented in the 2019 ISA (U.S. EPA, 2019a), on the human health effects of $PM_{2.5}$ associated with long- and short-term exposures[46] to $PM_{2.5}$ in the ambient air. Additionally, this rationale is based on a thorough evaluation of some studies that became available after the

[45] In addition to the 2020 review's opening "call for information" (79 FR 71764, December 3, 2014), the 2019 ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009, through approximately January 2018 (U.S. EPA, 2019a, p. ES-2). References that are cited in the 2019 ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: *https://hero.epa.gov/hero/particulate-matter*.

[46] Short-term exposures are defined as those exposures occurring over hours up to 1 month, whereas long-term exposures are defined as those exposures occurring over 1 month to years (U.S. EPA, 2019a, section P.3.1).

literature cutoff date of the 2019 ISA, as evaluated in the ISA Supplement, that could either further inform the adequacy of the current PM NAAQS or address key scientific topics that have evolved since the literature cutoff date for the 2019 ISA, generally through March 2021 (U.S. EPA, 2022b).[47] The Administrator's rationale also takes into account: (1) the PA evaluation of the policy-relevant information in the 2019 ISA and ISA Supplement and presentation of quantitative analyses of air quality and health risks; (2) CASAC advice and recommendations, as reflected in discussions of the drafts of the ISA Supplement and PA at public meetings and in the CASAC's letters to the Administrator; and (3) public comments received during the development of these documents.

In presenting the rationale for the Administrator's proposed decisions and its foundations, section II.A provides background and introductory information for this reconsideration of the primary $PM_{2.5}$ standards. It includes background on the 2020 final decision to retain the primary $PM_{2.5}$ standards (section II.A.1) and also describes the general approach for this reconsideration (section II.A.2). Section II.B summarizes the key aspects of the currently available health effects evidence, focusing on consideration of the key policy-relevant aspects. Section II.C summarizes the risk information for this reconsideration, drawing on the quantitative analyses for $PM_{2.5}$, presented in the PA. Section II.D presents the Administrator's proposed conclusions on the current primary annual and 24-hour $PM_{2.5}$ standards (section II.D.3), drawing on both the

[47] The ISA Supplement represents an evaluation of recent studies that are of greatest policy relevance to the reconsideration of the 2020 final decision on the PM NAAQS. Specifically, the ISA Supplement focuses on studies of health effects for which the evidence in the 2019 ISA supported a "causal relationship" (i.e., short- and long-term $PM_{2.5}$ exposure and mortality and cardiovascular effects) because those were the health effects that were most useful in informing conclusions in the 2020 PA. The ISA Supplement does not include an evaluation of studies for other $PM_{2.5}$-related health effects (U.S. EPA, 2022b).

evidence-based and risk-based considerations (section II.D.2) and advice from the CASAC (section II.D.1).

*A. General Approach*

This reconsideration of the 2020 final decision on the primary $PM_{2.5}$ standards relies on using the EPA's assessment of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding primary $PM_{2.5}$ standards that protect public health with an adequate margin of safety. The EPA's assessments are primarily documented in the 2019 ISA, ISA Supplement, and PA, all of which have received CASAC review and public comment (83 FR 53471, October 23, 2018; 83 FR 55529, November 6, 2018; 85 FR 4655, January 27, 2020; 86 FR 52673, September 22, 2021; 86 FR 54186, September 30, 2021; 86 FR 56263, October 8, 2021; 87 FR 958, January 7, 2022; 87 FR 22207, April 14, 2022; 87 FR 31965, May 26, 2022). In bridging the gap between the scientific assessments of the 2019 ISA and ISA Supplement and the judgments required of the Administrator in determining whether the current standards provide the requisite public health protection, the PA evaluates policy implications of the evaluation of the current evidence in the 2019 ISA and ISA Supplement, and the risk information documented in the PA. In evaluating the public health protection afforded by the current standards, the four basic elements of the NAAQS (indicator, averaging time, level, and form) are considered collectively.

The final decision on the adequacy of the current primary $PM_{2.5}$ standards is a public health policy judgment to be made by the Administrator. In reaching conclusions with regard to the standards, the decision will draw on the scientific information and analyses about health effects and population risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This

approach is based on the recognition that the available health effects evidence generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the Clean Air Act and with how the EPA and the courts have historically interpreted the Act (summarized in section I.A above). These provisions require the Administrator to establish primary standards that, in the judgment of the Administrator, are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of sensitive groups.[48]

The subsections below provide background and introductory information. Background on the 2020 decision to retain the current standards, including the rationale for that decision, is summarized in section II.A.1. This is followed, in section II.A.2, by an overview of the general approach for the reconsideration of the 2020 final decision. Following this introductory section and subsections, the subsequent sections summarize current information and analyses, including that newly available in this reconsideration. The Administrator's proposed conclusions on the primary PM2.5 standards, based on the current information, are provided in section II.D.3.

1. Background on the Current Standards

[48] As noted in section I.A above, the legislative history describes such protection for the sensitive group of individuals and not for a single person in the sensitive group (see S. Rep. No. 91-1196, 91st Cong, 2d Sess. 10 [1970]).

The current primary $PM_{2.5}$ standards were retained in 2020 based on the scientific evidence and quantitative risk analyses available at that time, as well as the Administrator's judgments regarding the available scientific information, the appropriate degree of public health protection for the standards, and the available risk information regarding the exposures and risk that may be allowed by the current standards (85 FR 82718, December 18, 2020). With the 2020 final decision, the EPA retained the primary 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$, and the primary annual $PM_{2.5}$ standard, with its level of 12.0 $\mu g/m^3$, this decision was informed by the scientific evidence evaluated in the 2019 ISA, the evidence and quantitative risk information in the 2020 PA, the advice and recommendations of the CASAC, and public comments on the proposed decision (85 FR 24094, April 30, 2020).

The health effects evidence base available in the 2020 review included extensive evidence from previous reviews as well as the evidence that had emerged since the prior review had been completed in 2012. This evidence base, spanning several decades, documents the relationship between short- and long-term $PM_{2.5}$ exposure and mortality or serious morbidity effects. The evidence available in the 2019 ISA reaffirmed, and in some cases strengthened, the conclusions from the 2009 ISA regarding the health effects of $PM_{2.5}$ exposures (U.S. EPA, 2009a). Much of the evidence came from epidemiologic studies conducted in North America, Europe, or Asia examining short-term and long-term exposures that demonstrated generally positive, and often statistically significant, $PM_{2.5}$ health effect associations with a range of outcomes including non-accidental, cardiovascular, or respiratory mortality; cardiovascular or respiratory hospitalizations or emergency department visits; and other mortality/morbidity outcomes (e.g., lung cancer mortality or incidence, asthma development). Experimental evidence, as well as evidence from panel studies, strengthened support for potential biological

pathways through which $PM_{2.5}$ exposures could lead to health effects reported in many population-based epidemiologic studies, including support for pathways that could lead to cardiovascular, respiratory, nervous system, and cancer-related effects. Based on this evidence, the 2019 ISA concludes there to be a causal relationship between long- and short-term $PM_{2.5}$ exposure and mortality and cardiovascular effects, as well as likely to be causal relationships between long- and short-term $PM_{2.5}$ exposures and respiratory effects, and between long-term $PM_{2.5}$ exposures and cancer and nervous system effects (U.S. EPA, 2019a, section 1.7).

Epidemiologic studies reported $PM_{2.5}$ health effect associations with mortality and/or morbidity across multiple U.S. cities and in diverse populations, including in studies examining populations and lifestages that may be at increased risk of experiencing a $PM_{2.5}$-related health effect (e.g., older adults, children). The 2019 ISA cited extensive evidence indicating that "both the general population as well as specific populations and lifestages are at risk for $PM_{2.5}$-related health effects" (U.S. EPA, 2019a, p. 12-1). Some of the evidence that supported conclusions on at-risk populations and lifestages also contributed to the conclusions of causal and likely to be causal relationships within the 2019 ISA, including:

- $PM_{2.5}$-related mortality and cardiovascular effects in older adults (U.S. EPA, 2019a, sections 11.1, 11.2, 6.1, and 6.2);
- $PM_{2.5}$-related cardiovascular effects in people with pre-existing cardiovascular disease (U.S. EPA, 2019a, section 6.1);
- $PM_{2.5}$-related respiratory effects in people with pre-existing respiratory disease, particularly asthma (U.S. EPA, 2019a, section 5.1);
- $PM_{2.5}$-related impairments in lung function growth and asthma development in children (U.S.

EPA, 2019a, sections 5.1, 5.2, and 12.5.1.1).

The 2019 ISA also noted that stratified analyses (i.e., analyses that allow for the comparison of PM-related health effects across different populations) provided strong evidence for racial and ethnic differences in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risk. Such analyses indicated that certain racial and ethnic groups, specifically Hispanic and non-Hispanic Black populations have higher $PM_{2.5}$ exposures than non-Hispanic White populations, thus contributing to risk of adverse $PM_{2.5}$-related health effects in minority populations (U.S. EPA, 2019a, section 12.5.4). Stratified analyses focusing on other groups also suggested that populations with pre-existing cardiovascular or respiratory disease, populations that are overweight or obese, populations that have particular genetic variants, and populations that are of low socioeconomic status (SES) could be at increased risk for $PM_{2.5}$-related adverse health effects (U.S. EPA, 2019a, chapter 12).

The risk information available in the 2020 review included risk estimates for air quality conditions just meeting the existing primary $PM_{2.5}$ standards, and also for air quality conditions just meeting potential alternative standards. The general approach to estimating $PM_{2.5}$-associated health risks combined concentration-response (C-R) functions from epidemiologic studies with model-based $PM_{2.5}$ air quality surfaces, baseline health incidence data, and population demographics for 47 urban areas (U.S. EPA, 2022b, section 3.3, Figure 3-10, Appendix C). The risk assessment estimated that the existing primary $PM_{2.5}$ standards could allow a substantial number of $PM_{2.5}$-associated deaths in the U.S. Uncertainty in risk estimates (e.g., in the size of risk estimates) can result from a number of factors, including assumptions about the shape of the C-R relationship with mortality at low ambient $PM_{2.5}$ concentrations, the potential for confounding and/or exposure measurement error, and the methods used to adjust $PM_{2.5}$ air quality.

Consistent with the general approach routinely employed in NAAQS reviews, the initial consideration in the 2020 review of the primary $PM_{2.5}$ standards was with regard to the adequacy of the protection provided by the existing standards. Key aspects of the consideration are summarized in section II.A.1.a below.

a. Considerations Regarding the Adequacy of the Existing Standards in the 2020 Review

With the 2020 final decision, the EPA retained the primary 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$, and the primary annual $PM_{2.5}$ standard, with its level of 12.0 $\mu g/m^3$. The Administrator's conclusions regarding the adequacy of the primary $PM_{2.5}$ standards at the time of the 2020 review was based on consideration of the evidence, analyses and conclusions contained in the 2019 ISA; the quantitative risk assessment in the 2020 PA; advice from the CASAC; and public comments. Key considerations informing the Administrator's decision to retain the standards that were promulgated in the 2012 review are summarized below.

As an initial matter, the Administrator considered the range of scientific evidence evaluating these effects, including studies of at-risk populations, to inform his review of the primary $PM_{2.5}$ standards, placing the greatest weight on evidence of effects for which the 2019 ISA determined there to be a causal or likely to be causal relationship with long- and short-term $PM_{2.5}$ exposures (85 FR 82714-82715, December 18, 2020).

With regard to indicator, the Administrator recognized that, consistent with the evidence available in prior reviews, the scientific evidence in the 2020 review continued to provide strong support for health effects following short- and long-term $PM_{2.5}$ exposures. He noted the 2020 PA conclusions that the information continued to support the $PM_{2.5}$ mass-based indicator and remained too limited to support a distinct standard for any specific $PM_{2.5}$ component or group of components, and too limited to support a distinct standard for the ultrafine fraction. Thus, the

Administrator concluded that it was appropriate to retain $PM_{2.5}$ as the indicator for the primary standards for fine particles (85 FR 82715, December 18, 2020).

With respect to averaging time and form, the Administrator noted that the scientific evidence continued to provide strong support for health effects associations with both long-term (e.g., annual or multi-year) and short-term (e.g., mostly 24-hour) exposures to $PM_{2.5}$, consistent with the conclusions in the 2020 PA. In the 2019 ISA, epidemiologic and controlled human exposure studies examined a variety of $PM_{2.5}$ exposure durations. Epidemiologic studies continued to provide strong support for health effects associated with short-term $PM_{2.5}$ exposures based on 24-hour $PM_{2.5}$ averaging periods, and the EPA noted that associations with sub-daily estimates are less consistent and, in some cases, smaller in magnitude (U.S. EPA, 2019a, section 1.5.2.1; U.S. EPA, 2020a, section 3.5.2.2). In addition, controlled human exposure and panel-based studies of sub-daily exposures typically examined subclinical effects, rather than the more serious population-level effects that have been reported to be associated with 24-hour exposures (e.g., mortality, hospitalizations). Taken together, the 2019 ISA concludes that epidemiologic studies did not indicate that sub-daily averaging periods were more closely associated with health effects than the 24-hour average exposure metric (U.S. EPA, 2019a, section 1.5.2.1). Additionally, while controlled human exposure studies provided consistent evidence for cardiovascular effects following $PM_{2.5}$ exposures for less than 24 hours (i.e., < 30 minutes to 5 hours), exposure concentrations in the studies were well-above the ambient concentrations typically measured in locations meeting the existing standards (U.S. EPA, 2020a, section 3.2.3.1). Thus, these studies also did not suggest the need for additional protection against sub-daily $PM_{2.5}$ exposures (U.S. EPA, 2020a, section 3.5.2.2). Therefore, the Administrator judged that the 24-hour averaging time remained appropriate (85 FR 82715, December 18, 2020).

With regard to the form of the 24-hour standard (98th percentile, averaged over three years), the Administrator noted that epidemiologic studies continued to provide strong support for health effect associations with short-term (e.g., mostly 24-hour) $PM_{2.5}$ exposures (U.S. EPA, 2020a, section 3.5.2.3) and that controlled human exposure studies provided evidence for health effects following single short-term "peak" $PM_{2.5}$ exposures. Thus, the evidence supported retaining a standard focused on providing supplemental protection against short-term peak exposures and supported a 98th percentile form for a 24-hour standard. The Administrator further noted that this form also provided an appropriate balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk management programs (U.S. EPA, 2020a, section 3.5.2.3). As such, the Administrator concluded that the available information supported retaining the form and averaging time of the current 24-hour standard (98th percentile, averaged over three years) and annual standard (annual average, averaged over three years) (85 FR 82715, December 18, 2020).

With regard to the level of the standards, in reaching his final decision, the Administrator considered the large body of evidence presented and assessed in the 2019 ISA (U.S. EPA, 2019a), the policy-relevant and risk-based conclusions and rationales as presented in the 2020 PA (U.S. EPA, 2020a), advice from the CASAC, and public comments. In particular, in considering the 2019 ISA and 2020 PA, he considered key epidemiologic studies that evaluated associations between $PM_{2.5}$ air quality distributions and mortality and morbidity, including key accountability studies; the availability of experimental studies to support biological plausibility; controlled human exposure studies examining effects following short-term $PM_{2.5}$ exposures; air quality analyses; and the important uncertainties and limitations associated with the information (85 FR 82715, December 18, 2020).

As an initial matter, the Administrator considered the protection afforded by both the annual and 24-hour standards together against long- and short-term $PM_{2.5}$ exposures and health effects. The Administrator recognized that the annual standard was most effective in controlling "typical" $PM_{2.5}$ concentrations near the middle of the air quality distribution (i.e., around the mean of the distribution), but also provided some control over short-term peak $PM_{2.5}$ concentrations. On the other hand, the 24-hour standard, with its 98$^{th}$ percentile form, was most effective at limiting peak 24-hour $PM_{2.5}$ concentrations, but in doing so also had an effect on annual average $PM_{2.5}$ concentrations. Thus, while either standard could be viewed as providing some measure of protection against both average exposures and peak exposures, the 24-hour and annual standards were not expected to be equally effective at limiting both types of exposures. Thus, consistent with previous reviews, the Administrator's consideration of the public health protection provided by the existing primary $PM_{2.5}$ standards was based on his consideration of the combination of the annual and 24-hour standards. Specifically, he recognized that the annual standard was more likely to appropriately limit the "typical" daily and annual exposures that are most strongly associated with the health effects observed in epidemiologic studies. The Administrator concluded that an annual standard (as the arithmetic mean, averaged over three years) remained appropriate for targeting protection against the annual and daily $PM_{2.5}$ exposures around the middle portion of the $PM_{2.5}$ air quality distribution. Further, recognizing that the 24-hour standard (with its 98$^{th}$ percentile form) was more directly tied to short-term peak $PM_{2.5}$ concentrations, and more likely to appropriately limit exposures to such concentrations, the Administrator concluded that the current 24-hour standard (with its 98$^{th}$ percentile form, averaged over three years) remained appropriate to provide a balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk

management programs. However, the Administrator recognized that changes in $PM_{2.5}$ air quality to meet an annual standard would likely result not only in lower short- and long-term $PM_{2.5}$ concentrations near the middle of the air quality distribution, but also in fewer and lower short-term peak $PM_{2.5}$ concentrations. The Administrator further recognized that changes in air quality to meet a 24-hour standard, with a $98^{th}$ percentile form, would result not only in fewer and lower peak 24-hour $PM_{2.5}$ concentrations, but also in lower annual average $PM_{2.5}$ concentrations (85 FR 82715-82716, December 18, 2020).

Thus, in considering the adequacy of the 24-hour standard, the Administrator noted the importance of considering whether additional protection was needed against short-term exposures to peak $PM_{2.5}$ concentrations. In examining the scientific evidence, he noted the limited utility of the animal toxicological studies in directly informing conclusions on the appropriate level of the standard given the uncertainty in extrapolating from effects in animals to those in human populations. The Administrator noted that controlled human exposure studies provided evidence for health effects following single, short-term $PM_{2.5}$ exposures that corresponded best to exposures that might be experienced in the upper end of the $PM_{2.5}$ air quality distribution in the U.S. (i.e., "peak" concentrations). However, most of these studies examined exposure concentrations considerably higher than are typically measured in areas meeting the standards (U.S. EPA, 2020a, section 3.2.3.1). In particular, controlled human exposure studies often reported statistically significant effects on one or more indicators of cardiovascular function following 2-hour exposures to $PM_{2.5}$ concentrations at and above 120 $\mu g/m^3$ (at and above 149 $\mu g/m^3$ for vascular impairment, the effect shown to be most consistent across studies). To provide insight into what these studies may indicate regarding the primary $PM_{2.5}$ standards, the 2020 PA (U.S. EPA, 2020a, p. 3-49) noted that 2-hour ambient

concentrations of $PM_{2.5}$ at monitoring sites meeting the current standards almost never exceeded 32 $\mu g/m^3$. In fact, even the extreme upper end of the distribution of 2-hour $PM_{2.5}$ concentrations at sites meeting the primary $PM_{2.5}$ standards remained well-below the $PM_{2.5}$ exposure concentrations consistently shown in controlled human exposure studies to elicit effects (i.e., $99.9^{th}$ percentile of 2-hour concentrations at these sites is 68 $\mu g/m^3$ during the warm season). Thus, the available experimental evidence did not indicate the need for additional protection against exposures to peak $PM_{2.5}$ concentrations, beyond the protection provided by the combination of the 24-hour and the annual standards (U.S. EPA, 2020a, section 3.2.3.1; 85 FR 82716, December 18, 2020).

With respect to the epidemiologic evidence, the Administrator noted that the studies did not indicate that associations in those studies were strongly influenced by exposures to peak concentrations in the air quality distribution and thus did not indicate the need for additional protection against short-term exposures to peak $PM_{2.5}$ concentrations (U.S. EPA, 2020a, section 3.5.1 The Administrator noted that this was consistent with CASAC consensus support for retaining the current 24-hour standard. Thus, the Administrator concluded that the 24-hour standard with its level of 35 $\mu g/m^3$ was adequate to provide supplemental protection (i.e., beyond that provided by the annual standard alone) against short-term exposures to peak $PM_{2.5}$ concentrations (85 FR 82716, December 18, 2020).

With regard to the level of the annual standard, the Administrator recognized that the annual standard, with its form based on the arithmetic mean concentration, was most appropriately meant to limit the "typical" daily and annual exposures that were most strongly associated with the health effects observed in epidemiologic studies. However, the Administrator also noted that while epidemiologic studies examined associations between distributions of $PM_{2.5}$

air quality and health outcomes, they did not identify particular $PM_{2.5}$ exposures that cause effects and thus, they could not alone identify a specific level at which the standard should be set, as such a determination necessarily required the Administrator's judgment. Thus, consistent with the approaches in previous NAAQS reviews, the Administrator recognized that any approach that used epidemiologic information in reaching decisions on what standards are appropriate necessarily required judgments about how to translate the information from the epidemiologic studies into a basis for appropriate standards. This approach included consideration of the uncertainties in the reported associations between daily or annual average $PM_{2.5}$ exposures and mortality or morbidity in the epidemiologic studies. Such an approach is consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the Clean Air Act (CAA) (85 FR 82716, December 18, 2020).

The Administrator emphasized uncertainties and limitations that were present in epidemiologic studies in previous reviews and persisted in the 2020 review. These uncertainties included exposure measurement error, potential confounding by copollutants, increasing uncertainty of associations at lower $PM_{2.5}$ concentrations, and heterogeneity of effects across different cities or regions (85 FR 82716, December 18, 2020). The Administrator also noted the advice given by the CASAC on this matter. As described in section I.C.5 above, the CASAC did not reach consensus on the adequacy of the primary annual $PM_{2.5}$ standard. "Some CASAC members" expressed support for retaining the primary annual $PM_{2.5}$ standard while "other members" expressed support for revising that standard in order to increase public health protection (Cox, 2019a, p. 1 of consensus letter). The CASAC members who supported retaining the annual standard expressed their concerns with the epidemiologic studies, asserting that these

studies did not provide a sufficient basis for revising the existing standards. They also identified several key concerns regarding the associations reported in epidemiologic studies and concluded that "while the data on associations should certainly be carefully considered, this data should not be interpreted more strongly than warranted based on its methodological limitations" (Cox, 2019a, p. 8 consensus responses).

Taking into consideration the views expressed by the CASAC members who supported retaining the annual standard, the Administrator recognized that epidemiologic studies examined associations between distributions of $PM_{2.5}$ air quality and health outcomes, and they did not identify particular $PM_{2.5}$ exposures that cause effects (U.S. EPA, 2020a, section 3.1.2). While the Administrator remained concerned about placing too much weight on epidemiologic studies to inform conclusions on the adequacy of the primary standards, he noted the approach to considering such studies in the 2012 review. In the 2012 review, it was noted that the evidence of an association in any epidemiologic study was "strongest at and around the long-term average where the data in the study are most concentrated" (78 FR 3140, January 15, 2013). In considering the characterization of epidemiologic studies, the Administrator viewed that when assessing the mean concentrations of the key short-term and long-term epidemiologic studies in the U.S. that use ground-based monitoring (i.e., those studies where the mean is most directly comparable to the current annual standard), the majority of studies had mean concentrations at or above the level of the existing annual standard, with the mean of the study-reported means or medians equal to 13.5 $\mu g/m^3$, a concentration level above the existing level of the primary annual standard of 12 $\mu g/m^3$. The Administrator further noted his caution in directly comparing the reported study mean values to the standard level given that study-reported mean concentrations, by design, are generally lower than the design value of the highest monitor in an area, which

determines compliance. In the 2020 PA, analyses of recent air quality in U.S. CBSAs indicated that maximum annual $PM_{2.5}$ design values for a given three-year period were often 10% to 20% higher than average monitored concentrations (i.e., averaged across multiple monitors in the same CBSA) (U.S. EPA, 2020a, Appendix B, section B.7). He further noted his concern in placing too much weight on any one epidemiologic study but instead judged that it was more appropriate to focus on the body of studies together and therefore noted the calculation of the mean of study-reported means (or medians). Thus, while the Administrator was cautious in placing too much weight on the epidemiologic evidence alone, he noted that: (1) the reported mean concentration in the majority of the key U.S. epidemiologic studies using ground-based monitoring data were above the level of the existing annual standard; (2) the mean of the reported study means (or medians) (i.e., 13.5 $\mu g/m^3$) was above the level of the current standard;[49] (3) air quality analyses showed the study means to be lower than their corresponding design values by 10-20%; and (4) these analyses must be considered in light of uncertainties inherent in the epidemiologic evidence. When taken together, the Administrator judged that, even if it were appropriate to place more weight on the epidemiologic evidence, this information did not call into question the adequacy of the current standards (85 FR 82716-82717, December 18, 2020).

In addition to the evidence, the Administrator also considered the potential implications of the risk assessment. He noted that all risk assessments have limitations and that he remained concerned about the uncertainties in the underlying epidemiologic data used in the risk assessment. The Administrator also noted that in previous reviews, these uncertainties and

[49] The median of the study-reported mean (or median) $PM_{2.5}$ concentrations is 13.3 $\mu g/m^3$, which was also above the level of the existing standard.

limitations have often resulted in less weight being placed on quantitative estimates of risk than on the underlying scientific evidence itself (e.g., 78 FR 3086, 3098-99, January 15, 2013). These uncertainties and limitations included uncertainty in the shapes of C-R functions, particularly at low concentrations; uncertainties in the methods used to adjust air quality; and uncertainty in estimating risks for populations, locations and air quality distributions different from those examined in the underlying epidemiologic study (U.S. EPA, 2020a, section 3.3.2.4). Additionally, the Administrator noted similar concern expressed by some members of the CASAC who support retaining the existing standards; they highlighted similar uncertainties and limitations in the risk assessment (Cox, 2019b). In light of all of this, the Administrator judged it appropriate to place little weight on quantitative estimates of $PM_{2.5}$-associated mortality risk in reaching conclusions about the level of the primary $PM_{2.5}$ standards (85 FR 82717, December 18, 2020).

The Administrator additionally considered an emerging body of evidence from accountability studies that examined past reductions in ambient $PM_{2.5}$ and the degree to which those reductions resulted in public health improvements. While the Administrator agreed with public commenters that well-designed and conducted accountability studies can be informative, he viewed the interpretation of such studies in the context of the primary $PM_{2.5}$ standards as complicated by the fact that some of the available studies had not evaluated $PM_{2.5}$ specifically (e.g., as opposed to $PM_{10}$ or total suspended particulates), did not show changes in $PM_{2.5}$ air quality, or had not been able to disentangle health impacts of the interventions from background trends in health (U.S. EPA, 2020a, section 3.5.1). He further recognized that the small number of available studies that did report public health improvements following past declines in ambient $PM_{2.5}$ had not examined air quality meeting the existing standards (U.S. EPA, 2020a, Table 3-3).

This included U.S. studies that reported increased life expectancy, decreased mortality, and decreased respiratory effects following past declines in ambient $PM_{2.5}$ concentrations. Such studies examined "starting" annual average $PM_{2.5}$ concentrations (i.e., prior to the reductions being evaluated) ranging from about 13.2 to > 20 $\mu g/m^3$ (i.e., U.S. EPA, 2020a, Table 3-3). Given the lack of available accountability studies reporting public health improvements attributable to reductions in ambient $PM_{2.5}$ in locations meeting the existing standards, together with his broader concerns regarding the lack of experimental studies examining $PM_{2.5}$ exposures typical of areas meeting the existing standards, the Administrator judged that there was considerable uncertainty in the potential for increased public health protection from further reductions in ambient $PM_{2.5}$ concentrations beyond those achieved under the existing primary $PM_{2.5}$ standards (85 FR 82717, December 18, 2020).

When the above considerations were taken together, the Administrator concluded that the scientific evidence assessed in the 2019 ISA, together with the analyses in the 2020 PA based on that evidence and consideration of CASAC advice and public comments, did not call into question the adequacy of the public health protection provided by the existing annual and 24-hour $PM_{2.5}$ standards. In particular, the Administrator judged that there was considerable uncertainty in the potential for additional public health improvements from reducing ambient $PM_{2.5}$ concentrations below the concentrations achieved under the existing primary standards and that, therefore, standards more stringent than the existing standards (e.g., with lower levels) were not supported. That is, he judged that more stringent standards would be more than requisite to protect the public health with an adequate margin of safety. This judgment reflected the Administrator's consideration of the uncertainties in the potential implications of the lower end of the air quality distributions from the epidemiologic studies due in part to the lack of

supporting evidence from experimental studies and retrospective accountability studies conducted at $PM_{2.5}$ concentrations meeting the existing standards (85 FR 82717, December 18, 2020).

In reaching this conclusion, the Administrator judged that the existing standards provided an adequate margin of safety. With respect to the annual standard, the level of 12 $\mu g/m^3$ was below the lowest "starting" concentration (i.e., 13.2 $\mu g/m^3$) in the available accountability studies that showed public health improvements attributable to reductions in ambient $PM_{2.5}$. In addition, while the Administrator placed less weight on the epidemiologic evidence for selecting a standard, he noted that the level of the annual standard was below the reported mean (and median) concentrations in the majority of the key U.S. epidemiologic studies using ground-based monitoring data (noting that these means tend to be 10-20% lower than their corresponding area design values which is the more relevant metric when considering the level of the standard) and below the mean of the reported means (or medians) of these studies (i.e., 13.5 $\mu g/m^3$). In addition, the Administrator recognized that concentrations in areas meeting the existing 24-hour and annual standards remained well-below the $PM_{2.5}$ exposure concentrations consistently shown to elicit effects in human exposure studies (85 FR 82717-82718, December 18, 2020).

In addition, based on the Administrator's review of the science, including controlled human exposure studies examining effects following short-term $PM_{2.5}$ exposures, the epidemiologic studies, and accountability studies conducted at levels just above the existing annual standard, he judged that the degree of public health protection provided by the existing annual standard is not greater than warranted. This judgment, together with the fact that no CASAC member expressed support for a less stringent standard, led the Administrator to conclude that standards less stringent than the existing standards (e.g., with higher levels) were

also not supported (85 FR 82718, December 18, 2020).

In reaching his final decision, the Administrator concluded that the scientific evidence and technical information continued to support the existing annual and 24-hour $PM_{2.5}$ standards. This conclusion reflected the Administrator's view that there were important limitations and uncertainties that remained in the evidence. The Administrator concluded that these limitations contributed to considerable uncertainty regarding the potential public health implications of revising the existing primary $PM_{2.5}$ standards. Given this uncertainty, and noting the advice from some CASAC members, he concluded that the primary $PM_{2.5}$ standards, including the indicators ($PM_{2.5}$), averaging times (annual and 24-hour), forms (arithmetic mean and $98^{th}$ percentile, averaged over three years) and levels (12.0 $\mu g/m^3$, 35 $\mu g/m^3$), when taken together, remained requisite to protect the public health. Therefore, in the 2020 review, the Administrator reached the conclusion that the primary 24-hour and annual $PM_{2.5}$ standards, together, were requisite to protect public health from fine particles with an adequate margin of safety, including the health of at-risk populations, and retained the standards, without revision (85 FR 82718, December 18, 2020).

2. General Approach and Key Issues in this Reconsideration of the 2020 Final Decision

To evaluate whether it is appropriate to consider retaining the current primary $PM_{2.5}$ standards, or whether consideration of revision is appropriate, the EPA has adopted an approach in this reconsideration that builds upon the general approach used in past reviews. This includes the substantial assessments and evaluations performed in those reviews, and also takes into account the more recent scientific evidence and risk information now available to inform understanding of the key policy-relevant issues in the reconsideration. As summarized above, the Administrator's decisions in the 2020 review were based on an integration of PM health effects

information with the judgments on the adversity and public health significance of key health effects, policy judgments as to when the standard is requisite to protect public health with an adequate margin of safety, and consideration of CASAC advice and public comments.

Similarly, in this reconsideration, we draw on the current evidence and quantitative assessments of exposure pertaining to the public health risk of PM in ambient air. In considering the scientific and technical information here, we consider both the information available at the time of the 2020 review and information more recently available, including that which has been critically analyzed and characterized in the 2019 ISA and ISA Supplement. The quantitative risk analyses, including a newly conducted at-risk analysis, provide a context for interpreting the evidence of mortality and the potential public health significance of risks associated with air quality conditions that just meet the current and potential alternative standards. The overarching purpose of these analyses is to inform the Administrator's conclusions on the public health protection afforded by the current primary standards, with an important focus on evaluating the potential for exposures and risks beyond those indicated by the information available at the time the current standards were established.

*B. Overview of the Health Effects Evidence*

The information summarized here is an overview of the policy-relevant aspects of the health effects evidence available in this reconsideration; the assessment of this evidence is documented in the 2019 ISA and ISA Supplement and its policy implications are further discussed in the PA. While the 2019 ISA provides the broad scientific foundation for this reconsideration, additional literature has become available since the cutoff date of the 2019 ISA that expands the body of evidence related to mortality and cardiovascular effects for both short- and long-term $PM_{2.5}$ exposure that can inform the Administrator's judgment on the adequacy of

the current primary $PM_{2.5}$ standards. As such, the ISA Supplement builds on the information presented within the 2019 ISA with a targeted identification and evaluation of new scientific information (U.S. EPA, 2022a, section 1.2). The ISA Supplement focuses on $PM_{2.5}$ health effects evidence where the 2019 ISA concludes a "causal relationship," because such health effects are given the most weight in an Administrator's decisions in a NAAQS review. As such, the ISA Supplement evaluates newly available evidence related to short- and long-term $PM_{2.5}$ exposure and mortality and cardiovascular effects given the strength of the evidence available in the 2019 ISA and past ISAs and AQCDs, as well as the clear adversity of these endpoints. Specifically, U.S. and Canadian epidemiologic studies for mortality and cardiovascular effects along with controlled human exposure studies associated with cardiovascular effects at near ambient concentrations, were considered to be of greatest utility in informing the Administrator's conclusions on the adequacy of the current primary $PM_{2.5}$ standards. While the ISA Supplement does not include information for health effects other than mortality and cardiovascular effects, the scientific evidence for other health effect categories is evaluated in the 2019 ISA, which in combination with the ISA Supplement represents the complete scientific record for the reconsideration of the 2020 final decision.

The ISA Supplement also assessed accountability studies because these types of epidemiologic studies were part of the body of evidence that was a focus of the 2020 review. Accountability studies inform our understanding of the potential for public health improvements as ambient $PM_{2.5}$ concentrations have declined over time. Further, the ISA Supplement considered studies that employed statistical approaches that attempt to more extensively account for confounders and are more robust to model misspecification (i.e., used alternative methods for

confounder control),[50] given that such studies were highlighted by the CASAC and identified in public comments in the 2020 review. Since the literature cutoff date for the 2019 ISA, multiple accountability studies and studies that employ alternative methods for confounder control have become available for consideration in the ISA Supplement and, subsequently, in this reconsideration.

The ISA Supplement also considered recent health effects evidence that addresses key scientific issues where the literature has expanded since the completion of the 2019 ISA.[51] The 2019 ISA evaluated a couple of controlled human exposure studies that investigated the effect of exposure to near-ambient concentrations of $PM_{2.5}$ (U.S. EPA, 2019a, section 6.1.10 and 6.1.13). The ISA Supplement adds to this limited evidence, including a recent study conducted in young healthy individuals exposed to near-ambient $PM_{2.5}$ concentrations (U.S. EPA, 2022a, section 3.3.1). Given the importance of identifying populations at increased risk of $PM_{2.5}$-related effects, the ISA Supplement also included epidemiologic or exposure studies that examined whether there is evidence of exposure or risk disparities by race/ethnicity or SES. These types of studies provide additional information related to factors that may increase risk of $PM_{2.5}$-related health effects and provide additional evidence for consideration by the Administrator in reaching

[50] As noted in the ISA Supplement (U.S. EPA, 2022a, p. 1-3): "In the peer-reviewed literature, these epidemiologic studies are often referred to as causal inference studies or studies that used causal modeling methods. For the purposes of this Supplement, this terminology is not used to prevent confusion with the main scientific conclusions (i.e., the causality determinations) presented within an ISA. In addition, as is consistent with the weight-of-evidence framework used within ISAs and discussed in the Preamble to the Integrated Science Assessments, an individual study on its own cannot inform causality, but instead represents a piece of the overall body of evidence."

[51] As with the epidemiologic studies for long- and short-term $PM_{2.5}$ exposure and mortality and cardiovascular effects, epidemiologic studies of exposure or risk disparities and SARS-CoV-2 infection and/or COVID-19 death were limited to those conducted in the U.S. and Canada.

conclusions regarding the adequacy of the current standards. In addition, the ISA Supplement evaluated studies that examined the relationship between short- and long-term $PM_{2.5}$ exposures and SARS-CoV-2 infection and/or COVID-19 death, as these studies are a new area of research and were raised by a number of public commenters in the 2020 review.

The evidence presented within the 2019 ISA, along with the targeted identification and evaluation of new scientific information in the ISA Supplement, provides the scientific basis for the reconsideration of the 2020 final decision on the primary $PM_{2.5}$ standards. The subsections below briefly summarize the nature of $PM_{2.5}$-related health effects, with a focus on those health effects for which the 2019 ISA concluded a "causal" or "likely to be causal" relationship.

1. Nature of Effects

The evidence base available in the reconsideration includes decades of research on $PM_{2.5}$-related health effects (U.S. EPA, 2004b; U.S. EPA, 2009b; U.S. EPA, 2019a), including the full body of evidence evaluated in the 2019 ISA (U.S. EPA, 2019a), along with the targeted evaluation of recent evidence in the ISA Supplement (U.S. EPA, 2022a). In considering the available scientific evidence, the sections below summarize the relationships between long-and short-term $PM_{2.5}$ exposures and mortality (II.B.1.a), cardiovascular effects (II.B.1.b), respiratory effects (II.B.1.c), cancer (II.B.1.d), and nervous system effects (II.B.1.e). For these outcomes, the 2019 ISA concluded that the evidence supports either a "causal" or a "likely to be causal" relationship.[52]

a. Mortality

[52] In this reconsideration of the PM NAAQS, the EPA considers the full body of health evidence, placing the greatest emphasis on the health effects for which the evidence has been judged in the 2019 ISA to demonstrate a "causal" or "likely to be causal" relationship with $PM_{2.5}$ exposures.

i. Long-term $PM_{2.5}$ exposures

In the 2012 review, the 2009 ISA reported that the evidence was "sufficient to conclude that the relationship between long-term $PM_{2.5}$ exposures and mortality is causal" (U.S. EPA, 2009a, p. 7-96). The strongest evidence supporting this conclusion was provided by epidemiologic studies, particularly those examining two seminal cohorts, the American Cancer Society (ACS) cohort and the Harvard Six Cities cohort. Analyses of the Harvard Six Cities cohort included evidence indicating that reductions in ambient $PM_{2.5}$ concentrations are associated with reduced mortality risk (Laden et al., 2006) and increases in life expectancy (Pope et al., 2009). Further support was provided by other cohort studies conducted in North America and Europe that reported positive associations between long-term $PM_{2.5}$ exposure and mortality (U.S. EPA, 2019a).

Cohort studies, which have become available since the completion of the 2009 ISA and evaluated in the 2019 ISA, continue to provide consistent evidence of positive associations between long-term $PM_{2.5}$ exposures and mortality. These studies add support for associations with all-cause and total (non-accidental) mortality,[53] as well as with specific causes of mortality, including cardiovascular disease and respiratory disease (U.S. EPA, 2019a, section 11.2.2). Several of these studies conducted analyses over longer study durations and periods of follow-up than examined in the original ACS and Harvard Six Cities cohort studies and continue to report positive associations between long-term exposure to $PM_{2.5}$ and mortality (U.S. EPA, 2019a, section 11.2.2.1; Figures 11-18 and 11-19). In addition to studies focusing on the ACS and Harvard Six Cities cohorts, additional studies examining other cohorts also provide evidence of

[53] The majority of these studies examined non-accidental mortality outcomes, though some Medicare studies lack cause-specific death information and, therefore, examine total mortality.

consistent, positive associations between long-term $PM_{2.5}$ exposure and mortality across a wide range of demographic groups (e.g., age, sex, occupation), spatial and temporal extents, exposure assessment metrics, and statistical techniques (U.S. EPA, 2019a, sections 11.2.2.1, 11.2.5; U.S. EPA, 2022a, Table 11-8). This includes some of the largest cohort studies conducted to date, such as analyses of the U.S. Medicare cohort that includes nearly 61 million enrollees and studies that control for a range of individual and ecological covariates, including race, age, SES, smoking status, body mass index, and annual weather variables (e.g., temperature, humidity) (U.S. EPA, 2019a).

In addition to those cohort studies evaluated in the 2019 ISA, recent North American cohort studies evaluated in the ISA Supplement continue to examine the relationship between long-term $PM_{2.5}$ exposure and mortality and report consistent, positive and statistically significant associations. These recent studies also utilize large and demographically diverse cohorts that are generally representative of the national populations in both the U.S. and Canada. These "studies published since the 2019 ISA support and extend the evidence base that contributed to the conclusion of a *causal relationship* between long-term $PM_{2.5}$ exposure and mortality" (U.S. EPA, 2022a, section 3.2.2.2.1, Figure 3-19, Figure 3-20).

Furthermore, studies evaluated in the 2019 ISA and the ISA Supplement that examined cause-specific mortality expand upon previous research that found consistent, positive associations between $PM_{2.5}$ exposure and specific mortality outcomes, which include cardiovascular and respiratory mortality, as well as other mortality outcomes. For cardiovascular-related mortality, the evidence evaluated in the ISA Supplement is consistent with the evidence evaluated in the 2019 ISA with recent studies reporting positive associations with long-term $PM_{2.5}$ exposure. When evaluating cause-specific cardiovascular mortality, recent

studies reported positive associations for a number of outcomes, such as ischemic heart disease (IHD) and stroke mortality (U.S. EPA, 2022a, Figure 3-23). Moreover, recent studies also provide some initial evidence that individuals with pre-existing health conditions, such as heart failure and diabetes, are at an increased risk of $PM_{2.5}$-related health effects (U.S. EPA, 2022a, section 3.2.2.4) and that these individuals have a higher risk of mortality overall, which was previously only examined in studies that used stratified analyses rather than a cohort of people with an underlying health condition (U.S. EPA, 2022a, section 3.2.2.4). With regard to respiratory mortality, epidemiologic studies evaluated in the 2019 ISA and ISA Supplement continue to provide support for associations between long-term $PM_{2.5}$ exposure and respiratory mortality (U.S. EPA, 2019a, section 5.2.10; U.S. EPA, 2022a, Table 3-2).

A series of epidemiologic studies evaluated in the 2019 ISA tested the hypothesis that past reductions in ambient $PM_{2.5}$ concentrations are associated with increased life expectancy or a decreased mortality rate (U.S. EPA, 2022a, section 11.2.2.5). Pope et al. (2009) conducted a cross-sectional analysis using air quality data from 51 metropolitan areas across the U.S., beginning in the 1970s through the early 2000s, and found that a 10 $\mu g/m^3$ decrease in long-term $PM_{2.5}$ concentration was associated with a 0.61-year increase in life expectancy. In a subsequent analysis, the authors extended the period of analysis to include 2000 to 2007, a time period with lower ambient $PM_{2.5}$ concentrations (Correia et al., 2013). In this follow-up study, a decrease in long-term $PM_{2.5}$ concentration continued to be associated with an increase in life expectancy, though the magnitude of the increase was smaller than during the earlier time period (i.e., a 10 $\mu g/m^3$ decrease in long-term $PM_{2.5}$ concentration was associated with a 0.35-year increase in life expectancy). Additional studies conducted in the U.S. or Europe similarly report that reductions in ambient $PM_{2.5}$ are associated with improvements in longevity (U.S. EPA, 2022a,

section 11.2.2.5). Since the literature cutoff date for the 2019 ISA, a few epidemiologic studies were published that examined the relationship between long-term $PM_{2.5}$ exposure and life-expectancy (U.S. EPA, 2022a, section 3.2.1.3) and report results that are consistent with and expand upon the body of evidence from the 2019 ISA. For example,  reported that $PM_{2.5}$ concentrations above the lowest observed concentration (2.8 $\mu g/m^3$) were associated with a 0.15 year decrease in national life expectancy for women and 0.13 year decrease in national life expectancy for men  (U.S. EPA, 2022a, section 3.2.2.2.4, Figure 3-25). Another study compared participants living in areas with $PM_{2.5}$ concentrations >12 $\mu g/m^3$ to participants living in areas with $PM_{2.5}$ concentrations <12 $\mu g/m^3$ and reported that the number of years of life lost due to living in areas with higher $PM_{2.5}$ concentrations was 0.84 years over a 5-year period (Ward-Caviness et al., 2020; U.S. EPA, 2022a, section 3.2.2.2.4).

Additionally, a number of accountability studies, which are epidemiologic studies that evaluate whether an environmental policy or air quality intervention resulted in reductions in ambient air pollution concentrations and subsequent reductions in mortality, have emerged and were evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.2.2.3). For example, Sanders et al. (2020a) examined whether policy actions (i.e., the first annual $PM_{2.5}$ NAAQS implementation rule in 2005 for the 1997 annual $PM_{2.5}$ standard with a 3-year annual average of 15.0 $\mu g/m^3$) reduced $PM_{2.5}$ concentrations and mortality rates in Medicare beneficiaries between 2000-2013, and found that following implementation of the annual $PM_{2.5}$ NAAQS, annual $PM_{2.5}$ concentrations decreased by 1.59 $\mu g/m^3$ (95% CI: 1.39, 1.80) which corresponded to a reduction in mortality rates among individuals 65 years and older (0.93% [95% CI: 0.10%, 1.77%]) in non-attainment counties relative to attainment counties.

The 2019 ISA also evaluated a small number of studies that used alternative methods for

confounder control to further assess relationship between long-term $PM_{2.5}$ exposure and mortality (U.S. EPA, 2019a, section 11.2.2.4). In addition, multiple epidemiologic studies that implemented alternative methods for confounder control and were published since the literature cutoff date of the 2019 ISA were evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.2.2.3). These studies used a variety of statistical methods including generalized propensity score (GPS), inverse probability weighting (IPW), and difference-in-difference (DID) to reduce uncertainties related to confounding bias in the association between long-term $PM_{2.5}$ exposure and mortality. Studies that employed these alternative methods for confounder control reported consistent positive associations between long-term $PM_{2.5}$ exposure and total mortality (U.S. EPA, 2022a, section 3.2.2.3), and provided further support for the associations reported in the cohort studies referenced above.

The 2019 ISA and ISA Supplement also evaluated the degree to which recent studies examining the relationship between long-term $PM_{2.5}$ exposure and mortality addressed key policy-relevant issues and/or previously identified data gaps in the scientific evidence, including methods to estimate exposure, methods to control for confounding (e.g., co-pollutant confounding), the shape of the C-R relationship, as well as examining whether a threshold exists below which mortality effects do not occur. For example, with respect to exposure assessment, based on its evaluation of the evidence, the 2019 ISA concludes that positive associations between long-term $PM_{2.5}$ exposures and mortality are robust across recent analyses using various approaches to estimate $PM_{2.5}$ exposures (e.g., based on monitors, models, satellite-based methods, or hybrid methods that combine information from multiple sources) (U.S. EPA, 2019a, section 11.2.5.1). Hart et al. (2015) report that correction for bias due to exposure measurement error increases the magnitude of the hazard ratios (confidence intervals widen but the association

remains statistically significant), suggesting that failure to correct for exposure measurement error could result in attenuation or underestimation of risk estimates.

The 2019 ISA additionally concludes that positive associations between long-term $PM_{2.5}$ exposures and mortality are robust across statistical models that use different approaches to control for confounders or different sets of confounders (U.S. EPA, 2019a, sections 11.2.3 and 11.2.5), across diverse geographic regions and populations, and across a range of temporal periods including periods of declining PM concentrations (U.S. EPA, 2019a, sections 11.2.2.5 and 11.2.5.3). Additional evidence further demonstrates that associations with mortality remain robust in copollutants analyses (U.S. EPA, 2019a, section 11.2.3), and that associations persist in analyses restricted to long-term exposures (annual average $PM_{2.5}$ concentrations) below 12 $\mu g/m^3$ (Di et al., 2017b) or 10 $\mu g/m^3$ (Shi et al., 2016), indicating that risks are not disproportionately driven by the upper portions of the air quality distribution. Recent studies evaluated in the ISA Supplement further assess potential copollutant confounding and indicate that while there is some evidence of potential confounding of the $PM_{2.5}$-mortality association by copollutants in some of the studies (i.e., those studies of the Mortality Air Pollution Associations in Low Exposure Environments (MAPLE) cohort), this result is inconsistent with other recent studies evaluated in the 2019 ISA that were conducted in the U.S. and Canada that found associations in both single and copollutant models (U.S. EPA, 2019a; U.S. EPA, 2022a, section 3.2.2.4)

Additionally, a few studies use statistical techniques to reduce uncertainties related to potential confounding to further inform conclusions on causality for long-term $PM_{2.5}$ exposure and mortality. For example, studies by Greven et al. (2011), Pun et al. (2017), and Eum et al. (2018) completed sensitivity analyses as part of their Medicare cohort study in which they

decompose ambient $PM_{2.5}$ into "spatial" and "spatiotemporal" components in order to evaluate the potential for bias due to unmeasured spatial confounding. Pun et al. (2017) observed positive associations for the "temporal" variation model and approximately null associations for the "spatiotemporal" variation model for all causes of death except for COPD mortality. The difference in the results of these two models for most causes of death suggests the presence of unmeasured confounding, though the authors do not indicate anything about the direction or magnitude of this bias. It is important to note that the "temporal" and "spatiotemporal" coefficients are not directly comparable to the results of other epidemiologic studies when examined individually and can only be used in comparison with one another to evaluate the potential for unmeasured confounding bias. Eum et al. (2018) and Wu et al. (2020) also attempted to address long-term trends and meteorological variables as potential confounders and found that not adjusting for temporal trends could overestimate the association, while effect estimates in analyses that excluded meteorological variables remained unchanged compared to the main analyses. While results of these analyses suggest the presence of some unmeasured confounding, they do not indicate the direction or magnitude of the bias.[54]

An additional important consideration in characterizing the public health impacts associated with $PM_{2.5}$ exposure is whether C-R relationships are linear across the range of concentrations or if nonlinear relationships exist along any part of this range. Studies evaluated in the 2019 ISA and the ISA Supplement examine this issue, and continue to provide evidence of

[54] In public comments on the 2019 draft PA, the authors of the Pun et al. (2017) study further note that "the presence of unmeasured confounding…was expected given that we did not control for several potential confounders that may impact $PM_{2.5}$-mortality associations, such as smoking, socio-economic status (SES), gaseous pollutants, $PM_{2.5}$ components, and long-term time trends in $PM_{2.5}$" and that "spatial confounding may bias mortality risks both towards and away from the null" (Docket ID EPA-HQ-OAR-2015-0072-0065; accessible in *https://www.regulations.gov/*).

linear, no-threshold relationships between long-term $PM_{2.5}$ exposures and all-cause and cause-specific mortality (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a, section 3.2.2.2.7, Table 3-6). Across the studies evaluated in the 2019 ISA and the ISA Supplement, a variety of statistical methods have been used to assess whether there is evidence of deviations in linearity (U.S. EPA, 2019a, Table 11-7; U.S. EPA, 2022a, section 2.2.3.2). Studies have also conducted cut-point analyses that focus on examining risk at specific ambient $PM_{2.5}$ concentrations. Generally, the evidence remains consistent in supporting a no-threshold relationship, and in supporting a linear relationship for $PM_{2.5}$ concentrations > 8 $\mu g/m^3$. However, uncertainties remain about the shape of the C-R curve at $PM_{2.5}$ concentrations < 8 $\mu g/m^3$, with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a, section 2.2.3.2). There was also some limited evidence indicating that the slope of the C-R function may be steeper (supralinear) at lower concentrations for cardiovascular mortality (U.S. EPA, 2022a, section 3.1.1.2.6).

The biological plausibility of $PM_{2.5}$-attributable mortality is supported by the coherence of effects across scientific disciplines (i.e., animal toxicological, controlled human exposure studies, and epidemiologic) when evaluating respiratory and cardiovascular morbidity effects, which are some of the largest contributors to total (nonaccidental) mortality. The 2019 ISA outlines the available evidence for biologically plausible pathways by which inhalation exposure to $PM_{2.5}$ could progress from initial events (e.g., pulmonary inflammation, autonomic nervous system activation) to endpoints relevant to population outcomes, particularly those related to cardiovascular diseases such as ischemic heart disease, stroke and atherosclerosis (U.S. EPA, 2019a, section 6.2.1), and to metabolic effects, including diabetes (U.S. EPA, 2019a, section 7.3.1). The 2019 ISA notes "more limited evidence from respiratory morbidity" (U.S. EPA,

2019a, p. 11-101) such as development of chronic obstructive pulmonary disease (COPD) (U.S. EPA, 2019a, section 5.2.1) to support the biological plausibility of mortality due to long-term $PM_{2.5}$ exposures (U.S. EPA, 2019a, section 11.2.1).

Taken together, epidemiologic studies evaluated in the 2019 ISA, including recent studies evaluated in the ISA Supplement, consistently report positive associations between long-term $PM_{2.5}$ exposure and mortality across different geographic locations, populations, and analytic approaches (U.S. EPA, 2019a; U.S. EPA, 2022a, section 3.2.2.4). As such, these studies reduce key uncertainties identified in previous reviews, including those related to potential copollutant confounding, and provide additional information on the shape of the C-R curve. As evaluated in the 2019 ISA, experimental and epidemiologic evidence for cardiovascular effects, and respiratory effects to a more limited degree, supports the plausibility of mortality due to long-term $PM_{2.5}$ exposures. Overall, studies evaluated in the 2019 ISA support the conclusion of a causal relationship between long-term $PM_{2.5}$ exposure and mortality, which is supported and extended by evidence from recent epidemiologic studies evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.2.2.4).

ii. Short-term $PM_{2.5}$ exposures

The 2009 ISA concluded that "a causal relationship exists between short-term exposure to $PM_{2.5}$ and mortality" (U.S. EPA, 2009a). This conclusion was based on the evaluation of both multi- and single-city epidemiologic studies that consistently reported positive associations between short-term $PM_{2.5}$ exposure and non-accidental mortality. These associations were strongest, in terms of magnitude and precision, primarily at lags of 0 to 1 days. Examination of the potential confounding effects of gaseous copollutants was limited, though evidence from single-city studies indicated that gaseous copollutants have minimal effect on the $PM_{2.5}$-mortality

relationship (i.e., associations remain robust to inclusion of other pollutants in copollutant models). The evaluation of cause-specific mortality found that effect estimates were larger in magnitude, but also had larger confidence intervals, for respiratory mortality compared to cardiovascular mortality. Although the largest mortality risk estimates were for respiratory mortality, the interpretation of the results was complicated by the limited coherence from studies of respiratory morbidity. However, the evidence from studies of cardiovascular morbidity provided both coherence and biological plausibility for the relationship between short-term $PM_{2.5}$ exposure and cardiovascular mortality.

Multicity studies evaluated in the 2019 ISA and the ISA Supplement provide evidence of primarily positive associations between daily $PM_{2.5}$ exposures and mortality, with percent increases in total mortality ranging from 0.19% (Lippmann et al., 2013) to 2.80% (Kloog et al.)[55] at lags of 0 to 1 days in single-pollutant models. Whereas many studies assign exposures using data from ambient monitors, other studies employ hybrid modeling approaches, which estimate $PM_{2.5}$ concentrations using data from a variety of sources (i.e., from satellites, land use information, and modeling, in addition to monitors) and enable the inclusion of less urban and more rural locations in analyses (Kloog et al., 2013, Lee et al., 2015, Shi et al., 2016).

Some studies have expanded the examination of potential confounders including long-term temporal trends, weather, and co-occurring pollutants. Mortality associations were found to remain positive, although in some cases were attenuated, when using different approaches to account for temporal trends or weather covariates (e.g., U.S. EPA, 2019a, section 11.1.5.1). For example, Sacks et al. (2012) examined the influence of model specification using the approaches

[55] As detailed in the Preface to the ISA, risk estimates are for a 10 $\mu g/m^3$ increase in 24-hour avg $PM_{2.5}$ concentrations, unless otherwise noted (U.S. EPA, 2019a).

for confounder adjustment from models employed in several multicity studies within the context of a common data set (U.S. EPA, 2019a, section 11.1.5.1). These models use different approaches to control for long-term temporal trends and the potential confounding effects of weather. The authors report that associations between daily $PM_{2.5}$ and cardiovascular mortality were similar across models, with the percent increase in mortality ranging from 1.5−2.0% (U.S. EPA, 2019a, Figure 11-4). Thus, alternative approaches to controlling for long-term temporal trends and for the potential confounding effects of weather may influence the magnitude of the association between $PM_{2.5}$ exposures and mortality but have not been found to influence the direction of the observed association (U.S. EPA, 2019a, section 11.1.5.1). Taken together, the 2019 ISA and the ISA Supplement conclude that recent multicity studies conducted in the U.S., Canada, Europe, and Asia continue to provide consistent evidence of positive associations between short-term $PM_{2.5}$ exposures and total mortality across studies that use different approaches to control for the potential confounding effects of weather (e.g., temperature) (U.S. EPA, 2019a, section 1.4.1.5.1; U.S. EPA, 2022a, section 3.2.1.2).

With regard to copollutants, studies evaluated in the 2019 ISA provide additional evidence that associations between short-term $PM_{2.5}$ exposures and mortality remain positive and relatively unchanged in copollutant models with both gaseous pollutants and $PM_{10-2.5}$ (U.S. EPA, 2019a, section 11.1.4). Additionally, the low ($r < 0.4$) to moderate correlations ($r = 0.4$-$0.7$) between $PM_{2.5}$ and gaseous pollutants and $PM_{10–2.5}$ increase the confidence in $PM_{2.5}$ having an independent effect on mortality (U.S. EPA, 2019a , section 11.1.4). Consistent with the studies evaluated in the 2019 ISA, studies evaluated in the ISA Supplement that used data from more recent years also indicate that associations between short-term $PM_{2.5}$ exposure and mortality remain unchanged in copollutant models. However, the evidence indicates that the association

could be larger in magnitude in the presence of some copollutants such as oxidant gases (Lavigne et al., 2018; Shin et al., 2021).

The generally positive associations reported with mortality are supported by a small group of studies employing alternative methods for confounder control or quasi-experimental statistical approaches (U.S. EPA, 2019a, section 11.1.2.1). For example, two studies by Schwartz et al. report associations between $PM_{2.5}$ instrumental variables and mortality (U.S. EPA, 2019a, Table 11-2), including in an analysis limited to days with 24-hour average $PM_{2.5}$ concentrations <30 $\mu g/m^3$ (Schwartz et al., 2015; Schwartz et al., 2017). In addition to the main analyses, these studies conducted Granger-like causality tests as sensitivity analyses to examine whether there was evidence of an association between mortality and $PM_{2.5}$ after the day of death, which would support the possibility that unmeasured confounders were not accounted for in the statistical model. Neither study reports evidence of an association with $PM_{2.5}$ after death (i.e., they do not indicate unmeasured confounding). Yorifuji et al. (2016) conducted a quasi-experimental study to examine whether a specific regulatory action in Tokyo, Japan (i.e., a diesel emission control ordinance) resulted in a subsequent reduction in daily mortality (Yorifuji et al., 2016). The authors reported a reduction in mortality in Tokyo due to the ordinance, compared to Osaka, which did not have a similar diesel emission control ordinance in place. In another study, Schwartz et al. (2018) utilized three statistical methods including instrumental variable analysis, a negative exposure control, and marginal structural models to estimate the association between $PM_{2.5}$ and daily mortality (Schwartz et al., 2018). Results from this study continue to support a relationship between short-term $PM_{2.5}$ exposure and mortality. Additional epidemiologic studies evaluated in the ISA Supplement that employed alternative methods for confounder control to examine the association between short-term $PM_{2.5}$ exposure and mortality also report consistent

positive associations in studies that examine effects across multiple cities in the U.S. (U.S. EPA, 2022a).

The positive associations for total mortality reported across the majority of studies evaluated are further supported by analyses reporting generally consistent, positive associations with both cardiovascular and respiratory mortality (U.S. EPA, 2019a, section 11.1.3). Recent multicity studies evaluated in the ISA Supplement add to the body of evidence indicating a relationship between short-term $PM_{2.5}$ exposure and cause-specific mortality, with more variability in the magnitude and precision of associations for respiratory mortality (U.S. EPA, 2022a; Figure 3-14. For both cardiovascular and respiratory mortality, there has been a limited assessment of potential copollutant confounding, though initial evidence indicates that associations remain positive and relatively unchanged in models with gaseous pollutants and $PM_{10-2.5}$. This evidence further supports the copollutant analyses conducted for total mortality. The strong evidence for ischemic events and heart failure, as detailed in the assessment of cardiovascular morbidity (U.S. EPA, 2019a, Chapter 6), provides biological plausibility for $PM_{2.5}$related cardiovascular mortality, which comprises the largest percentage of total mortality (i.e., ~33%) (NHLBI, 2017). Although there is evidence for exacerbations of COPD and asthma, the collective body of respiratory morbidity evidence provides limited biological plausibility for $PM_{2.5}$-related respiratory mortality (U.S. EPA, 2019a, Chapter 5).

In the 2009 ISA, one of the main uncertainties identified was the regional and city-to-city heterogeneity in $PM_{2.5}$mortality associations. Studies evaluated in the 2019 ISA examine both city-specific as well as regional characteristics to identify the underlying contextual factors that could contribute to this heterogeneity (U.S. EPA, 2019a, section 11.1.6.3). Analyses focusing on effect modification of the $PM_{2.5}$ mortality relationship by $PM_{2.5}$ components, regional patterns in

$PM_{2.5}$ components and city specific differences in composition and sources indicate some differences in the $PM_{2.5}$ composition and sources across cities and regions, but these differences do not fully explain the observed heterogeneity. Additional studies find that factors related to potential exposure differences, such as housing stock and commuting, as well as city specific factors (e.g., land use, port volume, and traffic information), may also explain some of the observed heterogeneity (U.S. EPA, 2019a, section 11.1.6.3). Collectively, studies evaluated in the 2019 ISA and the ISA Supplement indicate that the heterogeneity in $PM_{2.5}$ mortality risk estimates cannot be attributed to one factor, but instead a combination of factors including, but not limited to, PM composition and sources as well as community characteristics that could influence exposures (U.S. EPA, 2019a, section 11.1.12; U.S. EPA, 2022a, section 3.2.1.2.1).

A number of studies conducted systematic evaluations of the lag structure of associations for the $PM_{2.5}$-mortality relationship by examining either a series of single day or multiday lags and these studies continue to support an immediate effect (i.e., lag 0 to 1 days) of short-term $PM_{2.5}$ exposures on mortality (U.S. EPA, 2019a, section 11.1.8.1; U.S. EPA, 2022a, section 3.2.1.1). Recent studies also conducted analyses comparing the traditional 24-hour average exposure metric with a sub-daily metric (i.e., 1-hour max). These initial studies provide evidence of a similar pattern of associations for both the 24-hour average and 1-hour max metric, with the association larger in magnitude for the 24-hour average metric.

Multicity studies indicate that positive and statistically significant associations with mortality persist in analyses restricted to short-term (24-hour average $PM_{2.5}$ concentrations)

$PM_{2.5}$ exposures below 35 μg/m$^3$ (Lee et al., 2015),[56] below 30 μg/m$^3$ (Shi et al., 2016), and below 25 μg/m$^3$ (Di et al., 2017a), indicating that risks associated with short-term $PM_{2.5}$ exposures are not disproportionately driven by the peaks of the air quality distribution. Additional studies examined the shape of the C-R relationship for short-term $PM_{2.5}$ exposure and mortality and whether a threshold exists below which mortality effects do not occur (U.S. EPA, 2019a, section 11.1.10). These studies used various statistical approaches and consistently demonstrate linear C-R relationships with no evidence of a threshold. Moreover, recent studies evaluated in the ISA Supplement provide additional support for a linear, no-threshold C-R relationship between short-term $PM_{2.5}$ exposure and mortality, with confidence in the shape decreasing at concentrations below 5 μg/m$^3$ (Shi et al., 2016; Lavigne et al., 2018). Recent analyses provide initial evidence indicating that $PM_{2.5}$-mortality associations persist and may be stronger (i.e., a steeper slope) at lower concentrations (e.g., Di et al., 2017a; Figure 11-12 in U.S. EPA, 2019). However, given the limited data available at the lower end of the distribution of ambient $PM_{2.5}$ concentrations, the shape of the C-R curve remains uncertain at these low concentrations. Although difficulties remain in assessing the shape of the short-term $PM_{2.5}$-mortality C-R relationship, to date, studies have not conducted systematic evaluations of alternatives to linearity and recent studies evaluated in the ISA Supplement continue to provide evidence of a no-threshold linear relationship, with less confidence at concentrations lower than 5 μg/m$^3$.

Overall, epidemiologic studies evaluated in the 2019 ISA and the ISA Supplement build

[56] Lee et al. (2015) also report that positive and statistically significant associations between short-term $PM_{2.5}$ exposures and mortality persist in analyses restricted to areas with long-term concentrations below 12 μg/m$^3$.

upon and extend the conclusions of the 2009 ISA for the relationship between short-term $PM_{2.5}$ exposures and total mortality. Supporting evidence for $PM_{2.5}$-related cardiovascular morbidity, and more limited evidence from respiratory morbidity, provide biological plausibility for mortality due to short-term $PM_{2.5}$ exposures. The primarily positive associations observed across studies conducted in diverse geographic locations is further supported by the results from copollutant analyses indicating robust associations, along with evidence from analyses examining the C-R relationship. Overall, studies evaluated in the 2019 ISA support the conclusion of a causal relationship between short-term $PM_{2.5}$ exposure and mortality, which is supported by evidence from recent epidemiologic studies evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.2.1.4, p. 3-69).

b. Cardiovascular Effects

i. Long-term $PM_{2.5}$ exposures

The scientific evidence reviewed in the 2009 ISA was "sufficient to infer a causal relationship between long-term $PM_{2.5}$ exposure and cardiovascular effects" (U.S. EPA, 2009a). The strongest line of evidence comprised findings from several large epidemiologic studies of U.S. and Canadian cohorts that reported consistent positive associations between long-term $PM_{2.5}$ exposure and cardiovascular mortality (Pope et al., 2004; Krewski et al., 2009; Miller et al., 2007; Laden et al., 2006). Studies of long-term $PM_{2.5}$ exposure and cardiovascular morbidity were limited in number. Biological plausibility and coherence with the epidemiologic findings were provided by studies using genetic mouse models of atherosclerosis demonstrating enhanced atherosclerotic plaque development and inflammation, as well as changes in measures of impaired heart function, following 4- to 6-month exposures to $PM_{2.5}$ concentrated ambient particles (CAPs), and by a limited number of studies reporting CAPs-induced effects on

coagulation factors, vascular reactivity, and worsening of experimentally induced hypertension in mice (U.S. EPA, 2009b).

Consistent with the evidence assessed in the 2009 ISA, the 2019 ISA concludes that recent studies, together with the evidence available in previous reviews, support a causal relationship between long-term exposure to $PM_{2.5}$ and cardiovascular effects. Additionally, recent epidemiologic studies published since the completion of the 2019 ISA and evaluated in the ISA Supplement expands the body of evidence and further supports such a conclusion (U.S. EPA, 2022a). As discussed above (section II.B.1.a), results from U.S. and Canadian cohort studies evaluated in the 2019 ISA conducted at varying spatial and temporal scales and employing a variety of exposure assessment and statistical methods consistently report positive associations between long-term $PM_{2.5}$ exposure and cardiovascular mortality (U.S. EPA, 2019, Figure 6-19, section 6.2.10). Positive associations between long-term $PM_{2.5}$ exposures and cardiovascular mortality are generally robust in copollutant models adjusted for ozone, $NO_2$, $PM_{10-2.5}$, or $SO_2$. In addition, most of the results from analyses examining the shape of the C-R relationship between long-term $PM_{2.5}$ exposures and cardiovascular mortality support a linear relationship and do not identify a threshold below which mortality effects do not occur (U.S. EPA, 2019a, section 6.2.16, Table 6-52).

The body of literature examining the relationship between long-term $PM_{2.5}$ exposure and cardiovascular morbidity has greatly expanded since the 2009 ISA, with positive associations reported in several cohorts evaluated in the 2019 ISA (U.S. EPA, 2019a, section 6.2). Though results for cardiovascular morbidity are less consistent than those for cardiovascular mortality (U.S. EPA, 2019a, section 6.2), studies in the 2019 ISA and the ISA Supplement provide some evidence for associations between long-term $PM_{2.5}$ exposures and the progression of

cardiovascular disease. Positive associations with cardiovascular morbidity (e.g., coronary heart disease, stroke, arrhythmias, myocardial infarction (MI), atherosclerosis progression) are observed in several epidemiologic studies (U.S. EPA, 2019a, sections 6.2.2 to 6.2.9; U.S. EPA, 2022a, section 3.1.2.2).Additionally, studies evaluated in the ISA Supplement report positive associations among those with pre-existing conditions, among patients followed after a cardiac event procedure, and among those with a first hospital admission for heart attacks among older adults enrolled in Medicare (U.S. EPA, 2022a, sections 3.1.1 and 3.1.2).

Recent studies published since the literature cutoff date of the 2019 ISA further assessed the relationship between long-term $PM_{2.5}$ exposure and cardiovascular effects by conducting accountability analyses or by using alternative methods for confounder control in evaluating the association between long-term $PM_{2.5}$ exposure and cardiovascular hospital admissions (U.S. EPA, 2022a, section 3.1.2.3). Studies that apply alternative methods for confounder control increase confidence in the relationship between long-term $PM_{2.5}$ exposure and cardiovascular effects by using methods that reduce uncertainties related to potential confounding through statistical and/or study design approaches. For example, to control for potential confounding Wei et al. (2021) used a doubly robust additive model (DRAM) and found an association between long-term exposure to $PM_{2.5}$ and cardiovascular effects, including MI, stoke, and atrial fibrillation, among the Medicare population. Additionally, an accountability study by Henneman et al. (2019a) utilized a difference-in-difference (DID) approach to determine the relationship between coal-fueled power plant emissions and cardiovascular effects and found that reductions in $PM_{2.5}$ concentrations resulted in reductions of cardiovascular-related hospital admissions. Furthermore, several recent epidemiologic studies evaluated in the ISA Supplement reported that the association between long-term $PM_{2.5}$ exposure with stroke persisted after adjustment for $NO_2$

but was attenuated in the model with $O_3$ and oxidant gases represented by the redox weighted average of $NO_2$ and $O_3$ (U.S. EPA, 2022a, section 3.1.2.2.8). Overall, these studies report consistent findings that long-term $PM_{2.5}$ exposure is related to increased hospital admissions for a variety of cardiovascular disease outcomes among large nationally representative cohorts and provide additional support for a relationship between long-term $PM_{2.5}$ exposure and cardiovascular effects.

The positive associations reported in epidemiologic studies are supported by toxicological evidence for increased plaque progression in mice following long-term exposure to $PM_{2.5}$ collected from multiple locations across the U.S. (U.S. EPA, 2019a, section 6.2.4.2). A small number of epidemiologic studies also report positive associations between long-term $PM_{2.5}$ exposure and heart failure, changes in blood pressure, and hypertension (U.S. EPA, 2019a, sections 6.2.5 and 6.2.7). Associations with heart failure are supported by animal toxicological studies demonstrating decreased cardiac contractility and function, and increased coronary artery wall thickness following long-term $PM_{2.5}$ exposure (U.S. EPA, 2019a, section 6.2.5.2). Similarly, a limited number of animal toxicological studies demonstrating a relationship between long-term $PM_{2.5}$ exposure and consistent increases in blood pressure in rats and mice are coherent with epidemiologic studies reporting positive associations between long-term exposure to $PM_{2.5}$ and hypertension.

Moreover, a number of studies evaluated in the ISA Supplement focusing on morbidity outcomes, including those that focused on incidence of MI, atrial fibrillation (AF), stroke, and congestive heart failure (CHF), expand the evidence pertaining to the shape of the C-R relationship between long-term $PM_{2.5}$ exposure and cardiovascular effects. These studies use statistical techniques that allow for departures from linearity (U.S. EPA, 2022a, Table 3-3), and

generally support the evidence characterized in the 2019 ISA showing linear, no-threshold C-R relationship for most CVD outcomes. However, there is evidence for a sublinear or supralinear C-R relationship for some outcomes (U.S. EPA, 2022a, section 3.1.2.2.9).[57]

Longitudinal epidemiologic analyses also report positive associations with markers of systemic inflammation (U.S. EPA, 2019a, section 6.2.11), coagulation (U.S. EPA, 2019a, section 6.2.12), and endothelial dysfunction (U.S. EPA, 2019a, section 6.2.13). These results are coherent with animal toxicological studies generally reporting increased markers of systemic inflammation, oxidative stress, and endothelial dysfunction (U.S. EPA, 2019a, section 6.2.12.2 and 6.2.14).

The 2019 ISA concludes that there is consistent evidence from multiple epidemiologic studies illustrating that long-term exposure to $PM_{2.5}$ is associated with mortality from cardiovascular causes. Epidemiologic studies evaluated in the ISA Supplement provide additional evidence of positive associations between long-term $PM_{2.5}$ exposure and cardiovascular morbidity (U.S. EPA, 2022a, section 3.1.2.2). Associations with CHD, stroke and atherosclerosis progression were observed in several additional epidemiologic studies providing coherence with the mortality findings. Results from copollutant models generally support an independent effect of $PM_{2.5}$ exposure on mortality. Additional evidence of the independent effect of $PM_{2.5}$ on the cardiovascular system is provided by experimental studies in animals, which support the biological plausibility of pathways by which long-term exposure to $PM_{2.5}$ could potentially result in outcomes such as CHD, stroke, CHF and cardiovascular mortality. Overall, studies evaluated in the 2019 ISA support the conclusion of a causal relationship between long-

[57] As noted above for mortality, uncertainty in the shape of the C-R relationship increases near the upper and lower ends of the distribution due to limited data.

term $PM_{2.5}$ exposure and cardiovascular effects, which is supported and extended by evidence from recent epidemiologic studies evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.1.2.2).

ii. Short-term $PM_{2.5}$ exposures

The 2009 ISA concluded that "a causal relationship exists between short-term exposure to $PM_{2.5}$ and cardiovascular effects" (U.S. EPA, 2009a). The strongest evidence in the 2009 ISA was from epidemiologic studies of emergency department (ED) visits and hospital admissions for IHD and heart failure (HF), with supporting evidence from epidemiologic studies of cardiovascular mortality (U.S. EPA, 2009a). Animal toxicological studies provided coherence and biological plausibility for the positive associations reported with MI, ED visits, and hospital admissions. These included studies reporting reduced myocardial blood flow during ischemia and studies indicating altered vascular reactivity. In addition, effects of $PM_{2.5}$ exposure on a potential indicator of ischemia (i.e., ST segment depression on an electrocardiogram) were reported in both animal toxicological and epidemiologic panel studies.[58] Key uncertainties from the last review resulted from inconsistent results across disciplines with respect to the relationship between short-term exposure to $PM_{2.5}$ and changes in blood pressure, blood coagulation markers, and markers of systemic inflammation. In addition, while the 2009 ISA identified a growing body of evidence from controlled human exposure and animal toxicological studies, uncertainties remained with respect to biological plausibility.

Studies evaluated in the 2019 ISA provide additional support for a causal relationship

[58] Some animal studies included in the 2009 ISA examined exposures to mixtures, such as motor vehicle exhaust or woodsmoke. In these studies, it was unclear if the resulting cardiovascular effects could be attributed specifically to the fine particle component of the mixture.

between short-term $PM_{2.5}$ exposure and cardiovascular effects. This includes generally positive associations observed in multicity epidemiologic studies of emergency department visits and hospital admissions for IHD, heart failure (HF), and combined cardiovascular-related endpoints. In particular, nationwide studies of older adults (65 years and older) using Medicare records report positive associations between $PM_{2.5}$ exposures and hospital admissions for HF (U.S. EPA, 2019a , section 6.1.3.1). Moreover, recent multicity studies, published after the literature cutoff date of the 2019 ISA and evaluated in the ISA Supplement, are consistent with studies evaluated in the 2019 ISA that report positive association between short-term $PM_{2.5}$ exposure and ED visits and hospital admission for IHD, heart attacks, and HF (U.S. EPA, 2022a, section 3.1). Epidemiologic studies conducted in single cities contribute some support to the causality determination, though associations reported in single-city studies are less consistently positive than in multicity studies, and include a number of studies reporting null associations (U.S. EPA, 2019a, sections 6.1.2 and 6.1.3). When considered as a whole; however, the recent body of IHD and HF epidemiologic evidence supports the evidence from previous ISAs reporting mainly positive associations between short-term $PM_{2.5}$ concentrations and emergency department visits and hospital admissions.

The ISA Supplement also includes some epidemiologic studies, published since the literature cutoff date for the 2019 ISA, including accountability analyses and epidemiologic studies that employ alternative methods for confounder control to evaluate the association between short-term $PM_{2.5}$ exposure and cardiovascular-related effects (U.S. EPA, 2022a, section 3.1.1.3). These studies report positive associations across a number of statistical approaches, providing additional support for a relationship between short-term $PM_{2.5}$ exposure and cardiovascular effects, while also reducing uncertainties related to potential confounder bias.

Consistent with the evidence assessed in the 2019 ISA, some studies evaluated in the ISA Supplement report no evidence of an association with stroke, regardless of stroke subtype. Additionally, as in the 2019 ISA, evidence evaluated in the ISA Supplement continues to indicate an immediate effect of $PM_{2.5}$ on cardiovascular-related outcomes primarily within the first few days after exposure, and that associations generally persisted in models adjusted for copollutants (U.S. EPA, 2022a, section 3.1.1.2).

A number of controlled human exposure, animal toxicological, and epidemiologic panel studies provide evidence that $PM_{2.5}$ exposure could plausibly result in IHD or HF through pathways that include endothelial dysfunction, arterial thrombosis, and arrhythmia (U.S. EPA, 2019a, section 6.1.1). The most consistent evidence from recent controlled human exposure studies is for endothelial dysfunction, as measured by changes in brachial artery diameter or flow mediated dilation. Multiple controlled human exposure studies that examined the potential for endothelial dysfunction report an effect of $PM_{2.5}$ exposure on measures of blood flow (U.S. EPA, 2019a, section 6.1.13.2). However, these studies report variable results regarding the timing of the effect and the mechanism by which reduced blood flow occurs (i.e., availability vs sensitivity to nitric oxide). In addition, some controlled human exposure studies using CAPs report evidence for small increases in blood pressure (U.S. EPA, 2019a, section 6.1.6.3). Although not entirely consistent, there is also some evidence across controlled human exposure studies for conduction abnormalities/arrhythmia (U.S. EPA, 2019a, section 6.1.4.3), changes in heart rate variability (HRV) (U.S. EPA, 2019a, section 6.1.10.2), changes in hemostasis that could promote clot formation (U.S. EPA, 2019a, section 6.1.12.2), and increases in inflammatory cells and markers (U.S. EPA, 2019a, section 6.1.11.2). A recent study by Wyatt et al. (2020), evaluated in the ISA Supplement, adds to the limited evidence base of controlled human exposure studies

conducted at near ambient $PM_{2.5}$ concentrations. The study, completed in healthy young adults subject to intermittent exercise, found some significant cardiovascular effects (e.g., systematic inflammation markers, including C-reactive protein (CRP), and cardiac repolarization). Thus, when taken as a whole, controlled human exposure studies are coherent with epidemiologic studies in that they demonstrate that short-term exposures to $PM_{2.5}$ may result in the types of cardiovascular endpoints that could lead to emergency department visits, hospital admissions and mortality in some people.

Animal toxicological studies published since the 2009 ISA also support a relationship between short-term $PM_{2.5}$ exposure and cardiovascular effects. A study demonstrating decreased cardiac contractility and left ventricular pressure in mice is coherent with the results of epidemiologic studies that report associations between short-term $PM_{2.5}$ exposure and heart failure (U.S. EPA, 2019a, section 6.1.3.3). In addition, and as with controlled human exposure studies, there is generally consistent evidence in animal toxicological studies for indicators of endothelial dysfunction (U.S. EPA, 2019a, section 6.1.13.3). Some studies in animals also provide evidence for changes in a number of other cardiovascular endpoints following short-term $PM_{2.5}$ exposure including conduction abnormalities and arrhythmia (U.S. EPA, 2019a, section 6.1.4.4), changes in HRV (U.S. EPA, 2019a, section 6.1.10.3), changes in blood pressure (U.S. EPA, 2019a, section 6.1.6.4), and evidence for systemic inflammation and oxidative stress (U.S. EPA, 2019a, section 6.1.11.3).

In summary, evidence evaluated in the 2019 ISA extends the consistency and coherence of the evidence base evaluated in the 2009 ISA and prior assessments. Direct evidence for an independent effect of $PM_{2.5}$ on cardiovascular effects can be found in a number of controlled human exposure and animal toxicological studies, which supports the results of epidemiologic

studies reporting that associations remain relatively unchanged in copollutant models. These results concur with epidemiologic panel studies reporting that $PM_{2.5}$ exposure is associated with some of the same cardiovascular endpoints reported in experimental studies. For some cardiovascular effects, there are inconsistencies in results across some animal toxicological, controlled human exposure, and epidemiologic panel studies, though this may be due to substantial differences in study design and/or study populations. Overall, the results from epidemiologic panel, controlled human exposure, and animal toxicological studies, in particular those related to endothelial dysfunction, impaired cardiac function, ST segment depression, thrombosis, conduction abnormalities, and changes in blood pressure provide coherence and biological plausibility for the consistent results from epidemiologic studies observing positive associations between short-term $PM_{2.5}$ concentrations and IHD and HF, and ultimately cardiovascular mortality. Overall, studies evaluated in the 2019 ISA support the conclusion of a causal relationship between short-term $PM_{2.5}$ exposure and cardiovascular effects, which is supported and extended by evidence from recent epidemiologic studies evaluated in the ISA Supplement (U.S. EPA, 2022a, section 3.1.1.4).

c. Respiratory Effects

i. Long-term $PM_{2.5}$ exposures

The 2009 ISA concluded that "a causal relationship is likely to exist between long-term $PM_{2.5}$ exposure and respiratory effects" (U.S. EPA, 2009a). This conclusion was based mainly on epidemiologic evidence demonstrating associations between long-term $PM_{2.5}$ exposure and changes in lung function or lung function growth in children. Biological plausibility was provided by a single animal toxicological study examining pre- and post-natal exposure to $PM_{2.5}$ CAPs, which found impaired lung development. Epidemiologic evidence for associations

between long-term $PM_{2.5}$ exposure and other respiratory outcomes, such as the development of asthma, allergic disease, and COPD; respiratory infection; and the severity of disease was limited, both in the number of studies available and the consistency of the results. Experimental evidence for other outcomes was also limited, with one animal toxicological study reporting that long-term exposure to $PM_{2.5}$ CAPs results in morphological changes in nasal airways of healthy animals. Other animal studies examined exposure to mixtures, such as motor vehicle exhaust and woodsmoke, and effects were not attributed specifically to the particulate components of the mixture.

Cohort studies evaluated in the 2019 ISA provided additional support for the relationship between long-term $PM_{2.5}$ exposure and decrements in lung function growth (as a measure of lung development), indicating a robust and consistent association across study locations, exposure assessment methods, and time periods (U.S. EPA, 2019a, section 5.2.13). This relationship was further supported by a retrospective study that reports an association between declining $PM_{2.5}$ concentrations and improvements in lung function growth in children (U.S. EPA, 2019a, section 5.2.11). Epidemiologic studies also examine asthma development in children (U.S. EPA, 2019a, section 5.2.3), with prospective cohort studies reporting generally positive associations, though several are imprecise (i.e., they report wide confidence intervals). Supporting evidence is provided by studies reporting associations with asthma prevalence in children, with childhood wheeze, and with exhaled nitric oxide, a marker of pulmonary inflammation (U.S. EPA, 2019a, section 5.2.13). Additionally, the 2019 ISA includes an animal toxicological study showing the development of an allergic phenotype and an increase in a marker of airway responsiveness supports the biological plausibility of the development of allergic asthma (U.S. EPA, 2019a, section 5.2.13).(,). Other epidemiologic studies report a $PM_{2.5}$-related acceleration of lung

function decline in adults, while improvement in lung function was observed with declining $PM_{2.5}$ concentrations (U.S. EPA, 2019a, section 5.2.11). A longitudinal study found declining $PM_{2.5}$ concentrations are also associated with an improvement in chronic bronchitis symptoms in children, strengthening evidence reported in the 2009 ISA for a relationship between increased chronic bronchitis symptoms and long-term $PM_{2.5}$ exposure (U.S. EPA, 2019a, section 5.2.11). A common uncertainty across the epidemiologic evidence is the lack of examination of copollutants to assess the potential for confounding. While there is some evidence that associations remain robust in models with gaseous pollutants, a number of these studies examining copollutant confounding were conducted in Asia, and thus have limited generalizability due to high annual pollutant concentrations.

When taken together, the 2019 ISA concludes that the "epidemiologic evidence strongly supports a relationship with decrements in lung function growth in children" and "with asthma development in children, with increased bronchitis symptoms in children with asthma, with an acceleration of lung function decline in adults, and with respiratory mortality and cause-specific respiratory mortality for COPD and respiratory infection" (U.S. EPA, 2019a, p. 1-34). In support of the biological plausibility of such associations reported in epidemiologic studies of respiratory health effects, animal toxicological studies continue to provide direct evidence that long-term exposure to $PM_{2.5}$ results in a variety of respiratory effects. Animal studies in the 2019 ISA show pulmonary oxidative stress, inflammation, and morphologic changes in the upper (nasal) and lower airways. Other results show that changes are consistent with the development of allergy and asthma, and with impaired lung development. Overall, the 2019 ISA concludes that "the collective evidence is sufficient to conclude that a causal relationship is likely to exist between long-term $PM_{2.5}$ exposure and respiratory effects" (U.S. EPA, 2019a, section 5.2.13).

ii. Short-term $PM_{2.5}$ exposures

The 2009 ISA (U.S. EPA, 2009a) concluded that a "causal relationship is likely to exist" between short-term $PM_{2.5}$ exposure and respiratory effects. This conclusion was based mainly on the epidemiologic evidence demonstrating positive associations with various respiratory effects. Specifically, the 2009 ISA described epidemiologic evidence as consistently showing $PM_{2.5}$-associated increases in hospital admissions and ED visits for COPD and respiratory infection among adults or people of all ages, as well as increases in respiratory mortality. These results were supported by studies reporting associations with increased respiratory symptoms and decreases in lung function in children with asthma, though the epidemiologic evidence was inconsistent for hospital admissions or emergency department visits for asthma. Studies examining copollutant models showed that $PM_{2.5}$ associations with respiratory effects were robust to inclusion of CO or $SO_2$ in the model, but often were attenuated (though still positive) with inclusion of $O_3$ or $NO_2$. In addition to the copollutant models, evidence supporting an independent effect of $PM_{2.5}$ exposure on the respiratory system was provided by animal toxicological studies of $PM_{2.5}$ CAPs demonstrating changes in some pulmonary function parameters, as well as inflammation, oxidative stress, injury, enhanced allergic responses, and reduced host defenses. Many of these effects have been implicated in the pathophysiology for asthma exacerbation, COPD exacerbation, or respiratory infection. In the few controlled human exposure studies conducted in individuals with asthma or COPD, $PM_{2.5}$ exposure mostly had no effect on respiratory symptoms, lung function, or pulmonary inflammation. Available studies in healthy people also did not clearly demonstrate respiratory effects following short-term $PM_{2.5}$ exposures.

Epidemiologic studies evaluated in the 2019 ISA continue to provide strong evidence for

a relationship between short-term $PM_{2.5}$ exposure and several respiratory-related endpoints, including asthma exacerbation (U.S. EPA, 2019a, section 5.1.2.1), COPD exacerbation (U.S. EPA, 2019a, section 5.1.4.1), and combined respiratory-related diseases (U.S. EPA, 2019a, section 5.1.6), particularly from studies examining ED visits and hospital admissions. The generally positive associations between short-term $PM_{2.5}$ exposure and asthma and COPD as well as ED visits and hospital admissions are supported by epidemiologic studies demonstrating associations with other respiratory-related effects such as symptoms and medication use that are indicative of asthma and COPD exacerbations (U.S. EPA, 2019a, sections 5.1.2.2 and 5.4.1.2). The collective body of epidemiologic evidence for asthma exacerbation is more consistent in children than in adults. Additionally, epidemiologic studies examining the relationship between short-term $PM_{2.5}$ exposure and respiratory mortality provide evidence of consistent positive associations, demonstrating a continuum of effects (U.S. EPA, 2019a, section 5.1.9).

Building off the studies evaluated in the 2009 ISA, epidemiologic studies evaluated in the 2019 ISA expand the assessment of potential copollutant confounding. There is some evidence that $PM_{2.5}$ associations with asthma exacerbation, combined respiratory-related diseases, and respiratory mortality remain relatively unchanged in copollutant models with gaseous pollutants (i.e., $O_3$, $NO_2$, $SO_2$, with more limited evidence for CO) and other particle sizes (i.e., $PM_{10–2.5}$) (U.S. EPA, 2019a, section 5.1.10.1

In the 2019 ISA, the uncertainty related to whether there is an independent effect of $PM_{2.5}$ on respiratory health is also partially addressed by findings from animal toxicological studies. Specifically, short-term exposure to $PM_{2.5}$ enhanced asthma-related responses in an animal model of allergic airways disease and enhanced lung injury and inflammation in an animal model of COPD (U.S. EPA, 2019a, sections 5.1.2.4.4 and 5.1.4.4.3). The experimental evidence

provides biological plausibility for some respiratory-related endpoints, including limited evidence of altered host defense and greater susceptibility to bacterial infection as well as consistent evidence of respiratory irritant effects. Animal toxicological evidence for other respiratory effects is inconsistent and a recent study by Wyatt et al. (2020) that was evaluated in the ISA Supplement, conducted at near ambient $PM_{2.5}$ concentrations, adds to the limited evidence base of controlled human exposure studies. The study, completed in healthy young adults subject to intermittent exercise, found some significant respiratory effects (including decrease in lung function), however these findings were inconsistent with the controlled human exposure studies evaluated in the 2019 ISA (U.S. EPA, 2019a, section 5.1.7.2, 5.1.2.3, and 6.1.11.2.1).

The 2019 ISA concludes that "[t]he strongest evidence of an effect of short-term $PM_{2.5}$ exposure on respiratory effects is provided by epidemiologic studies of asthma and COPD exacerbation. While animal toxicological studies provide biological plausibility for these findings, some uncertainty remains with respect to the independence of $PM_{2.5}$ effects" (U.S. EPA, 2019a, p. 5-155). When taken together, the 2019 ISA concludes that this evidence "is sufficient to conclude that a causal relationship is likely to exist between short-term $PM_{2.5}$ exposure and respiratory effects" (U.S. EPA, 2019a, p. 5-155).

d. Cancer

The 2009 ISA concluded that the overall body of evidence was "suggestive of a causal relationship between relevant $PM_{2.5}$ exposures and cancer" (U.S. EPA, 2009a). This conclusion was based primarily on positive associations observed in a limited number of epidemiologic studies of lung cancer mortality. The few epidemiologic studies that had evaluated $PM_{2.5}$ exposure and lung cancer incidence or cancers of other organs and systems generally did not

show evidence of an association. Toxicological studies did not focus on exposures to specific PM size fractions, but rather investigated the effects of exposures to total ambient PM, or other source-based PM such as wood smoke. Collectively, results of in vitro studies were consistent with the larger body of evidence demonstrating that ambient PM and PM from specific combustion sources are mutagenic and genotoxic. However, animal inhalation studies found little evidence of tumor formation in response to chronic exposures. A small number of studies provided preliminary evidence that PM exposure can lead to changes in methylation of DNA, which may contribute to biological events related to cancer.

Since the completion of the 2009 ISA, additional cohort studies provide evidence that long-term $PM_{2.5}$ exposure is positively associated with lung cancer mortality and with lung cancer incidence, and provide initial evidence for an association with reduced cancer survival (U.S. EPA, 2019a, section 10.2.5). Re-analyses of the ACS cohort using different years of $PM_{2.5}$ data and follow up, along with various exposure assignment approaches, provide consistent evidence of positive associations between long-term $PM_{2.5}$ exposure and lung cancer mortality (U.S. EPA, 2019a, Figure 10-3). Additional support for positive associations with lung cancer mortality is provided by recent epidemiologic studies using individual level data to control for smoking status, by studies of people who have never smoked (though such studies generally report wide confidence intervals due to the small number of lung cancer mortality cases within this population), and in analyses of cohorts that relied upon proxy measures to account for smoking status (U.S. EPA, 2019a, section 10.2.5.1.1). Although studies that evaluate lung cancer incidence, including studies of people who have never smoked, are limited in number, studies in the 2019 ISA generally report positive associations with long-term $PM_{2.5}$ exposures (U.S. EPA, 2019a, section 10.2.5.1.2). A subset of the studies focusing on lung cancer incidence also

examined histological subtype, providing some evidence of positive associations for adenocarcinomas, the predominate subtype of lung cancer observed in people who have never smoked (U.S. EPA, 2019a, section 10.2.5.1.2). Associations between long-term $PM_{2.5}$ exposure and lung cancer incidence were found to remain relatively unchanged, though in some cases confidence intervals widened, in analyses that attempted to reduce exposure measurement error by accounting for length of time at residential address or by examining different exposure assignment approaches (U.S. EPA, 2019a, section 10.2.5.1.2).

The 2019 ISA evaluates the degree to which epidemiologic studies have addressed the potential for confounding by copollutants and the shape of the C-R relationship. To date, relatively few studies have evaluated the potential for copollutant confounding of the relationship between long-term $PM_{2.5}$ exposure and lung cancer mortality or incidence. A small number of such studies have generally focused on $O_3$ and report that $PM_{2.5}$ associations remain relatively unchanged in copollutant models (U.S. EPA, 2019a, section 10.2.5.1.3). However, available studies have not systematically evaluated the potential for copollutant confounding by other gaseous pollutants or by other particle size fractions (U.S. EPA, 2019a, section 10.2.5.1.3). Compared to total (non-accidental) mortality (U.S. EPA, 2019a, section 10.2.4.1.4), fewer studies have examined the shape of the C-R curve for cause-specific mortality outcomes, including lung cancer. Several studies of lung cancer mortality and incidence have reported no evidence of deviations from linearity in the shape of the C-R relationship (Lepeule et al., 2012; Raaschou-Nielsen et al., 2013; Puett et al., 2014), though authors provided only limited discussions of results (U.S. EPA, 2019a, section 10.2.5.1.4).

In support of the biological plausibility of an independent effect of $PM_{2.5}$ on lung cancer, the 2019 ISA notes evidence from experimental and epidemiologic studies demonstrating that

$PM_{2.5}$ exposure can lead to a range of effects indicative of mutagenicity, genotoxicity, and carcinogenicity, as well as epigenetic effects (U.S. EPA, 2019a, section 10.2.7). For example, both in vitro and in vivo toxicological studies have shown that $PM_{2.5}$ exposure can result in DNA damage (U.S. EPA, 2019a, section 10.2.2). Although such effects do not necessarily equate to carcinogenicity, the evidence that PM exposure can damage DNA, and elicit mutations, provides support for the plausibility of epidemiologic associations with lung cancer mortality and incidence. Additional supporting studies indicate the occurrence of micronuclei formation and chromosomal abnormalities (U.S. EPA, 2019a, section 10.2.2.3), and differential expression of genes that may be relevant to cancer pathogenesis, following PM exposures. Experimental and epidemiologic studies that examine epigenetic effects indicate changes in DNA methylation, providing some support for $PM_{2.5}$ exposure contributing to genomic instability (U.S. EPA, 2019a, section 10.2.3). Overall, there is limited evidence that long-term $PM_{2.5}$ exposure is associated with cancers in other organ systems, but there is some evidence that $PM_{2.5}$ exposure may reduce survival in individuals with cancer (U.S. EPA, 2019a, section 10.2.7; U.S. EPA, 2022a, section 2.1.1.4.1).

Epidemiologic evidence for associations between $PM_{2.5}$ and lung cancer mortality and incidence, together with evidence supporting the biological plausibility of such associations, contributes to the 2019 ISA's conclusion that the evidence "is sufficient to conclude that a causal relationship is likely to exist between long-term $PM_{2.5}$ exposure and cancer" (U.S. EPA, 2019, section 10.2.7).

e. Nervous System Effects

Reflecting the very limited evidence available in the 2012 review, the 2009 ISA did not make a causality determination for long-term $PM_{2.5}$ exposures and nervous system effects (U.S.

EPA, 2009c). Since the 2012 review, this body of evidence has grown substantially (U.S. EPA, 2019, section 8.2). Animal toxicological studies assessed in in the 2019 ISA report that long-term $PM_{2.5}$ exposures can lead to morphologic changes in the hippocampus and to impaired learning and memory. This evidence is consistent with epidemiologic studies reporting that long-term $PM_{2.5}$ exposure is associated with reduced cognitive function (U.S. EPA, 2019a, section 8.2.5). Further, while the evidence is limited, the presence of early markers of Alzheimer's disease pathology has been demonstrated in rodents following long-term exposure to $PM_{2.5}$ CAPs. These findings support reported associations with neurodegenerative changes in the brain (i.e., decreased brain volume), all-cause dementia, or hospitalization for Alzheimer's disease in a small number of epidemiologic studies (U.S. EPA, 2019a, section 8.2.6). Additionally, loss of dopaminergic neurons in the substantia nigra, a hallmark of Parkinson disease, has been reported in mice (U.S. EPA, 2019a, section 8.2.4), though epidemiologic studies provide only limited support for associations with Parkinson's disease (U.S. EPA, 2019a, section 8.2.6). Overall, the lack of consideration of copollutant confounding introduces some uncertainty in the interpretation of epidemiologic studies of nervous system effects, but this uncertainty is partly addressed by the evidence for an independent effect of $PM_{2.5}$ exposures provided by experimental animal studies.

In addition to the findings described above, which are most relevant to older adults, several studies of neurodevelopmental effects in children have also been conducted. Positive associations between long-term exposure to $PM_{2.5}$ during the prenatal period and autism spectrum disorder (ASD) are observed in multiple epidemiologic studies (U.S. EPA, 2019a, section 8.2.7.2), while studies of cognitive function provide little support for an association (U.S. EPA, 2019a, section 8.2.5.2). Interpretation of these epidemiologic studies is limited due to the

small number of studies, their lack of control for potential confounding by copollutants, and uncertainty regarding the critical exposure windows. Biological plausibility is provided for the ASD findings by a study in mice that found inflammatory and morphologic changes in the corpus collosum and hippocampus, as well as ventriculomegaly (i.e., enlarged lateral ventricles) in young mice following prenatal exposure to $PM_{2.5}$ CAPs.

Taken together, the 2019 ISA concludes that studies indicate long-term $PM_{2.5}$ exposures can lead to effects on the brain associated with neurodegeneration (i.e., neuroinflammation and reductions in brain volume), as well as cognitive effects in older adults (U.S. EPA, 2019a, Table 1-2). Animal toxicological studies provide evidence for a range of nervous system effects in adult animals, including neuroinflammation and oxidative stress, neurodegeneration, and cognitive effects, and effects on neurodevelopment in young animals. The epidemiologic evidence is more limited, but studies generally support associations between long-term $PM_{2.5}$ exposure and changes in brain morphology, cognitive decrements and dementia. There is also initial, and limited, evidence for neurodevelopmental effects, particularly ASD. The consistency and coherence of the evidence supports the 2019 ISA's conclusion that "the collective evidence is sufficient to conclude that a causal relationship is likely to exist between long-term $PM_{2.5}$ exposure and nervous system effects" (U.S. EPA, 2019a, section 8.2.9).

f. Other Effects

For other health effect categories that were evaluated for their relationship with $PM_{2.5}$ exposures (i.e., short-term $PM_{2.5}$ exposure and nervous system effects and short- and long-term $PM_{2.5}$ exposure and metabolic effects, reproduction and fertility, and pregnancy and birth outcomes (U.S. EPA, 2022a, Table ES-1), the currently available evidence is "suggestive of, but not sufficient to infer, a causal relationship," mainly due to inconsistent evidence across specific

outcomes and uncertainties regarding exposure measurement error, the potential for confounding, and potential modes of action (U.S. EPA, 2019a, sections 7.14, 7.2.10, 8.1.6, and 9.1.5). The causality determination for short-term $PM_{2.5}$ exposure and nervous system effects in the 2019 ISA reflects a revision to the causality determination in the 2009 ISA from "inadequate to infer a causal relationship," while this is the first time assessments of causality were conducted for long-term $PM_{2.5}$ exposure and nervous system effects, as well as short- and long-term $PM_{2.5}$ exposure and metabolic effects reflect.

Recent studies evaluated in the 2019 ISA also further explored the relationship between short-and long-term ultrafine particle (UFP) exposure and health effects. (i.e., cardiovascular effects and short-term UFP exposures; respiratory effects and short-term UFP exposures; and nervous system effects and long- and short-term exposures (U.S. EPA, 2022a, Table ES-1). The currently available evidence is "suggestive of, but not sufficient to infer, a causal relationship" for short-term UFP exposure and cardiovascular and respiratory effects and for short- and long-term UFP exposure and nervous system effects, primarily due to uncertainties and limitations in the evidence, specifically, variability across studies in the definition of UFPs and the exposure metric used (U.S. EPA, 2019a, P.3.1; U.S. EPA, 2022a, section 3.3.1.6.3). The causality determinations for the other health effect categories evaluated in the 2019 ISA are "inadequate to infer a causal relationship." Additionally, this is the first time assessments of causality were conducted for short- and long-term UFP exposure and metabolic effects and long-term UFP exposure and nervous system effects (U.S. EPA, 2022a, Table ES-1).

With the advent of the global COVID-19 pandemic, a number of recent studies evaluated in the ISA Supplement examined the relationship between ambient air pollution, specifically $PM_{2.5}$, and SARS-CoV-2 infections and COVID-19 deaths, including a few studies within the

U.S. and Canada (U.S. EPA, 2022a, section 3.3.2).[59] Some studies examined whether daily changes in $PM_{2.5}$ can influence SARS-CoV-2 infection and COVID-19 death (U.S. EPA, 2022a, section 3.3.2.1). Additionally, several studies evaluated whether long-term $PM_{2.5}$ exposure increases the risk of SARS-CoV-2 infection and COVID-19 death in North America (U.S. EPA, 2022a, section 3.3.2.2). While there is initial evidence of positive associations with SARS-CoV-2 infection and COVID-19 death, uncertainties remain due to methodological issues that may influence the results, including: (1) the use of ecological study design; (2) studies were conducted during the ongoing pandemic when the etiology of COVID-19 was still not well understood (e.g., specifically, there are important differences in COVID-19-related outcomes by a variety of factors such as race and SES); and (3) studies did not account for crucial factors that could influence results (e.g., stay-at-home orders, social distancing, use of masks, and testing capacity) (U.S. EPA, 2022a, chapter 5). Taken together, while there is initial evidence of positive associations with SARS-CoV-2 infection and COVID-19 death, uncertainties remain due to methodological issues.

2. Public Health Implications and At-Risk Populations

[59] While there is no exact corollary within the 2019 ISA for these types of studies, the 2019 ISA presented evidence that evaluates the potential relationship between short- and long-term $PM_{2.5}$ exposure and respiratory infection (U.S. EPA, 2022a, section 5.1.5 and 5.2.6). Studies assessed in the 2019 ISA report some evidence of positive associations between short-term $PM_{2.5}$ and hospital admissions and ED visits for respiratory infections, however the interpretation of these studies is complicated by the variability in the type of respiratory infection outcome examined (U.S. EPA, 2022a, Figure 5-7). In the 2019 ISA, studies of long-term $PM_{2.5}$ exposure were limited and while there were some positive associations reported, there was minimal overlap in respiratory infection outcomes examined across studies. Exposure to $PM_{2.5}$ has been shown to impair host defense, specifically altering macrophage function, providing a biological pathway by which $PM_{2.5}$ exposure could lead to respiratory infection (U.S. EPA, 2022a, sections 5.1.1 and 5.1.5.) There is some additional evidence that $PM_{2.5}$ exposure can lead to decreases in an individual's immune response, which can subsequently facilitate replication of respiratory viruses (Bourdrel et al., 2021).

The public health implications of the evidence regarding $PM_{2.5}$-related health effects, as for other effects, are dependent on the type and severity of the effects, as well as the size of the population affected. Such factors are discussed here in the context of our consideration of the health effects evidence related to $PM_{2.5}$ in ambient air. This section also summarizes the current information on population groups at increased risk of the effects of $PM_{2.5}$ in ambient air.

The information available in this reconsideration has not altered our understanding of human populations at risk of health effects from $PM_{2.5}$ exposures. As recognized in the 2020 review, the 2019 ISA cites extensive evidence indicating that "both the general population as well as specific populations and lifestages are at risk for $PM_{2.5}$-related health effects" (U.S. EPA, 2019a, p. 12-1). Factors that may contribute to increased risk of $PM_{2.5}$-related health effects include lifestage (children and older adults), pre-existing diseases (cardiovascular disease and respiratory disease), race/ethnicity, and SES.[60]

Children make up a substantial fraction of the U.S. population, and often have unique factors that contribute to their increased risk of experiencing a health effect due to exposures to ambient air pollutants because of their continuous growth and development.[61] Children may be particularly at risk for health effects related to ambient $PM_{2.5}$ exposures compared with adults because they have (1) a developing respiratory system, (2) increased ventilation rates relative to body mass compared with adults, and (3) an increased proportion of oral breathing, particularly in boys, relative to adults (U.S. EPA, 2019a, section 12.5.1.1). There is strong evidence that demonstrates $PM_{2.5}$ associated health effects in children, particularly from epidemiologic studies

[60] As described in the 2019 ISA, other factors that have the potential to contribute to increased risk include obesity, diabetes, genetic factors, smoking status, sex, diet, and residential location (U.S. EPA, 2019, chapter 12).

[61] Children, as used throughout this notice, generally refers to those younger than 18 years old.

of long-term $PM_{2.5}$ exposure and impaired lung function growth, decrements in lung function, and asthma development. However, there is limited evidence from stratified analyses that children are at increased risk of $PM_{2.5}$-related health effects compared to adults. Additionally, there is some evidence that indicates that children receive higher $PM_{2.5}$ exposures than adults, and dosimetric differences in children compared to adults can contribute to higher doses (U.S. EPA, 2019a, section 12.5.1.1).

In the U.S., older adults, often defined as adults 65 years of age and older, represent an increasing portion of the population and often have pre-existing diseases or conditions that may compromise biological function. While there is limited evidence to indicate that older adults have higher exposures than younger adults, older adults may receive higher doses of $PM_{2.5}$ due to dosimetric differences. There is consistent evidence from studies of older adults demonstrating generally consistent positive associations in studies examining health effects from short- and long-term $PM_{2.5}$ exposure and cardiovascular or respiratory hospital admissions, emergency department visits, or mortality (U.S. EPA, 2019a, sections 6.1, 6.2, 11.1, 11.2, 12.5.1.2). Additionally, several animal toxicological, controlled human exposure, and epidemiologic studies did not stratify results by lifestage, but instead focused the analyses on older individuals, and can provide coherence and biological plausibility for the occurrence among this lifestage (U.S. EPA, 2019a, section 12.5.1.2).

Individuals with pre-existing disease may be considered at greater risk of an air pollution-related health effect than those without disease because they are likely in a compromised biological state that can vary depending on the disease and severity. With regard to cardiovascular disease, we first note that cardiovascular disease is the leading cause of death in the U.S., accounting for one in four deaths, and approximately 12% of the adult population in the

U.S. has a cardiovascular disease (U.S. EPA, 2019a, section 12.3.1). Strong evidence demonstrates that there is a causal relationship between cardiovascular effects and long- and short-term exposures to $PM_{2.5}$. Some of the evidence supporting this conclusion is from studies of panels or cohorts with pre-existing cardiovascular disease, which provide supporting evidence but do not directly demonstrate an increased risk (U.S. EPA, 2019a, section 12.3.1). Epidemiologic evidence indicates that individuals with pre-existing cardiovascular disease may be at increased risk for $PM_{2.5}$-associated health effects compared to those without pre-existing cardiovascular disease. While the evidence does not consistently support increased risk for all pre-existing cardiovascular diseases, there is evidence that certain pre-existing cardiovascular diseases (e.g., hypertension) may be a factor that increases $PM_{2.5}$-related risk. Furthermore, there is strong evidence supporting a causal relationship for long- and short-term $PM_{2.5}$ exposure and cardiovascular effects, particularly for IHD (U.S. EPA, 2019a, chapter 6, section 12.3.1).

With regard to respiratory disease, we first note that the most chronic respiratory diseases in the U.S. are asthma and COPD. Asthma affects a substantial fraction of the U.S. population and is the leading chronic disease among children. COPD primarily affects older adults and contributes to compromised respiratory function and underlying pulmonary inflammation. The body of evidence indicates that individuals with pre-existing respiratory diseases, particularly asthma and COPD, may be at increased risk for $PM_{2.5}$-related health effects compared to those without pre-existing respiratory diseases (U.S. EPA, 2019a, section 12.3.5). There is strong evidence indicating $PM_{2.5}$-associated respiratory effects among those with asthma which forms the primary evidence base for the likely to be causal relationship between short-term exposures to $PM_{2.5}$ and respiratory health effects (U.S. EPA, 2019a, section 12.3.5). For asthma, epidemiologic evidence demonstrates associations between short-term $PM_{2.5}$ exposures and

respiratory effects, particularly evidence for asthma exacerbation, and controlled human exposure and animal toxicological studies demonstrate biological plausibility for asthma exacerbation with $PM_{2.5}$ exposures (U.S. EPA, 2019a, section 12.3.5.1). For COPD, epidemiologic studies report positive associations between short-term $PM_{2.5}$ exposures and hospital admissions and emergency department visits for COPD, with supporting evidence from panel studies demonstration COPD exacerbation. Epidemiologic evidence is supported by some experimental evidence of COPD-related effects, which provides support for the biological plausibility for COPD in response to $PM_{2.5}$ exposures (U.S. EPA, 2019a, section 12.3.5.2).

There is strong evidence for racial and ethnic disparities in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risk, as assessed in the 2019 ISA and with even more evidence available since the literature cutoff date for the 2019 ISA and evaluated in the ISA Supplement. There is strong evidence demonstrating that Black and Hispanic populations, in particular, have higher $PM_{2.5}$ exposures than non-Hispanic White populations (U.S. EPA, 2019a, Figure 12-2; U.S. EPA, 2022a, Figure 3-38). Black populations or individuals that live in predominantly Black neighborhoods experience higher $PM_{2.5}$ exposures, in comparison to non-Hispanic White populations. There is also consistent evidence across multiple studies that demonstrate increased risk of $PM_{2.5}$-related health effects, with the strongest evidence for health risk disparities for mortality (U.S. EPA, 2019a, section 12.5.4). There is also evidence of health risk disparities for both Hispanic and non-Hispanic Black populations compared to non-Hispanic White populations for cause-specific mortality and incident hypertension (U.S. EPA, 2022a, section 3.3.3.2).

Socioeconomic status (SES) is a composite measure that includes metrics such as income, occupation, or education, and can play a role in access to healthy environments as well as access to healthcare. SES may be a factor that contributes to differential risk from $PM_{2.5}$-

related health effects. Studies assessed in the 2019 ISA and ISA Supplement provide evidence that lower SES communities are exposed to higher concentrations of $PM_{2.5}$ compared to higher SES communities (U.S. EPA, 2019a, section 12.5.3; U.S. EPA, 2022a, section 3.3.3.1.1). Studies using composite measures of neighborhood SES consistently demonstrated a disparity in both $PM_{2.5}$ exposure and the risk of $PM_{2.5}$-related health outcomes. There is some evidence that supports associations larger in magnitude between mortality and long-term $PM_{2.5}$ exposures for those with low income or living in lower income areas compared to those with higher income or living in higher income neighborhoods (U.S. EPA, 2019a, section 12.5.3; U.S. EPA, 2022a, section 3.3.3.1.1). Additionally, evidence supports conclusions that lower SES is associated with cause-specific mortality and certain health endpoints (i.e., HI and CHF), but less so for all-cause or total (non-accidental) mortality (U.S. EPA, 2022a, section 3.3.3.1).

The magnitude and characterization of a public health impact is dependent upon the size and characteristics of the populations affected, as well as the type or severity of the effects. As summarized above, lifestage (children and older adults), race/ethnicity and SES are factors that increase the risk of $PM_{2.5}$-related health effects. The American Community Survey (ACS) for 2019 estimates that approximately 22% and 16% of the U.S. population are children (age<18) and older adults (age 65+), respectively. For all ages, non-Hispanic Black and Hispanic populations are approximately 12% and 18% of the overall U.S. population in 2019. Currently available information that helps to characterize key features of these population is included in the PA (U.S. EPA, 2022b, Table 3-2).

As noted above, individuals with pre-existing cardiovascular disease and pre-existing respiratory disease may also be at increased risk of $PM_{2.5}$-related health effects. Currently available information that helps to characterize key features of populations with cardiovascular

or respiratory diseases or conditions is included in the PA (U.S. EPA, 2022b, Table 3-3). The National Center for Health Statistics data for 2018 indicate that, for adult populations, older adults (e.g., those 65 years and older) have a higher prevalence of cardiovascular diseases compared to younger adults (e.g., those 64 years and younger). For respiratory diseases, older adults also have a higher prevalence of emphysema than younger adults, and adults 44 years or older have a higher prevalence of chronic bronchitis. However, the prevalence for asthma is generally similar across all adult age groups.

With respect to race, American Indians or Alaskan Natives have the highest prevalence of all heart disease and coronary heart disease, while Blacks have the highest prevalence of hypertension and stroke. Hypertension has the highest prevalence across all racial groups compared to other cardiovascular diseases or conditions, ranging from approximately 22% to 32% of each racial group. Overall, the prevalence of cardiovascular diseases or conditions is lowest for Asians compared to Whites, Blacks, and American Indians or Alaskan Natives. Asthma prevalence is highest among Black and American Indian or Alaska Native populations, while prevalence is generally similar across racial groups for chronic bronchitis and emphysema. Overall, the prevalence for respiratory diseases is lowest for Asians compared to Whites, Blacks, and American Indians or Alaskan Natives. With regard to ethnicity, cardiovascular and respiratory disease prevalence across all diseases or conditions is generally similar between Hispanic and non-Hispanic populations, although non-Hispanics have a slightly higher prevalence compared to Hispanics.

Taken together, this information indicates that the groups at increased risk of $PM_{2.5}$-related health effects represent a substantial portion of the total U.S. population. In evaluating the primary $PM_{2.5}$ standards, an important consideration is the potential $PM_{2.5}$-related public health

impacts in these populations.

3. $PM_{2.5}$ Concentrations in Key Studies Reporting Health Effects

To inform conclusions on the adequacy of the public health protection provided by the current primary $PM_{2.5}$ standards, the sections below summarize the PA's evaluation of the $PM_{2.5}$ exposure concentrations that have been examined in controlled human exposure studies, animal toxicological studies, and epidemiologic studies. The PA places the greatest emphasis on the health outcomes for which the 2019 ISA concludes that the evidence supports a "causal" or a "likely to be causal" relationship with $PM_{2.5}$ exposures (U.S. EPA, 2022b, section 3.3.3). As described in greater detail in section II.B.1 above, this includes mortality, cardiovascular effects, and respiratory effects associated with short- or long-term $PM_{2.5}$ exposures and cancer and nervous system effects associated with long-term $PM_{2.5}$ exposures. While the causality determinations in the 2019 ISA are informed by studies evaluating a wide range of $PM_{2.5}$ concentrations, the sections below summarize the considerations in the PA regarding the degree to which the evidence assessed in the 2019 ISA and ISA Supplement supports the occurrence of PM-related health effects at concentrations relevant to informing conclusions on the primary $PM_{2.5}$ standards.

a. $PM_{2.5}$ Exposure Concentrations Evaluated in Experimental Studies

Evidence for a particular $PM_{2.5}$-related health outcome is strengthened when results from experimental studies demonstrate biologically plausible mechanisms through which adverse human health outcomes could occur (U.S. EPA, 2015, Preamble p. 20). Two types of experimental studies are of particular importance in understanding the effects of PM exposures: controlled human exposure and animal toxicological studies. In such studies, investigators expose human volunteers or laboratory animals, respectively, to known concentrations of air

pollutants under carefully regulated environmental conditions and activity levels. Thus, controlled human exposure and animal toxicological studies can provide information on the health effects of experimentally administered pollutant exposures under highly controlled laboratory conditions (U.S. EPA, 2015, Preamble, p. 11).

Controlled human exposure studies have reported that $PM_{2.5}$ exposures lasting from less than one hour up to five hours can impact cardiovascular function,[62] and the most consistent evidence from these studies is for impaired vascular function (U.S. EPA, 2019a, section 6.1.13.2). In addition, although less consistent, the 2019 ISA notes that studies examining $PM_{2.5}$ exposures also provide evidence for increased blood pressure (U.S. EPA, 2019a, section 6.1.6.3), conduction abnormalities/arrhythmia (U.S. EPA, 2019a, section 6.1.4.3), changes in heart rate variability (U.S. EPA, 2019a, section 6.1.10.2), changes in hemostasis that could promote clot formation (U.S. EPA, 2019a, section 6.1.12.2), and increases in inflammatory cells and markers (U.S. EPA, 2019a, section 6.1.11.2). The 2019 ISA concludes that, when taken as a whole, controlled human exposure studies demonstrate that short-term exposure to $PM_{2.5}$ may impact cardiovascular function in ways that could lead to more serious outcomes (U.S. EPA, 2019a, section 6.1.16). Thus, such studies can provide insight into the potential for specific $PM_{2.5}$ exposures to result in physiological changes that could increase the risk of more serious effects.

Table 3-4 in the PA summarizes information from the 2019 ISA on available controlled human exposure studies the evaluate effects on markers of cardiovascular function following exposure to $PM_{2.5}$ (U.S. EPA, 2022b). Most of the controlled human exposure studies in Table 3-

[62] In contrast, controlled human exposure studies provide little evidence for respiratory effects following short-term $PM_{2.5}$ exposures (U.S. EPA, 2019a, section 5.1, Table 5-18). Therefore, this section focuses on cardiovascular effects evaluated in controlled human exposure studies of $PM_{2.5}$ exposure.

4 in the PA have evaluated average $PM_{2.5}$ concentrations at or above about 100 $\mu g/m^3$, with exposure durations typically up to about two hours. Statistically significant effects on one or more indicators of cardiovascular function are often, though not always, reported following 2-hour exposures to average $PM_{2.5}$ concentrations at and above about 120 $\mu g/m^3$, with less consistent evidence for effects following exposures to concentrations lower than 120 $\mu g/m^3$. Impaired vascular function, the effect identified in the 2019 ISA as the most consistent across studies (U.S. EPA, 2019a, section 6.1.13.2) is shown following 2-hour exposures to $PM_{2.5}$ concentrations at and above 149 $\mu g/m^3$. Mixed results are reported in the studies that evaluated longer exposure durations (i.e., longer than 2 hours) and lower (i.e., near-ambient) $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section 3.3.3.1). For example, significant effects for some outcomes were reported following 5-hour exposures to 24 $\mu g/m^3$ in Hemmingsen et al. (2015b), but not for other outcomes following 5-hour exposures to 24 $\mu g/m^3$ in Hemmingsen et al. (2015a) and not following 24-hour exposures to 10.5 $\mu g/m^3$ in Bräuner et al. (2008). Additionally, Wyatt et al. (2020) found significant effects for some cardiovascular (e.g., systematic inflammation markers, cardiac repolarization, and decreased pulmonary function) effects following 4-hour exposures to 37.8 $\mu g/m^3$ in healthy young participants (18-35 years, n=21) who were subject to intermittent moderate exercise. The higher ventilation rate and longer exposure duration in this study compared to most controlled human exposure studies is roughly equivalent to a 2-hour exposure of 75-100 $\mu g/m^3$ of $PM_{2.5}$. Therefore, dosimetric considerations may explain the observed changes in inflammation in young healthy individuals. Though this study provides evidence of some effects at lower $PM_{2.5}$ concentrations, overall there is inconsistent evidence for inflammation in other controlled human exposure studies evaluated in the 2019 ISA (U.S. EPA, 2019a, sections 5.1.7., 5.1.2.3.3, and 6.1.11.2.1; U.S. EPA, 2022a,

section 3.3.1).

While controlled human exposure studies are important in establishing biological plausibility, it is unclear how the results from these studies alone and the importance of the effects observed in these studies, should be interpreted with respect to adversity to public health. More specifically, impaired vascular function can signal an intermediate effect along the potential biological pathways for cardiovascular effects following short-term exposure to $PM_{2.5}$ and show a role for exposure to $PM_{2.5}$ leading to potential worsening of IHD and heart failure followed potentially by ED visits, hospital admissions, or mortality (U.S. EPA, 2019, section 6.1 and Figure 6-1). However, just observing the occurrence of impaired vascular function alone does not clearly suggest an adverse health outcome. Additionally, associated judgments regarding adversity or health significance of measurable physiological responses to air pollutants have been informed by guidance, criteria or interpretative statements developed within the public health community, including the American Thoracic Society (ATS) and the European Respiratory Society (ERS), which cooperatively updated the ATS 2000 statement *What Constitutes an Adverse Health Effect of Air Pollution* (ATS, 2000) with new scientific findings, including the evidence related to air pollution and the cardiovascular system (Thurston et al.,

2017).[63] With regard to vascular function, the ATS/ERS statement considers the adversity of both chronic and acute reductions in endothelial function. While the ATS/ERS statement concluded that chronic endothelial and vascular dysfunction can be judged to be a biomarker of an adverse health effect from air pollution, they also conclude that "the health relevance of acute reductions in endothelial function induced by air pollution is less certain" (Thurston et al., 2017). This is particularly informative to our consideration of the controlled human exposure studies which are short-term in nature (i.e., ranging from 2- to 5-hours), including those studies that are conducted at near-ambient $PM_{2.5}$ concentrations.

The PA also notes that it is important to recognize that controlled human exposure studies include a small number of individuals compared to epidemiologic studies. Additionally, these studies tend to include generally healthy adult individuals, who are at a lower risk of experiencing health effects. These studies, therefore, often do not include including children, or older adults, or individuals with pre-existing conditions. As such, these studies are somewhat limited in their ability to inform at what concentrations effects may be elicited in at-risk populations.

Nonetheless, to provide some insight into what these controlled human exposure studies

[63] The ATS/ERS described its 2017 statement as one "intended to provide guidance to policymakers, clinicians and public health professionals, as well as others who interpret the scientific evidence on the health effects of air pollution for risk management purposes" and further notes that "considerations as to what constitutes an adverse health effect, in order to provide guidance to researchers and policymakers when new health effects markers or health outcome associations might be reported in future." The most recent policy statement by the ATS, which once again broadens its discussion of effects, responses and biomarkers to reflect the expansion of scientific research in these areas, reiterates that concept, conveying that it does not offer "strict rules or numerical criteria, but rather proposes considerations to be weighed in setting boundaries between adverse and nonadverse health effects," providing a general framework for interpreting evidence that proposes a "set of considerations that can be applied in forming judgments" for this context (Thurston et al., 2017).

may indicate regarding short-term exposure to peak $PM_{2.5}$ concentrations and how concentrations relate to ambient $PM_{2.5}$ concentrations, analyses in the PA (U.S. EPA, 2022b, Figure 2-19) examine monitored 2-hour $PM_{2.5}$ concentrations (the exposure window most often utilized in the controlled human exposure studies) at sites meeting the current primary $PM_{2.5}$ standards to evaluate the degree to which 2-hour ambient $PM_{2.5}$ concentrations at such locations are likely to exceed the 2-hour exposure concentrations in the controlled human exposure studies at which statistically significant effects are reported in multiple studies for one or more indicators of cardiovascular function. At sites meeting the current primary $PM_{2.5}$ standards, most 2-hour concentrations are below 10 $\mu g/m^3$, and almost never exceed 30 $\mu g/m^3$. The extreme upper end of the distribution of 2-hour $PM_{2.5}$ concentrations is shifted higher during the warmer months (April to September), generally corresponding to the period of peak wildfire frequency in the U.S. At sites meeting the current primary $PM_{2.5}$ standards, the highest 2-hour concentrations measured tend to occur during the period of peak wildfire frequency (i.e., $99.9^{th}$ percentile of 2-hour concentrations is 62 $\mu g/m^3$ during the warm season considered as a whole). Most of the sites measuring these very high concentrations are in the northwestern U.S. and California (U.S. EPA, 2022b, Appendix A, Figure A-1), where wildfires have been relatively common in recent years. When the typical fire season is excluded from the analysis, the extreme upper end of the distribution is reduced (i.e., $99.9^{th}$ percentile of 2-hour concentrations is 55 $\mu g/m^3$).[64] Given these results, the PA concludes that $PM_{2.5}$ exposure concentrations evaluated in most of these controlled human exposure studies are well-above the 2-hour ambient $PM_{2.5}$ concentrations typically measured in locations meeting the current primary standards.

[64] Similar analyses of 4-hour and 5-hour $PM_{2.5}$ concentrations are presented in Appendix A, Figure A-2 and Figure A-3, respectively of the PA (U.S. EPA, 2022b).

With respect to animal toxicological studies, the 2019 ISA relies on animal toxicological studies to support the plausibility of a wide range of $PM_{2.5}$-related health effects. While animal toxicological studies often examine more severe health outcomes and longer exposure durations than controlled human exposure studies, there is uncertainty in extrapolating the effects seen in animals, and the $PM_{2.5}$ exposures and doses that cause those effects, to human populations. The PA considers these uncertainties when evaluating what the available animal toxicological studies may indicate with regard to the current primary $PM_{2.5}$ standards.

As with controlled human exposure studies, most animal toxicological studies evaluated in the 2019 ISA have examined effects following exposure to $PM_{2.5}$ well-above the concentrations likely to be allowed by the current $PM_{2.5}$ standards. Such studies have generally examined short-term exposures to $PM_{2.5}$ concentrations ranging from 100 to >1,000 $\mu g/m^3$ and long-term exposures to concentrations from 66 to >400 $\mu g/m^3$ (e.g., see U.S. EPA, 2019a, Table 1-2). Two exceptions are animal toxicological studies reporting impaired lung development following long-term exposures (i.e., 24 hours per day for several months prenatally and postnatally) to an average $PM_{2.5}$ concentration of 16.8 $\mu g/m^3$ (Mauad et al., 2008) and increased carcinogenic potential following long-term exposures (i.e., 2 months) to an average $PM_{2.5}$ concentration of 17.7 $\mu g/m^3$ (Cangerana Pereira et al., 2011). These two studies report serious effects following long-term exposures to $PM_{2.5}$ concentrations similar to the ambient concentrations reported in some $PM_{2.5}$ epidemiologic studies (U.S. EPA, 2019a, Table 1-2), though still above the ambient concentrations likely to occur in areas meeting the current primary $PM_{2.5}$ standards. However, noting uncertainty in extrapolating the effects seen in animals, and the $PM_{2.5}$ exposures and doses that cause those effects to human populations, animal toxicological studies are of limited utility in informing decisions on the public health protection

provided by the current or alternative primary $PM_{2.5}$ standards. Therefore, the animal toxicological studies are most useful in providing further evidence to support the biological mechanisms and plausibility of various adverse effects.

b. Ambient $PM_{2.5}$ Concentrations in Locations of Epidemiologic Studies

As summarized in section II.B.1 above, epidemiologic studies examining associations between daily or annual average $PM_{2.5}$ exposures and mortality or morbidity represent a large part of the evidence base supporting several of the 2019 ISA's "causal" and "likely to be causal" determinations. The PA considers the ambient $PM_{2.5}$ concentrations present in areas where epidemiologic studies have evaluated associations with mortality or morbidity, and what such concentrations may indicate regarding the adequacy of the primary $PM_{2.5}$ standards. The use of information from epidemiologic studies to inform conclusions on the primary $PM_{2.5}$ standards is complicated by the fact that such studies evaluate associations between distributions of ambient $PM_{2.5}$ and health outcomes, and do not identify the specific exposures that can lead to the reported effects. Rather, health effects can occur over the entire distribution of ambient $PM_{2.5}$ concentrations evaluated, and epidemiologic studies conducted to date do not identify a population-level threshold below which it can be concluded with confidence that $PM_{2.5}$-associated health effects do not occur. Therefore, the PA evaluates the $PM_{2.5}$ air quality distributions over which epidemiologic studies support health effect associations (U.S. EPA, 2022b, section 3.3.3.2). In the absence of discernible thresholds, the PA considers the study-reported ambient $PM_{2.5}$ concentrations reflecting estimated exposure with a focus around the middle portion of the $PM_{2.5}$ air quality distribution, where the bulk of the observed data reside and which provides the strongest support for reported health effect associations. The section below describes the consideration of the key epidemiologic studies and observations from these

studies, as evaluated in the PA (U.S. EPA, 2022b, section 3.3.3.2).

i. $PM_{2.5}$ Air Quality Distributions Associated with Mortality or Morbidity in Key Epidemiologic Studies

As an initial matter, in considering the $PM_{2.5}$ air quality distributions associated with mortality or morbidity in the key epidemiologic studies, the PA recognizes that in previous reviews, the decision framework used to judge adequacy of the existing $PM_{2.5}$ standards, and what levels of any potential alternative standards should be considered, placed significant weight on epidemiologic studies that assessed associations between $PM_{2.5}$ exposure and health outcomes that were most strongly supported by the body of scientific evidence. In doing so, the decision framework recognized that while there is no specific point in the air quality distribution of any epidemiologic study that represents a "bright line" at and above which effects have been observed and below which effects have not been observed, there is significantly greater confidence in the magnitude and significance of observed associations for the part of the air quality distribution corresponding to where the bulk of the health events in each study have been observed, generally at or around the mean concentration. This is the case both for studies of daily $PM_{2.5}$ exposures and for studies of annual average $PM_{2.5}$ exposures (U.S. EPA, 2022b, section 3.3.3.2.1).

As discussed further in the PA, studies of daily $PM_{2.5}$ exposures examine associations between day-to-day variation in $PM_{2.5}$ concentrations and health outcomes, often over several years (U.S. EPA, 2022b, section 3.3.3.2.1). While there can be considerable variability in daily exposures over a multi-year study period, most of the estimated exposures reflect days with ambient $PM_{2.5}$ concentrations around the middle of the air quality distributions examined (i.e., "typical" days rather than days with extremely high or extremely low concentrations). Similarly,

for studies of annual $PM_{2.5}$ exposures, most of the health events occur at estimated exposures that reflect annual average $PM_{2.5}$ concentrations around the middle of the air quality distributions examined. In both cases, epidemiologic studies provide the strongest support for reported health effect associations for this middle portion of the $PM_{2.5}$ air quality distribution, which corresponds to the bulk of the underlying data, rather than the extreme upper or lower ends of the distribution. Consistent with this, as noted in the PA (U.S. EPA, 2022b, section 3.3.1.1), several epidemiologic studies report that associations persist in analyses that exclude the upper portions of the distributions of estimated $PM_{2.5}$ exposures, indicating that "peak" $PM_{2.5}$ exposures are not disproportionately responsible for reported health effect associations.

Thus, in considering $PM_{2.5}$ air quality data from epidemiologic studies, consistent with approaches in the 2012 and 2020 reviews (78 FR 3161, January 15, 2013; U.S. EPA, 2011 , sections 2.1.3 and 2.3.4.1; 85 FR 82716-82717, December 18, 2020; U.S. EPA, 2020a , sections 3.1.2 and 3.2.3), the PA evaluates study-reported means (or medians) of daily and annual average $PM_{2.5}$ concentrations as indicators for the middle portions of the air quality distributions, over which studies generally provide strong support for reported associations and for which confidence in the magnitude and significance of associations observed in the epidemiologic studies is greatest (78 FR 3101, January 15, 2013). In addition to the overall study means, the PA also focuses on concentrations somewhat below the means (e.g., $25^{th}$ and $10^{th}$ percentiles), when such information is available from the epidemiologic studies, which again is consistent with approaches used in previous reviews. In so doing, the PA notes, as in previous reviews, that a relatively small portion of the health events are observed in the lower part of the air quality distribution and confidence in the magnitude and significance of the associations begins to decrease in the lower part of the air quality distribution. Furthermore, consistent with past

reviews, there is no single percentile value within a given air quality distribution that is most appropriate or "correct" to use to characterize where our confidence in associations becomes appreciably lower. However, and as detailed further in the PA, the range from the 25$^{th}$ to 10$^{th}$ percentiles is a reasonable range to consider as a region where there is appreciably less confidence in the associations observed in epidemiologic studies compared to the means (U.S. EPA, 2022b, p. 3-69).[65]

In evaluating the overall study-reported means, and concentrations somewhat below the means from epidemiologic studies, the PA focuses on the form, averaging time and level of the current primary annual $PM_{2.5}$ standard. Consistent with the approaches used in the 2012 and 2020 reviews (78 FR 3161-3162, January 15, 2013; 85 FR 82716-82717, December 18, 2020), the annual standard has been utilized as the primary means of providing public health protection against the bulk of the distribution of short- and long-term $PM_{2.5}$ exposures. Thus, the evaluation of the study-reported mean concentrations from key epidemiologic studies lends itself best to evaluating the adequacy of the annual $PM_{2.5}$ standard (rather than the 24-hour standard with its 98$^{th}$ percentile form). This is true for the study-reported means from both long-term and short-term exposure epidemiologic studies, recognizing that the overall mean $PM_{2.5}$ concentrations reported in studies of short-term (24-hour) exposures reflect averages across the study population and over the years of the study. Thus, mean concentrations from short-term exposure studies reflect long-term averages of 24-hour $PM_{2.5}$ exposure estimates. In this manner, the examination of study-reported means in key epidemiologic studies in the PA aims to evaluate the protection

[65] As detailed in the 2011 PA, we note the interrelatedness of the distributional statistics and a range of one standard deviation around the mean which represents approximately 68% of normally distributed data, and in that one standard deviation below the mean falls between the 25th and 10th percentiles (U.S. EPA, 2011, p. 2-71; U.S. EPA, 2005, p. 5-22).

provided by the annual $PM_{2.5}$ standard against the exposures where confidence is greatest for associations with mortality and morbidity. In addition, the protection provided by the annual standard is evaluated in conjunction with that provided by the 24-hour standard, with its 98$^{th}$ percentile form, which aims to provide supplemental protection against the short-term exposures to peak $PM_{2.5}$ concentrations that can occur in areas with strong contributions from local or seasonal sources, even when overall ambient mean $PM_{2.5}$ concentrations in an area remain relatively low.

In focusing on the annual standard, and in evaluating the range of study-reported exposure concentrations for which the strongest support for adverse health effects exists, the PA examines exposure concentrations in key epidemiologic studies to determine whether the current primary annual $PM_{2.5}$ standard provides adequate protection against these exposure concentrations. This means, as in past reviews, application of a decision framework based on assessing means reported in key epidemiologic studies must also consider how the study means were computed and how these values compare to the annual standard metric (including the level, averaging time and form) and the use of the monitor with the highest $PM_{2.5}$ design value in an area for compliance. In the 2012 review, it was recognized that the key epidemiologic studies computed the study mean using an average across monitor-based $PM_{2.5}$ concentrations. As such, the Agency noted that this decision framework applied an approach of using maximum monitor concentrations to determine compliance with the standard, while selecting the standard level based on consideration of composite monitor concentrations. Further, the Agency included analyses (Hassett-Sipple et al., 2010; Frank, 2012) that examined the differences in these two metrics (i.e., maximum monitor concentrations and composite monitor concentrations) across the U.S. and in areas included in the key epidemiologic studies and found that the maximum design

value in an area was generally higher than the monitor average across that area, with that amount varying based on location and concentration. This information was taken into account in the Administrator's final decision in selecting a level for the primary annual $PM_{2.5}$ standard the 2012 review and discussed more specifically in her considerations on adequate margin of safety.

Consistent with the approach taken in 2012, in assessing how the overall mean (or median) $PM_{2.5}$ concentrations reported in key epidemiologic studies can inform conclusions on the annual primary $PM_{2.5}$ standard, the PA notes that the relationship between mean $PM_{2.5}$ concentrations and the area design value continues to be an important consideration in evaluating the adequacy of the current or potential alternative annual $PM_{2.5}$ standard levels in this reconsideration. In a given area, the area design value is based on the monitor in an area with the highest $PM_{2.5}$ concentrations and is used to determine compliance with the standard. The highest $PM_{2.5}$ concentrations spatially distributed in the area would generally occur at or near the area design value monitor and the distribution of $PM_{2.5}$ concentrations would generally be lower in other locations and at monitors in that area. As such, when an area is meeting a specific annual standard level, the annual average exposures in that area are expected to be at concentrations lower than that level and the average of the annual average exposures across that area are expected (i.e., a metric similar to the study-reported mean values) to be lower than that level.[66]

Another important consideration is that there are a substantial number of different types of epidemiologic studies available since the 2012 review, included in both the 2019 ISA and the

[66] In setting a standard level that would require the design value monitor to meet a level equal to the study-reported mean $PM_{2.5}$ concentrations would generally result in lower concentrations of $PM_{2.5}$ across the entire area, such that even those people living near an area design value monitor (where PM concentrations are generally highest) will be exposed to $PM_{2.5}$ concentrations below the air quality conditions reported in the epidemiologic studies.

ISA Supplement, that make understanding the relationship between the mean $PM_{2.5}$ concentrations and the area design value even more important (U.S. EPA, 2019a; U.S. EPA, 2022a). While the key epidemiologic studies in the 2012 review were all monitor-based studies, the newer studies include hybrid modeling approaches, which have emerged in the epidemiologic literature as an alternative to approaches that only use ground-based monitors to estimate exposure. As assessed in the 2019 ISA and ISA Supplement, a substantial number of epidemiologic studies used hybrid model-based methods in evaluating associations between $PM_{2.5}$ exposure and health effects (U.S. EPA, 2019a; U.S. EPA, 2022a). Hybrid model-based studies employ various fusion techniques that combine ground-based monitored data with air quality modeled estimates and/or information from satellites to estimate $PM_{2.5}$ exposures.[67] Additionally, hybrid modeling approaches tend to broaden the areas captured in the exposure assessment, and in so doing, tend to report lower mean $PM_{2.5}$ concentrations than monitor-based approaches because they include more suburban and rural areas where concentrations are lower. While these studies provide a broader estimation of $PM_{2.5}$ exposures compared to monitor-based studies (i.e., $PM_{2.5}$ concentrations are estimated in areas without monitors), the hybrid modeling approaches result in study-reported means that are more difficult to relate to the annual standard metric and to the use of maximum monitor design values to assess compliance. In addition, to further complicate the comparison, when looking across these studies, variations in how exposure is estimated are present between such studies, which affects how the study means are calculated. Two important variations across studies include: (1) variability in spatial scale used (i.e., averages computed across the nation (or large portions of the country) versus a focus on

[67] More detailed information about hybrid model methods and performance is described in section 2.3.3.2 of the PA (U.S. EPA, 2022b).

only CBSAs) and (2) variability in exposure assignment methods (i.e., averaging across all grid cells [non-population weighting], averaging across a scaled-up area like a ZIP code [aspects of population weighting applied], and/or applying population weighting). To elaborate further on the variability in exposure assignment methods, studies that use hybrid modeling approaches can estimate $PM_{2.5}$ concentrations at different spatial resolutions, including at 1 km x 1 km grid cells, at 12 km x 12 km grid cells, or at the census level tract. Mean reported $PM_{2.5}$ concentrations can then be estimated either by averaging up to a larger spatial resolution that corresponds to the spatial resolution for which health data exists (e.g., ZIP code level) and therefore apply aspects of population weighting. These values are then averaged across all study locations at the larger spatial resolution (e.g., averaged across all ZIP codes in the study) over the study period, resulting in the study-reported mean 24-hour average or average annual $PM_{2.5}$ concentration. Other studies that use hybrid modeling methods to estimate $PM_{2.5}$ concentrations may use each grid cell to report the study-reported mean 24-hour average or average annual $PM_{2.5}$ concentration. As such, these types of studies do not apply population weighting in their mean concentrations. In studies that use each grid cell to report a mean $PM_{2.5}$ concentration and do not apply aspects of population weighting, the study mean may not reflect the exposure concentrations used in the epidemiologic study to assess the reported association. The impact of the differences in methods is an important consideration when comparing mean concentrations across studies (U.S. EPA, 2022b, section 3.3.3.2.1). Thus, the PA also considers the methods used to estimate $PM_{2.5}$ concentrations, which vary from traditional methods using monitoring

data from ground-based monitors[68] to those using more complex hybrid modeling approaches.[69]

Given the emergence of the hybrid model-based epidemiologic studies since the 2012 review, the PA explores the relationship between the approaches used in these studies to estimate $PM_{2.5}$ concentrations and the impact that the different methods have on the study-reported mean $PM_{2.5}$ concentrations. The PA further seeks to understand how the approaches and resulting mean concentrations compare across studies, as well as what the resulting mean values represent relative to the annual standard. In so doing, the PA presents analyses that compare the area annual design values, composite monitor $PM_{2.5}$ concentrations, and mean concentrations from two hybrid modeling approaches, including evaluation of the means when population weighting is applied and when population weighting is not applied (U.S. EPA, 2022b, section 2.3.3.1). In the air quality analyses comparing composite monitored $PM_{2.5}$ concentrations with annual $PM_{2.5}$ design values in U.S. CBSAs, maximum annual $PM_{2.5}$ design values were approximately 10% to 20% higher than annual average composite monitor concentrations (i.e., averaged across multiple monitors in the same CBSA) (sections I.D.5.a above and U.S. EPA, 2022b, section 2.3.3.1, Figure 2-28 and Table 2-3). The difference between the maximum annual design value and average concentration in an area can be smaller or larger than this range (10-20%), depending on a variety of factors such as the number of monitors, monitor siting characteristics, the

[68] In those studies that use ground-based monitors alone to estimate long- or short-term $PM_{2.5}$ concentrations, approaches include: (1) $PM_{2.5}$ concentrations from a single monitor within a city/county; (2) average of $PM_{2.5}$ concentrations across all monitors within a city/county or other defined study area (e.g., CBSA); or (3) population-weighted averages of exposures. Once the study location average $PM_{2.5}$ concentration is calculated, the study-reported long-term average is derived by averaging daily/annual $PM_{2.5}$ concentrations across all study locations over the entire study period.

[69] Detailed information on the methods by which mean $PM_{2.5}$ concentrations are calculated in key monitor- and hybrid model-based U.S. and Canadian epidemiologic studies are presented in Tables 3-6 through 3-9 in the PA (U.S. EPA, 2022b).

distribution of ambient $PM_{2.5}$ concentrations, and how the average concentrations are calculated (i.e., averaged across monitors versus across modeled grid cells). Results of this analysis suggest that there will be a distribution of concentrations and the maximum annual average monitored concentration in an area (at the design value monitor, used for compliance with the standard), will generally be 10-20% higher than the average $PM_{2.5}$ concentration across the other monitors in the area. Thus, in considering how the annual standard levels would relate to the study-reported means from key monitor-based epidemiologic studies, the PA generally concludes that an annual standard level that is no more than 10-20% higher than monitor-based study-reported mean $PM_{2.5}$ concentrations would generally maintain air quality exposures to be below those associated with the study-reported mean $PM_{2.5}$ concentrations, exposures for which the strongest support for adverse health effects occurring is available.

The PA also evaluates data from two hybrid modeling approaches (DI 2019 and HA2020) that have been used in several recent epidemiologic studies (U.S. EPA, 2022b, section 2.3.3.2.4).[70] The analysis shows that the means vary when $PM_{2.5}$ concentrations are estimated in urban areas only (CBSAs) versus when the averages were calculated with all or most grid cells nationwide, likely because areas included outside of CBSAs tend to be more rural and have lower estimated $PM_{2.5}$ concentrations. The PA recognizes the importance of this variability in the means since the study areas included in the calculation of the mean, and more specifically whether a study is focused on nationwide, regional, or urban areas, will affect the calculation of the study mean based on how many rural areas are included with lower estimated $PM_{2.5}$ concentrations. While the determination of what spatial scale to use to estimate $PM_{2.5}$

[70] More details on the evaluation of the two hybrid modeling approaches is provided in section 2.3.3.2.4 of the PA (U.S. EPA, 2022b).

concentrations does not inherently affect the quality of the epidemiologic study, the spatial scale can influence the calculated long-term mean concentration across the study area and period. The results of the analysis show that, regardless of the hybrid modeling approach assessed, the annual average $PM_{2.5}$ concentrations in CBSA-only analyses are 4-8% higher than for nationwide analyses, likely as a result of higher $PM_{2.5}$ concentrations in more densely populated areas, and exclusion of more rural areas (U.S. EPA, 2022b, Table 2-4). When evaluating comparisons between surfaces that estimate exposure using population weighting versus surfaces that do not calculate means using population weighting, surfaces that calculate long-term mean $PM_{2.5}$ concentrations with population-weighted averages have higher average annual $PM_{2.5}$ concentrations, compared to annual $PM_{2.5}$ concentrations in analyses that do not apply population weighting.[71] Analyses show that average maximum annual design values are 40 to 50% higher when compared to annual average $PM_{2.5}$ concentrations estimated without population weighting and are 15% to 18% higher when compared to average annual $PM_{2.5}$ concentrations with population weighting applied (similar to the differences observed for the composite monitor comparison values for the monitor-based epidemiologic studies) (U.S. EPA, 2022b, section 2.3.3.2.4). Given these results, it is worth noting that for the studies using the hybrid modeling approaches, the choice of methodology employed in calculating the study-reported means (i.e., using population weighting or not), and not a difference in estimates of exposure in the study itself, can produce substantially different study-reported mean values, with the approach that does not utilize population weighting producing a much lower value.

[71] The annual $PM_{2.5}$ concentrations for the population-weighted averages ranged from 8.2-10.2 $\mu g/m^3$, while those that do not apply population weighting ranged from 7.0-8.6 $\mu g/m^3$. Average maximum annual design values ranged from 9.5 to 11.7 $\mu g/m^3$.

Based on these results, and similar to conclusions for the monitor-based studies, the PA generally concludes that study-reported mean concentrations in the studies that employ hybrid modeling approaches and population-weight the mean are associated with air quality conditions that would be achieved by meeting annual standard levels that are 15-18% higher than study-reported means. Therefore, an annual standard level that is no more than 15-18% higher than the study-reported means would generally maintain air quality exposures to be below those associated with the study-reported mean $PM_{2.5}$ concentrations, exposures for which we have the strongest support for adverse health effects occurring. For the studies that utilize hybrid modeling approaches but do not incorporate population weighting in calculating the mean, the annual design values associated with these air quality conditions are expected to be much higher (i.e., 40-50% higher) and this larger difference makes it more difficult to consider how these studies can be used to determine the adequacy of the protection afforded by the current or potential alternative annual standards. Additionally, as noted above in studies that utilize hybrid modeling approaches and that do not incorporate population weighting in calculating the mean (e.g., use each grid cell to calculate a mean $PM_{2.5}$ concentration), the study mean does not reflect the exposure concentrations used in the epidemiologic study to assess the reported association.

The PA notes that while these analyses can be useful to informing the understanding of the relationship between study-reported mean concentrations and the level of the annual standard, some limitations of this assessment of the information must be recognized (U.S. EPA, 2022a, section 3.3.3.2.1). First, the comparisons used only two hybrid modeling approaches. Although the two hybrid modeling surfaces have been used in a number of recent epidemiologic studies, they represent just two of the many hybrid modeling approaches that have been used in epidemiologic studies to estimate $PM_{2.5}$ concentrations. These methods continue to evolve over

time, with further development and improvement to prediction models that estimate $PM_{2.5}$ concentrations in epidemiologic studies. In addition to differences in hybrid modeling approaches, epidemiologic studies also use different methods to assign a population-weighted average $PM_{2.5}$ concentration to their study population, and the assessment presented in the PA does not evaluate all of the potential methods that could be used.

Additionally, while some of these epidemiologic studies also provide information on the broader distributions of exposure estimates and/or health events and the $PM_{2.5}$ concentrations corresponding to the lower percentiles of those data (e.g., $25^{th}$ and/or $10^{th}$), the air quality analysis in the PA focuses on mean $PM_{2.5}$ concentrations and a similar comparison for these lower percentiles was not assessed. Therefore, any direct comparison of study-reported $PM_{2.5}$ concentrations corresponding to lower percentiles and annual design values is more uncertain than such comparisons with the mean. Finally, air quality analysis presented in the PA and detailed above in section I.D.5 included two hybrid modeling-based approaches that used U.S.-based air quality information for estimating $PM_{2.5}$ concentrations. As such, the analyses are most relevant to interpreting the study-reported mean concentrations from U.S. epidemiologic studies and do not provide additional information about how the mean exposures concentrations reported in epidemiologic studies in other countries would compare to annual design values observed in the U.S. In addition, while information from Canadian studies can be useful in assessing the adequacy of the annual standard, differences in the exposure environments and population characteristics between the U.S. and other countries can affect the study-reported mean value and its relationship with the annual standard level. Sources and pollutant mixtures, as well as $PM_{2.5}$ concentration gradients, may be different between countries, and the exposure environments in other countries may differ from those observed in the U.S. Furthermore, differences in

population characteristics and population densities can also make it challenging to directly compare studies from countries outside of the U.S. to a design value in the U.S.

As with the experimental studies discussed above, the PA focuses on epidemiologic studies assessed in the 2019 ISA and ISA Supplement that have the potential to be most informative in reaching decisions on the adequacy of the primary $PM_{2.5}$ standards. The PA focuses on epidemiologic studies that provide strong support for "causal" or "likely to be causal" relationships with $PM_{2.5}$ exposures in the 2019 ISA. Further, the PA also focuses on the health effect associations that are determined in the 2019 ISA and ISA Supplement to be consistent across studies, coherent with the broader body of evidence (e.g., including animal and controlled human exposure studies), and robust to potential confounding by co-occurring pollutants and other factors. [72] In particular the PA considers the U.S. and Canadian epidemiologic studies to be more useful for reaching conclusions on the current standards than studies conducted in other countries, given that the results of the U.S. and Canadian studies are more directly applicable for quantitative considerations, whereas studies conducted in other countries reflect different

[72] As described in the Preamble to the ISAs (U.S. EPA, 2015), "the U.S. EPA emphasizes the importance of examining the pattern of results across various studies and does not focus solely on statistical significance or the magnitude of the direction of the association as criteria of study reliability. Statistical significance is influenced by a variety of factors including, but not limited to, the size of the study, exposure and outcome measurement error, and statistical model specifications. Statistical significance may be informative; however, it is just one of the means of evaluating confidence in the observed relationship and assessing the probability of chance as an explanation. Other indicators of reliability such as the consistency and coherence of a body of studies as well as other confirming data may be used to justify reliance on the results of a body of epidemiologic studies, even if results in individual studies lack statistical significance. Traditionally, statistical significance is used to a larger extent to evaluate the findings of controlled human exposure and animal toxicological studies. Understanding that statistical inferences may result in both false positives and false negatives, consideration is given to both trends in data and reproducibility of results. Thus, in drawing judgments regarding causality, the U.S. EPA emphasizes statistically significant findings from experimental studies, but does not limit its focus or consideration to statistically significant results in epidemiologic studies."

populations, exposure characteristics, and air pollution mixtures. Additionally, epidemiologic studies outside of the U.S. and Canada generally reflect higher $PM_{2.5}$ concentrations in ambient air than are currently found in the U.S., and are less relevant to informing questions about adequacy of the current standards.[73] However, and as noted above, the PA also recognizes that while information from Canadian studies can be useful in assessing the adequacy of the annual standard, there are still important differences between the exposure environments in the U.S. and Canada and interpreting the data (e.g., mean concentrations) from the Canadian studies in the context of a U.S.-based standard may present challenges in directly and quantitatively informing questions regarding the adequacy of the current or potential alternative the levels of the annual standard. Lastly, the PA emphasizes multicity/multistate studies that examine health effect associations, as such studies are more encompassing of the diverse atmospheric conditions and population demographics in the U.S. than studies that focus on a single city or state. Figures 3-4 through 3-7 in the PA summarize the study details for the key U.S. and Canadian epidemiologic studies (U.S. EPA, 2022b, section 3.3.3.2.1).[74]

The key epidemiologic studies identified in the PA indicate generally positive and statistically significant associations between estimated $PM_{2.5}$ exposures (short- or long-term) and mortality or morbidity across a range of ambient $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section

[73] This emphasis on studies conducted in the U.S. or Canada is consistent with the approach in the 2012 and 2020 reviews of the PM NAAQS (U.S. EPA, 2011, section 2.1.3; U.S. EPA, 2020a, section 3.2.3.2.1) and with approaches taken in other NAAQS reviews. However, the importance of studies in the U.S., Canada, and other countries in informing an ISA's considerations of the weight of the evidence that informs causality determinations is recognized.

[74] The cohorts examined in the studies included in Figure 3-4 to Figure 3-7 of the PA include large numbers of individuals in the general population, and often also include those populations identified as at-risk (i.e., children, older adults, minority populations, and individuals with pre-existing cardiovascular and respiratory disease).

3.3.3.2.1), report overall mean (or median) $PM_{2.5}$ concentrations, and include those for which the years of $PM_{2.5}$ air quality data used to estimate exposures overlap entirely with the years during which health events are reported.[75] Additionally, for studies that estimate $PM_{2.5}$ exposure using hybrid modeling approaches, the PA also considers the approach used to estimate $PM_{2.5}$ concentrations and the approach used to validate hybrid model predictions when determining those studies considered as key epidemiologic studies[76] and focuses on those studies that use recent methods based on surfaces with fused with monitored $PM_{2.5}$ concentration data (U.S. EPA, 2022b, section 3.3.3.2.1).

Figure 1 below (U.S. EPA, 2022b, Figure 3-8) highlights the overall mean (or median) $PM_{2.5}$ concentrations reported in key U.S. studies that use ground-based monitors alone to estimate long- or short-term $PM_{2.5}$ exposure.[77] For the small subset of studies with available information on the broader distributions of underlying data, Figure 1 below also identifies the study-period mean $PM_{2.5}$ concentrations corresponding to the 25th and 10th percentiles of health

[75] For some studies of long-term $PM_{2.5}$ exposures, exposure is estimated from air quality data corresponding to only part of the study period, often including only the later years of the health data, and are not likely to reflect the full ranges of ambient $PM_{2.5}$ concentrations that contributed to reported associations. While this approach can be reasonable in the context of an epidemiologic study that is evaluating health effect associations with long-term $PM_{2.5}$ exposures, under the assumption that spatial patterns in $PM_{2.5}$ concentrations are not appreciably different during time periods for which air quality information is not available (e.g., Chen et al., 2016), the PA focuses on the distribution of ambient $PM_{2.5}$ concentrations that could have contributed to reported health outcomes. Therefore, the PA identifies studies as key epidemiologic studies when the years of air quality data and health data overlap in their entirety.

[76] Such studies are identified as those that use hybrid modeling approaches for which recent methods and models were used (e.g., recent versions and configurations of the air quality models); studies that are fused with $PM_{2.5}$ data from national monitoring networks (i.e., FRM/FEM data); and studies that reported a thorough model performance evaluation for core years of the study.

[77] Canadian studies that use ground-based monitors estimate long- or short-term $PM_{2.5}$ exposures are found in Figure 3-9 of the PA, including concentrations corresponding to the $25^{th}$ and $10^{th}$ percentiles of estimated exposures or health events, when available (U.S. EPA, 2022b).

events[78] (see Appendix B, Section B.2 of the PA for more information). Figure 2 (U.S. EPA, 2022a, Figure 3-14) presents overall means of predicted $PM_{2.5}$ concentrations for key U.S. model-based epidemiologic studies that apply aspects of population-weighting, and the concentrations corresponding to the 25th and 10th percentiles of estimated exposures or health events[79] when available (see Appendix B, section B.3 for additional information).[80]

[78] That is, 25% of the total health events occurred in study locations with mean $PM_{2.5}$ concentrations (i.e., averaged over the study period) below the 25th percentiles identified in Figure 3-8 of the PA and 10% of the total health events occurred in study locations with mean $PM_{2.5}$ concentrations below the 10th percentiles identified.

[79] For most studies in Figure 2 below (Figure 3-14 in the PA), 25th percentiles of exposure estimates are presented. The exception is Di et al. (2017b), for which Figure 2 (U.S. EPA, 2022b, Figure 3-14) presents the short-term $PM_{2.5}$ exposure estimates corresponding to the 25th and 10th percentiles of deaths in the study population (i.e., 25% and 10% of deaths occurred at concentrations below these concentrations). In addition, the authors of Di et al. (2017b) provided population-weighted exposure values. The 10th and 25th percentiles of these population-weighted exposure estimates are 7.9 and 9.5 $\mu g/m^3$, respectively.

[80] Overall mean (or median) $PM_{2.5}$ concentrations reported in key Canadian studies that use model-based approaches to estimate long- or short-term $PM_{2.5}$ concentrations and the concentrations corresponding to the 25th and 10th percentiles of estimated exposures or health events, when available are found in Figure 3-9 of the PA (U.S. EPA, 2022b).

Figure 1 Monitor-based $PM_{2.5}$ concentrations in key U.S. epidemiologic studies. (Asterisks denote studies included in the ISA Supplement).

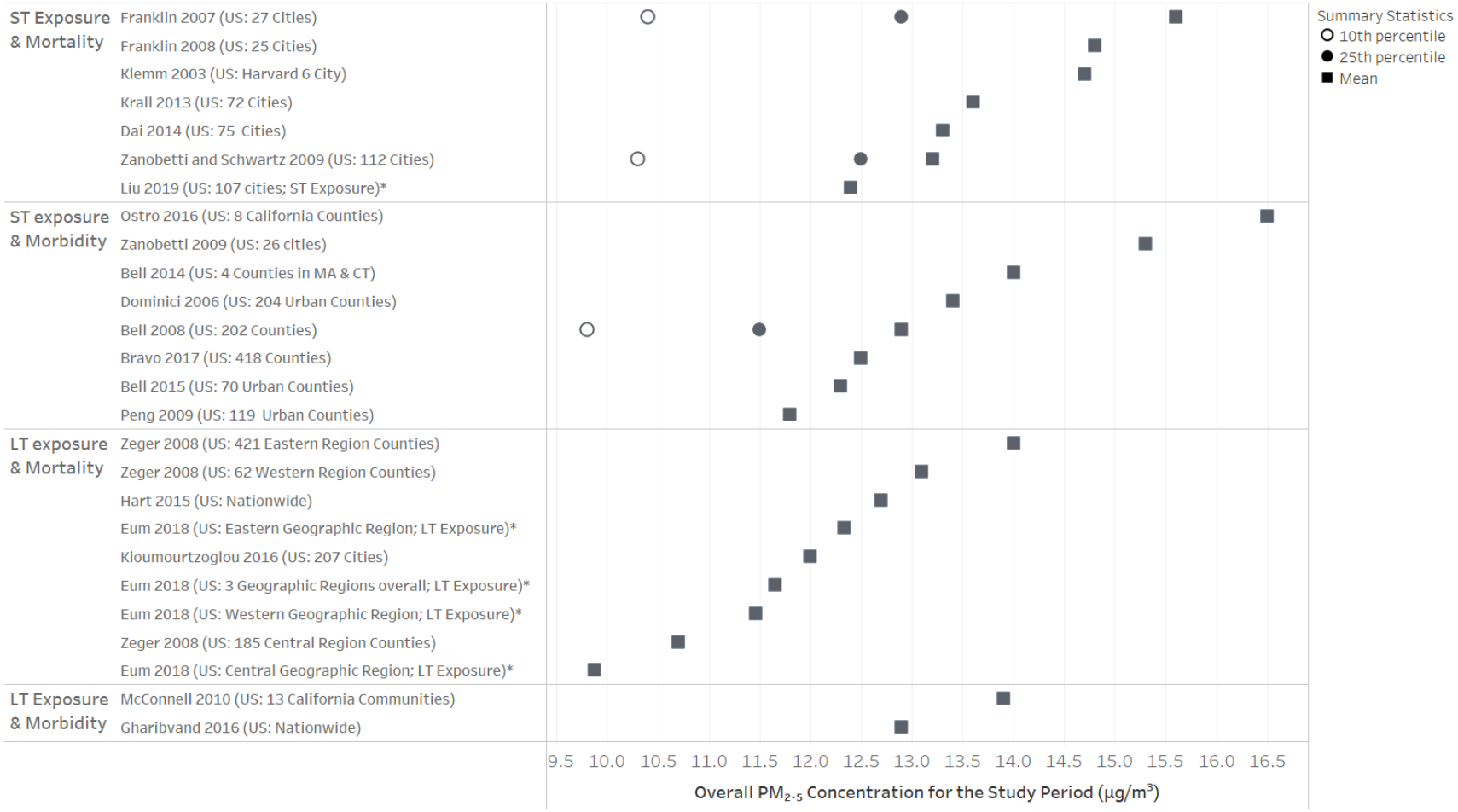
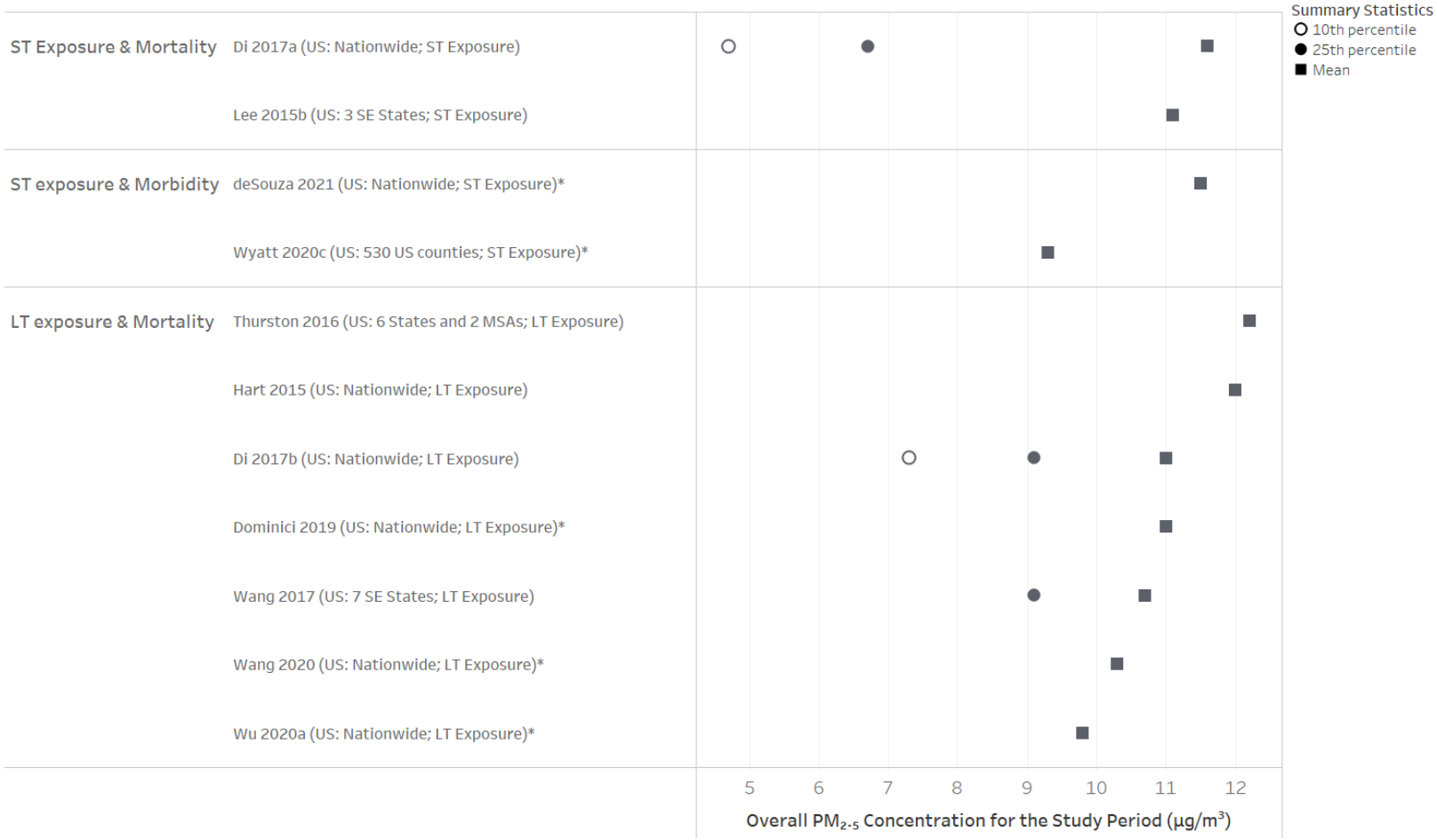


Figure 2. Hybrid model-predicted $PM_{2.5}$ concentrations in key U.S. epidemiologic studies that apply aspects of population-weighting. (Asterisks denote studies included in the ISA Supplement)



Based on its evaluation of study-reported mean concentrations, the PA notes that key epidemiologic studies conducted in the U.S. or Canada report generally positive and statistically significant associations between estimated $PM_{2.5}$ exposures (short- or long-term) and mortality or morbidity across a wide range of ambient $PM_{2.5}$ concentrations (U.S. EPA, 2022b, section 3.3.3.2.1). The PA makes a number of observations with regard to the study-reported $PM_{2.5}$ concentrations in the key U.S. and Canadian epidemiologic studies.

The PA first considers the $PM_{2.5}$ concentrations from the key U.S. epidemiologic studies. For studies that use monitors to estimate $PM_{2.5}$ exposures, overall mean $PM_{2.5}$ concentrations range between 9.9 $\mu g/m^3$ [81] to 16.5 $\mu g/m^3$ (Figure 1 and U.S. EPA, 2022b, Figure 3-8). For key U.S. epidemiologic studies that use hybrid model-predicted exposures and apply aspects of population-weighting, mean $PM_{2.5}$ concentrations range from 9.3 $\mu g/m^3$ to just above 12.2 $\mu g/m^3$ (Figure 2 and U.S. EPA, 2022b, Figure 3-14). In studies that average up from the grid cell level to the ZIP code, postal code, or census tract level, mean $PM_{2.5}$ concentrations range from 9.8 $\mu g/m^3$ to 12.2 $\mu g/m^3$. In the one study that population-weighted the grid cell prior to averaging up to the ZIP code or census tract level report mean $PM_{2.5}$ concentrations of 9.3 $\mu g/m^3$. Based on air quality analyses noted above, these hybrid modelled epidemiologic studies are expected to report means similar to those from monitor-based studies.

Other key U.S. epidemiologic studies that use hybrid modeling approaches estimate mean $PM_{2.5}$ exposure by averaging from the grid cell spatial resolution across the entire study area, whether that be the nation or a region of the country. These studies do not weight the estimated

[81] This is generally consistent with, but slightly below, the lowest study-reported mean $PM_{2.5}$ concentration from monitor-based studies available in the 2020 PA, which was 10.7 $\mu g/m^3$ (U.S. EPA, 2020a, Figure 3-7).

exposure concentrations based on population density or location of health events. Additionally, the study mean reported in these studies may not reflect the exposure concentrations used in the epidemiologic study to assess the reported association. Because of this, these reported mean concentrations are the most different (and much lower) than the means reported in monitor-based studies. Due to the methodology employed in calculating the study-reported means and not necessarily a difference in estimates of exposure, these epidemiologic studies are expected to report some of the lowest mean values. For these studies, the reported mean $PM_{2.5}$ concentrations range from 8.1 $\mu g/m^3$ to 11.9 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-14). As noted above, for studies that utilize hybrid modeling approaches but do not incorporate population weighting in calculating the mean, the associated annual design values would be expected to be much higher (i.e., 40-50% higher) than the study-reported means. This larger difference between design values and study-reported mean concentrations makes it more difficult to consider how these studies can be used to determine the adequacy of the protection afforded by the current or potential alternative annual standards (U.S. EPA, 2022b, section 3.3.3.2.1).

In addition to the mean $PM_{2.5}$ concentrations, a subset of the key U.S. epidemiologic studies report $PM_{2.5}$ concentrations corresponding to the $25^{th}$ and $10^{th}$ percentiles of health data or exposure estimates to provide insight into the concentrations that comprise the lower quartiles of the air quality distributions. In studies that use monitors to estimate $PM_{2.5}$ exposures, $25^{th}$ percentiles of health events correspond to $PM_{2.5}$ concentrations (i.e., averaged over the study period for each study city) at or above 11.5 $\mu g/m^3$ and 10th percentiles of health events correspond to $PM_{2.5}$ concentrations at or above 9.8 $\mu g/m^3$ (i.e., 25% and 10% of health events, respectively, occur in study locations with $PM_{2.5}$ concentrations below these values) (Figure 1 and U.S. EPA, 2022b, Figure 3-8). Of the key U.S. epidemiologic studies that use hybrid

modeling approaches and population-weighting to estimate long-term $PM_{2.5}$ exposures, the ambient $PM_{2.5}$ concentrations corresponding to 25th percentiles of estimated exposures are 9.1 $\mu g/m^3$ (Figure 2 and U.S. EPA, 2022b, Figure 3-14). In key U.S. epidemiologic studies that use hybrid modeling approaches and apply population-weighting to estimate short-term $PM_{2.5}$ exposures, the ambient concentrations corresponding to $25^{th}$ percentiles of estimated exposures, or health events, are 6.7 $\mu g/m^3$ (Figure 2 and U.S. EPA, 2022b, Figure 3-14). In key U.S. epidemiologic studies that use hybrid modeling approaches and do not apply population-weighting to estimate $PM_{2.5}$ exposures, the ambient concentrations corresponding to $25^{th}$ percentiles of estimated exposures, or health events, range from 4.6 to 9.2 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-14).[82] In the key epidemiologic studies that apply hybrid modeling approaches with population-weighting and with information available on the 10th percentile of health events, the ambient $PM_{2.5}$ concentration corresponding to that 10th percentile range from 4.7 $\mu g/m^3$ to 7.3 $\mu g/m^3$ (Figure 2 and U.S. EPA, 2022b, Figure 3-14).

The PA next considers the $PM_{2.5}$ concentrations from the key Canadian epidemiologic studies. Generally, the study-reported mean concentrations in Canadian studies are lower than those reported in the U.S. studies for both monitor-based and hybrid model methods. For the majority of key Canadian epidemiologic studies that use monitor-based exposure, mean $PM_{2.5}$ concentrations generally ranged from 7.0 $\mu g/m^3$ to 9.0 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-9). For these studies, $25^{th}$ percentiles of health events correspond to $PM_{2.5}$ concentrations at or above 6.5 $\mu g/m^3$ and 10th percentiles of health events correspond to $PM_{2.5}$ concentrations at or above 6.4 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-9). For the key Canadian epidemiologic studies that use

[82] As noted above, in this study (Shi et al., 2016), the authors report that most deaths occurred at or above the $75^{th}$ percentile of annual exposure estimates (i.e., 10 $\mu g/m^3$). The short-term exposure estimates accounting for most deaths are not presented in the published study.

hybrid model-predicted exposure, the mean $PM_{2.5}$ concentrations are generally lower than in U.S. model-based studies (U.S. EPA, 2022b, Figure 3-10), ranging from approximately 6.0 $\mu g/m^3$ to just below 10.0 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-11). The majority of the key Canadian epidemiologic studies that used hybrid modeling were completed at the nationwide scale, while four studies were completed at the regional geographic spatial scale. In addition, all the key Canadian epidemiologic studies apply aspects of population weighting, where all grid cells within a postal code are averaged, individuals are assigned exposure at the postal code resolution, and study mean $PM_{2.5}$ concentrations are based on the average of individual exposures. The majority of studies estimating exposure nationwide range between just below 6.0 $\mu g/m^3$ to 8.0 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-11). One study by Erickson et al. (2020) presents an analysis related immigrant status and length of residence in Canada versus non-immigrant populations, which accounts for the four highest mean $PM_{2.5}$ concentrations which range between 9.0 $\mu g/m^3$ and 10.0 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-11). The four studies that estimate exposure at the regional scale report mean $PM_{2.5}$ concentrations that range from 7.8 $\mu g/m^3$ to 9.8 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-11). Three key Canadian epidemiologic studies report information on the $25^{th}$ percentile of health events. In these studies, the ambient $PM_{2.5}$ concentration corresponding to the $25^{th}$ percentile is approximately 8.0 $\mu g/m^3$ in two studies, and 4.3 $\mu g/m^3$ in a third study (U.S. EPA, 2022b, Figure 3-11).

In addition to the expanded body of evidence from the key U.S. epidemiologic studies discussed above, there are also a subset of epidemiologic studies that have emerged that further inform an understanding of the relationship between $PM_{2.5}$ exposure and health effects, including studies with the highest exposures excluded (restricted analyses), epidemiologic studies that employed statistical approaches that attempt to more extensively account for confounders and are

more robust to model misspecification (i.e., used alternative methods for confounder control),[83] and accountability studies (U.S. EPA, 2019a, U.S. EPA, 2021a, U.S. EPA, 2022b).

Restricted analyses are studies that examine health effect associations in analyses with the highest exposures excluded, restricting analyses to daily exposures less than the 24-hour primary $PM_{2.5}$ standard and annual exposures less than the annual $PM_{2.5}$ standard. The PA presents a summary of restricted analyses evaluated in the 2019 ISA and ISA Supplement (U.S. EPA, 2022b, Table 3-10). The restricted analyses can be informative in assessing the nature of the association between long-term exposures (e.g., annual average concentrations < 12.0 $\mu g/m^3$) or short-term exposures (e.g., daily concentrations < 35 $\mu g/m^3$) when looking only at exposures to lower concentrations, including whether the association persists in such restricted analyses compared to the same analyses for all exposures, as well as whether the association is stronger, in terms of magnitude and precision, than when completing the same analysis for all exposures. While these studies are useful in supporting the confidence and strength of associations at lower concentrations, these studies also have inherent uncertainties and limitations, including uncertainty in how studies exclude concentrations (e.g., are they excluded at the modeled grid cell level, the ZIP code level) and in how concentrations in studies that restrict air quality data relate to design values for the annual and 24-hour standards. Further, these studies often do not report descriptive statistics (e.g., mean $PM_{2.5}$ concentrations, or concentrations at other percentiles) that allow for additional consideration of this information. As such, while these

[83] As noted in the ISA Supplement (U.S. EPA, 2022a, p. 1-3): "In the peer-reviewed literature, these epidemiologic studies are often referred to as alternative methods for confounder control. For the purposes of this Supplement, this terminology is not used to prevent confusion with the main scientific conclusions (i.e., the causality determinations) presented within an ISA. In addition, as is consistent with the weight-of-evidence framework used within ISAs and discussed in the Preamble to the Integrated Science Assessments, an individual study on its own cannot inform causality, but instead represents a piece of the overall body of evidence."

studies can provide additional supporting evidence for associations at lower concentrations, the PA notes that there are also limitations in how to interpret these studies when evaluating the adequacy of the current or potential alternative standards. Restricted analyses provide additional information on the nature of the association between long- or short-term exposures when analyses are restricted to lower $PM_{2.5}$ concentrations. Further, these studies indicate that effect estimates are generally greater in magnitude in the restricted analyses for long- and short-term $PM_{2.5}$ exposure compared to the main analyses.

In two U.S. studies that report mean $PM_{2.5}$ concentrations in restricted analyses and that estimate effects associated with long-term exposure to $PM_{2.5}$, the effect estimates are greater in the restricted analyses than in the main analyses. Di et al. (2017a) and Dominici et al. (2019) report positive and statistically significant associations in analyses restricted to concentrations less than 12.0 $\mu g/m^3$ for all-cause mortality and effect estimates are greater in the restricted analyses than effect estimates reported in main analyses. In addition, both studies report mean $PM_{2.5}$ concentrations of 9.6 $\mu g/m^3$. While none of the U.S. studies of short-term exposure present mean $PM_{2.5}$ concentrations for the restricted analyses, these studies generally have mean 24-hour average $PM_{2.5}$ concentrations in the main analyses below 12.0 $\mu g/m^3$, and report increases in the effect estimates in the restricted analyses compared to the main analyses. Additionally, in the one Canadian study of long-term $PM_{2.5}$ exposure, Zhang et al. (2021) conducted analyses where annual $PM_{2.5}$ concentrations were restricted to concentrations below 10.0 $\mu g/m^3$ and 8.8 $\mu g/m^3$, which presumably have lower mean concentrations than the mean of 7.8 $\mu g/m^3$ reported in the main analyses, though restricted analysis mean $PM_{2.5}$ concentrations are not reported. Effect estimates for non-accidental mortality are greater in analyses restricted to $PM_{2.5}$ concentrations less than 10.0 $\mu g/m^3$, but less in analyses restricted to $< 8.8$ $\mu g/m^3$.

The second type of studies that have recently emerged and further inform the consideration of the relationship between $PM_{2.5}$ exposure and health effects in the PA are those that employ alternative methods for confounder control. Alternative methods for confounder control seek to mimic randomized experiments through the use of study design and statistical methods to more extensively account for confounders and are more robust to model misspecification. The PA presents a summary of the studies that employ alternative methods for confounder control, and employ a variety of statistical methods, which are evaluated in the 2019 ISA and ISA Supplement (U.S. EPA, 2022b, Table 3-11). These studies reported consistent results among large study populations across the U.S. and can further inform the relationship between long- and short-term $PM_{2.5}$ exposure and total mortality. Studies that employ alternative methods for confounder control to assess the association between long-term exposure to $PM_{2.5}$ and mortality provide additional support for the associations reported in the broader body of cohort studies that examined long-term $PM_{2.5}$ exposure and mortality.

Lastly, there is a subset of epidemiologic studies that assess whether long-term reductions in ambient $PM_{2.5}$ concentrations result in corresponding reductions in health outcomes. These include studies that evaluate the potential for improvements in public health, including reductions in mortality rates, increases in life expectancy, and reductions in respiratory disease as ambient $PM_{2.5}$ concentrations have declined over time. Some of these studies, accountability analyses, provide insight on whether the implementation of environmental policies or air quality interventions result in changes/reductions in air pollution concentrations and the corresponding effect on health outcomes.[84] The PA presents a summary of these studies, which are assessed in

[84] Given the nature of these studies, the majority tend to focus on time periods in the past during which ambient $PM_{2.5}$ concentrations were substantially higher than those measured more recently (e.g., see U.S. EPA, 2022b, Figure 2-16).

the 2019 ISA and ISA Supplement (U.S. EPA, 2022b, Table 3-12). These studies lend support for the conclusion that improvements in air quality are associated with improvements in public health.

More specifically, of the accountability studies that account for changes in $PM_{2.5}$ concentrations due to a policy or the implementation of an intervention to assess whether there was evidence of changes in associations with mortality or cardiovascular effects due to changes in annual $PM_{2.5}$ concentrations, Corrigan et al. (2018), Henneman et al. (2019b) and Sanders et al. (2020a) present analyses with starting concentrations (or concentrations prior to the policy or intervention) below 12.0 $\mu g/m^3$. Henneman et al. (2019b) explored the changes in modeled $PM_{2.5}$ concentrations following the retirement of coal fired power plants in the U.S., and found that reductions from mean annual $PM_{2.5}$ concentrations of 10.0 $\mu g/m^3$ in 2005 to mean annual $PM_{2.5}$ concentrations of 7.2 $\mu g/m^3$ in 2012 from coal-fueled power plants resulted in corresponding reductions in the number of cardiovascular-related hospital admissions, including for all cardiovascular disease, acute MI, stroke, heart failure, and ischemic heart disease in those aged 65 and older. Corrigan et al. (2018) examined whether there was a change in the cardiovascular mortality rate before (2000-2004) and after (2005-2010) implementation of the first annual $PM_{2.5}$ NAAQS implementation based on mortality data from the National Center for Health Statistics and reported 1.10 (95% CI: 0.37, 1.82) fewer cardiovascular deaths per year per 100,000 people for each 1 $\mu g/m^3$ reduction in annual $PM_{2.5}$ concentrations. When comparing whether counties met the annual $PM_{2.5}$ standard (attainment counties), there were 1.96 (95% CI: 0.77, 3.15) fewer cardiovascular deaths for each 1 $\mu g/m^3$ reduction in annual $PM_{2.5}$ concentrations between the two periods for attainment counties, whereas for non-attainment counties (e.g., counties that did not meet the annual $PM_{2.5}$ standard), there were 0.59 (95% CI: −0.54, 1.71) fewer cardiovascular

deaths between the two periods. And lastly, Sanders et al. (2020a) examined whether policy actions (i.e., the first annual $PM_{2.5}$ NAAQS implementation rule in 2005 for the 1997 annual $PM_{2.5}$ standard with a 3-year annual average of 15 $\mu g/m^3$) reduced $PM_{2.5}$ concentrations and mortality rates in Medicare beneficiaries between 2000-2013. They report evidence of changes in associations with mortality (a decreased mortality rate of ~ 0.5 per 1,000 in attainment and non-attainment areas) due to changes in annual $PM_{2.5}$ concentrations in both attainment and non-attainment areas. Additionally, attainment areas had starting concentrations below 12.0 $\mu g/m^3$ prior to implementation of the annual $PM_{2.5}$ NAAQS in 2005. In addition, following implementation of the annual $PM_{2.5}$ NAAQS, annual $PM_{2.5}$ concentrations decreased by 1.59 $\mu g/m^3$ (95% CI: 1.39, 1.80) which corresponded to a reduction in mortality rates among individuals 65 years and older (0.93% [95% CI: 0.10%, 1.77%]) in non-attainment counties relative to attainment counties. In a life expectancy study, Bennett et al. (2019) reports increases in life expectancy in all but 14 counties (1325 of 1339 counties) that have exhibited reductions in $PM_{2.5}$ concentrations from 1999 to 2015. These studies provide support for improvements in public health following the implementation of policies, including in areas with $PM_{2.5}$ concentrations below the level of the current annual standard, as well as increases in life expectancy in areas with reductions in $PM_{2.5}$ concentrations.

4. Uncertainties in the Health Effects Evidence

The PA recognizes that there are a number of uncertainties and limitations associated with the available health effects evidence. Although the epidemiologic studies clearly demonstrate associations between long- and short-term $PM_{2.5}$ exposures and health outcomes, several uncertainties and limitations in the health effects evidence remain. Epidemiologic studies evaluating short-term $PM_{2.5}$ exposure and health effects have reported heterogeneity in

associations between cities and geographic regions within the U.S. Heterogeneity in the associations observed across epidemiologic studies may be due in part to exposure error related to measurement-related issues, the use of central fixed-site monitors to represent population exposure to $PM_{2.5}$, and a limited understanding of factors including exposure error related to measurement-related issues, variability in $PM_{2.5}$ composition regionally, and factors that result in differential exposures (e.g., topography, the built environment, housing characteristics, personal activity patterns). Heterogeneity is expected when the methods or the underlying distribution of covariates vary across studies (U.S. EPA, 2019a, p. 6-221). Studies assessed in the 2019 ISA and ISA Supplement have advanced the state of exposure science by presenting innovative methodologies to estimate PM exposure, detailing new and existing measurement and modeling methods, and further informing our understanding of the influence of exposure measurement error due to exposure estimation methods on the associations between $PM_{2.5}$ and health effects reported in epidemiologic studies (U.S. EPA, 2019a, section 1.2.2; U.S. EPA, 2022a). Data from $PM_{2.5}$ monitors continue to be commonly used in health studies as a surrogate for $PM_{2.5}$ exposure, and often provide a reasonable representation of exposures throughout a study area (U.S. EPA, 2019a, section 3.4.2.2; U.S. EPA, 2022a, section 3.2.2.2.2). However, an increasing number of studies employ hybrid modeling methods to estimate $PM_{2.5}$ exposure using data from several sources, often including satellites and models, in addition to ground-based monitors. These hybrid models typically have good cross-validation, especially for $PM_{2.5}$, and have the potential to reduce exposure measurement error and uncertainty in the health effect estimates from epidemiologic models of long-term exposure (U.S. EPA, 2019a, section 3.5; U.S. EPA, 2022a, section 2.3.3).

While studies using hybrid modeling methods have reduced exposure measurement error

and uncertainty in the health effect estimates, these studies use a variety of approaches to estimate $PM_{2.5}$ concentrations and to assign exposure to assess the association between health outcomes and $PM_{2.5}$ exposure. This variability in methodology has inherent limitations and uncertainties, as described in more detail in section 2.3.3.1.5 of the PA, and the performance of the modeling approaches depends on the availability of monitoring data which varies by location. Factors that likely contribute to poorer model performance often coincide with relatively low ambient $PM_{2.5}$ concentrations, in areas where predicted exposures are at a greater distance to monitors, and under conditions where the reliability and availability of key datasets (e.g., air quality modeling) are limited. Thus, uncertainty in hybrid model predictions becomes an increasingly important consideration as lower predicted concentrations are considered.

Regardless of whether a study uses monitoring data or a hybrid modeling approach when estimating $PM_{2.5}$ exposures, one key limitation that persists is associated with the interpretation of the study-reported mean $PM_{2.5}$ concentrations and how they compare to design values, the metric that describe the air quality status of a given area relative to the NAAQS.[85] As discussed above in section II.B.3.b, the overall mean $PM_{2.5}$ concentrations reported by key epidemiologic studies reflect averaging of short- or long-term $PM_{2.5}$ exposure estimates across location (i.e., across multiple monitors or across modeled grid cells) and over time (i.e., over several years). For monitor-based studies, the comparison is somewhat more straightforward than for studies that use hybrid modeling methods, as the monitors used to estimate exposure in the epidemiologic studies are generally the same monitors that are used to calculate design values for

[85] For the annual $PM_{2.5}$ standard, design values are calculated as the annual arithmetic mean $PM_{2.5}$ concentration, averaged over 3 years. For the 24-hour standard, design values are calculated as the 98th percentile of the annual distribution of 24-hour $PM_{2.5}$ concentrations, averaged over three years (Appendix N of 40 CFR Part 50).

a given area. It is expected that areas meeting a $PM_{2.5}$ standard with a particular level would be expected to have average $PM_{2.5}$ concentrations (i.e., averaged across space and over time in the area) somewhat below that standard level., but the difference between the maximum annual design value and average concentration in an area can be smaller or larger than analyses presented above in section I.D.5.a, likely depending on factors such as the number of monitors, monitor siting characteristics, and the distribution of ambient $PM_{2.5}$ concentrations. For studies that use hybrid modeling methods to estimate $PM_{2.5}$ concentrations, the comparison between study-reported mean $PM_{2.5}$ concentrations and design values is more complicated given the variability in the modeling methods, temporal scales (i.e., daily versus annual), and spatial scales (i.e., nationwide versus urban) across studies. Analyses above in section I.D.5.b and detailed more in the PA (U.S. EPA, 2022b, section 2.3.3.2.4) present a comparison between two hybrid modeling surfaces, which explored the impact of these factors on the resulting mean $PM_{2.5}$ concentrations and provided additional information about the relationship between mean concentrations from studies using hybrid modeling methods and design values. However, the results of those analyses only reflect two surfaces and two types of approaches, so uncertainty remains in understanding the relationship between estimated modeled $PM_{2.5}$ concentrations and design values more broadly across hybrid modeling studies. Moreover, this analysis was completed using two hybrid modeling methods that estimate $PM_{2.5}$ concentrations in the U.S., thus an additional uncertainty includes understanding the relationship between modeled $PM_{2.5}$ concentrations and design values reported in Canada.

In addition, where $PM_{2.5}$ and other pollutants (e.g., ozone, nitrogen dioxide, and carbon monoxide) are correlated, it can be difficult to distinguish whether attenuation of effects in some studies results from copollutant confounding or collinearity with other pollutants in the ambient

mixture (U.S. EPA, 2019a, section 1.5.1; U.S. EPA, 2022a, section 2.2.1). Studies evaluated in the 2019 ISA and ISA Supplement further examined the potential confounding effects of both gaseous and particulate copollutants on the relationship between long- and short-term $PM_{2.5}$ exposure and health effects. As noted in the Appendix (Table A-1) to the 2019 ISA (U.S. EPA, 2019a), copollutant models are not without their limitations, such as instances for which correlations are high between pollutants resulting in greater bias in results.. However, the studies continue to provide evidence indicating that associations with $PM_{2.5}$ are relatively unchanged in copollutants models (U.S. EPA, 2019a, section 1.5.1; U.S. EPA, 2022a, section 2.2.1).

Another area of uncertainty is associated with other potential confounders, beyond copollutants. Some studies have expanded the examination of potential confounders to not only include copollutants, but also systematic evaluations of the potential impact of inadequate control from long-term temporal trends and weather (U.S. EPA, 2019a, section 11.1.5.1). Analyses examining these covariates further confirm that the relationship between $PM_{2.5}$ exposure and mortality is unlikely to be biased by these factors. Other studies have explored the use of alternative methods for confounder control to more extensively account for confounders and are more robust to model misspecification that can further inform the causality determination for long-term and short-term $PM_{2.5}$ and mortality and cardiovascular effects (U.S. EPA, 2019a, section 11.2.2.4; U.S. EPA, 2022a, sections 3.1.1.3, 3.1.2.3, 3.2.1.2, and 3.2.2.3). These studies indicate that bias from unmeasured confounders can occur in either direction, although controlling for these confounders did not result in the elimination of the association, but instead provided additional support for associations between long-term $PM_{2.5}$ exposure and mortality when accounting for additional confounders (U.S. EPA, 2022a, section 3.2.2.2.6).

Another important limitation associated with the evidence is that, while epidemiologic

studies indicate associations between $PM_{2.5}$ and health effects, they do not identify particular $PM_{2.5}$ exposures that cause effects. Rather, health effects can occur over the entire distribution of ambient $PM_{2.5}$ concentrations evaluated, and epidemiologic studies conducted to date do not identify a population-level threshold below which it can be concluded with confidence that $PM_{2.5}$-related effects do not occur.

Overall, evidence assessed in the 2019 ISA and ISA Supplement continues to indicate a linear, no-threshold C-R relationship for $PM_{2.5}$ concentrations > 8 $\mu g/m^3$. However, uncertainties remain about the shape of the C-R curve at $PM_{2.5}$ concentrations < 8 $\mu g/m^3$, with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations (U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a , section 2.2.3.2).

There are also a number of uncertainties and limitations associated with the experimental evidence (i.e., controlled human exposure studies and animal toxicological studies). With respect to controlled human exposure studies, the PA recognizes that these studies include a small number of individuals compared to epidemiologic studies. Additionally, these studies tend to include generally healthy adult individuals, who are at a lower risk of experiencing health effects. These studies, therefore, often do not include populations that are at increased risk of $PM_{2.5}$-related health effects, including children, older adults, or individuals with pre-existing conditions. As such, these studies are somewhat limited in their ability to inform at what concentrations effects may be elicited in at-risk populations. With respect to animal toxicological studies, while these studies often examine more severe health outcomes and longer exposure durations than controlled human exposure studies, there is uncertainty in extrapolating the effects seen in animals, and the $PM_{2.5}$ exposures and doses that cause those effects, to human populations.

*C. Summary of Exposure and Risk Estimates*

Beyond the consideration of the scientific evidence, discussed above in section II.B, the EPA also considers the extent to which new or updated quantitative analyses of $PM_{2.5}$ air quality, exposure, or health risks could inform conclusions on the adequacy of the public health protection provided by the current primary $PM_{2.5}$ standards. Conducting such quantitative analyses, if appropriate, could inform judgments about the potential for additional public health improvements associated with $PM_{2.5}$ exposure and related health effects and could help to place the evidence for specific effects into a broader public health context.

In addition to consideration of the scientific evidence, the PA includes an at-risk analysis that assesses $PM_{2.5}$-attributable risk associated with $PM_{2.5}$ air quality that has been adjusted to simulate air quality scenarios of policy interest (e.g., "just meeting" the current or potential alternative standards).

1. Key Design Aspects

Risk assessments combine data from multiple sources and involve various assumptions and uncertainties. Input data for these analyses includes C-R functions from epidemiologic studies for each health outcome and ambient annual or 24-hour $PM_{2.5}$ concentrations for the study areas utilized in the risk assessment (U.S. EPA, 2022b, section 3.4.1). Additionally, quantitative and qualitative methods were used to characterize variability and uncertainty in the risk estimates (U.S. EPA, 2022b, section 3.4.1.7).

Concentration-response functions used in the risk assessment are from large, multicity U.S. epidemiologic studies that evaluate the relationship between $PM_{2.5}$ exposures and mortality. Epidemiologic studies and concentration-response studies that were used in the risk assessment to estimate risk were identified using criteria that take into account factors such as study design, geographic coverage, demographic populations, and health endpoints (U.S. EPA, 2022b, section

3.4.1.1).[86] The risk assessment focuses on all-cause or nonaccidental mortality associated with long-term and short-term $PM_{2.5}$ exposures, for which the 2019 ISA concluded that the evidence provides support for a "causal relationship" (U.S. EPA, 2022b, section 3.4.1.2).[87]

As described in more detail in the PA, the risk assessment first estimated health risks associated with air quality for 2015 adjusted to simulate "just meeting" the current primary $PM_{2.5}$ standards (i.e., the annual standard with its level of 12.0 $\mu g/m^3$ and the 24-hour standard with its level of 35 $\mu g/m^3$). Air quality modeling was then used to simulate air quality just meeting an alternative standard with a level of 10.0 $\mu g/m^3$ (annual) and 30 $\mu g/m^3$ (24-hour). In addition to the model-based approach, for the subset of 30 areas controlled by the annual standard linear interpolation and extrapolation were employed to simulate just meeting alternative annual standards with levels of 11.0 (interpolated between 12.0 and 10.0 $\mu g/m^3$), 9.0 $\mu g/m^3$, and 8.0 $\mu g/m^3$ (both extrapolated from 12.0 and 10.0 $\mu g/m^3$) (U.S. EPA, 2022b, section 3.4.1.3). The PA notes that there is greater uncertainty regarding whether a revised 24-hour standard (i.e., with a lower level) is needed to further limit "peak" $PM_{2.5}$ concentration exposure and whether a lower 24-hour standard level would most effectively reduce $PM_{2.5}$-associated health risks associated with "typical" daily exposures. The risk assessment estimates health risks associated with air quality adjusted to meet a revised 24-hour standard with a level of 30 $\mu g/m^3$, in conjunction with estimating the health risks associated with meeting a revised annual standard with a level of 10.0 $\mu g/m^3$ (U.S. EPA, 2022b, section 3.4.1.3). More details on the air quality adjustment approaches

[86] Additional detail regarding the selection of epidemiologic studies and specification of C-R functions is provided in the PA (U.S. EPA, 2022b, Appendix C, section C.1.1).
[87] While the 2019 ISA also found that evidence supports the determination of a "causal relationship" between long- and short-term $PM_{2.5}$ exposures and cardiovascular effects, cardiovascular mortality was not included as a health outcome as it will be captured in the estimates of all-cause mortality.

used in the risk assessment are described in section 3.4.1.4 and Appendix C of the PA (U.S. EPA, 2022b).

When selecting U.S. study areas for inclusion in the risk assessment, the available ambient monitors, geographic diversity, and ambient $PM_{2.5}$ air quality concentrations were taken into consideration (U.S. EPA, 2022b, section 3.4.1.4). When these factors were applied, 47 urban study areas were identified, which include nearly 60 million people aged 30-99, or approximately 30% of the U.S population in this age range (U.S. EPA, 2022b, section 3.4.1.5, Appendix C, section C.1.3). Of the 47 study areas, there were 30 study areas where just meeting the current standards is controlled by the annual standard,[88] 11 study areas where just meeting the current standards is controlled by the daily standard,[89] and 6 study areas where the controlling standard differed depending on the air quality adjustment approach (U.S. EPA, 2022b, section 3.4.1.5).[90]

In addition to the overall risk assessment, the PA also includes an at-risk analysis and estimates exposures and health risks of specific populations identified as at-risk that would be allowed under the current and potential alternative standards to further inform the Administrator's conclusions regarding the adequacy of the public health protection provided by the current primary $PM_{2.5}$ standards. In so doing, the PA evaluates exposure and $PM_{2.5}$ mortality risk for older adults (e.g., 65 years and older), stratified for White, Black, Asian, Native

[88] For these areas, the annual standard is the "controlling standard" because when air quality is adjusted to simulate just meeting the current or potential alternative annual standards, that air quality also would meet the 24-hour standard being evaluated.
[89] For these areas, the 24-hour standard is the controlling standard because when air quality is adjusted to simulate just meeting the current or potential alternative 24-hour standards, that air quality also would meet the annual standard being evaluated. Some areas classified as being controlled by the 24-hour standard also violate the annual standard.
[90] In these 6 areas, the controlling standard depended on the air quality adjustment method used and/or the standard scenarios evaluated.

American, Non-Hispanic, and Hispanic individuals residing in the same study areas included in the overall risk assessment. This analysis utilizes a recent epidemiologic study that provides race- and ethnicity-specific risk coefficients (Di et al., 2017b).

2. Key Limitations and Uncertainties

Uncertainty in risk estimates (e.g., in the size of risk estimates) can result from a number of factors, including the assumptions about the shape of the C-R function with mortality at low ambient PM concentrations, the potential for confounding and/or exposure measurement error in the underlying epidemiologic studies, and the methods used to adjust $PM_{2.5}$ air quality. More specifically, the use of air quality modeling to adjust $PM_{2.5}$ concentrations are limited as they rely on model predictions, are based on emission changes are scaled by fixed percentages, and use only two of the full set of possible emission scenarios and linear interpolation/extrapolation to adjust air quality that may not fully capture potential non-linearities associated with real-world changes in air quality. Additionally, the selection of case study areas is limited to urban areas predominantly located CA and in the Eastern U.S. that are controlled by the annual standard. While the risk assessment does not report quantitative uncertainty in the risk estimates as exposure concentrations are reduced, it does provide information on the distribution of concentrations associated with the risk estimates when evaluating progressively lower alternative annual standards. Based on these data, as lower alternative annual standards are evaluated, larger proportions of the distributions in risk occur at or below 10 $\mu g/m^3$ (a concentrations which is below or near most of the study reported means from the key U.S. epidemiologic studies) and at or below 8 $\mu g/m^3$ (the concentration at which the ISA reports increasing uncertainty in the shape of the C-R curve based on the body of epidemiologic evidence). Similarly, the at-risk analysis is also subject to many of these same uncertainties. Additionally, the at-risk analysis included C-R

functions from only one study (Di et al., 2017b), which reported associations between long-term $PM_{2.5}$ exposures and mortality, stratified by race/ethnicity, in populations age 65 and older, as opposed to the multiple studies used in the overall risk assessment to convey risk estimate variability. These and other sources of uncertainty in the overall risk assessment and the at-risk analyses are characterized in the PA (U.S. EPA, 2022, section 3.4.1.7, section 3.4.1.8, Appendix C, section C.3).

3. Summary of Risk Estimates

Although limitations in the underlying data and approaches lead to some uncertainty regarding estimates of $PM_{2.5}$-associated risk, the risk assessment estimates that the current primary $PM_{2.5}$ standards could allow a substantial number of $PM_{2.5}$-associated deaths in the U.S. For example, when air quality in the 47 study areas is adjusted to simulate just meeting the current standards, the risk assessment estimates up to 45,100 deaths in 2015 are attributable to long-term $PM_{2.5}$ exposures associated with just meeting the current annual and 24-hour $PM_{2.5}$ standards (U.S. EPA, 2022, section 3.4.2.1). Additionally, as described in more detail in the PA, the at-risk analysis indicates that Black populations may experience disproportionally higher exposures and risk under air quality conditions just meeting the current primary annual $PM_{2.5}$ standard in the study areas, as compared to White populations. Risk disparities include exposure disparities, as well as the relationship between exposure and health effect and baseline rates of the health effect. While risk disparities may be a more meaningful metric, they are also subject to additional uncertainties.

Compared to the current annual standard, meeting a revised annual standard with a lower level is estimated to reduce $PM_{2.5}$-associated health risks in the 30 study areas controlled by the annual standard by about 7-9% a level of 11.0 $\mu g/m^3$, 15-19% for a level of 10.0 $\mu g/m^3$, 22-28%

for a level of 9.0 μg/m$^3$, and 30-37% for a level of 8.0 μg/m$^3$) (U.S. EPA, 2022b, Table 3-17). Meeting a revised annual standard with a lower level may also reduce exposure and risk in Black populations slightly more so than in White populations in simulated scenarios just meeting alternative annual standards. However, though reduced, disparities by race and ethnicity persist even at an alternative annual standard level of 8 μg/m$^3$, the lowest alternative annual standard included in the risk assessment (U.S. EPA, 2022b, section 3.4.2.4).

Revising the level of the 24-hour standard to 30 μg/m$^3$ is estimated to lower $PM_{2.5}$-associated risks across a more limited population and number of areas then revising the annual standard (U.S. EPA, 2022, section 3.4.2.4). Risk reduction predictions are largely confined to areas located in the western U.S., several of which are also likely to experience risk reductions upon meeting a revised annual standard. In the 11 areas controlled by the 24-hour standard, when air quality is simulated to just meet the current 24-hour standard, $PM_{2.5}$ exposures are estimated to be associated with as many as 2,570 deaths annual. Compared to just meeting the current standard, air quality just meeting an alternative 24-hour standard level of 30 μg/m$^3$ is associated with reductions in estimated risk of 9-13% (U.S. EPA, 2022b, section 3.4.2.3).

*D. Proposed Conclusions on the Primary $PM_{2.5}$ Standards*

In reaching proposed conclusions on the current primary $PM_{2.5}$ standards (presented in section II.D.3), the Administrator has taken into account the current evidence and associated conclusions in the 2019 ISA and ISA Supplement, in light of the policy-relevant evidence-based and risk-based considerations discussed in the PA (summarized in section II.D.2), as well as advice from the CASAC, and public comment received on the standards thus far in the reconsideration (section II.D.1). In general, the role of the PA is to help "bridge the gap" between the Agency's assessment of the current evidence and quantitative analyses (of air

quality, exposure, and risk), and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the NAAQS. Evidence-based considerations draw upon the EPA's integrated assessment of the scientific evidence of health effects related to $PM_{2.5}$ exposure presented in the 2019 ISA and ISA Supplement (summarized in section II.B above) to address key policy-relevant questions in the reconsideration. Similarly, the risk-based considerations draw upon the assessment of population exposure and risk (summarized in section II.C above) in addressing policy-relevant questions focused on the potential for $PM_{2.5}$ exposures associated with mortality under air quality conditions just meeting the current and potential alternative standards.

The approach to reviewing the primary standards is consistent with requirements of the provisions of the CAA related to the review of the NAAQS and with how the EPA and the courts have historically interpreted the CAA. As discussed in section I.A above, these provisions require the Administrator to establish primary standards that, in the Administrator's judgment, are requisite (i.e., neither more nor less stringent than necessary) to protect public health with an adequate margin of safety. Consistent with the Agency's approach across all NAAQS reviews, the EPA's approach to informing these judgments is based on a recognition that the available health effects evidence generally reflects a continuum that includes ambient air exposures for which scientists generally agree that health effects are likely to occur through lower levels at which the likelihood and magnitude of response become increasingly uncertain. The CAA does not require the Administrator to establish a primary standard at a zero-risk level or at background concentration levels, but rather at level that reduces risk sufficiently so as to protect public health, including the health of sensitive groups, with an adequate margin of safety.

The proposed decisions on the adequacy of the current primary $PM_{2.5}$ standards described

below is a public health policy judgment by the Administrator that draws on the scientific evidence for health effects, quantitative analyses of population exposures and/or health risks, and judgments about how to consider the uncertainties and limitations that are inherent in the scientific evidence and quantitative analyses. The four basic elements of the NAAQS (i.e., indicator, averaging time, form, and level) have been considered collectively in evaluating the public health protection afforded by the current standards. The Administrator's final decisions will additionally consider public comments received on these proposed decisions.

1. CASAC Advice in this Reconsideration

The CASAC has provided advice on the adequacy of the current primary $PM_{2.5}$ standards in the context of its review of the draft PA.[91] The range of views summarized here generally reflects differing judgments as to the relative weight to place on various types of evidence, the risk-based information, and the associated uncertainties, as well as differing judgments about the importance of various $PM_{2.5}$-related health effects from a public health perspective.

In its comments on the draft PA, the CASAC stated that: "[o]verall the CASAC finds the Draft PA to be well-written and appropriate for helping to 'bridge the gap' between the agency's scientific assessments and quantitative technical analyses, and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the National Ambient Air Quality Standards (NAAQS)" (Sheppard, 2022a, p. 1 of consensus letter). The CASAC also stated that the "[d]raft PA adequately captures and appropriately characterizes the key aspects of the evidence assessed and integrated in the 2019 ISA and Draft ISA Supplement of $PM_{2.5}$-related

[91] A limited number of public comments have also been received in this reconsideration to date, including comments focused on the draft PA. Of the public comments that addressed adequacy of the current primary $PM_{2.5}$ standards, some expressed agreement with staff conclusions in the draft PA, while others expressed the view that the standards should be more stringent.

health effects" (Sheppard, 2022b, p. 2 of consensus letter). The CASAC also stated that "[t]he interpretation of the risk assessment for the purpose of evaluating the adequacy of the current primary $PM_{2.5}$ annual standard is appropriate given the scientific findings presented" (Sheppard, 2022a, p. 2 of consensus letter). The CASAC also stated that the "[d]raft PA adequately captures and appropriately characterizes the key aspects of the evidence assessed and integrated in the 2019 ISA and Draft ISA Supplement of $PM_{2.5}$-related health effects" (Sheppard, 2022a, p. 2 of consensus letter). The CASAC also stated that "[t]he interpretation of the risk assessment for the purpose of evaluating the adequacy of the current primary $PM_{2.5}$ annual standard is appropriate given the scientific findings presented" (Sheppard, 2022a, p. 2 of consensus letter).

With regard to the adequacy of the current primary annual $PM_{2.5}$ standard, "all CASAC members agree that the current level of the annual standard is not sufficiently protective of public health and should be lowered" (Sheppard, 2022a, p. 2 of consensus letter). Additionally, "the CASAC reached consensus that the indicator, form, and averaging time should be retained, without revision" (Sheppard, 2022a, p. 2 of consensus letter). With regard to the level of the primary annual $PM_{2.5}$ standard, the CASAC had differing recommendations for the appropriate range for an alternative level. The majority of the CASAC "judge[d] that an annual average in the range of 8-10 $\mu g/m^3$" was most appropriate, while the minority of the CASAC members stated that "the range of the alternative standard of 10-11 $\mu g/m^3$ is more appropriate" (Sheppard, 2022a, p. 16 of consensus responses). The CASAC did highlight, however, that "the alternative standard level of 10 $\mu g/m^3$ is within the range of acceptable alternative standards recommended by all CASAC members, and that an annual standard below 12 $\mu g/m^3$ is supported by a larger and coherent body of evidence" (Sheppard, 2022a, p. 16 of consensus responses).

In reaching conclusions on a recommended range of 8-10 $\mu g/m^3$ for the primary annual

$PM_{2.5}$ standard, the majority of the CASAC placed weight on various aspects of the available scientific evidence and quantitative risk assessment information (Sheppard, 2022a, p. 16 of consensus responses). In particular, these members cited recent U.S.- and Canadian-based epidemiologic studies that show positive associations between $PM_{2.5}$ exposure and mortality with study-reported means below 10 $\mu g/m^3$. Further, these members also noted that the lower portions of the air quality distribution (i.e., concentrations below the mean) provide additional information to support associations between health effects and $PM_{2.5}$ concentrations lower than the long-term mean concentration. In addition, the CASAC members recognized that the available evidence has not identified a threshold concentration, below which an association no longer remains, pointing to the conclusion in the draft ISA Supplement that the "evidence remains clear and consistent in supporting a no-threshold relationship, and in supporting a linear relationship for $PM_{2.5}$ concentrations >8 $\mu g/m^3$" (Sheppard, 2022a, p. 16 of consensus responses). Finally, these CASAC members placed weight on the at-risk analysis as providing support for protection of at-risk demographic groups, including minority populations.

In reaching conclusions on a recommended range of 10-11 $\mu g/m^3$ for the primary annual $PM_{2.5}$ standard, the minority of the CASAC emphasized that there were few key epidemiologic studies that reported positive and statistically significant health effects associations for $PM_{2.5}$ air quality distributions with overall mean concentrations below 9.6 $\mu g/m^3$ (Sheppard, 2022a, p. 17 of consensus responses). In so doing, the minority of the CASAC specifically noted the variability in the relationship between study-reported means and area annual design values based on the methods utilized in the studies, noting that design values are generally higher than area average exposure levels. Further, the minority of the CASAC stated that "uncertainties related to copollutants and confounders make it difficult to justify a recommendation below 10-11 $\mu g/m^3$"

(Sheppard, 2022a, p. 17 of consensus responses). Finally, the minority of the CASAC placed less weight on the risk assessment results, noting large uncertainties, including the approaches used for adjusting air quality to simulate just meeting the current and alternative standards.

With regard to the current primary 24-hour $PM_{2.5}$ standard, the CASAC did not reach consensus regarding the adequacy of the public health protection provided by the current standard. The majority of the CASAC members concluded "that the available evidence calls into question the adequacy of the current 24-hour standard" (Sheppard, 2022a, p. 3 of consensus letter), while the minority of the CASAC members agreed with "the EPA's preliminary conclusion [in the draft PA] to retain the current 24-hour $PM_{2.5}$ standard without revision" (Sheppard, 2022a, p. 4 of consensus letter). The CASAC recommended that in future reviews, the EPA also consider alternative forms for the primary 24-hour $PM_{2.5}$ standard. Specifically, the CASAC "suggests considering a rolling 24-hour average and examining alternatives to the $98^{th}$ percentile of the 3-year average," pointing to concerns that computing 24-hour average $PM_{2.5}$ concentrations using the current midnight-to-midnight timeframe could potentially underestimate the effects of high 24-hour exposures, especially in areas with wood-burning stoves and wintertime stagnation (Sheppard, 2022a, p. 18 of consensus responses).

The majority of the CASAC favored revising the level of the primary 24-hour $PM_{2.5}$ standard and suggested that a range of 25-30 $\mu g/m^3$ would be adequately protective. In so doing, the CASAC placed weight on the available epidemiologic evidence, including epidemiologic studies that restricted analyses to 24-hour $PM_{2.5}$ concentrations below 25 $\mu g/m^3$. These members also placed weight on results of controlled human exposure studies with exposures close to the current standard, which they note provide support for the epidemiologic evidence to lower the standard. These members noted the limitations in using controlled human exposure studies alone

in considering adequacy of the 24-hour standard, recognizing that controlled human exposure studies preferentially recruit less susceptible individuals and have a typical exposure duration much shorter than 24 hours. These members also placed "greater weight on the scientific evidence than on the values estimated by the risk assessment," citing their concerns that the risk assessment "may not adequately capture areas with wintertime stagnation and residential wood-burning where the annual standard is less likely to be protective" (Sheppard, 2022a, p. 17 of consensus responses). Furthermore, these CASAC members "also are less confident that the annual standard could adequately protect against health effects of short-term exposures" (Sheppard, 2022a, p. 17 of consensus responses).

The minority of the CASAC agreed with the EPA's preliminary conclusion in the draft PA to retain the current primary 24-hour $PM_{2.5}$ standard, without revision. In so doing, the minority of the CASAC placed greater weight on the risk assessment, noting that the risk assessment accounts for both the level and the form of the current standard and the way attainment with the standard is determined. Further, the minority of the CASAC stated that the "risk assessment indicates that the annual standard is the controlling standard across most of the urban study areas evaluated and revising the level of the 24-hour standard is estimated to have minimal impact on the $PM_{2.5}$-associated risks" and that, because of this, "the annual standard can be used to limit both long- and short-term $PM_{2.5}$ concentrations" (Sheppard, 2022a, p. 18 of consensus responses). Further, the minority of the CASAC placed more weight on the controlled human exposure studies, which show "effects at $PM_{2.5}$ concentrations well above those typically measured in areas meeting the current standards" and which suggest that "the current standards are providing adequate protection against these exposures" (Sheppard, 2022a, p. 18 of consensus responses).

While the CASAC members expressed differing opinions on the appropriate revisions to the current standards, they did "find that both primary standards, 24-hour and annual, are critical to protect public health given the evidence on detrimental health outcomes at both short-term and long-term exposures including peak events" (Sheppard, 2022a, p. 13 of consensus responses). The comments from the CASAC also took note of uncertainties that remain in this reconsideration of the primary $PM_{2.5}$ standards and they identified a number of additional areas for future research and data gathering that would inform future reviews of the primary $PM_{2.5}$ NAAQS (Sheppard, 2022a, pp. 14-15 of consensus responses).

2. Evidence- and Risk-Based Considerations in the Policy Assessment

The main focus of the policy-relevant considerations in the PA is consideration of the question: Does the currently available scientific evidence- and exposure/risk-based information support or call into question the adequacy of the protection afforded by the current primary $PM_{2.5}$ standards? The PA response to this overarching question takes into account discussions that address the specific policy-relevant questions for this reconsideration, focusing first on consideration of the scientific evidence, as evaluated in the 2019 ISA and ISA Supplement, including that newly available in this reconsideration (section II.D.2.a). The PA also considers the quantitative risk estimates drawn from the risk assessment (presented in detail in section 3.4 and Appendix C of the PA; U.S. EPA, 2022b) including associated limitations and uncertainties, and the extent to which they may indicate different conclusions from those in previous reviews regarding the magnitude of risk, as well as the level of protection from adverse effects, associated with the current and alternative standards (section II.D.2.b). The PA additionally considers the key aspects of the evidence and exposure/risk estimates that were emphasized in previous reviews of the current standards, as well as the associated public health policy

judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that are integral to consideration of whether the currently available information supports or calls into question the adequacy of the current primary $PM_{2.5}$ standards (U.S. EPA, 2022b, section 3.6).

a. Evidence-Based Considerations

The currently available evidence on the health effects of $PM_{2.5}$, including evidence newly available in this reconsideration, is largely consistent with the evidence that was available in previous reviews regarding health effects causally related to $PM_{2.5}$ exposures. Specifically, as in the 2012 review, mortality and cardiovascular effects are concluded to be causally related to long- and short-term exposures to $PM_{2.5}$, while respiratory effects are concluded to likely be causally related to long- and short-term $PM_{2.5}$ exposures. Also, since the 2012 review, recent evidence provides additional support that is sufficient to conclude that the relationship between long-term $PM_{2.5}$ exposures and nervous system effects and cancer are likely to be causal (U.S. EPA, 2019a, Table ES-1). These determinations are based on evidence from experimental and epidemiologic studies that is newly available since the completion of the 2009 ISA (U.S. EPA, 2019, Table ES-1). The current evidence base is concluded to be suggestive of, but not sufficient to infer, causal relationships between nervous system effects and short-term $PM_{2.5}$ exposures; metabolic effects, reproduction and fertility, and pregnancy and birth outcomes and long- and short-term $PM_{2.5}$ exposures (U.S. EPA, 2019a, Table ES-1). Additionally, the current evidence base supports a suggestive of, but not sufficient to infer, a causal relationship for cardiovascular effects and short-term UFP exposures; respiratory effects and short-term UFP exposures; and nervous system effects and long- and short-term exposures (U.S. EPA, 2019a, Table ES-1).

The available evidence in the 2019 ISA continues to provide support for factors that may

contribute to increased risk of $PM_{2.5}$-related health effects including lifestage (children and older adults), pre-existing diseases (cardiovascular disease and respiratory disease), race/ethnicity, and SES. Other factors that have the potential to contribute to increased risk, but for which the evidence is less clear, include obesity, diabetes, genetic factors, smoking status, sex, diet, and residential location (U.S. EPA, 2019a, chapter 12). In addition to these population groups, the 2019 ISA and ISA Supplement conclude that there is strong evidence for racial and ethnic differences in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risk. There is strong evidence demonstrating that Black and Hispanic populations, in particular, have higher $PM_{2.5}$ exposures than non-Hispanic White populations (U.S. EPA, 2019a, Figure 12-2; U.S. EPA, 2022a, Figure 3-38). Further, there is consistent evidence across multiple studies that demonstrate increased risk of $PM_{2.5}$-related health effects for Black populations, with the strongest evidence for health risk disparities for mortality (U.S. EPA, 2019a, section 12.5.4). In addition, studies assessed in the 2019 ISA and ISA Supplement also provide evidence of exposure and health risk disparities based on SES. The evidence indicates that lower SES communities are exposed to higher concentrations of $PM_{2.5}$ compared to higher SES communities (U.S. EPA, 2019a, section 12.5.3; U.S. EPA, 2022b, section 3.3.3.1.1). Additionally, evidence supports the conclusions that lower SES is associated with cause-specific mortality and certain health endpoints (i.e., MI and CHF), but less so for all-cause or total (non-accidental) mortality (U.S. EPA, 2019a, section 12.5.3; U.S. EPA, 2022b, section 3.3.3.1).

Consistent with the evidence available in the 2009 ISA, controlled human exposure studies have demonstrated effects on cardiovascular function following 1- to 5-hour exposures to $PM_{2.5}$, with the most consistent evidence for impaired vascular function. The PA notes that most of the controlled human exposure studies have evaluated average $PM_{2.5}$ concentrations at or

above about 100 $\mu g/m^3$, with exposure durations up to two hours. These studies have often, though not always, reported statistically significant effects on one or more indicators of cardiovascular function following 2-hour exposures to average $PM_{2.5}$ concentrations at and above about 120 $\mu g/m^3$, with less consistent effects following exposures to concentrations lower than 120 $\mu g/m^3$.

In considering the controlled human exposure studies in reaching conclusions on the primary $PM_{2.5}$ standards, the PA notes that air quality analyses indicate that 2-hour $PM_{2.5}$ concentrations to which individuals were exposed in most of these studies, including those that report the most consistent results, are well-above the ambient $PM_{2.5}$ concentrations typically measured in locations meeting the current primary standards. Additionally, the PA recognizes that the results are variable across controlled human exposure studies that evaluated near-ambient $PM_{2.5}$ concentrations.

Furthermore, the PA recognizes that controlled human exposure studies often include small numbers of individuals and do not include populations that are at increased risk of $PM_{2.5}$-related health effects (e.g., children). While the PA recognizes that the controlled human exposure studies are important in establishing biological plausibility, it emphasizes that it is unclear how the results from these studies alone, particularly in studies conducted at near-ambient $PM_{2.5}$ concentrations, and the importance of the effects observed in the studies should be interpreted with respect to adversity to public health.

With regard to the animal toxicological studies, the PA recognizes that, unlike the controlled human exposure studies that provide insight on the exposure concentrations that directly elicit health effects in humans, there is uncertainty associated with translating the observations in the animal toxicological studies to potential adverse health effects in humans.

The PA notes that the interpretation of these studies is complicated by the fact that $PM_{2.5}$ concentrations in animal toxicological studies are much higher than those shown to elicit effects in human populations. Moreover, the PA recognizes that there are also significant anatomical and physiological difference between animal models and humans. In considering the information from the animal toxicological studies, the PA specifically notes two studies, one of which is newly available in the 2019 ISA, that report serious effects following long-term exposures to $PM_{2.5}$ concentrations close to the ambient concentrations reported in some epidemiologic studies, although still above the ambient concentrations likely to occur in areas meeting the current primary standards (U.S. EPA, 2022b, section 3.3.3.1).

Since the 2012 review, a large number of epidemiologic studies have become available that report generally positive, and often statistically significant, associations between long- and short-term $PM_{2.5}$ exposures and mortality and morbidity. Available studies additionally indicate that $PM_{2.5}$ health effect associations are robust across various approaches to estimating $PM_{2.5}$ exposures and across various exposure windows. Since the 2012 review, there are also a number of studies that employ alternative methods for confounder control that further inform the causal nature of the relationship between long- or short-term term $PM_{2.5}$ exposure and mortality, and these studies provide support for the findings from the broad body of epidemiologic studies.

In addition to broadening our understanding of the health effects that can result from exposures to $PM_{2.5}$ and strengthening support for some key effects (e.g., nervous system effects, cancer, and metabolic effects), recent epidemiologic studies strengthen support for health effect associations at relatively low ambient $PM_{2.5}$ concentrations. Studies that examine the shapes of C-R functions over the full distribution of ambient $PM_{2.5}$ concentrations have not identified a threshold concentration below which associations no longer exist (U.S. EPA, 2019a, section

1.5.3; U.S. EPA, 2022a, sections 2.2.3.1 and 2.2.3.2). While such analyses are complicated by the relatively sparse data available at the lower end of the air quality distribution (U.S. EPA, 2019a, section 1.5.3), the evidence remains consistent in supporting a no-threshold relationship, and in supporting a linear relationship for $PM_{2.5}$ concentrations > 8 $\mu g/m^3$. However, uncertainties remain about the shape of the C-R curve at $PM_{2.5}$ concentrations < 8 $\mu g/m^3$, with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations.

Consistent with previous reviews, the PA notes that the use of information from epidemiologic studies to inform conclusions on the current standards is complicated by the fact that such studies evaluate associations between distributions of ambient $PM_{2.5}$ and health outcomes, and do not identify the specific exposures that can lead to the reported effects. Rather, health effects can occur over the entire distribution of ambient $PM_{2.5}$ concentrations evaluated, and epidemiologic studies do not identify a population-level threshold below which it can be concluded with confidence that PM-associated health effects do not occur (U.S. EPA, 2019a, section 1.5.3). However, the study-reported ambient $PM_{2.5}$ concentrations reflecting estimated exposure in the middle portion of the $PM_{2.5}$ air quality distribution, which corresponds to the bulk of the underlying data, provide the strongest support for reported health effect associations and can inform conclusions on the current and potential alternative standards. In considering this information, the PA recognizes that the mean $PM_{2.5}$ concentrations reported by key epidemiologic studies differ in how mean concentrations were calculated, as well as their interpretation in what means represent in the context of the current standards.

In identifying key epidemiologic studies for consideration, the PA places the greatest emphasis on studies conducted in the U.S. and Canada, although recognizes a number of

limitations associated with interpreting the results of Canadian studies compared to studies conducted in the U.S. Generally, there are differences in the exposure environments and population characteristics between the U.S. and other countries, including Canada, that can affect the study-reported mean $PM_{2.5}$ concentration and its comparability with the annual standard level. A number of other differences, including sources and pollutant mixtures, concentration gradients, and populations densities, can make it challenging to interpret the mean $PM_{2.5}$ concentrations in Canadian studies in the context of a U.S.-based standard. Specifically, it may be difficult to use such studies to directly and quantitatively inform questions regarding the adequacy of the current or potential alternative levels of the annual standard. Therefore, while the PA considers the mean $PM_{2.5}$ concentrations from U.S. and Canadian studies in reaching conclusions, it notes that the U.S.-based epidemiologic studies are most informative for comparisons with the annual standard metric and for reaching conclusions on the current standards and for informing potential alternative levels of the standard.

Consistent with previous reviews, in considering information that can be used from the available epidemiologic evidence to inform proposed decisions on the current standards, the PA focuses on $PM_{2.5}$ concentrations near or somewhat below long-term mean concentrations reported in epidemiologic studies. In so doing, the PA notes that, in previous reviews, the epidemiologic studies used ground-based monitors to estimate exposures, and that, in addition to newly available monitor-based studies, there are also newly available epidemiologic studies estimate exposures using hybrid modeling approaches. In considering how the study-reported mean $PM_{2.5}$ concentrations reported in studies using hybrid modeling approaches compare to studies using ground-based monitors, the PA notes that the hybrid modeling approaches provide a broader estimation of $PM_{2.5}$ exposures compared to monitor-based studies (i.e., because hybrid

modeling studies include $PM_{2.5}$ concentrations estimated in areas without monitors). However, compared to monitor-based studies, the PA recognizes that it is more difficult to relate these means to an annual standard metric which relies on maximum monitor design values to assess compliance. Further complicating the comparison is the variability in how $PM_{2.5}$ concentrations are estimated between studies that use hybrid modeling approaches. Two important variations across studies include: (1) variability in spatial scale used (i.e., averages computed across the national (or large portions of the country) versus a focus on only CBSAs) and (2) variability in exposure assignment methods (i.e., averaging across all grid cells, averaging across a scaled-up area like a ZIP code, and population weighting).

As described in more detail in section I.D.5 above, the PA included analyses that considered how the study-reported mean $PM_{2.5}$ concentrations were computed and how the means compare to the annual standard metric (including the level, averaging time, and form) and the use of the monitor with the highest $PM_{2.5}$ design value in an area for compliance. In so doing, the PA included a comparison of $PM_{2.5}$ fields in estimating exposure relative to design values using two hybrid modeling surface with annual average $PM_{2.5}$ concentrations estimated per year at a 1 km x 1 km spatial resolution. The PA notes that the means vary when $PM_{2.5}$ concentrations are estimated in urban areas only (CBSAs) versus when the averages were calculated with all or most grid cells nationwide. This is likely indicative of the fact that areas included outside of CBSAs tend to be more rural and have lower estimated $PM_{2.5}$ concentrations. The PA acknowledges that this is an important consideration since the study areas included in the calculation of the mean, and more specifically whether a study is focused on nationwide, regional, or urban areas, will affect the calculation of the study mean based on how many rural areas are included with lower estimated $PM_{2.5}$ concentrations. While the determination of what

spatial scale to use to estimate $PM_{2.5}$ concentrations does not inherently affect the quality of the epidemiologic study, the spatial scale can influence the calculated long-term mean concentration across the study area and period.

Additionally, the PA analyses indicate that for the studies using the hybrid modeling approaches, the use of population weighting in calculating study-reported mean $PM_{2.5}$ concentrations, and not a difference in estimates of exposures in the study itself, can produce substantially different study-reported mean $PM_{2.5}$ concentrations compared to an approach that does not utilize population weighting. In studies that do not apply population weighting in the calculation of the mean $PM_{2.5}$ concentrations, study-reported means are lower, as a result of including areas with lower estimated $PM_{2.5}$ concentrations that may not be as densely populated, as well as areas that may not include health events. To elaborate, in hybrid modeling approaches that present mean $PM_{2.5}$ concentrations based on an average $PM_{2.5}$ concentration across all grid cells (i.e., do not apply aspects of population weighting), health events may not exist in each grid cell, and thus the mean reported $PM_{2.5}$ concentration is not necessarily based on the mean $PM_{2.5}$ concentrations assigned as the exposure in the health study. In other words, the mean $PM_{2.5}$ concentration that is reported and based on an average of all grid cells is not necessarily the same as the mean $PM_{2.5}$ concentration for each person assigned an exposure in the study. This is an important consideration, as the purpose of the epidemiologic study is to evaluate whether an association between $PM_{2.5}$ exposure and health outcomes exists. As such, it is unclear whether the mean concentration reported using each grid cell is associated with a health outcome (i.e., not all grid cells have health events). This leads to uncertainty in evaluating how the mean concentration can be used in the context of the approach above to evaluate the adequacy of the standard as well as potential alternative levels of the annual standard.

In considering the variability in how exposure in estimated between studies that use hybrid modeling approaches, the PA focuses on the key epidemiologic studies that use hybrid modeling approaches and apply population weighting in calculating the study-reported mean, as well as those studies that use monitors to estimate exposure, as described in more detail in section II.B.3.b above. For key U.S. epidemiologic studies that use monitors to estimate $PM_{2.5}$ exposures, overall mean $PM_{2.5}$ concentrations range between 9.9 $\mu g/m^3$ [92] to 16.5 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-8). For U.S. studies that use hybrid model-predicted exposures and apply aspects of population weighting, mean $PM_{2.5}$ concentrations range from 9.3 $\mu g/m^3$ to 12.2 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-14). In U.S. studies that average up from the grid cell level to the ZIP code or census tract level, mean $PM_{2.5}$ concentrations range from 9.8 $\mu g/m^3$ to 12.2 $\mu g/m^3$. In the one U.S. study that population-weighted the grid cells prior to averaging up to the ZIP code or census tract level, the reported mean $PM_{2.5}$ concentration is 9.3 $\mu g/m^3$. As described above, the PA also considers the study-reported means from the key Canadian epidemiologic studies, which are consistently much lower than those reported for key U.S. epidemiologic studies, while noting that for the reasons described above, there are uncertainties and limitations associated with comparisons between Canadian studies and the annual standard metric. For the key Canadian epidemiologic studies that use monitors to estimate $PM_{2.5}$ exposures, overall mean $PM_{2.5}$ concentrations range from 6.9 $\mu g/m^3$ to 13.3 $\mu g/m^3$, while the range of mean $PM_{2.5}$ concentrations in Canadian studies that use hybrid modeling (all of which average up to postal codes and thus include some aspects of population weighting) is 5.9 $\mu g/m^3$ to 9.8 $\mu g/m^3$.

As described in more detail in section II.B.3.b above, in assessing the range of reported

[92] This is generally consistent with, but slightly below, the lowest study-reported mean $PM_{2.5}$ concentration from monitor-based studies available in the 2020 PA, which was 10.7 $\mu g/m^3$ (U.S. EPA, 2020a, Figure 3-7).

exposure concentrations for which the strongest support exists for adverse health effects occurring, the PA evaluates whether the available evidence supports or calls into question the adequacy of public health protection afforded by the current primary annual $PM_{2.5}$ standard against these exposure concentrations. This means, as in past reviews, the application of a decision framework based on assessing means reported in key epidemiologic studies must also consider how the study means were computed and how these values compare to the annual standard metric (including the level, averaging time and form) and the use of the monitor with the highest $PM_{2.5}$ design value in an area for compliance. Based on the air quality analyses in presented in the PA and discussed above (section I.D.5.a and section I.D.5.b), design values associated with the study-reported means in these key U.S. based epidemiologic studies are only somewhat higher: 10-20% for monitor-based studies and 15-18% higher for the studies that include hybrid modeling approaches and utilize population weighting. Based on these results, it can generally be concluded that the study-reported mean concentrations in the studies are associated with air quality conditions that would be achieved by meeting annual standard levels that are 10-20% higher and 15-18% higher than study-reported means for monitor-based studies and hybrid modeling-based studies that use population weighting, respectively. Therefore, an annual standard level that is no more than 10-20% higher than the study-reported means in the monitor-based studies (i.e., 9.9-16.5 $\mu g/m^3$), and no more than 15-18% higher than the study-reported means in the studies that include hybrid modeling approaches and utilize population weighting (i.e., 9.3-12.2 $\mu g/m^3$), would generally maintain air quality exposures at or below those associated with the study-reported mean $PM_{2.5}$ concentrations, exposures for which we have the strongest support for adverse health effects occurring. This relationship is indicative of the fact that $PM_{2.5}$ exposures in an area are represented by a distribution of concentrations across

that area, with the annual standard level at the design value monitor being associated with the highest annual average exposure concentration for that area.

In addition to the study-reported mean concentrations, in considering the level of the annual standard, the PA uses an approach consistent with that used in previous reviews and also considers reported $PM_{2.5}$ concentrations corresponding to the $25^{th}$ and $10^{th}$ percentiles of health data or exposure estimates when available in the key epidemiologic studies. In using such an approach, the PA recognized that there is an interrelatedness of the distributional statistics in epidemiologic studies (e.g., $10^{th}$ and $25^{th}$ percentiles of $PM_{2.5}$ concentrations) and a range of one standard deviation around the mean which contains approximately 68% of normally distributed data, in that one standard deviation below the mean falls between the 25th and 10th percentiles (U.S. EPA, 2022b, p. 2-71). Further, the PA notes that in past reviews, some weight was placed on studies that provided mean $PM_{2.5}$ concentrations around the $25^{th}$ percentile of the distributions of deaths and cardiovascular-related hospitalizations and the Administrator judged the region around the $25^{th}$ percentile as a reasonable part of the distribution to guide the decision on the appropriate standard level (78 FR 3161, January 15, 2013).

As such, the PA concludes that focusing on concentrations somewhat below the means (e.g., $25^{th}$ and $10^{th}$ percentiles), when such information is available from epidemiologic studies, is a reasonable approach for considering lower portions of the air quality distribution. However, the PA recognizes that the health data are appreciably more sparse and an understanding of the magnitude and significance of the associations correspondingly become more uncertain in the lower part of the air quality distribution. While health effects can occur over the entire distribution of ambient $PM_{2.5}$ concentrations evaluated, and epidemiologic studies do not identify a population-level threshold below which it can be concluded with confidence that PM-

associated health effects do not occur (U.S. EPA, 2019a, section 1.5.3), using values below the 10th percentile would lead to even greater uncertainties and diminished confidence in the magnitude and significance of the associations.

In considering the available key U.S. epidemiologic studies, the PA notes that a small number of studies report $PM_{2.5}$ concentrations corresponding to the 25th and 10th percentiles of health data or exposure estimates that can be considered to provide insight into the concentrations that comprise the lower quartiles of the air quality distributions is examined below. In studies that use monitors to estimate $PM_{2.5}$ exposures, 25th percentiles of health events correspond to $PM_{2.5}$ concentrations (i.e., averaged over the study period for each study city) at or above 11.5 $\mu g/m^3$ and 10th percentiles of health events correspond to $PM_{2.5}$ concentrations at or above 9.8 $\mu g/m^3$ (i.e., 25% and 10% of health events, respectively, occur in study locations with $PM_{2.5}$ concentrations below these values) (U.S. EPA, 2022b, Figure 3-8). Of the key U.S. epidemiologic studies that use hybrid modeling approaches to estimate long-term $PM_{2.5}$ exposures, the ambient $PM_{2.5}$ concentrations corresponding to 25th percentiles of estimated exposures are 9.1 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-14). In key U.S. epidemiologic studies that use hybrid modeling approaches to estimate short-term $PM_{2.5}$ exposures, the ambient concentrations corresponding to 25th percentiles of estimated exposures, or health events, are 6.7 $\mu g/m^3$ and the ambient $PM_{2.5}$ concentration corresponding to that 10th percentile range from 4.7 $\mu g/m^3$ to 7.3 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-14).

As with the mean $PM_{2.5}$ concentrations, in considering these values relative to an area annual design value, the PA notes the 25th and 10th percentiles provide information about the lower quartiles of the air quality distributions, while the study-reported mean provides information about the average or typical exposures, and the corresponding area annual design

value provides the highest average annual $PM_{2.5}$ concentration being measured. In this way, the PA recognizes that all of these metrics (i.e., lower percentiles, study mean, annual design value) have a relationship relative to the other, and each of these metrics can be used to inform the consideration of the level of the current annual standard. Further, the PA recognizes that the air quality analyses described above (section I.D.5) and in the PA (U.S. EPA, 2022b, section 2.3.3.1 and section 2.3.3.2.4) that evaluated the relationship between a mean $PM_{2.5}$ concentration in an area and the design value focuses on mean $PM_{2.5}$ concentrations and similar analyses were not conducted for other $PM_{2.5}$ concentrations in the lower portion of the air quality distribution. Therefore, given the lack of additional information regarding the relationship between percentiles of the air quality distribution other than the mean and the annual design value, the PA concludes that any direct comparison of study-reported $PM_{2.5}$ concentrations corresponding to lower percentiles (e.g., $25^{th}$ and/or $10^{th}$) and annual design values is more uncertain than such comparisons with the mean.

Since the completion of the 2009 ISA, a number of epidemiologic studies have become available that can provide additional consideration to inform conclusions regarding the adequacy of the current standards. Studies that examine health effect associations in analyses that exclude the highest exposures (i.e., studies that restrict analyses below certain $PM_{2.5}$ concentrations), and which report positive and statistically significant associations in analyses restricted to annual average $PM_{2.5}$ exposures at or below 12 $\mu g/m^3$ and/or to daily exposures below 35 $\mu g/m^3$ (section II.B.3.b above and U.S. EPA, 2022b, Table 3-10). The PA notes that these restricted analyses provide additional support for effects at lower concentrations, exhibiting associations for mean concentrations presumably below the mean concentrations for the main analyses. While mean $PM_{2.5}$ concentrations for these restricted analyses may not be reported in most studies, the

PA asserts that it would not be unreasonable to presume that the mean $PM_{2.5}$ concentrations in the restricted analyses are less than the study-reported mean $PM_{2.5}$ concentrations in the main analyses. The two studies (Di et al., 2017b and Dominici et al., 2019) which report means in their restricted analyses (restricting annual average $PM_{2.5}$ exposure below 12 $\mu g/m^3$) and used population-weighted approaches to estimate $PM_{2.5}$ exposures report mean $PM_{2.5}$ concentrations of 9.6 $\mu g/m^3$. However, it is important to note that, even if the other studies had reported the mean $PM_{2.5}$ concentrations for the restricted analysis, these means would not necessarily have been useful in the context of the decision framework as was used in past reviews (above in section II.B.3.b.), given uncertainties associated with identifying the relationship between a calculated mean concentration that excludes specific daily or annual average concentrations above a certain threshold and the design value used to determine compliance with a standard (either the annual or 24-hour standard). Moreover, the PA emphasizes there is uncertainty in how studies exclude concentrations (e.g., at what spatial resolution are concentrations being excluded), which would make any comparisons of mean concentrations in restricted analyses difficult to compare to design values.

The PA also takes note of studies that restrict 24-hour average $PM_{2.5}$ concentrations to values of less than 35 $\mu g/m^3$ and again recognizes that these studies do not report the mean $PM_{2.5}$ concentration for the restricted analysis, as noted above, although the mean of the restricted analysis is presumably less than the mean $PM_{2.5}$ concentration in the main analysis. However, in some studies, the majority of $PM_{2.5}$ concentrations from the main study are already less than the restricted concentration (e.g., in Di et al., 2017a, where of all case and control days, 93.6% had $PM_{2.5}$ concentrations below 25 $\mu g/m^3$), which contributes to the uncertainty in how much lower a mean concentration in a restricted study is compared to the mean $PM_{2.5}$ concentration in the main

analysis. As a result, the PA recognizes that there are limitations in how this information can be used in evaluating the adequacy of the current or potential alternative levels of the 24-hour standard. Additionally, the PA further recognizes that it is difficult to use the means, when reported, from studies of restricted analyses to evaluate the level of protection afforded by the current or potential alternative levels of the primary 24-hour $PM_{2.5}$ standard because the relationship between the study-reported mean concentration and the $98^{th}$ percentile form of the 24-hour standard is not well understood, in particular for a short-term standard designed to limit exposures to peak $PM_{2.5}$ concentrations.

Finally, the PA notes the availability of accountability studies, which evaluate whether environmental policies or air quality interventions led to changes in air quality and are also associated with improvements in public health, including a number of recent studies evaluated in the ISA Supplement (summarized above in section II.B.3.b and U.S. EPA, 2022b, Table 3-12). These studies report positive and significant associations, including some studies with annual $PM_{2.5}$ concentrations below 12.0 $\mu g/m^3$ at the start of the study period, indicating that public health improvements may occur following $PM_{2.5}$ reductions in areas that already meet the current annual $PM_{2.5}$ standard. For example, the PA notes that the studies by Corrigan et al. (2018) and Sanders et al. (2020a) and both found improvements in mortality rates due to improvements in air quality in both attainment and nonattainment areas following implementation of the 1997 primary annual $PM_{2.5}$ NAAQS. Additionally, the PA notes that an accountability study by Henneman et al. (2019a) evaluated the changes in modeled $PM_{2.5}$ concentrations following the retirement of coal fired power plants in the U.S found that reductions in $PM_{2.5}$ concentrations

resulted in reductions of cardiovascular-related hospital admissions.[93] Other recent studies additionally report that declines in ambient $PM_{2.5}$ concentrations over a period of years have been associated with decreases in mortality rates and increases in life expectancy, improvements in respiratory development, and decreased incidence of respiratory disease in children, further supporting the robustness of $PM_{2.5}$ health effect associations reported in the epidemiologic evidence.

In considering the available scientific evidence, the PA recognizes that there are a number of uncertainties associated with the evidence that persist from previous reviews. The PA notes that, for controlled human exposures studies, there are uncertainties related to inconsistent results observed at concentrations near ambient $PM_{2.5}$ levels. Additionally, the PA recognizes that it is unclear how the results of controlled human exposure studies alone and the importance of the effects observed in these studies, particularly in studies conducted at near-ambient $PM_{2.5}$ concentrations, should be interpreted with respect to adversity to public health. With respect to animal toxicological studies, the PA notes that while these studies also help establish biological plausibility, uncertainty exists in extrapolating the effects observed in animal toxicological studies, and the $PM_{2.5}$ concentrations that cause those effects, to human populations.

Furthermore, the PA recognizes that uncertainties associated with the epidemiologic evidence (e.g., the potential for copollutant confounding and exposure measurement error) remain, although new studies evaluated in the ISA Supplement employ statistical methods such as alternative methods for confounder control, to more extensively account for confounders, which are more robust to model misspecification. With regard to controlling for potential

[93] We note that the studies by Corrigan et al. (2018) and Sanders et al. (2020a) report monitor-based average $PM_{2.5}$ concentrations, and the study by  reports model-based average $PM_{2.5}$ concentrations, and that these studies do not report design values.

confounders in particular, the PA notes that the key epidemiologic studies use a wide array of approaches to control for potential confounders. Time-series studies control for potential confounders that vary over short time intervals (e.g., including temperature, humidity, dew point temperature, and day of the week), while cohort studies control for community- and/or individual-level confounders that vary spatially (e.g., including income, race, age, SES, smoking, body mass index, and annual weather variables such as temperature and humidity) (U.S. EPA, 2022b, Table B-4). Sensitivity analyses indicate that adding covariates to control for potential confounders can either increase or decrease the magnitude of $PM_{2.5}$ effect estimates, depending on the covariate, and that none of the covariates examined can fully explain the association with mortality (e.g., Di et al., 2017b, Figure S2 in Supplementary Materials). Thus, while no individual study adjusts for all potential confounders, a broad range of approaches have been adopted across studies to examine confounding, supporting the robustness of reported associations. Available studies additionally indicate that $PM_{2.5}$ health effect associations are robust across various approaches to estimating $PM_{2.5}$ exposures and across various exposure windows. This includes recent studies that estimate exposures using ground-based monitors alone and studies that estimate exposures using data from multiple sources (e.g., satellites, land use information, modeling), in addition to monitors. While none of these approaches eliminates the potential for exposure error in epidemiologic studies, the PA concludes that such error does not call into question the fundamental findings of the broad body of $PM_{2.5}$ epidemiologic evidence.

Additionally, the PA notes the uncertainties associated with the studies that examine the shapes of C-R functions over the full distribution of ambient $PM_{2.5}$ concentrations have not identified a threshold concentration, below which associations no longer exist (section II.B.4

above, U.S. EPA, 2019a, section 1.5.3; U.S. EPA, 2022a, sections 2.2.3.1 and 2.2.3.2). While such analyses are complicated by the relatively sparse data available at the lower end of the air quality distribution (U.S. EPA, 2019a, section 1.5.3), the evidence remains consistent in supporting a no-threshold relationship, and in supporting a linear relationship for $PM_{2.5}$ concentrations > 8 $\mu g/m^3$. However, uncertainties remain about the shape of the C-R curve at $PM_{2.5}$ concentrations < 8 $\mu g/m^3$, with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations.

While studies using hybrid modeling methods have demonstrated reduced exposure measurement error and reduced uncertainty in the health effect estimates, these methodologies have inherent limitations and uncertainties, as described in more detail above in section II.B.3.b and in sections 2.3.3.1.5 and 3.3.4 of the PA, and the performance of the modeling approaches depends on the availability of monitoring data which varies by location. Factors likely contributing to poorer model performance often coincide with relatively low ambient $PM_{2.5}$ concentrations, in areas where predicted exposures are at a greater distance to monitors, and under conditions where the reliability and availability of key datasets (e.g., air quality modeling) are limited. Thus, the PA concludes that the uncertainty in hybrid model predictions becomes an increasingly important consideration as lower predicted concentrations are considered.

In addition, the PA recognizes that there are uncertainties and limitations in the analysis evaluating the comparison of estimated $PM_{2.5}$ concentrations using hybrid modeling surfaces and their relationship to design values that should be considered (section II.B.3.b above; U.S. EPA, 2022b, section 2.3.3.2.4). While design values in general are higher than estimated $PM_{2.5}$ concentrations using these two hybrid modeling approaches (DI2019 and HA2020), the PA recognizes that these are just two hybrid modeling approaches to estimating $PM_{2.5}$ concentrations

and other models/approaches/spatial scales may result in somewhat different $PM_{2.5}$ concentrations and relationships with design values. The analysis evaluating the relationship between two different hybrid modeling surfaces and design values estimates $PM_{2.5}$ concentrations by CBSAs, but not every health study uses $PM_{2.5}$ estimates at this spatial scale, and spatial scales for exposure estimates can vary by study (section I.D.5 above; U.S. EPA, 2022b, section 2.3.3.2.4). The analysis completed was a nationwide analysis and ratios between design values and mean concentrations are based on national estimates. However, not all health studies are national studies (i.e., some studies are completed in different regions of the country, like the southeast or northeast) and ratios in different parts of the country could be higher or lower, depending on factors like population, as well as the proportion of rural versus urban areas. This analysis used specific air quality years (2000-2016) and the use of other air quality years could result in higher or lower ratios.

Regardless of whether an epidemiologic study uses monitoring data or a hybrid modeling approach when estimating $PM_{2.5}$ exposures, the PA recognizes that it is challenging to interpret the study-reported mean $PM_{2.5}$ concentrations and how they compare to design values. This is particularly true given the variability that exists across the various approaches to estimate exposure and to calculate the study-reported mean. The PA also acknowledges that these types of challenges are also present in using information from Canadian studies to directly and quantitatively inform questions on the level of the annual standard given the difficulty of interpreting what the Canadian study means represent relative to U.S. design values.

b. Risk-Based Considerations

As in previous reviews, consideration of the scientific evidence in this reconsideration is informed by results from a quantitative analysis of risk. The overarching PA consideration

regarding these results is whether they alter the overall conclusions from previous reviews regarding health risk associated with exposure to $PM_{2.5}$ in ambient air and associated judgments on the adequacy of public health protection provided by the current primary $PM_{2.5}$ standards. The risk assessment conducted for this reconsideration develops exposure and risk estimates for populations in 47 urban study areas, as well as subsets of those study areas depending on which of the primary $PM_{2.5}$ standards is controlling in a given study area. The primary analyses focus on exposure and risk associated with air quality that might occur in an area under air quality conditions that just meet the current and potential alternative standards. These study areas include nearly 60 million people ages 30 years or older and illustrate the differences likely to occur across various locations with such air quality as a result of area-specific differences in emissions, meteorological, and population characteristics. While the same conceptual air quality scenarios are simulated in all study areas (i.e., conditions that just meet the existing or alternate standards), source, meteorological and population characteristics in the study areas contribute to variability in the estimated magnitude of risk across study areas (U.S. EPA, 2022b, section 3.6.2.1). In this way, the 47 areas provide a variety of examples of exposure patterns that can be informative to the Administrator's consideration of potential exposures and risks that may be associated with air quality conditions occurring under the current and potential alternative $PM_{2.5}$ standards.

In considering the risk assessment in this reconsideration, the PA notes a number of ways in which the current analyses update and improve upon those available in previous reviews. As an initial matter, the PA notes that, consistent with the overall approach for this reconsideration, the risk assessment has a targeted scope that focuses on all-cause or nonaccidental mortality associated with long- and short-term $PM_{2.5}$ exposures (U.S. EPA, 2022b, section 3.4.1.2). As

noted in section II.B.1 above, the evidence assessed in the 2019 ISA and ISA Supplement support a causal relationship between long- and short-term $PM_{2.5}$ exposures and mortality. Concentration-response functions used in the risk assessment are from large, multicity U.S. epidemiologic studies that evaluate the relationship between $PM_{2.5}$ exposures and mortality and were identified using criteria that take into account factors such as study design, geographic coverage, demographic populations, and health endpoints (U.S. EPA, 2022b, section 2.1).

The risk assessment also includes updates and improvements to input data and modeling approaches, summarized in section II.C above and in section 3.4 of the PA (U.S. EPA, 2022b). As in previous reviews, exposure and risk are estimated from air quality scenarios defined by the highest design value in the study area, which is the monitor location with the highest 3-year average of the annual mean $PM_{2.5}$ concentrations (e.g., equal to 12.0 $\mu g/m^3$ for the current standard scenario) for the annual $PM_{2.5}$ standard and with the highest 3-year average of the $98^{th}$ percentile 24-hour $PM_{2.5}$ concentrations (e.g., equal to 35 $\mu g/m^3$ for the current standard scenario) for the 24-hour $PM_{2.5}$ standard. As described in more detail in section II.C above and in section 3.4 of the PA (U.S. EPA, 2022b), air quality modeling was used to simulate just meeting the existing annual and 24-hour standards of 12.0 $\mu g/m^3$ and 35 $\mu g/m^3$ and to just meeting potential alternative annual and 24-hour standards of 10.0 $\mu g/m^3$ and 30 $\mu g/m^3$. In addition to the air quality modeling approach, linear interpolation and extrapolation were used to simulate just meeting alternative annual standards with levels of 11.0 (interpolated between 12.0 and 10.0 $\mu g/m^3$), 9.0 $\mu g/m^3$, and 8.0 $\mu g/m^3$ (both extrapolated from 12.0 and 10.0 $\mu g/m^3$) in the subset of study areas controlled by the annual standard.

In addition to the risk assessment described above, the PA presents quantitative analyses that also assess long-term $PM_{2.5}$-attributable exposure and mortality risk, stratified by

racial/ethnic demographics. As described in more detail in section II.B.2 above, the evidence suggests that different racial and ethnic groups, such as Black and Hispanic populations residing in the study areas, have higher $PM_{2.5}$ exposures than White and non-Hispanic populations also residing in the study areas, respectively, thus contributing to increased risk of PM-related effects. Of the available studies, Di et al. (2017b) was identified as best characterizing populations potentially at increased risk of long-term exposure-attributable all-cause mortality effects and provides race- and ethnicity-stratified C-R functions for ages 65 and over (U.S. EPA, 2022b, section 3.4.1.6 and Appendix C). Risk and exposure are quantitatively assessed within racial and ethnic minority populations of older adults in the full set of 47 areas and the subset of 30 areas controlled by the annual $PM_{2.5}$ standard. This analysis, when considered alongside estimates of risk across all populations in the 47 study areas, can help to inform conclusions on the annual primary $PM_{2.5}$ standards that would be requisite to protect the public health of demographic populations potentially at increased risk of long-term $PM_{2.5}$-related mortality effects.

In considering the risk results, the PA focuses first on estimates for the full set of 47 urban study areas. The risk assessment estimates that the current primary $PM_{2.5}$ standards could allow a substantial number of deaths in the U.S., with the large majority of those deaths associated with long-term $PM_{2.5}$ exposures. For example, when air quality in the 47 study areas is adjusted to just meet the current standards, the risk assessment estimates about 41,000 to 45,000 deaths from all-cause mortality in a single year (i.e., for long-term exposures; confidence intervals range from about 30,000 to 59,000) (U.S. EPA, 2022b, section 3.4.2.1). For the 30

study areas[94] where just meeting the current standards is controlled by the annual standard,[95] long-term $PM_{2.5}$ exposures are estimated to be associated with as many as 39,000 (confidence intervals range from about 26,000 to 51,000) deaths from all-cause mortality in a single year (U.S. EPA, 2022b, section 3.4.2.2). For the 11 study areas[96] where just meeting the current standards is controlled by the daily standard,[97] long-term $PM_{2.5}$ exposures are estimated to be associated with as many as 2,600 (confidence intervals ranging from 1,700 to 3,400) deaths in a single year (U.S. EPA, 2022b, section 3.4.2.3). The risk assessment estimates far fewer deaths in a single year for short-term $PM_{2.5}$ exposures as compared to long-term $PM_{2.5}$ exposures, across all of the study area subsets (U.S. EPA, 2022b, section 3.6.2.2).

While the absolute numbers of estimated deaths vary across exposure durations, populations, and C-R functions, the general magnitude of risk estimates supports the potential for significant public health impacts in locations meeting the current primary $PM_{2.5}$ standards. This is particularly the case given that the large majority of $PM_{2.5}$-associated deaths for air quality just meeting the current standards are estimated at annual average $PM_{2.5}$ concentrations from about 10 to 12 $\mu g/m^3$. These annual average $PM_{2.5}$ concentrations fall within the range of long-term average concentrations over which key epidemiologic studies provide strong support for reported

[94] These 30 areas controlled by the annual standard under all scenarios evaluated include a population of approximately 48 million adults aged 30-99, or about 75% of the population included in the full set of 47 areas.
[95] For these areas, the annual standard is the "controlling standard" because when air quality is adjusted to simulate just meeting the current or potential alternative annual standards, that air quality also would meet the 24-hour standard being evaluated.
[96] These 11 areas controlled by the 24-hour standard under all scenarios evaluated include a population of approximately 10 million adults aged 30-99, or about 17% of the population included in the full set of 47 areas.
[97] For these areas, the 24-hour standard is the controlling standard because when air quality is adjusted to simulate just meeting the current or potential alternative 24-hour standards, that air quality also would meet the annual standard being evaluated. Some areas classified as being controlled by the 24-hour standard also violate the annual standard.

positive and statistically significant health effect associations (U.S. EPA, 2022b, section 3.6.2.2).

In the 47 urban study areas, when air quality is simulated to just meet alternative standards, the PA notes that there are substantially larger risk reductions associated with lowering the annual standard than with lowering the 24-hour standard. Risks are estimated to decrease by 13-17% when air quality is adjusted to just meet an alternative annual standard with a level of 10.0 $\mu g/m^3$ or by 1-2% when adjusted to just meet an alternative 24-hour standard with a level of 30 $\mu g/m^3$ (U.S. EPA, 2022b, section 3.4.2.1). The percentage decrease when just meeting an alternative annual standard with a level of 10.0 $\mu g/m^3$ corresponds to approximately 7,400 fewer deaths per year (confidence intervals ranging from about 4,100 to 9,800) attributable to long-term $PM_{2.5}$ exposures (U.S. EPA, 2022b, section 3.4.2.1).

In the 30 study areas where just meeting the current and alternative standards is controlled by the annual standard, air quality adjusted to meet alternative annual standards with lower levels is associated with reductions in estimated all-cause mortality risk. These reductions in risk for alternative annual levels are as follows: 7-9% reduction for an alternative annual level of 11.0 $\mu g/m^3$, 15-19% reduction for a level of 10.0 $\mu g/m^3$, 22-28% reduction for a level of 9.0 $\mu g/m^3$, and 30-37% reduction for a level of 8.0 $\mu g/m^3$ (U.S. EPA, 2022b, section 3.4.2.2). For each of these standards, most of the risk remaining is estimated at annual average $PM_{2.5}$ concentrations that fall somewhat below the alternative standard levels (U.S. EPA, 2022b, section 3.4.2.2).

In considering the at-risk analysis, the PA notes that across all simulated air quality for both the full set of 47 and the subset of 30 study areas, Blacks experience the highest average $PM_{2.5}$ concentrations of the demographic groups analyzed. Native Americans experienced the lowest average $PM_{2.5}$ concentrations, particularly in the full set of 47 study areas. White,

Hispanic, and Asian populations were exposed to similar average $PM_{2.5}$ concentrations. Additionally, as the levels of potential alternative annual $PM_{2.5}$ standards decrease, there is comparatively less disproportionate exposure between demographic populations (U.S. EPA, 2022b, section 3.4.2.4).

The PA recognizes that the risk estimates can provide additional information beyond the exposure information to inform our understanding of potentially disproportionate impacts, in this instance by including demographic-specific information on baseline incidence and the relationship between exposure and health effect. Across all air quality scenarios and demographic groups evaluated, Black populations in the study areas are associated with the largest $PM_{2.5}$-attributable mortality risk rate per 100,000 people, while White populations in the study areas are associated with the smallest $PM_{2.5}$-attributative mortality risk rate (U.S. EPA, 2022b, section 3.4.2.4, Figure 3-20). Generally, as the levels of potential alternative annual $PM_{2.5}$ standards decrease in the 30 areas controlled by the annual standard, the average reductions in $PM_{2.5}$ concentration and mortality risk rates increase across all demographic populations (U.S. EPA, 2022b, section 3.4.2.4, Figure 3-21).

In comparing the reductions in average national $PM_{2.5}$ concentrations and risk rates within each demographic population, the average percent $PM_{2.5}$ concentrations and risk reductions are slightly greater in the Black population than in the White population for each alternative standard evaluated (11.0 $\mu g/m^3$, 10.0 $\mu g/m^3$, 9.0 $\mu g/m^3$, and 8.0 $\mu g/m^3$), when shifting from the current annual $PM_{2.5}$ standard (12.0 $\mu g/m^3$) in the full set of 47 areas and the subset of 30 areas controlled by the annual standard. Furthermore, the difference in average percent risk reductions increases slightly more in Blacks than in Whites as the level of the potential alternative annual standard decreases (U.S. EPA, 2022b, section 3.4.2.4, Table 3-19 and Table 3-

20).

The PA also recognizes that there are several particularly important uncertainties that affect the quantitative estimates of risk rates and exposure in the at-risk analysis and their interpretation in the context of considering the current primary $PM_{2.5}$ standards. These include uncertainties related to the modeling and adjustment methods for simulating air quality scenarios; the potential influence of confounders on the relationship between $PM_{2.5}$ exposure and mortality; and the interpretation of the shapes of C-R functions, particularly at lower concentrations. It is also important to recognize the limited availability of studies to inform the at-risk analysis. As noted in section II.C above and in section 3.4 of the PA, the at-risk analysis included C-R functions from one study, Di et al. (2017b), which reported associations between long-term $PM_{2.5}$ exposures and mortality, stratified by race/ethnicity, in populations age 65 and older. Of the studies available from the 2019 ISA, Di et al. (2017b) was identified as best characterizing potentially at-risk minority populations across the U.S.[98] While the at-risk analyses provide additional insight on the estimated exposures and risks for certain demographic groups, it is not clear how the results would vary if: (1)analyses included populations that were younger than 65 years old, (2) the analyses were conducted areas that are demographically different than the 47 study areas included in this analysis, and (3) the air quality adjustments reflected source-specific emissions reduction strategies. Therefore, in light of the limitations and uncertainties associated with the at-risk analyses, the results should be considered within the context of the full risk assessment. The uncertainties associated with the quantitative risk assessment and at-risk analyses are described in more detail in the PA (U.S. EPA, 2022b, section

[98] Additional details on concentration-response function identification can be found in Appendix C, section C.3.2 of the PA.

3.4.2.5 and Appendix C) and are summarized in section II.C.2 above.

In considering the public health implications of the risk assessment, the PA notes that the purpose for the study areas is to illustrate circumstances that may occur in areas that just meet the current or potential alternative standards, and not to estimate risk associated with conditions occurring in those specific locations currently. The PA notes that some areas across the U.S. have air quality for $PM_{2.5}$ that is near or above the existing standards. Risks associated with air quality above the current standards are not informative to decisions about the adequacy of the current standards. This is because the risk assessment uses an approach to adjust air quality to just meet the current standards, which means that areas that have air quality that is above the current standards would be adjusted to just meet the current standards such that the evaluation of changes in risk and risk remaining would be associated with those areas meeting the current standards. The same is true for air quality adjusted to simulate just meeting alternative standard levels as well. Thus, the air quality and exposure circumstances assessed in the study areas in the risk assessment are specifically designed to inform whether the currently available information calls into question the adequacy of the public health protection afforded by the current standards, as well as to provide information regarding potential alternative standard levels.

The risk estimates for the study areas assessed in this reconsideration reflect differences in exposure circumstances among those areas and illustrate the exposures and risks that might be expected to occur in other areas with such circumstances under air quality conditions that just meet the current standards or the alternative standards assessed. Thus, the exposure and risk estimates indicate the magnitude of exposure and risk that might be expected in many areas of the U.S. with $PM_{2.5}$ concentrations at or near the current or alternative standards. Although the methodologies and data used to estimate risks in this reconsideration differ in several ways from

what was used in the 2020 review, the findings and considerations summarized in the PA present a pattern of exposure and risk that is generally similar to that considered in the 2020 review, and indicate a level of protection generally consistent with that described in the 2020 PA.

The PA notes that the considerations related to the potential public health implications of the risk assessment and at-risk analysis are important to informing the Administrator's proposed decisions regarding the public health significance of the risk assessment results. Specifically, the PA notes that available evidence and information suggests that both long- and short-term $PM_{2.5}$ exposures are associated with adverse health effects, including more severe effects such as mortality. In addition, the PA further notes that such effects impact large segments of the U.S. population, including those populations that may have other factors that influence risk (i.e., lifestage, pre-existing cardiovascular and respiratory diseases, race/ethnicity), as well as disparities in $PM_{2.5}$ exposures and health risks based on race and ethnicity (U.S. EPA, 2022b, section 3.6.2.5). Therefore, the PA recognizes that the air quality allowed by the current primary $PM_{2.5}$ standards could be judged to be associated with significant public health risk. The PA also recognizes that such conclusions also depend in part on public health policy judgments that will weigh in the Administrator's decision in this reconsideration with regard to the adequacy of protection afforded by the current standards. Such judgments that are common to NAAQS decisions include those related to public health implications of effects of differing severity. Such judgments also include those concerning the public health significance of effects at exposures for which evidence is limited or lacking, such as effects at lower concentrations than those demonstrated in the key epidemiologic studies and in those population groups for which population-specific information, such as C-R functions, are not available from the epidemiologic literature.

3. Administrator's Proposed Conclusions on the Primary $PM_{2.5}$ Standards

This section summarizes the Administrator's considerations and proposed conclusions related to the adequacy of the current primary $PM_{2.5}$ standards and presents his proposed decision to revise the primary annual $PM_{2.5}$ standard and retain the primary 24-hour $PM_{2.5}$ standard. In establishing primary standards under the Act that are "requisite" to protect public health with an adequate margin of safety, the Administrator is seeking to establish standards that are neither more nor less stringent than necessary for this purpose. He recognizes that the requirement to provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information and to provide a reasonable degree of protection against hazards that research has not yet identified. However, the Act does not require that primary standards be set at a zero-risk level; rather, the NAAQS must be sufficiently protective, but not more stringent than necessary.

Given these requirements, the Administrator's final decision in this reconsideration will be a public health policy judgment drawing upon scientific and technical information examining the health effects of $PM_{2.5}$ exposures, including how to consider the range and magnitude of uncertainties inherent in that information. This public health policy judgment will be based on an interpretation of the scientific and technical information that neither overstates nor understates its strengths and limitations, nor the appropriate inferences to be drawn, and will be informed by the Administrator's consideration of advice from the CASAC and public comments received on this proposal notice.

a. Adequacy of the Current Primary $PM_{2.5}$ Standards

In considering whether the currently available scientific evidence and quantitative risk-based information support or call into question the adequacy of the public health protection

afforded by the current primary $PM_{2.5}$ standards, and as is the case with NAAQS reviews in general, the extent to which the current primary $PM_{2.5}$ standards are judged to be adequate will depend on a variety of factors, including science policy and public health policy judgments to be made by the Administrator on the strength and uncertainties of the scientific evidence. The factors relevant to judging the adequacy of the standards also include the interpretation of, and decisions as to the weight to place on, different aspects of the results of the risk assessment for the study areas included and the associated uncertainties. Thus, the Administrator's proposed conclusions regarding the adequacy of the current standards will depend in part on judgments regarding aspects of the evidence and risk estimates, and judgments about the degree of protection that is requisite to protect public health with an adequate margin of safety.

i. Proposed Conclusions on the Adequacy of the Current Primary $PM_{2.5}$ Standards

In reaching proposed conclusions on the adequacy of the current primary $PM_{2.5}$ standards, the Administrator has considered the scientific evidence, including that assessed in the 2019 ISA and the ISA Supplement. The Administrator has also considered the quantitative estimates of risk developed in this reconsideration, including associated uncertainties and limitations, and the extent to which they indicate differing conclusions regarding the magnitude of risk, as well as level of protection from adverse effects, associated with the current standards. The Administrator has additionally considered the key aspects of the evidence and risk estimates emphasized in establishing the current standards, and the associated public health policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that are integral to the proposed conclusions on the adequacy of the current primary $PM_{2.5}$ standards.

First, as described above in section II.A.2, the Administrator's approach recognizes that

the current annual standard (based on arithmetic mean concentrations) and 24-hour standard (based on 98$^{th}$ percentile concentrations), together, are intended to provide public health protection against the full distribution of short- and long-term $PM_{2.5}$ exposures. In evaluating the adequacy of the current standards, the Administrator focuses on evaluating the public health protection afforded by the annual and 24-hour standards, taken together, against adverse health effects associated with long- or short-term $PM_{2.5}$ exposures. This approach recognizes that changes in $PM_{2.5}$ air quality designed to meet either the annual or the 24-hour standard would likely result in changes to both long-term average and short-term peak $PM_{2.5}$ concentrations.

In general, the Administrator recognizes that the annual standard is most effective at controlling exposures to "typical" daily $PM_{2.5}$ concentrations that are experienced over the year, while the 24-hour standard, with its 98th percentile form, is most effective at limiting peak daily or 24-hour $PM_{2.5}$ concentrations. In considering the combined effects of these standards, the Administrator recognizes that changes in $PM_{2.5}$ air quality designed to meet an annual standard would likely result not only in lower short- and long-term $PM_{2.5}$ concentrations near the middle of the air quality distribution, but also in fewer and lower short-term peak $PM_{2.5}$ concentrations. Additionally, changes designed to meet a lower 24-hour standard, with a 98$^{th}$ percentile form, would most effectively result in fewer and lower peak 24-hour $PM_{2.5}$ concentrations, but also have an effect on lowering the annual average $PM_{2.5}$ concentrations. Thus, the Administrator acknowledges the focus in evaluating the current primary standards is on the protection provided by the combination of the annual and 24-hour standards against the distribution of both short- and long-term $PM_{2.5}$ exposures.

The Administrator recognizes the longstanding body of health evidence supporting relationships between $PM_{2.5}$ exposures (short- and long-term) and mortality or serious morbidity

effects. The evidence available in this reconsideration (i.e., that assessed in the 2019 ISA (U.S. EPA, 2019a) and ISA Supplement (U.S. EPA, 2022a) and summarized above in section II.B.1 and section II.D.2.a reaffirms, and in some cases strengthens, the conclusions from the 2009 ISA regarding the health effects of $PM_{2.5}$ exposures (U.S. EPA, 2009a). As noted above, epidemiologic studies demonstrate generally positive, and often statistically significant, $PM_{2.5}$ health effect associations. Such studies report associations between estimated $PM_{2.5}$ exposures and non-accidental, cardiovascular, or respiratory mortality; cardiovascular or respiratory hospitalizations or emergency room visits; and other mortality/morbidity outcomes (e.g., lung cancer mortality or incidence, asthma development). Recent experimental evidence, as well as evidence from panel studies, strengthens support for potential biological pathways through which $PM_{2.5}$ exposures could lead to the serious effects reported in many population-level epidemiologic studies, including support for pathways that could lead to cardiovascular, respiratory, nervous system, and cancer-related effects. The Administrator also recognizes that the PA notes that while the full body of health effects evidence is considered in this reconsideration of the PM NAAQS, the greatest emphasis in the PA is placed on the health effects for which the evidence has been judged in the 2019 ISA to demonstrate a "causal" or "likely to be causal" relationship with $PM_{2.5}$ exposures (i.e., mortality, cardiovascular effects, respiratory effects, cancer, and nervous system effects). In considering the available scientific evidence, consistent with approaches employed in past NAAQS reviews, the Administrator places the most weight on evidence supporting "causal" or "likely to be causal" relationship with long or short-term $PM_{2.5}$ exposures. In addition, the Administrator also takes note of those populations identified to be at greater risk of $PM_{2.5}$-related health effects, as characterized in the 2019 ISA and ISA Supplement, and the potential public health implications.

In evaluating the public health protection afforded by the current primary $PM_{2.5}$ standards against long- and short-term $PM_{2.5}$ exposures, the Administrator considers the four basic elements of the NAAQS (indicator, averaging time, form, and level) collectively. With respect to indicator, the Administrator recognizes that the scientific evidence in this reconsideration, as in previous reviews, continues to provide strong support for health effects associated with $PM_{2.5}$ mass. He notes the PA conclusion that the available information continues to support the $PM_{2.5}$ mass-based indicator and remains too limited to support a distinct standard for any specific $PM_{2.5}$ component or group of components, and too limited to support a distinct standard for the ultrafine fraction (U.S. EPA, 2022b, section 3.6.3.2.1). In its advice on the adequacy of the current primary $PM_{2.5}$ standards, the CASAC reached consensus that the $PM_{2.5}$ mass-based indicator should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter). Thus, as in the 2020 review (85 FR 82715, December 18, 2020) and consistent with the advice from the CASAC, the Administrator proposes to conclude that it is appropriate to consider retaining $PM_{2.5}$ mass as the indicator for the primary standards for fine particles.

With respect to averaging time and form, the Administrator notes that the scientific evidence continues to provide strong support for health effect associations with both long-term (e.g., annual or multi-year) and short-term (e.g., mostly 24-hour exposures to $PM_{2.5}$) (U.S. EPA, 2022b, section 3.6.3.2.2). In this reconsideration, the epidemiologic and controlled human exposure studies have examined a variety of $PM_{2.5}$ exposure durations. Epidemiologic studies continue to provide strong support for health effects associated with short-term $PM_{2.5}$ exposures based on 24-hour $PM_{2.5}$ averaging periods, and the EPA notes that associations with sub-daily estimates are less consistent and, in some cases, smaller in magnitude (U.S. EPA, 2019a, section 1.5.2.1; U.S. EPA, 2022b, section 3.6.3.2.2). In addition, controlled human exposure and panel-

based studies of sub-daily exposures typically examine subclinical effects rather than the more serious population-level effects that have been reported to be associated with 24-hour exposures (e.g., mortality, hospitalizations). Taken together, the 2019 ISA concludes that epidemiologic studies do not indicate that subdaily averaging periods are more closely associated with health effects than the 24-hour average exposure metric (U.S. EPA, 2019a, section 1.5.2.1). Additionally, while recent controlled human exposure studies provide consistent evidence for cardiovascular effects following $PM_{2.5}$ exposures for less than 24 hours (i.e., < 30 minutes to 5 hours), exposure concentrations in these studies are well-above the ambient concentrations typically measured in locations meeting the current standards (U.S. EPA, 2022b, section 3.3.3.1). Therefore, these studies do not provide support for additional protection against sub-daily $PM_{2.5}$ exposures, beyond that provided by the current primary standards. In its advice on the adequacy of the current primary $PM_{2.5}$ standards, the CASAC reached consensus that averaging times for the standards should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter). Thus, as in the 2020 review (85 FR 82715, December 18, 2020), and consistent with the advice from the CASAC, the Administrator reaches the proposed conclusion that the currently available evidence does not support considering alternatives to the annual and 24-hour averaging times for standards meant to protect against long- and short-term $PM_{2.5}$ exposures.

With regard to form, the Administrator proposes to conclude that it is appropriate to consider retaining the current form of both the annual and the 24-hour standards. In so doing, he first notes that, in the 1997 review, the EPA set both an annual standard, to provide protection from health effects associated with both long- and short-term exposures to $PM_{2.5}$, and a 24-hour standard to a supplement the protection afforded by the annual standard (62 FR 38667, July 18, 1997). With regard to the form of the annual standard, the Administrator recognizes that a large

majority of the recently available epidemiologic studies continue to report associations between health effects and annual average $PM_{2.5}$ concentrations. These studies of annual average $PM_{2.5}$ concentrations provide support for retaining the current form of the annual standard to provide protection against long- and short-term $PM_{2.5}$ exposures. In its advice on the adequacy of the current standards, the CASAC reached consensus that the form of the annual standard (i.e., annual mean, averaged over 3 years) should be retained, without revision (Sheppard, 2022a, p. 2 of consensus letter). In relation to the form of the 24-hour standard (98th percentile, averaged over three years), the Administrator notes that epidemiologic studies continue to provide strong support for health effect associations with short-term (e.g., mostly 24-hour) $PM_{2.5}$ exposures (U.S. EPA, 2022b, section 3.6.3.2.3) and that controlled human exposure studies provide evidence for health effects following single short-term "peak" $PM_{2.5}$ exposures. Thus, the evidence supports retaining a standard focused on providing supplemental protection against short-term peak exposures and supports a 98th percentile form for a 24-hour standard. The Administrator further notes that this form also provides an appropriate balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk management programs (U.S. EPA, 2022b, section 3.6.3.2.3). While the CASAC provided recommendations regarding the adequacy of the current 24-hour standard conditional on the current form (i.e., $98^{th}$ percentile, averaged over three years), they recommended that in future reviews, the EPA also consider alternative forms for the primary 24-hour $PM_{2.5}$ standard (Sheppard, 2022a, p. 18 of consensus responses). Furthermore, the Administrator notes that the multi-year percentile form (i.e., averaged over three years) offers greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values will lead to transient violations of the standard. Thus, in considering the information summarized

above, and consistent with the advice from the CASAC, the Administrator reaches the preliminary conclusion that it is appropriate to consider retaining the forms of the current annual and 24-hour $PM_{2.5}$ standards. The Administrator solicits public comment on the proposed decision to retain the current form ($98^{th}$ percentile, averaged over three years) of the primary 24-hour $PM_{2.5}$ standard. The Administrator acknowledges that the CASAC recommended retaining the current form at this time but also recommended that the EPA consider alternatives to the current form in future reviews. The EPA agrees that it would be appropriate to gather additional air quality and scientific information and further consider these issues in future reviews. This information will not be utilized for this reconsideration process.

With regard to the level of the current standards, the Administrator first considers the scientific evidence evaluated in the 2019 ISA and ISA Supplement, and considerations regarding the evidence as presented in the PA. The Administrator recognizes that the PA places greater weight on epidemiologic studies conducted in the U.S. and Canada, as these studies are more directly applicable for quantitative considerations compared to studies conducted in other countries. Studies conducted in other countries outside of the U.S. and Canada generally reflect different populations, exposure characteristics, air pollution mixtures, and higher $PM_{2.5}$ concentrations in ambient air than are currently found in the U.S. Therefore, consistent with approaches in previous reviews, the Administrator judges that it is appropriate to place greater weight on the U.S. and Canadian epidemiologic studies in reaching conclusions regarding the adequacy of the current standards. In so doing, the Administrator notes that the epidemiologic studies in the U.S. and Canada report health effect associations with mortality and/or morbidity across multiple cities and in diverse populations, including in studies examining populations and lifestages that may be at increased risk of experiencing a $PM_{2.5}$-related health effect (e.g., older

adults, children, populations with pre-existing cardiovascular and respiratory disease, minority populations, and low SES communities). Further, he notes the epidemiologic studies that use a variety of statistical designs and employ a variety of methods to examine exposure measurement error as well as to control for confounding effects, and he acknowledges that results of these analyses support the robustness of the reported associations. Additionally, the Administrator notes findings from an expanded body of studies that employ alternative methods for confounder control and accountability methods further inform the causal nature of the relationship between long or short-term term $PM_{2.5}$ exposure and mortality as described in the 2019 ISA and ISA Supplement (U.S. EPA, 2019, sections 11.1.2.1, 11.2.2.4; U.S. EPA, 2022a, sections 3.1.1.3, 3.1.2.3, 3.2.1.3, and 3.2.2.3). These studies, summarized above in II.B.3 above and in Table 3-11 and Table 3-12 of the PA (U.S. EPA, 2022b) examine both short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality, and, using a variety of statistical methods to control for confounding bias, consistently report positive associations, which further supports the broader body of epidemiologic evidence for both cardiovascular effects and mortality. Moreover, the Administrator notes that recent epidemiologic studies strengthen support for health effect associations at $PM_{2.5}$ concentrations lower than in those evaluated in epidemiologic studies available at the time of previous reviews. Lastly, the Administrator notes that studies that examine the shape of the C-R relationship over the full distribution of ambient $PM_{2.5}$ concentrations have not identified a threshold concentration, below which associations no longer exist (U.S. EPA, 2019a, section 1.5.3; U.S. EPA, 2022a, sections 2.1.1.5.1 and 2.1.1.5.2). However, the Administrator also notes that uncertainties remain about the shape of the C-R curve at $PM_{2.5}$ concentrations < 8 $\mu g/m^3$, with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations (section II.B.4 above;

U.S. EPA, 2019a, section 11.2.4; U.S. EPA, 2022a , section 2.2.3.2).

In considering the available scientific evidence to inform proposed decisions on the adequacy of the current level of the annual standard, the Administrator acknowledges that the evidence available in this reconsideration provides support for adverse health effect associations at lower ambient $PM_{2.5}$ concentrations than in previous reviews. The Administrator notes that in previous reviews (including 1997, 2006 and 2012 reviews), evidence-based approaches focused on identifying standard levels near or somewhat below long-term mean concentrations reported in key epidemiologic studies. These approaches were supported by the CASAC in previous reviews and are supported in this reconsideration by the current CASAC, who also referenced the potential for considering other lines of epidemiologic evidence.[99] The Administrator notes that in this reconsideration, a large number of key U.S. epidemiologic studies report positive and statistically significant associations for air quality distributions with overall mean $PM_{2.5}$ concentrations that are well below the current level of the annual standard of 12 $\mu g/m^3$ (i.e., Figure 1 and Figure 2 above with concentrations ranging down as low as 9.9 $\mu g/m^3$ in U.S.-based monitor-based studies and 9.3 $\mu g/m^3$ in U.S.-based hybrid model-based studies). The Administrator also recognizes that, while Canadian studies can be more difficult to directly compare to the annual design value used to determine in compliance in the U.S., the overall mean $PM_{2.5}$ concentrations from the key Canadian epidemiologic studies are close to, though somewhat lower than, those from the U.S. studies. The range of monitor-based mean $PM_{2.5}$ concentrations is from 6.9 $\mu g/m^3$ to 13.3 $\mu g/m^3$ while the range of mean $PM_{2.5}$ concentrations in

[99] The Administrator notes that some members of the CASAC advised that "for the purpose of informing the adequacy of the standards" (Sheppard, 2022a, p. 8 of consensus responses) that the EPA in future reviews include evaluation of other metrics, including the distribution of concentrations reported in epidemiologic studies and in analyses restricting concentrations to below the current standard level.

studies that use hybrid modeling is 5.9 $\mu g/m^3$ to 9.8 $\mu g/m^3$.

In assessing the adequacy of the current annual standard, the Administrator also examines additional epidemiologic studies, consistent with CASAC advice, that provide supplementary information for consideration in reaching conclusions regarding the current annual standard. These studies include analyses that restrict annual average $PM_{2.5}$ concentrations to values below level the annual standard (described above in section II.B.3.b and in Table 3-10 of the PA) and the CASAC advised that "for the purpose of informing the adequacy of the standards" that the EPA evaluate the means from these studies. In this reconsideration, there are two key studies available that restrict average annual $PM_{2.5}$ concentrations to less than 12 $\mu g/m^3$ (Di et al., 2017a and Dominici et al., 2019). These restricted analyses report positive and statistically significant associations with all-cause mortality and report mean $PM_{2.5}$ concentrations of 9.6 $\mu g/m^3$. Thus, these two epidemiologic studies provide support for positive and statistically significant associations at lower mean $PM_{2.5}$ concentrations. The Administrator does note that uncertainties exist in these analyses (described in more detail in sections II.B.3.b and II.D.2.a above), including uncertainty in how studies exclude concentrations (e.g., at what spatial resolution are concentrations being excluded), which would make any comparisons of concentrations in restricted analyses difficult to compare directly to design values.

In considering the available key U.S. epidemiologic studies, the Administrator also notes that CASAC recommended looking at the distribution of concentrations reported in epidemiologic studies for purposes of informing the adequacy of the standards and notes that a small number of studies report $PM_{2.5}$ concentrations corresponding to the $25^{th}$ and $10^{th}$ percentiles of health data or exposure estimates. He observes that in studies that use monitors to estimate $PM_{2.5}$ exposures, $25^{th}$ percentiles of health events correspond to $PM_{2.5}$ concentrations

(i.e., averaged over the study period for each study city) at or above 11.5 $\mu g/m^3$ and 10th percentiles of health events correspond to $PM_{2.5}$ concentrations at or above 9.8 $\mu g/m^3$ (i.e., 25% and 10% of health events, respectively, occur in study locations with $PM_{2.5}$ concentrations below these values) (Figure 1 above and U.S. EPA, 2022b, Figure 3-8). The Administrator further observes that of the key U.S. epidemiologic studies that use hybrid modeling approaches to estimate long-term $PM_{2.5}$ exposures, the ambient $PM_{2.5}$ concentrations corresponding to 25th percentiles of estimated exposures are 9.1 $\mu g/m^3$ (Figure 2 above and U.S. EPA, 2022b, Figure 3-14). In key U.S. epidemiologic studies that use hybrid modeling approaches to estimate short-term $PM_{2.5}$ exposures, the ambient concentrations corresponding to $25^{th}$ percentiles of estimated exposures, or health events, are 6.7 $\mu g/m^3$ and the ambient $PM_{2.5}$ concentration corresponding to that 10th percentile range from 4.7 $\mu g/m^3$ to 7.3 $\mu g/m^3$ (Figure 2 above and U.S. EPA, 2022b, Figure 3-14). While the Administrator places less weight on the limited number of studies that report these lower quartiles of the air quality distributions, he notes these concentrations are generally below the level of the annual standard of 12 $\mu g/m^3$.

In further assessing the adequacy of the current annual standard, the Administrator also evaluates what the accountability studies may indicate with respect to potential for improvements in public health with improvements in air quality. In so doing, he takes note of three accountability studies (Sanders et al., 2020b; Corrigan et al., 2018; and Henneman et al., 2019a) newly available in this reconsideration with starting concentrations at or below 12.0 $\mu g/m^3$ that indicate positive and significant associations with mortality and morbidity and reductions in ambient $PM_{2.5}$ (described above in section II.B.3.b and in Table 3-12 of the PA) and notes that these studies suggest public health improvements may occur at concentrations below 12 $\mu g/m^3$.

Thus, in considering the available scientific evidence to inform proposed decisions on the

adequacy of the current primary annual $PM_{2.5}$ standard, the Administrator recognizes that there is a long-standing body of epidemiologic evidence that provides support for associations between $PM_{2.5}$ exposures and health effects across a distribution of air quality that includes concentrations near (i.e., at, above, and below) the current standards. As such, the Administrator recognizes that the available scientific evidence, as assessed in the 2019 ISA and ISA Supplement, including the newly available epidemiologic studies and the supplemental information from specific types of epidemiologic studies, provides a strong scientific foundation for consideration of the adequacy of the level of the current annual standard.

In considering the available scientific evidence to inform proposed decisions on the adequacy of the current 24-hour standard, the Administrator finds that there is less information available to support decisions on the 24-hour standard than that summarized above for the annual standard. When looking to the experimental studies, he notes that controlled human exposure studies provide evidence for health effects following single, short-term exposures to $PM_{2.5}$ concentrations that are greater than those typically present in ambient air. In the controlled human exposure studies, the Administrator observes that results are inconsistent, particularly at lower $PM_{2.5}$ concentrations, but that studies do report statistically significant effects on one or more indicators of cardiovascular function following 2-hour exposures to $PM_{2.5}$ concentrations at and above 120 $\mu g/m^3$ (and at and above 149 $\mu g/m^3$ for vascular impairment, the effect shown to be most consistent across studies). As noted in the 2019 ISA, these studies are important in establishing biological plausibility for $PM_{2.5}$ exposures causing more serious health effects, such as those seen in short-term exposure epidemiologic studies. However, as noted in the PA, the observed effects in these controlled human exposures studies are ones that signal an intermediate effect in the body, likely due to short-term exposure to $PM_{2.5}$, and which may provide support

that more adverse effects may be experienced following longer exposure durations and/or exposure to higher concentrations but such intermediate effects typically would not, by themselves, be judged as adverse. Additionally, he acknowledges, as noted by the CASAC, that these controlled human exposure studies generally do not include populations with substantially increased risk from exposure to $PM_{2.5}$, such as children, older adults, or those with more severe underlying illness. So, noting these points and balancing these limitations (i.e., that the health outcomes observed in these controlled human exposure studies are not clearly adverse and that the studies generally do not include those at increased risk from $PM_{2.5}$ exposure), the Administrator examines the air quality analyses, described in more detail in section II.B.3.a above, to assess whether during recent air quality conditions, areas meeting the current standards would experience the concentrations reported in these controlled human exposure studies. He observes that these air quality analyses demonstrate that the $PM_{2.5}$ exposures shown to cause consistent effects in the controlled human exposure studies are well-above the ambient concentrations typically measured in locations meeting the current primary standards, thus suggesting that the current primary $PM_{2.5}$ standards provide protection against these "peak" concentrations. In fact, at air quality monitoring sites meeting the current primary $PM_{2.5}$ standards (i.e., the 24-hour standard and the annual standard), the 2-hour concentrations generally remain below 10 $\mu g/m^3$, and rarely exceed 30 $\mu g/m^3$. Two-hour concentrations are higher at monitoring sites violating the current standards, but generally remain below 16 $\mu g/m^3$ and rarely exceed 80 $\mu g/m^3$. Based on this information, the Administrator finds that the current suite of standards maintains sub-daily concentrations far below the current concentrations in controlled human exposure studies where consistent effects have been observed, and notes that while these studies generally do not include the most at-risk individuals, the exposure

concentrations in these studies also do not elicit adverse effects.

In addition, the Administrator also notes that the majority of the CASAC provide support for their advice to revise the current daily standard by pointing to "substantial epidemiologic evidence from both morbidity and mortality studies" which "includes three U.S. air pollution studies with analyses restricted to 24-hour concentrations below 25 $\mu g/m^3$" (Sheppard, 2022a, p. 17 consensus responses). In considering this advice from the majority of the CASAC, the Administrator notes that the substantial epidemiologic evidence available in this reconsideration, including the studies that restrict short-term (24-hour average $PM_{2.5}$ concentrations) $PM_{2.5}$ exposures below 25 $\mu g/m^3$, provides support for positive and statistically significant associations between exposure to short-term $PM_{2.5}$ concentrations and all-cause mortality (Di et al., 2017a) and CVD hospital admissions (deSouza et al., 2021 and Di et al., 2017a). In particular, for the available epidemiologic studies that employ restricted analyses of short-term exposure studies, multicity studies indicate that positive and statistically significant associations with mortality persist in analyses restricted to short-term (24-hour average $PM_{2.5}$ concentrations) $PM_{2.5}$ exposures below 35 $\mu g/m^3$ (Lee et al., 2015), below 30 $\mu g/m^3$ (Shi et al., 2016), and below 25 $\mu g/m^3$ (Di et al., 2017a). Thus, the Administrator agrees that these studies help to provide additional support for reaching conclusions on causality in the 2019 ISA. Additionally, when considering these studies, the restricted approach in these short-term studies most clearly indicates that risks associated with short-term $PM_{2.5}$ exposures are not disproportionately driven by the peaks of the air quality distribution. While this is useful information, it does not help to inform questions on the adequacy of the current 24-hour standard given that the 24-hour standard focuses on reducing "peak" exposures (with its $98^{th}$ percentile form). In further evaluating these studies, the Administrator notes that the fact that there are positive and significant associations in

these analyses does not mean that one can conclude that there would be short-term effects occurring in areas that meet a 24-hour standard at these levels. This is true for multiple reasons. First, there are uncertainties with respect to the methodologies used in these studies to exclude concentrations and the specific methodology used (e.g., are individual days with concentrations above the concentration of interest in the restricted analyses excluded at the modeled grid cell level or the ZIP code level rather than removing entire areas with day(s) that exceed that concentration) has direct implications for the resulting air quality scenario(s). This in turn affects how the adjusted air quality scenarios in these studies can be related to air quality distributions and exposures to $PM_{2.5}$ concentrations in ambient air and thus how the data can be interpreted with regard to the current standard level. Second, given that these studies are only evaluating daily or annual average $PM_{2.5}$ concentrations that would correspond to the levels of the standards, they do not consider these levels along with the forms and averaging times of the standards. This is quite limiting for use in judging the adequacy of the 24-hour standard given that the study-reported mean concentration is not useful in informing the level of a standard with a $98^{th}$ percentile form that is designed to limit exposures to peak $PM_{2.5}$ concentrations. Further, as noted in the PA, the study-reported means from these studies, are not useful in identifying a level at which we can say with some confidence that effects are occurring due to impacts from "peak" exposures (i.e., those most closely aligned with the protection provide by the 24-hour standard, with its $98^{th}$ percentile form) but are instead more useful in informing questions about impacts from "typical" or average 24-hour exposures (i.e., those most closely aligned with the protection provided by the annual standard). These uncertainties and lack of information available from these studies are quite limiting and as such, the Administrator concludes that it is unclear how to apply these studies to a decision framework that could inform whether the level

of the current 24-hour standard is or is not adequate. However, the Administrator notes this uncertainty may not be quite as limiting for using restricted analyses studies to inform conclusions regarding the adequacy of the annual standard, given that the study-reported means could be evaluated in the context of the decision framework described above for informing proposed decisions on the level of the annual standard. However, in considering the available evidence with regard to the current 24-hour $PM_{2.5}$ standard, while the Administrator agrees with the majority of the CASAC's comment that the controlled human exposure studies have significant limitations which must be considered when reaching conclusions on the adequacy of the current 24-hour standard, he finds that restricted analyses studies have significant limitations and do not provide a stronger line of evidence with which to inform his proposed decisions on the current 24-hour standard.

In addition to the evidence above, the Administrator also considers what the risk assessment indicates with regard to the adequacy of the current primary annual and 24-hour $PM_{2.5}$ standards. These analyses provide estimates of $PM_{2.5}$-attributable mortality which are estimated based on input data that include C-R functions from epidemiologic studies that have no threshold and a linear C-R relationship down to zero, as well an air quality adjustment approach that incorporates proportional decreases in $PM_{2.5}$ concentrations to meet lower standard levels. The Administrator observes that the risk assessment estimates that the current primary annual $PM_{2.5}$ standard could allow a substantial number of deaths in the U.S. For example, when air quality in 30 study areas is adjusted to simulate just meeting the current annual standard, the risk assessment estimates long-term $PM_{2.5}$ exposures to be associated with as many as 39,000 total deaths, with confidence intervals ranging from 26,000-51,000. The Administrator notes that these estimates do not reflect uncertainties in associations of health effects at lower

concentrations and simulated air quality improvements will always lead to proportional decreases in risk (i.e., each additional $\mu g/m^3$ reduction produces additional benefits with no clear stopping point). Noting these limitations and noting that the absolute numbers of estimated deaths vary across exposure durations, populations, and C-R functions, he also observes that the general magnitude of risk estimates supports the potential for significant public health impacts in locations meeting the current primary annual $PM_{2.5}$ standard. He observes that this is particularly the case given that the large majority of $PM_{2.5}$-associated deaths for air quality just meeting the current annual standard are estimated at annual average $PM_{2.5}$ concentrations from about 10 to 12 $\mu g/m^3$, annual average $PM_{2.5}$ concentrations that fall well within the range of long-term average concentrations over which key epidemiologic studies provide strong support for reported positive and statistically significant $PM_{2.5}$ health effect associations. With respect to the CASAC's advice on the risk assessment, the Administrator notes that the majority of the CASAC agreed that "[t]he results support the conclusion that the current primary annual $PM_{2.5}$ standard does not adequately protect public health" (Sheppard, 2022a, p. 2 of consensus letter) and that "[t]he CASAC concurs with the EPA's assessment that meaningful risk reductions will result from lowering the annual $PM_{2.5}$ standard" (Sheppard, 2022a, p. 3 of consensus letter). Additionally, the minority of CASAC also agreed that the risk assessment results support revision to the annual standard but commented that there were important uncertainties in the analyses and interpretation of the analyses for annual standard levels below 10 $\mu g/m^3$ (Sheppard, 2022a, p. 3 of consensus letter).

The Administrator also recognizes that the risk assessment was able to include a new analysis based on the availability of a new study in this reconsideration that provided mortality risk coefficients for older adults (i.e., 65 years and older) based on $PM_{2.5}$ exposure and stratified

by racial and ethnic demographics. This at-risk analysis provided estimates of potential long-term $PM_{2.5}$-attributable exposure and mortality risk in older adults, stratified by racial/ethnic demographics, when meeting a revised annual standard with a lower level. The Administrator recognizes that this analysis is subject to the same uncertainties as those associated with the main risk assessment estimates, including being limited to a subset of areas across the U.S. and influenced by air quality adjustment methodologies that may not produce estimates of $PM_{2.5}$ concentration exposures that match those that can result from control strategies implemented to meet more stringent standards, and that the results are based on the risk coefficients of only one epidemiologic study. Taking into account these uncertainties and limitations, he does judge that the analysis supports that a lower annual standard level (i.e., below 12 $\mu g/m^3$ and down as low as 8 $\mu g/m^3$) will help to reduce $PM_{2.5}$ exposure and may also help to mitigate risk disparities. The Administrator notes that what urban areas are included in the risk assessment analysis will greatly influence the results but notes that based on the areas included in the analyses, the results show the largest impact is on reducing exposure and risk in Black populations, who were estimated in the risk assessment case study areas to have the highest levels of exposures and the greatest rates of premature mortality risk.

With respect to the 24-hour standard, the risk assessment indicates that the annual standard is the controlling standard across most of the urban study areas evaluated. When air quality is adjusted to just meet an alternative 24-hour standard level of 30 $\mu g/m^3$ in the areas where the 24-hour standard is controlling, the risk assessment estimates reductions in $PM_{2.5}$-associated risks across a more limited population and number of areas compared to when air quality is adjusted to simulate alternative levels for the annual standard, and these predictions are largely confined to areas located in the western U.S., several of which are also likely to

experience risk reductions upon meeting a revised annual standard. With respect to CASAC advice, the Administrator notes that the minority of CASAC advised that these results suggest that the annual standard can be used to limit both long- and short-term $PM_{2.5}$ concentrations and views these risk assessment results as supporting the conclusion that the current 24-hour standard is adequate (Sheppard, 2022a, p. 4 of consensus letter). In contrast, the majority of CASAC members commented that they placed greater weight on the evidence-based considerations than on the values estimated by the risk assessment, noting the potential for uncertainties in how the risk assessment was able to "capture areas with wintertime stagnation and residential wood-burning where the annual standard is less likely to be protective" (Sheppard, 2022a, p. 4 of consensus letter). The majority of the CASAC members further state that "[t]here is also less confidence that the annual standard could adequately protect against health effects of short-term exposures. A range of 25-30 $\mu g/m^3$ for the 24-hour $PM_{2.5}$ standard would be adequately protective" (Sheppard, 2022a, p. 4 of consensus letter). The majority of the CASAC members further state that "[t]here is also less confidence that the annual standard could adequately protect against health effects of short-term exposures. A range of 25-30 $\mu g/m^3$ for the 24-hour $PM_{2.5}$ standard would be adequately protective" (Sheppard, 2022a, p.4 of consensus letter).

In considering the application of the risk assessment in a decision framework assessing the adequacy of the current 24-hour standard, the Administrator again notes that the risk assessment analyses of $PM_{2.5}$-attributable mortality use input data that include C-R functions from epidemiologic studies that have no threshold and a linear C-R relationship down to zero, as well an air quality adjustment approach that incorporates proportional decreases in $PM_{2.5}$ concentrations to meet lower standard levels, and that this quantitative approach does not incorporate any elements of uncertainty in associations of health effects at lower concentrations

and simulated air quality improvements will always lead to proportional decreases in risk (i.e., each additional $\mu g/m^3$ reduction produces additional benefits with no clear stopping point). Therefore, the Administrator recognizes that the risk estimates can help to place the evidence for specific health effects into a broader public health context but should be considered along with the inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with $PM_{2.5}$ exposure and related health effects. The Administrator also notes that in the U.S., current air quality shows that the 24-hour standard is controlling in very few areas and thus, it is understandable that there are very few areas that would be included in the study areas in the risk assessment. The Administrator also recognizes that the risk assessment did not provide quantitative information on risk impacts associated with an alternative 24-hour standard level of 25 $\mu g/m^3$.

Based on the above considerations, the Administrator reaches the proposed conclusion that the available scientific evidence (summarized above in section II.B) and quantitative risk assessment (summarized above in section II.C), can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current annual standard. In reaching this conclusion, the Administrator places weight on the extensive epidemiologic evidence available in this reconsideration, strengthened from previous reviews, showing associations between adverse health effects (particularly cardiovascular effects and mortality) and long-term mean $PM_{2.5}$ concentrations, and notes the number and strength of studies available showing associations with mean $PM_{2.5}$ concentrations well below the current annual standard of 12.0 $\mu g/m^3$. The Administrator also takes note of the evidence supporting the biological plausibility of these associations, including toxicological studies and controlled human exposure studies. When turning to additional information from the epidemiologic evidence base, he notes

the advice from CASAC to also consider the 25th percentile of the data that is available and the study reported means from long-term studies that restrict concentrations to below 12 $\mu g/m^3$. When considering the 25th percentile of the data, the Administrator notes that it is available from a limited number of epidemiologic studies and that the current level of the annual standard is above most of the 25th percentile values reported in the key epidemiologic studies. When looking to the restricted analyses studies, he notes that there are two studies that report positive and statistically significant associations with all-cause mortality, and report a study mean $PM_{2.5}$ concentration of 9.6 $\mu g/m^3$. While noting the limited nature of these two lines of evidence and the associated uncertainties, the Administrator does judge that these data support the need to revise the annual standard level. Lastly, with respect to the epidemiologic evidence, the Administrator also takes into account accountability studies newly available in this reconsideration with starting concentrations at or below 12.0 $\mu g/m^3$ that indicate positive and significant associations with mortality and morbidity and reductions in ambient $PM_{2.5}$ and notes that these studies suggest public health improvements may occur at concentrations below 12 $\mu g/m^3$.

The Administrator also considers the results of the risk assessment in light of the information it provides on risks associated with the current and more stringent levels of the annual standard. While he recognizes a number of uncertainties and limitations associated with the quantitative estimates of the risk assessment, he judges that the estimated risks remaining under air quality adjusted to just meet the current suite of standards are too high to be considered requisite to protect public health with an adequate margin of safety, noting in particular the large number of premature deaths estimated to remain with air quality that just meets the current annual standard. The Administrator also recognizes that the risk assessment was able to include a

new analysis (at-risk analysis) that provided estimates of potential long-term $PM_{2.5}$-attributable exposure and mortality risk in older adults, stratified by racial/ethnic demographics, when meeting a revised annual standard with a lower level. While the Administrator recognizes that this analysis is subject to multiple uncertainties and limitations (as noted above in sections II.C.2 and II.D.2.b), he does judge that the analysis suggests that a lower annual standard level (i.e., below 12 $\mu g/m^3$ and down as low as 8 $\mu g/m^3$) will help to reduce $PM_{2.5}$ exposure and may also help to mitigate exposure and risk disparities. Finally, the Administrator considers the advice from the CASAC, who unanimously recommended revising the annual standard.

The Administrator finds it is less clear whether the available scientific evidence and quantitative information call into question the adequacy of the public health protection afforded by the current 24-hour standard, particularly when considered in conjunction with the protection provided by the suite of standards and the proposed decision to revise the annual standard. In considering the scientific evidence, he notes that the controlled human exposure studies do not provide a threshold below which no effects occur and they do not include the most at-risk populations. However, the concentrations reported in these studies are for observed effects that signal a change in the body likely due to short-term exposure to $PM_{2.5}$ and which may be the prelude to more adverse effects following longer duration and/or higher concentration exposures but typically would not, by themselves, be judged as adverse. Balancing this with the observation that the air quality concentrations in areas meeting the current standards are well below the $PM_{2.5}$ concentrations shown to elicit effects in these studies, the Administrator does not judge that these studies call into question the adequacy of the current 24-hour standard. With respect to the epidemiologic evidence, the Administrator notes that the body of epidemiologic evidence provides limited support for judging adequacy of the level of the 24-hour standard. As discussed

in detail above (section II.B.3.b), epidemiologic studies provide the strongest support for reported health effect associations for the part of the air quality distribution corresponding to the bulk of the underlying data (i.e., estimated exposures and/or health events), often around the overall mean concentrations evaluated rather than near the upper end of the distribution. While there are three studies available in this reconsideration that restricted 24-hour concentrations to concentrations below 25 $\mu g/m^3$ and while some members of CASAC pointed to these studies as the basis for their recommendation to revise the 24-hour standard, the Administrator preliminarily concludes that the results from these studies, particularly in light of the uncertainties associated with these studies (as discussed above), are an inadequate basis for revising the level of the 24-hour $PM_{2.5}$ standard.

When evaluating the risk assessment information, the Administrator notes that the risk assessment estimates a reduction of 9-13% $PM_{2.5}$ attributable mortality in areas where the 24-hour standard is controlling when the 24-hour $PM_{2.5}$ standard is reduced from a level of 35 $\mu g/m^3$ to 30 $\mu g/m^3$. The Administrator notes that this estimated reduction in $PM_{2.5}$-associated risks is across a more limited population and is largely confined to a small number of areas located in the western U.S. Other areas included in the risk assessment were shown to experience risk reductions that were driven primarily by meeting a lower annual standard level (though the associated change in air quality also resulted in lower 24-hour standard concentrations). With respect to CASAC advice, the Administrator notes that the majority of CASAC advised that less weight be placed, while the minority of CASAC advised that these risk assessment results support the conclusion that the current 24-hour standard is adequate (Sheppard, 2022a, p. 4 of consensus letter), the majority of CASAC advised that less weight be placed on the risk assessment results and noted the potential for uncertainties in how the risk assessment was able to

"capture areas with wintertime stagnation and residential wood-burning where the annual standard is less likely to be protective" (Sheppard, 2022a, p. 4 of consensus letter).

Based on the current evidence and quantitative information, as well as consideration of CASAC advice and public comment thus far in this reconsideration, the Administrator proposes to conclude that the current primary $PM_{2.5}$ standards are not adequate to protect public health with an adequate margin of safety. While he notes that the scientific evidence and quantitative information clearly call into question the adequacy of the public health protection afforded by the current annual standard, the Administrator finds it is less clear whether the available scientific evidence and quantitative information calls into question the adequacy of the public health protection afforded by the current 24-hour standard. In considering how to revise the suite of standards to provide the requisite degree of protection, he recognizes that changes in $PM_{2.5}$ air quality designed to meet either the annual or the 24-hour standard would likely result in changes to both long-term average and short-term peak $PM_{2.5}$ concentrations. He also recognizes that the current annual standard and 24-hour standard, together, are intended to provide public health protection against the full distribution of short- and long-term $PM_{2.5}$ exposures. As noted above, the annual standard is targeted at controlling the typical exposures for which the evidence of adverse health effects is strongest. The Administrator places the most weight on the large number and strength of epidemiologic studies that report positive, and often statistically significant, associations with long-term mean reported $PM_{2.5}$ concentrations well below the current level of the annual standard of 12.0 $\mu g/m^3$, as well as corroborating evidence from U.S. accountability studies with starting concentrations below 12 $\mu g/m^3$ and studies that found positive and statistically significant associations in analyses restricted to concentrations less than 12 $\mu g/m^3$. In considering the risk assessment information, he notes that, for most of the U.S., the

annual standard is the controlling standard and that the risk assessment estimates reductions in $PM_{2.5}$-associated risks across more of the population and in more areas with alternative annual standard levels compared to estimates for alternative 24-hour standard levels. Moreover, the Administrator notes that a more stringent annual standard has been shown to effectively reduce both average (annual) concentrations and peak (daily) concentrations, ensuring the broadest protection of public health. Finally, the Administrator notes that the CASAC was unanimous in its advice regarding the need to revise the annual standard, although they did not reach consensus on what range of alternative levels would be most appropriate to consider. Thus, in considering how to revise the suite of standards to provide the requisite degree of protection, the Administrator proposes to conclude it is appropriate to focus on revising the annual standard.

b. Consideration of Alternative Primary Annual $PM_{2.5}$ Standard Levels

This section summarizes the Administrator's conclusions and proposed decisions related to the current primary annual $PM_{2.5}$ standard and presents his proposed decision to revise the level of the current annual standard within the range of 9.0 to 10.0 $\mu g/m^3$, in conjunction with retaining the current indicator, averaging time, and form of that standard. The EPA is also soliciting public comment on alternative annual standard levels down to 8.0 $\mu g/m^3$ and up to 11.0 $\mu g/m^3$, on an alternative 24-hour standard level as low as 25 $\mu g/m^3$ and on the combination of annual and 24-hour standards that commenters may believe is appropriate, along with the approaches and rationales used to support such levels.

In establishing primary standards under the Act that are "requisite" to protect public health with an adequate margin of safety, the Administrator is seeking to establish standards that are neither more nor less stringent than necessary for this purpose. He recognizes that the requirement to provide an adequate margin of safety was intended to address uncertainties

associated with inconclusive scientific and technical information and to provide a reasonable degree of protection against hazards that research has not yet identified. However, the Act does not require that primary standards be set at a zero-risk level; rather, the NAAQS must be sufficiently protective, but not more stringent than necessary.

Having reached the conclusion that the current indicator, averaging time, and form of the standard are appropriate for the reasons outlined above, the Administrator next considers the range of potential alternative standard levels that could be reasonably supported by the available scientific evidence and risk-based information to increase public health protection against short-term and long-term $PM_{2.5}$ exposures. The evidence available in this reconsideration regarding $PM_{2.5}$ exposures associated with health effects affirms and strengthens the evidence available at the completion of the 2009 ISA, taking into account studies evaluated in the 2019 ISA and ISA Supplement. The Administrator recognizes that the weight of evidence is strongest for health effects for which the 2019 ISA concludes that the evidence provides support for a causal relationship between $PM_{2.5}$ exposures and health effects, including those between long- and short-term $PM_{2.5}$ exposures and mortality and cardiovascular effects. He recognizes that the weight of evidence is also strong for health effects for which the 2019 ISA concludes that the evidence supports a likely to be causal relationship, which include long- and short-term $PM_{2.5}$ exposures and respiratory effects and long-term $PM_{2.5}$ exposures and cancer, and nervous system effects.

In considering the available scientific evidence that could inform conclusions regarding potential alternative levels of the annual $PM_{2.5}$ standard, the Administrator notes that in past reviews, the decision framework used to judge adequacy of the existing $PM_{2.5}$ standards, and what levels of any potential alternative standards should be considered, placed significant weight

on epidemiologic studies that assessed associations between $PM_{2.5}$ exposure and health outcomes that were most strongly supported by the body of scientific evidence (i.e., causal or likely to be causal determinations). In so doing, the Administrator recognizes that the number of epidemiologic studies has expanded since the completion of the 2009 ISA and the epidemiologic studies evaluated in the 2019 ISA and the ISA Supplement continue to report positive and statistically significant associations between long- and short-term exposure to $PM_{2.5}$ and mortality and morbidity.

Additionally, the Administrator recognizes that the available epidemiologic studies enable the examination of the entire population and include, and even focus on, those that may be at comparatively higher risk of experiencing a $PM_{2.5}$-related health effects. The Administrator notes that the 2019 ISA found that factors that may contribute to increased risk of $PM_{2.5}$-related health effects include lifestage (children and older adults), pre-existing diseases (cardiovascular disease and respiratory disease), and SES, and that the ISA Supplement noted new evidence that further supported racial and ethnic differences in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risks. The Administrator also observes that at-risk populations make up a substantial portion of the U.S. population (section II.B.2 above), including children (22%) and older adults (16%), as well as non-Hispanic Black (12%) and Hispanic populations (18%) and that the prevalence of pre-existing diseases varies by lifestage and race/ethnicity**.** The Administrator notes that the cohorts examined in the epidemiologic studies available in this reconsideration include diverse populations that are broadly representative of the U.S. population as a whole, and include those populations identified as at-risk (i.e., children and older adults), as well as individuals in the general population with pre-existing disease, such as cardiovascular disease and respiratory disease.

Recent epidemiologic studies also strengthen support for health effect associations at lower ambient $PM_{2.5}$ concentrations than previous reviews and studies that examine the shapes of C-R functions over the full distribution of ambient $PM_{2.5}$ concentrations have not identified a threshold concentration, below which associations no longer exist (U.S. EPA, 2019a, section 1.5.3; U.S. EPA, 2022a, sections 2.2.3.1 and 2.2.3.2).,Though these analyses are complicated by the relatively sparse data available at the lower end of the air quality distribution (U.S. EPA, 2019a, section 1.5.3), the evidence remains consistent in supporting a no-threshold relationship, and in supporting a linear relationship for $PM_{2.5}$ concentrations > 8 $\mu g/m^3$, though uncertainties remain about the shape of the C-R curve at $PM_{2.5}$ concentrations < 8 $\mu g/m^3$.

With respect to uncertainties in epidemiologic studies, a broad range of approaches have been adopted across studies to examine confounding and the results of those examinations support the robustness of reported associations. Additionally, there is a considerable amount of new epidemiologic evidence in this reconsideration, including a large number of new epidemiologic studies that use varying study designs that reduce uncertainties, including studies that employ alternative methods for confounder control and support associations between exposure and adverse health effects at lower $PM_{2.5}$ concentrations. Consistent findings from the broad body of epidemiologic studies are supported by studies employing alternative methods for confounder control, which used a variety of statistical methods to control for confounding bias and consistently report positive associations. The results of these studies support the positive and significant effects seen in cohort studies associated with short- and long-term exposure to $PM_{2.5}$ and mortality. Moreover, epidemiologic studies continue to evaluate the uncertainty related to exposure measurement error, and while none of these approaches eliminates the potential for exposure error in epidemiologic studies, the consistent reporting of $PM_{2.5}$ health effect

associations across exposure estimation approaches, even in the face of exposure error, together with the larger effect estimates reported in some studies that have attempted to reduce exposure error, provides further support for the robustness of associations between $PM_{2.5}$ exposures and mortality and morbidity. Therefore, given the strength of the available epidemiologic evidence, including the ability of these studies to provide information about impacts on the most at-risk populations, the Administrator concludes that the strongest available evidence for evaluating alternative levels of the annual standard continues to be the epidemiologic studies.

The evidence base available in this reconsideration also consists of experimental studies that include controlled human exposure studies and animal toxicological studies. These studies demonstrate health outcomes following long-term and short-term exposure to $PM_{2.5}$ at exposures that are well-above those typically found in ambient air. This body of evidence provides support for the biological mechanisms and the plausibility of the serious health effects associated with ambient $PM_{2.5}$ exposures in epidemiologic studies. Thus, the Administrator recognizes that while experimental studies may not be as useful in a decision-making framework alone, results from these studies lend further support to the use of the epidemiologic evidence base in informing the level of the annual standard.

In considering the level of the annual standard, the Administrator recognizes that the annual standard, with its form based on the arithmetic mean concentration, is most appropriately meant to limit the "typical" daily and annual exposures that are most strongly associated with the health effects observed in epidemiologic studies. However, the Administrator also recognizes that while epidemiologic studies examine associations between distributions of $PM_{2.5}$ air quality and health outcomes, they do not identify particular $PM_{2.5}$ exposures that cause effects. Thus, any approach that uses epidemiologic information in reaching decisions on what standards are

appropriate necessarily requires judgments of the Administrator about how to consider the information available from the epidemiologic studies as a basis for appropriate standards. This includes consideration of how to weigh the uncertainties in the reported associations between daily or annual average $PM_{2.5}$ exposures and mortality or morbidity in the epidemiologic studies. Such an approach is consistent with setting standards that are neither more nor less stringent than necessary, recognizing that a zero-risk standard is not required by the CAA.

Thus, in recognizing the need to weigh these uncertainties in reaching decisions on alternative standard levels to propose, the Administrator judges that it is most appropriate to examine where the evidence of associations observed in the epidemiologic studies is strongest and, conversely, where he has appreciably less confidence in the associations observed in the epidemiologic studies. Based on information evaluated in the 2019 ISA and ISA Supplement, the Administrator recognizes that health effects may occur over the full range of concentrations observed in the long- and short-term epidemiologic studies and that no discernible threshold for any effects can be identified based on the currently available evidence (U.S. EPA, 2019a, section 1.5.3, U.S. EPA, 2022a, section 2.2.3.1 and 2.2.3.2). He also recognizes, in taking note of CASAC advice and the distributional statistics analysis discussed in section II.B.3.b above and in the PA, that there is significantly greater confidence in observed associations over certain parts of the air quality distributions in the studies, and conversely, that there is significantly diminished confidence in ascribing effects to concentrations toward the lower part of the distributions.

The Administrator notes that in previous reviews, evidence-based approaches noted that the evidence of an association in any epidemiologic study is "strongest at and around the long-term average where the data in the study are most concentrated" (78 FR 3140, January 15, 2013).

Given this, these approaches focused on identifying standard levels near or somewhat below long-term mean concentrations reported in key epidemiologic studies. These approaches were supported by previous CASAC advice. The current CASAC also supported assessing the mean (or median) concentrations, but also suggested additional approaches that could be explored.[100] In utilizing this evidence-based approach, the Administrator looks to study-reported means from the key epidemiologic studies (as shown in Figure 1 and Figure 2) available in this reconsideration. He notes that there have been new approaches to estimating exposure concentrations since the 2012 review, such that many of the available key epidemiologic studies include new approaches that apply hybrid modeling techniques to estimate exposures. In looking at the epidemiologic studies, he considers these studies in two groups: (1) monitor-based studies (epidemiologic studies that used ground-based monitors to estimate exposure, similar to approaches used in past reviews), and (2) hybrid modeling-based studies (epidemiologic studies that used hybrid modeling approaches to estimate exposures). As such, he recognizes that reported mean $PM_{2.5}$ concentrations in monitor-based studies are averaged across monitors in each study area with multiple monitors, referred to as a composite monitor concentration, in contrast to the highest concentration monitored in the study area, referred to as a maximum monitor concentration (i.e., the "design value" concentration), which is used to determine whether an area meets a given standard. Further, he recognizes that studies that use hybrid modeling approaches employ methods to estimate ambient $PM_{2.5}$ concentrations across large

[100] The Administrator notes that some members of the CASAC advised that "use of the mean to define where the data provide the most evidence is conservative…" (Sheppard, 2022a, p. 3 of consensus letter) and advised that "for the purpose of informing the adequacy of the standards" (Sheppard, 2022a, p. 8 of consensus responses) that the EPA in future reviews include evaluation of other metrics, including the distribution of concentrations reported in epidemiologic studies and in analyses restricting concentrations to below the current standard level.

geographical areas, including those without monitors, and thus, when compared to monitor-based studies, require additional information to inform the relationship between the estimated $PM_{2.5}$ concentrations across an area to the maximum monitor design values used to assess compliance. For the key U.S. monitor-based epidemiologic studies, the study reported mean concentrations range from 9.9-16.5 $\mu g/m^3$ and for the U.S. hybrid modeling based key epidemiologic studies, the mean concentrations range from 9.3-12.2 $\mu g/m^3$.

In thinking further about the relationship between mean $PM_{2.5}$ concentrations in key epidemiologic studies and annual design values, the Administrator specifically notes that in a given area, the area design value is determined by the monitor in an area with the highest $PM_{2.5}$ concentrations and is used to determine compliance with the standard. He observes, as detailed above in the air quality analyses in section I.D.5, that the highest $PM_{2.5}$ concentrations spatially distributed in the area would generally occur at or near the area design value monitor and that $PM_{2.5}$ concentrations will be equal to or lower at other monitors in the area. Furthermore, since monitoring strategies aim to site monitors in areas with higher concentrations, monitored areas will generally have higher concentrations than areas without monitors. Thus, when a study reports a mean that reflects the average of annual average measured concentrations for an area, the area design value will generally be higher. Similarly, when a study reports a mean that reflects the average of annual average concentrations estimated at various points across an area using a hybrid modeling approach, the area design value will generally be higher. More specifically, the Administrator observes that the additional air quality analyses (described in section I.D.5) suggest that the area annual design value is greater than the study-reported mean values by 10-20% for monitor-based studies and 15-18% for hybrid modeling with population

weighting applied.[101] As such, the Administrator observes that a policy approach for setting a standard level that requires the design value monitor to meet study-reported means will generally result in lower concentrations of $PM_{2.5}$ across the entire area, such that even those people living near an area design value monitor (where $PM_{2.5}$ concentrations are generally highest) will be exposed to $PM_{2.5}$ concentrations below the air quality conditions reported in the epidemiologic studies where there is the highest confidence of an association.[102] In addition, he specifically notes that an annual standard level that is no more than 10-20% higher than the study-reported means in the U.S. monitor-based studies (i.e., for the lowest study reported mean value of 9.9 $\mu g/m^3$, this means an annual standard level of approximately 10.9-11.9 $\mu g/m^3$) and no more than 15-18% higher for the U.S. hybrid modeling with population weighting applied (i.e., for the lowest study reported mean value of 9.3 $\mu g/m^3$, this means an annual standard level of approximately 10.7-11.0 $\mu g/m^3$), would generally maintain air quality exposures at or below those associated with the study-reported mean $PM_{2.5}$ concentrations, exposures for which we have the strongest support for adverse health effects occurring. Based on this, the Administrator concludes that a revised standard level of 9.0 to 10.0 $\mu g/m^3$ would generally limit air quality exposures to levels well below those associated with the study-reported mean $PM_{2.5}$

[101] The Administrator also notes that there are a limited number of studies that report a study mean that does not reflect the exposure concentrations used in the epidemiologic study to assess the reported association. These studies do not report population-weighted study means and are not considered here given the substantial difference in concentrations used to assess the association versus those used to calculate the study-reported means.

[102] Based on the available air quality information, it would be expected that an area with a study reported mean of 10 $\mu g/m^3$ would have a gradient of concentrations across the area, with higher concentrations near the design value monitor and lower concentrations away from it. If the level of the standard were revised to 10.0 $\mu g/m^3$, then it would be expected that there would still be a gradient of concentrations, but the $PM_{2.5}$ concentrations across the area would be reduced in order to meet the revised standard at the design value monitor, and therefore areas away from the design value monitor would be expected to have a gradient of $PM_{2.5}$ concentrations at or below 10.0 $\mu g/m^3$ as well.

concentrations in the key epidemiologic studies. A revised standard level of 11.0 $\mu g/m^3$ would maintain air quality exposures to below those associated with most of these study-reported means, and a revised standard level of 8.0 $\mu g/m^3$ would maintain air quality exposures to far below all of these study-reported means. The Administrator notes that every member of the CASAC found that the information on study-reported means supported revising the annual standard level to 10.0 $\mu g/m^3$, with the minority of the CASAC advising that these data also supported a revised annual standard level of 10.0-11.0 $\mu g/m^3$ and the majority of the CASAC advising that these study-reported means, in conjunction with additional bodies of evidence, supported a revised annual standard level of 8.0-10.0 $\mu g/m^3$.

The Administrator also considers additional information from epidemiologic studies, consistent with CASAC advice, to take into account the broader distribution of $PM_{2.5}$ concentrations, including the 25$^{th}$ percentiles of the distributions, and the degree of confidence in the observed associations over the broader air quality distribution. In considering this additional information, he understands that the PA presented information on the distributions of $PM_{2.5}$ concentrations, when available, from key epidemiologic studies to provide a general frame of reference as to the part of the distribution within which the data become appreciably more sparse and, thus, where his confidence in the associations observed in epidemiologic studies would become appreciably less. As discussed in section II.B.3.b above and presented in Figure 1 and Figure 2 above, he observes that most studies do not report such data and the conclusions that can be drawn from such information across the full body of evidence are quite limited. However, the Administrator takes note of additional population-level data that are available and in considering the long-term $PM_{2.5}$ concentrations associated with the 25$^{th}$ percentile values of the population-level data for the studies for which such data are available, he observes that for the

three key U.S. epidemiologic studies that use hybrid modeling approaches that apply population weighting and report these data, the values reported were 6.7 $\mu g/m^3$, 9.1 $\mu g/m^3$ and 9.1 $\mu g/m^3$. For the U.S.-based studies that use ground-based monitors, the 25$^{th}$ percentiles ranged from 11.5 $\mu g/m^3$ to just below 13.0 $\mu g/m^3$.

The Administrator notes that there are substantial uncertainties associated with using 25$^{th}$ percentile data for purposes of setting this standard and these uncertainties are heightened by the relatively few studies which report such data and the fact that, by definition, this data is relatively less common even within a study for which it is reported. At the same time, the Administrator is conscious of his obligation to set primary standards with an adequate margin of safety and recognizes that some members of the CASAC advised that these data indicate that effects are occurring below the reported means of studies. Balancing these concerns about the need to provide some protection against uncertain risks with the obligation to not set standards that are more stringent than necessary, the Administrator preliminarily concludes that a revised standard should limit exposures to ambient concentrations near the 25$^{th}$ percentile of reported studies. Given this consideration, the Administrator recognizes that a standard level of 8.0-10.0 $\mu g/m^3$ is generally within the range of these values, while a standard level of 11.0 $\mu g/m^3$ is above the 25$^{th}$ percentile values reported in the hybrid model-based studies but below the 25$^{th}$ percentile values in studies that use ground-based monitors. Based on this, the Administrator recognizes that a standard within the range of 8.0-11.0 $\mu g/m^3$ would limit exposures to ambient concentrations near the 25$^{th}$ percentile reported in the available studies, with the lower end of this range further limiting those exposures.

The Administrator also takes into consideration the long-term mean $PM_{2.5}$ concentrations reported in Canadian epidemiologic studies that, in the context of the larger body of available

evidence, provided support for causal or likely to be causal determinations between $PM_{2.5}$ exposure and health effects, as summarized in the 2019 ISA and ISA Supplement. He notes that the study-reported means from these Canadian studies tend to be somewhat lower than those reported from the key epidemiologic studies in the U.S. ranging from 6.9-13.3 $\mu g/m^3$ for the monitor-based studies and 5.9-9.8 $\mu g/m^3$ for the hybrid model-based studies. However, the Administrator is also mindful that there are important differences between the exposure environments in the U.S. and Canada and that interpreting the data (e.g., mean concentrations) from the Canadian studies in the context of a U.S.-based standard may present challenges in directly and quantitatively informing decisions regarding potential alternative levels of the annual standard, as detailed above. He additionally notes that the majority of the CASAC pointed to the Canadian studies as supporting their recommendation to revise the annual standard level to within the range of 8.0-10.0 $\mu g/m^3$. Based on this, the Administrator is not excluding Canadian studies from his consideration in this reconsideration, but he is considering them in light of the limitations and challenges presented.

The Administrator also notes that the CASAC recommended looking at the studies that included analyses that restrict annual average $PM_{2.5}$ concentrations to concentrations below the level of the current annual standard in evaluating an appropriate range of levels for a revised annual standard. In this reconsideration, there are two key studies available (Di et al., 2017b and Dominici et al., 2019) that restrict annual average $PM_{2.5}$ concentrations to less than 12 $\mu g/m^3$. These restricted analyses report positive and statistically significant associations with all-cause mortality, and both report mean $PM_{2.5}$ concentrations of 9.6 $\mu g/m^3$. The Administrator does note that uncertainties exist in these analyses (described in more detail in sections II.B.3.b and II.D.2.a above), including uncertainty in how the studies exclude concentrations (e.g., at what

spatial resolution are concentrations being excluded), which would make it difficult to compare concentrations in restricted analyses directly to design values. However, he does note that an annual standard level of 9.0-10.0 $\mu g/m^3$ would be close to these reported mean values, while a standard level of 11.0 $\mu g/m^3$ would be above and a standard level of 8.0 $\mu g/m^3$ would be much further below.

The Administrator additionally considers recent U.S. accountability studies, which assess the health effects associated with actions that improve air quality (e.g., air quality policies or implementation of an intervention). The Administrator notes that there are three studies available in this reconsideration (Henneman et al. (2019b), Corrigan et al. (2018), and Sanders et al. (2020a)) that account for changes in $PM_{2.5}$ concentrations due to implementation of policies and assess whether there was evidence of changes in associations with mortality or cardiovascular morbidity due to changes in annual $PM_{2.5}$ concentrations. The Administrator notes that in each of these studies, prior to implementation of the policies, mean $PM_{2.5}$ concentrations were below the level of the current annual standard level (12.0 $\mu g/m^3$) and ranged from 10.0 $\mu g/m^3$ to 11.1 $\mu g/m^3$. The Administrator notes that these studies report positive and significant associations between mortality and cardiovascular morbidity and reductions in ambient $PM_{2.5}$ (described above in section II.B.3.b and in Table 3-12 of the PA) and notes that these studies suggest public health improvements may occur following the implementation of a policy that reduces annual average $PM_{2.5}$ concentrations below the level of the current standard of 12.0 $\mu g/m^3$. The Administrator notes that a revised annual standard level of 9.0-10.0 $\mu g/m^3$ would be at or below the lowest starting concentration of these accountability studies (i.e., 10.0 $\mu g/m^3$).

In addition to the evidence, the Administrator also considers the results of the risk assessment. The PA includes a risk assessment that estimates $PM_{2.5}$-attributable mortality risk

associated with $PM_{2.5}$ air quality that has been adjusted to simulate "just meeting" the current standards, as well as potential alternative standards. These analyses of $PM_{2.5}$-attributable mortality use input data that include C-R functions from epidemiologic studies that have no-threshold and a linear C-R relationship down to zero, as well an air quality adjustment approach that incorporates proportional decreases in $PM_{2.5}$ concentrations to meet lower standard levels. Such an approach does not incorporate any elements of uncertainty in associations of health effects at lower concentrations and simulated air quality improvements will always lead to proportional decreases in risk (i.e., each additional $\mu g/m^3$ reduction produces additional benefits with no clear stopping point). Therefore, the Administrator recognizes that the risk estimates can help to place the evidence for specific health effects into a broader public health context, but should be considered along with the inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with $PM_{2.5}$ exposure and related health effects.

The risk assessment estimates that the current primary $PM_{2.5}$ standards could allow a substantial number of $PM_{2.5}$-associated deaths in the U.S. Additionally, compared to the current annual standard, meeting a revised annual standard with a lower level is estimated to reduce $PM_{2.5}$-associated health risks in the 30 study areas controlled by the annual standard by about 7-9% for a level of 11.0 $\mu g/m^3$, 15-19% for a level of 10.0 $\mu g/m^3$, 22-28% for a level of 9.0 $\mu g/m^3$, and 30-37% for a level of 8.0 $\mu g/m^3$) (U.S. EPA, 2022a, Table 3-17). The CASAC concurred with the PA's assessment that meaningful risk reductions will result from lowering the annual $PM_{2.5}$ standard (Sheppard, 2022a, p. 16 of consensus responses).

The PA also provides information on the distribution of concentrations associated with the estimated mortality risk at each alternative standard level assessed (U.S. EPA, 2022a, sections

3.4.2.2 and 3.6.2.2, Figure 3-18 and 3-19). Further evaluating these results can help clarify the percentage of the exposure reductions that fall within the range of concentrations in which there is the most confidence in the associations and thus, confidence that estimated risk reductions will actually occur. When meeting a standard level of 11.0 $\mu g/m^3$, the risk is estimated to be associated with exposure concentrations that are generally greater than 10.0 $\mu g/m^3$, while for a standard level of 10.0 $\mu g/m^3$, the majority of the days contributing to the risk estimates are estimated to be below 10.0 $\mu g/m^3$. When meeting an annual standard or 9.0 $\mu g/m^3$, the majority of the exposure concentrations are estimated to be 8.0-9.0 $\mu g/m^3$, while for a standard level of 8.0 $\mu g/m^3$, most of the days are below 8.0 $\mu g/m^3$. The Administrator notes that the evidence suggests that majority of the study-reported means are above 10.0 $\mu g/m^3$ (concentrations at which the evidence is the strongest in supporting an association between exposure to $PM_{2.5}$ and adverse health effects observed in the key epidemiologic studies available in this reconsideration) and that at $PM_{2.5}$ concentrations less than 8.0 $\mu g/m^3$, the 2019 ISA notes that uncertainties remain in the shape of the C-R curve. He thus recognizes that there is increasing uncertainty in quantitative estimates of $PM_{2.5}$-associated mortality risk for alternative standard levels at the lower end of the range of 8.0-11.0 $\mu g/m^3$.

As discussed more above, the Administrator also recognizes that the risk assessment was able to include an at-risk analysis that estimated the potential long-term $PM_{2.5}$-attributable exposure and mortality risk in older adults, stratified by racial/ethnic demographics, when meeting a revised annual standard with a lower level. While the Administrator recognizes that this analysis is subject to the multiple uncertainties and limitations (sections II.C.2 and II.D.2.b), he does note that the analysis suggests that a revised annual standard level within the range of 8.0 to 11.0 $\mu g/m^3$ is estimated to reduce $PM_{2.5}$ exposure and may also help to mitigate risks. Based

on the case study areas included in the analysis, The Administrator notes that what urban areas are included in the risk assessment analysis will greatly influence the results but notes that based on the areas included in the analyses, the results show the largest impact is on reducing exposure and risk in Black populations, who were estimated in the risk assessment case study areas to have the highest levels of exposures and the greatest rates of premature mortality risk. The Administrator also notes that, similar to the main risk estimates discussed above, there is increasing uncertainty in quantitative estimates of stratified risk estimates at the lower end of the range of standard levels assessed.

The Administrator recognizes that judgments about the appropriate weight to place on any of the factors discussed above should reflect consideration not only of the relative strength of the evidence but also of the important uncertainties that remain in the evidence and the quantitative information being considered in this reconsideration. The Administrator also recognizes that the CAA requires him to set standards that in his judgment are neither more stringent nor less stringent than necessary to protect public health with an adequate margin of safety. Based on the above considerations, the Administrator concludes that it is appropriate to propose to set a level for the primary annual $PM_{2.5}$ standard within the range of 9.0 to 10.0 $\mu g/m^3$, while also taking comment on a level for the primary annual $PM_{2.5}$ standard as low as 8.0 $\mu g/m^3$ and as high as 11.0 $\mu g/m^3$. The Administrator provisionally concludes that a standard level within the range of 9.0 to 10.0 $\mu g/m^3$ would reflect appropriate approaches to placing the most weight on the strongest available evidence, while placing less weight on much more limited evidence and on more uncertain analyses of information available from a relatively small number of studies. He notes that a standard set at 9.0 to 10.0 $\mu g/m^3$ would be at or below the study-reported mean $PM_{2.5}$ concentrations in the key U.S. epidemiologic studies, exposures for which we have the strongest

support for adverse health effects occurring. Further, in considering margin of safety, he notes that an annual standard level that is no more than 10-20% higher than the study-reported means in the U.S. monitor-based studies (i.e., for the lowest study reported mean value of 9.9 $\mu g/m^3$, this means an annual standard level of approximately 10.9-11.9 $\mu g/m^3$) and no more than 15-18% higher for the U.S. hybrid modeling with population weighting (i.e., for the lowest study reported mean value of 9.3 $\mu g/m^3$, this means an annual standard level of approximately 10.7-11.0 $\mu g/m^3$), would generally maintain air quality exposures at or below those associated with the study-reported mean $PM_{2.5}$ concentrations. Additionally, the Administrator also notes that these key U.S. epidemiologic studies utilize cohorts that include populations identified as at-risk, including children and older adults, as well as individuals in the general population with pre-existing disease, like cardiovascular disease and respiratory disease. Based on this information, he concludes that a revised standard level of 9.0-10.0 $\mu g/m^3$ would limit air quality exposures to concentrations well below those associated with the study reported mean, studies which include and assess impacts on the most at-risk populations. Thus, the Administrator provisionally concludes that a standard level within this range would appropriately provide an adequate margin of safety for the populations most at risk for adverse health effects associated with exposure to $PM_{2.5}$.

The Administrator also considers other lines of evidence, including the study reported means from epidemiologic studies that restrict concentrations to levels below 12 $\mu g/m^3$, the $25^{th}$ percentiles values reported by a subset of epidemiologic studies, and the information from the accountability studies. He notes that a standard in the range of 9.0 to 10.0 $\mu g/m^3$ would limit exposures to ambient concentrations near the $25^{th}$ percentile reported in the available studies, with a standard level of 9.0 $\mu g/m^3$ limiting those exposures somewhat more than a standard level

of 10.0 μg/m$^3$. He also notes that a standard in the range of 9.0 to 10.0 μg/m$^3$ would be near the value of the study reported means from the two available long-term restricted analyses studies (i.e., 9.6 μg/m$^3$). The Administrator notes a standard level of 9.0-10.0 μg/m$^3$, would also be at or below the lowest starting concentration of the newest available accountability studies (i.e., 10.0-11.1 μg/m$^3$). The Administrator also considers the results from the risk assessment. He recognizes that the risk estimates should be considered along with the inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with $PM_{2.5}$ exposure and related health effects. When looking at the risk assessment results, he notes that an annual standard level of 9.0-10.0 μg/m$^3$ is estimated to reduce exposure concentrations such that those remaining risks are associated with exposure concentrations that are below most of the study-reported means in the key U.S. epidemiologic studies, where we have the strongest support for adverse health effects occurring, and below $PM_{2.5}$ concentrations (i.e., 8 μg/m$^3$) where the 2019 ISA notes that uncertainties remain in the shape of the C-R curve, particularly for a standard level as low as 9.0 μg/m$^3$. Lastly, the Administrator also notes that every member of the CASAC found that the available scientific evidence and information supported revising the annual standard level to a level of 10.0 μg/m$^3$. Additionally, the majority of the CASAC also recommended that the available evidence and information supported revision to a level of 9.0 μg/m$^3$. Thus, recognizing the uncertainties in the evidence and the necessity of providing requisite protection, with an adequate margin of safety, the Administrator is proposing to set the level of the annual standard in the range of 9.0-10.0 μg/m$^3$, and solicits comments on the appropriate standard level within that range.

While the Administrator recognizes that some members of the CASAC advised, and the PA concluded, that the available scientific information provides support for considering a range

that extends up to 11.0 $\mu g/m^3$ and down to 8.0 $\mu g/m^3$, he provisionally concludes that proposing such an extended range would not be appropriate at this time. More specifically, the Administrator provisionally concludes that proposing to revise the annual standard level to above 10.0 $\mu g/m^3$ and as high as 11.0 $\mu g/m^3$ would reflect a public health policy approach that would place less weight on setting a standard level at or below the study-reported means from a number of key U.S. epidemiologic studies and less weight on the risk assessment results. Such an approach would also place little or no weight on the study reported means from epidemiologic studies that restrict concentrations to below 12 $\mu g/m^3$ and the 25$^{th}$ percentile concentrations reported by a subset of epidemiologic studies. The Administrator notes that such an approach may fail to provide an adequate margin of safety in light of the evidence available in this reconsideration. In considering revision to the annual standard level to below 9.0 $\mu g/m^3$ and as low as 8.0 $\mu g/m^3$, the Administrator notes that such a level would be substantially below the study-reported means and would not recognize the controlling nature of the design value monitor with respect to the concentration gradients consistently occurring across urban areas. The Administrator also recognizes that the evidence and uncertainties for public health benefits of lower standards exists on a continuum across the range of possible standard levels. He preliminarily judges that the evidence is sufficient to support standards in the range of 9.0-10.0 $\mu g/m^3$, recognizing that the selection of a final standard level will depend on judgments about the relative weight to place on various aspects of the evidence and how to provide for an adequate margin of safety. However, the Administrator preliminarily judges that the available information and evidence are not sufficient to warrant revising the level of the annual standard below 9.0 $\mu g/m^3$. He finds the uncertainties as to the public health risks and benefits associated with such a standard to be too great at this time. Nonetheless, while the Administrator notes these

considerations above, he solicits comment on revising the annual standard down to a level below 9.0 μg/$m^3$ and as low as 8.0 μg/$m^3$, as well as to above 10.0 μg/$m^3$ and as high as 11.0 μg/$m^3$, and on approaches for interpreting the scientific evidence and rationales that would support such a level.

*E. Proposed Decisions on the Primary $PM_{2.5}$ Standards*

Taking the above considerations into account, upon reconsidering the current primary $PM_{2.5}$ standards in light of the currently available scientific evidence and quantitative information, the Administrator proposes to revise the level of the primary annual $PM_{2.5}$ standard from 12.0 μg/$m^3$ to within the range of 9.0 to 10.0 μg/$m^3$ and to retain the 24-hour standard level at 35 μg/$m^3$. In the Administrator's judgment, such a suite of primary $PM_{2.5}$ standards and the rationale supporting such levels could reasonably be judged to reflect the appropriate consideration of the strength of the available evidence and other information and their associated uncertainties and the advice of the CASAC.

The Administrator recognizes that the final suite of standards will reflect the Administrator's ultimate judgments in the final rulemaking as to the suite of primary $PM_{2.5}$ standards that are requisite to protect the public health with an adequate margin of safety from effects associated with $PM_{2.5}$ exposures. The final judgments to be made by the Administrator will appropriately consider the requirement for standards that are neither more nor less stringent than necessary and will recognize that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

Having reached his provisional judgment to propose revising the annual standard level from 12.0 to within a range of 9.0 to 10.0 μg/$m^3$ and to propose retaining the 24-hour standard level at 35 μg/$m^3$, the Administrator solicits public comment on this range of levels and on

approaches to considering the available evidence and information that would support the choice of levels within this range. The Administrator also solicits public comment on alternative annual standard levels down to 8.0 $\mu g/m^3$ and up to 11.0 $\mu g/m^3$, on an alternative 24-hour standard level as low as 25 $\mu g/m^3$ and on the combination of annual and 24-hour standards that commenters may believe is appropriate, along with the approaches and rationales used to support such levels. For example, the EPA solicits comments on the uncertainties in the reported associations between daily or annual average $PM_{2.5}$ exposures and mortality or morbidity in the epidemiologic studies, the significance of the 25$^{th}$ percentile of ambient concentrations reported in studies, the relevance and limitations of international studies, and other topics discussed in section II.D.3.b.

## III. Rationale for Proposed Decisions on the Primary $PM_{10}$ Standard

This section presents the rationale for the Administrator's proposed decision to retain the existing primary $PM_{10}$ standard. This decision is based on a thorough review of the latest scientific information, published through January 2018,[103] and evaluated in the 2019 ISA, on human health effects associated with $PM_{10–2.5}$ in ambient air. As described in section 1.2 of the ISA Supplement, the scope of the updated scientific evaluation of the health effects evidence is based on those PM size fractions, exposure durations, and health effects category combinations where the 2019 ISA concluded a causal relationship exists (U.S. EPA, 2019a, U.S. EPA, 2022a). Therefore, because the 2019 ISA did not conclude a causal relationship for $PM_{10-2.5}$ for any

[103] In addition to the review's opening "call for information" (79 FR 71764, December 3, 2014), the current ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 through approximately January 2018 (U.S. EPA, 2019a, p. ES-2). References that are cited in the 2019 ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: *https://hero.epa.gov/hero/particulate-matter*.

exposure durations or health effect categories, the ISA Supplement does not include an evaluation of additional studies for $PM_{10-2.5}$. As a result, the 2019 ISA continues to serve as the scientific foundation for assessing the adequacy of the primary $PM_{10}$ standard in this reconsideration of the 2020 final decision (U.S. EPA, 2019a, section 1.7; U.S. EPA, 2022a). The Administrator's rationale also takes into account: (1) the PA evaluation of the policy-relevant information in the 2019 ISA; (2) CASAC advice and recommendations, as reflected in discussions of the draft of the PA at public meetings and in the CASAC's letter dated March 18, 2022, to the Administrator; and (3) public comments received during the development of the PA.

In presenting the rationale for the Administrator's proposed decision and its foundations, section III.A provides background and introductory information for this reconsideration of the primary $PM_{10}$ standard. It includes background on the 2020 final decision to retain the primary $PM_{10}$ standard (section III.A.1) and also describes the general approach for this reconsideration (section III.A.2) Section III.B summarizes the key aspects of the currently available scientific evidence for $PM_{10-2.5}$-related health effects. Section III.C presents the Administrator's proposed conclusions regarding the adequacy of the primary $PM_{10}$ standard (section III.C.3), drawing on evidence-based considerations (section III.C.2) and advice from the CASAC (section III.C.1).

*A. General Approach*

The current primary $PM_{10}$ standard was affirmed in 2020 based on the scientific information available at that time, as well as the Administrator's judgments regarding the available public health effects evidence, and the appropriate degree of public health protection for the existing standards (85 FR 82725, December 18, 2020). With the 2020 decision, the Administrator retained the existing 24-hour primary $PM_{10}$ standard, with its level of 150 $\mu g/m^3$ and its one-expected-exceedance form on average over three years, to continue to provide public health protection against short-term exposures to $PM_{10-2.5}$ (85 FR 82725, December 18, 2020).

The subsection below focuses on the key considerations, and the prior Administrator's conclusions, for $PM_{10-2.5}$-related health effects and the adequacy of the primary $PM_{10}$ standard in the 2020 review.

1. Background on the Current Standard

In the 2019 ISA, the strongest evidence for $PM_{10-2.5}$-related health effects was for cardiovascular effects, respiratory effects, and premature mortality following short-term exposures. For each of these categories of effects, the 2019 ISA concludes that the evidence was "suggestive of, but not sufficient to infer, a causal relationship". Specifically, the health effects evidence evaluated in the 2019 ISA included an expanded body of scientific evidence that has become available since the completion of the 2009 ISA linking short-term $PM_{10-2.5}$ to health outcomes such as premature death and hospital visits (U.S. EPA, 2009a; U.S. EPA, 2019a). This evidence base evaluated the causal relationships between short-term exposure to $PM_{10-2.5}$ and a broad range of health effects (U.S. EPA, 2019a, section 1.4.2). These effects associated with short-term exposure ranged from hospital admissions and emergency department visits for cardiovascular effects (documented in epidemiologic studies that reported $PM_{10-2.5}$ associations with cardiovascular hospital admissions and emergency department visits in study locations with mean 24-hour average $PM_{10-2.5}$ concentrations ranging from 7.4 to 13 $\mu g/m^3$) and respiratory effects (documented in epidemiologic studies that reported $PM_{10-2.5}$ associations with respiratory hospital admissions and emergency department visits in study locations with mean 24-hour average concentrations ranging from 5.6 to 16.2 $\mu g/m^3$) to mortality (documented in epidemiologic studies that reported $PM_{10-2.5}$ associations with mortality in study areas with mean 24-hour average concentrations ranging from 6.1 to 16.4 $\mu g/m^3$). In addition to the epidemiologic studies, the evidence base included a small number of controlled human exposure

studies and animal toxicological studies that provided insight into the biological plausibility of these effects. Collectively, the epidemiologic studies, controlled human exposure, and animal toxicological studies, with their inherent uncertainties, contributed to the causality determinations of "suggestive of, but not sufficient to infer, a causal relationship" between short-term exposures to $PM_{10-2.5}$ and cardiovascular effects, respiratory effects, cancer, and mortality (U.S. EPA, 2019a, section 1.4.2). The 2019 ISA includes expanded evidence for the relationships between long-term exposures and cardiovascular effects, metabolic effects, nervous system effects, cancer, and mortality. While the evidence available in the 2019 ISA included additional health outcomes, including those associated with long-term $PM_{10-2.5}$ exposure, key limitations in the evidence that were identified in the 2009 ISA persist in studies evaluated in the 2019 ISA.

In considering the available body of evidence, it was noted in the 2020 review there were considerable uncertainties and limitations associated with the experimental evidence for $PM_{2.5}$ exposures and health effects, and as such more weight was placed on the available epidemiologic evidence. Therefore, the primary focus in the 2020 review was on multi-city and single-city epidemiologic studies that evaluated associations between short-term $PM_{10-2.5}$ and mortality, cardiovascular effects (hospital admissions and emergency department visits, as well as blood pressure and hypertension), and respiratory effects. Despite differences in the approaches[104] used to estimate ambient $PM_{10-2.5}$ concentrations, the majority of the studies reported positive, though often not statistically significant, associations with short-term $PM_{10-2.5}$ exposures. Most $PM_{10-2.5}$ effect estimates remained positive in copollutant models that included either gaseous pollutants

[104] As discussed further below, methods employed by the epidemiologic studies to estimate ambient $PM_{10-2.5}$ concentrations include: (1) calculating the difference between $PM_{10}$ and $PM_{2.5}$ at co-located monitors, (2) calculating the difference between county-wide averages of monitored $PM_{10}$ and $PM_{2.5}$ based on monitors that are not necessarily co-located, and (3) direct measurement of $PM_{10-2.5}$ using a dichotomous sampler (U.S. EPA, 2019a, section 1.4.2).

or other particulate matter size fractions (e.g., $PM_{2.5}$). In U.S. study locations likely to have met the $PM_{10}$ standard during the study period, a few studies reported positive associations between $PM_{10-2.5}$ and mortality that were statistically significant and remained so in copollutant models (U.S. EPA, 2019a). In addition to the epidemiologic studies, there were a small number of controlled human exposure studies evaluated in the 2019 ISA that reported alterations in heart rate variability or increased pulmonary inflammation following short-term exposure to $PM_{10-2.5}$, providing some support for the associations in the epidemiologic studies. Animal toxicological studies examined the effect of short-term $PM_{10-2.5}$ exposures using non-inhalation (e.g., intratracheal instillation) route.[105] Therefore, these studies provided limited evidence for the biological plausibility of $PM_{10-2.5}$-induced effects (U.S. EPA, 2019a). Although the scientific evidence available in the 2019 ISA expanded the understanding of health effects associated with $PM_{10-2.5}$ exposures, a number of important uncertainties remained. These uncertainties, and their implications for interpreting the scientific evidence, include the following:

- The potential for confounding by copollutants, notably $PM_{2.5}$, was addressed with copollutant models in a relatively small number of $PM_{10-2.5}$ epidemiologic studies (U.S. EPA, 2019a). This was particularly important given the relatively small body of experimental evidence (i.e., controlled human exposure and animal toxicological studies) available to support the independent effect of $PM_{10-2.5}$ on human health. This increases the uncertainty regarding the extent to which $PM_{10-2.5}$ itself, rather than one or more copollutants, is responsible for the mortality and morbidity effects reported in epidemiologic studies.
- There was greater spatial variability in $PM_{10-2.5}$ concentrations than $PM_{2.5}$ concentrations,

[105] Non-inhalation exposure experiments (i.e., intratracheal [IT] instillation) are informative for size fractions (e.g., $PM_{10–2.5}$) that cannot penetrate the airway of a study animal and may provide information relevant to biological plausibility and dosimetry (U.S. EPA, 2019a, section A-12).

resulting in the potential for increased exposure error for $PM_{10-2.5}$ (U.S. EPA, 2019a). Available measurements did not provide sufficient information to adequately characterize the spatial distribution of $PM_{10-2.5}$ concentrations (U.S. EPA, 2019a). The limitations in estimates of ambient $PM_{10-2.5}$ concentrations "would tend to increase uncertainty and make it more difficult to detect effects of $PM_{10-2.5}$ in epidemiologic studies" (U.S. EPA, 2019a).

- Estimation of $PM_{10-2.5}$ concentrations over which reported health outcomes occur remain highly uncertain. When compared with $PM_{2.5}$, there is uncertainty spanning all epidemiologic studies examining associations with $PM_{10–2.5}$ including deficiencies in the existing monitoring networks, the lack of a systematic evaluation of the various methods used to estimate $PM_{10–2.5}$ concentrations and the resulting uncertainty in the spatial as well as the temporal variability in $PM_{10–2.5}$ concentration (U.S. EPA, 2019a). Given these limitations in routine monitoring, epidemiologic studies employed a number of different approaches for estimating $PM_{10-2.5}$ concentrations, including (1) calculating the difference between $PM_{10}$ and $PM_{2.5}$ at co-located monitors, (2) calculating the difference between county-wide averages of monitored $PM_{10}$ and $PM_{2.5}$ based on monitors that are not necessarily co-located, and (3) direct measurement of $PM_{10-2.5}$ using a dichotomous sampler (U.S. EPA, 2019a, section 1.4.2). Given the relatively small number of $PM_{10-2.5}$ monitoring sites, the relatively large spatial variability in ambient $PM_{10-2.5}$ concentrations, the use of different approaches to estimating ambient $PM_{10-2.5}$ concentrations across epidemiologic studies, and the limitations inherent in such estimates, the distributions of $PM_{10-2.5}$ concentrations over which reported health outcomes occur remain highly uncertain (U.S. EPA, 2019a).

- There was relatively little information available to characterize the apparent variability in associations between short-term $PM_{10-2.5}$ exposures and health effects across study locations (U.S. EPA, 2019a). Specifically, the relative lack of information on the chemical and biological composition of $PM_{10-2.5}$ as well as potential spatial and temporal variability in $PM_{10-2.5}$ exposures complicates the interpretation of results between study locations (U.S. EPA, 2009b; U.S. EPA, 2019a).

Consistent with the general approach routinely employed in NAAQS reviews, the initial consideration in the 2020 review of the primary $PM_{10}$ standard was with regard to the adequacy of protection provided by the then-existing standard. Key aspects of that consideration are summarized below.

i. Considerations Regarding the Adequacy of the Existing Standard in the 2020 Review

In the 2020 final decision, the EPA retained the existing 24-hour primary $PM_{10}$ standard with its level of 150 $\mu g/m^3$ and its one-expected-exceedance form on average over three years to continue to provide public health protection against exposures to $PM_{10-2.5}$ (85 FR 82727, December 18, 2020). In reaching his decision, the Administrator specifically noted that, while the health effects evidence was somewhat expanded since the prior reviews, the overall conclusions in the 2019 ISA, including uncertainties and limitations, were generally consistent with what was considered in the 2012 review (85 FR 82725, December 18, 2020). In addition, the Administrator recognized that there were still a number of uncertainties and limitations associated with the available evidence. With regard to the evidence on $PM_{10-2.5}$-related health effects, the Administrator noted that epidemiologic studies continued to report positive associations with mortality and morbidity in cities across North America, Europe, and Asia, where $PM_{10-2.5}$ sources and composition were expected to vary widely. While significant

uncertainties remained in the 2020 review, the Administrator recognized that this expanded body of evidence had broadened the range of effects that have been linked with $PM_{10-2.5}$ exposures. The studies evaluated in the 2019 ISA expanded the scientific foundation presented in the 2009 ISA and led to revised causality determinations (and new determinations) for long-term $PM_{10-2.5}$ exposures and mortality, cardiovascular effects, metabolic effects, nervous system effects, and cancer (85 FR 82726, December 18, 2020). Drawing from his consideration of this evidence, the Administrator concluded that the scientific information available since the time of the last review supported a decision to maintain a primary $PM_{10}$ standard to provide public health protection against $PM_{10-2.5}$ exposures, regardless of location, source of origin, or particle composition (85 FR 82726, December 18, 2020). With regard to uncertainties in the available evidence, the Administrator first noted that a number of limitations were identified in the 2012 review related to: (1) estimates of ambient $PM_{10-2.5}$ concentrations used in epidemiologic studies; (2) limited evaluation of copollutant models to address the potential for confounding; and (3) limited experimental studies supporting biological plausibility for $PM_{10-2.5}$-related effects. Despite the expanded body of evidence for $PM_{10-2.5}$ exposures and health effects, the Administrator recognized that uncertainties in the 2020 review continued to include those associated with the exposure estimates used in epidemiologic studies, the independence of the $PM_{10-2.5}$ health effect associations, and the biologically plausible pathways for $PM_{10-2.5}$ health effects (85 FR 82726, December 18, 2020). These uncertainties contributed to the 2019 ISA determinations that the evidence is at most "suggestive of, but not sufficient to infer" causal relationships (85 FR 82726, December 18, 2020). In considering the available evidence in his basis for the proposed decision, the Administrator emphasized evidence supporting "causal" and "likely to be causal" relationships, and therefore, judged that the $PM_{10-2.5}$-related health effects evidence provided an

uncertain scientific foundation for making standard-setting decisions. He further judged limitations in the evidence raised questions as to whether additional public health improvements would be achieved by revising the existing $PM_{10}$ standard (85 FR 24126, April 30, 2020). In the 2020 decision, for all of the reasons discussed above and recognizing the CASAC conclusion that the evidence provided support for retaining the current standard, the Administrator concluded that it was appropriate to retain the existing primary $PM_{10}$ standard, without revision. His decision was consistent with the CASAC advice related to the primary $PM_{10}$ standard. Specifically, the CASAC agreed with the 2020 PA conclusions that, while these effects are important, the "evidence does not call into question the adequacy of the public health protection afforded by the current primary $PM_{10}$ standard" and "supports consideration of retaining the current standard in this review" (Cox, 2019b, p. 3 of consensus letter). Thus, the Administrator concluded that the primary $PM_{10}$ standard (in all of its elements) was requisite to protect public health with an adequate margin of safety against effects that have been associated with $PM_{10-2.5}$. In light of this conclusion, the EPA retained the existing $PM_{10}$ standard.

2. General Approach and Key Issues in this Reconsideration of the 2020 Final Decision

To evaluate whether it is appropriate to consider retaining the current primary $PM_{10}$ standard, or whether consideration of revision is appropriate, the EPA has adopted an approach in this reconsideration that builds upon the general approach used in past reviews and reflects the body of evidence and information now available, as well as the assessments and evaluations performed in those reviews. As summarized above, the Administrator's decision in the 2020 review was based on an integration of $PM_{10-2.5}$-related health effects information with the judgments on the public health significance of key effects, policy judgments as to when the standard is requisite, consideration of CASAC advice, and consideration of public comments.

Similarly, in this reconsideration, information is drawn from recent studies of $PM_{10-2.5}$-related health effects. In so doing, the PA considers information critically analyzed and characterized in the 2019 ISA, as well as consideration of the associated uncertainties and limitations for the available evidence.

*B. Overview of the Health Effects Evidence*

The information summarized here is based on the scientific assessment of the health effects evidence available in this reconsideration; this evaluation is documented in the 2019 ISA and its policy implications are discussed further in the PA. As noted above, the ISA Supplement does not include an evaluation of studies for $PM_{10-2.5}$ and the 2019 ISA continues to serve as the scientific foundation for this reconsideration.

1. Nature of Effects

For the health effect categories and exposure duration combinations evaluated, the 2019 ISA concludes that the evidence supports causality determinations for $PM_{10-2.5}$ that are at most "suggestive of, but not sufficient to infer, a causal relationship. While the evidence supporting the causal nature of relationships between exposure to $PM_{10-2.5}$ has been strengthened for some health effect categories since the completion of the 2009 ISA, the 2019 ISA concludes that overall "the uncertainties in the evidence identified in the 2009 ISA have, to date, still not been addressed" (U.S. EPA, 2019a, section 1.4.2, p. 1- 41; U.S. EPA, 2022b, section 4.3.1). Specifically, epidemiologic studies available in the 2012 review relied on various methods to estimate $PM_{10-2.5}$ concentrations, and these methods had not been systematically compared to evaluate spatial and temporal correlations in $PM_{10-2.5}$ concentrations. Methods included: (1) calculating the difference between $PM_{10}$ and $PM_{2.5}$ concentrations at co-located monitors, (2) calculating the difference between county-wide averages of monitored $PM_{10}$- and $PM_{2.5}$-based on monitors that are not necessarily co-located, and (3) direct measurement of $PM_{10-2.5}$ using a

dichotomous sampler (U.S. EPA, 2019a, section 1.4.2). As described in the 2019 ISA, there continues to be variability across epidemiologic studies in the approaches used to estimate $PM_{10-2.5}$ concentrations. Additionally, some studies estimate long-term $PM_{10-2.5}$ exposures as the difference between $PM_{10}$ and $PM_{2.5}$ concentrations based on information from spatiotemporal or land use regression (LUR) models, in addition to monitors. The various methods used to estimate $PM_{10-2.5}$ concentrations have not been systematically evaluated (U.S. EPA, 2019a, section 3.3.1.1), contributing to uncertainty regarding the spatial and temporal correlations in $PM_{10-2.5}$ concentrations across methods and in the $PM_{10-2.5}$ exposure estimates used in epidemiologic studies (U.S. EPA, 2019a, section 2.5.1.2.3). Given the greater spatial and temporal variability of $PM_{10-2.5}$ and the lower number of $PM_{10-2.5}$ monitoring sites, compared to $PM_{2.5}$, this uncertainty is particularly important for the coarse size fraction. Beyond the uncertainty associated with $PM_{10-2.5}$ exposure estimates in epidemiologic studies, the limited information on the potential for confounding by copollutants and the limited support available for the biological plausibility of health effects following $PM_{10-2.5}$ exposures also continue to contribute to uncertainty in the $PM_{10-2.5}$ health evidence. Uncertainty related to potential confounding stems from the relatively small number of epidemiologic studies that have evaluated $PM_{10-2.5}$ health effect associations in copollutants models with both gaseous pollutants and other PM size fractions. On the other hand, uncertainty related to the biological plausibility of effects attributed to $PM_{10-2.5}$ exposures results from the small number of controlled human exposure and animal toxicological studies that have evaluated the health effects of experimental $PM_{10-2.5}$ inhalation exposures. The evidence supporting the 2019 ISA's "suggestive of, but not sufficient to infer, a causal relationship" causality determinations for $PM_{10-2.5}$, including uncertainties in this evidence, is summarized below in sections III.B.1.a through III.B.1.f.

a. Mortality

i. Long-term Exposures

Due to the dearth of studies examining the association between long-term $PM_{10–2.5}$ exposure and mortality, the 2009 ISA concluded that the evidence was "inadequate to determine if a causal relationship exists" (U.S. EPA, 2009a). As reported in the 2019 ISA, some cohort studies conducted in the U.S. and Europe report positive associations between long-term $PM_{10–2.5}$ exposure and total (nonaccidental) mortality, though results are inconsistent across studies (U.S. EPA, 2019a, Table 11-11). The examination of copollutant models in these studies remains limited and, when included, $PM_{10–2.5}$ effect estimates are often attenuated after adjusting for $PM_{2.5}$ (U.S. EPA, 2019a, Table 11-11). Across studies, $PM_{10–2.5}$ exposure concentrations are estimated using a variety of approaches, including direct measurements from dichotomous samplers, calculating the difference between $PM_{10}$ and $PM_{2.5}$ concentrations measured at collocated monitors, and calculating difference of area-wide concentrations of $PM_{10}$ and $PM_{2.5}$. As discussed above, temporal and spatial correlations between these approaches have not been evaluated, contributing to uncertainty regarding the potential for exposure measurement error (U.S. EPA, 2019a, section 3.3.1.1 and Table 11-11). The 2019 ISA concludes that this uncertainty "reduces the confidence in the associations observed across studies" (U.S. EPA, 2019a, p. 11-125). The 2019 ISA additionally concludes that the evidence for long-term $PM_{10–2.5}$ exposures and cardiovascular effects, respiratory morbidity, and metabolic disease provide limited biological plausibility for $PM_{10–2.5}$-related mortality (U.S. EPA, 2019a, sections 11.4.1 and 11.4). Taken together, the 2019 ISA concludes that, "this body of evidence is suggestive, but not sufficient to infer, that a causal relationship exists between long-term $PM_{10-2.5}$ exposure and total mortality" (U.S. EPA, 2019a, p. 11-125).

ii. Short-term Exposures

The 2009 ISA concluded that the evidence is "suggestive of a causal relationship between short-term exposure to $PM_{10–2.5}$ and mortality" (U.S. EPA, 2009a). The 2019 ISA included multicity epidemiologic studies conducted primarily in Europe and Asia that continue to provide consistent evidence of positive associations between short-term $PM_{10–2.5}$ exposure and total (nonaccidental) mortality (U.S. EPA, 2019a, Table 11-9). Although these studies contribute to increasing confidence in the $PM_{10–2.5}$-mortality relationship, the use of a variety of approaches to estimate $PM_{10-2.5}$ exposures continues to contribute uncertainty to the associations observed. Recent studies expand the assessment of potential copollutant confounding of the $PM_{10–2.5}$-mortality relationship and provide evidence that $PM_{10-2.5}$ associations generally remain positive in copollutant models, though associations are attenuated in some instances (U.S. EPA, 2019a, section 11.3.4.1, Figure 11-28, Table 11-10). The 2019 ISA concludes that, overall, the assessment of potential copollutant confounding is limited due to the lack of information on the correlation between $PM_{10–2.5}$ and gaseous pollutants and the small number of locations in which copollutant analyses have been conducted. Associations with cause-specific mortality (i.e., cardiovascular and respiratory mortality) provide some support for associations with total (nonaccidental) mortality, though associations with respiratory mortality are more uncertain (i.e., wider confidence intervals) and less consistent (U.S. EPA, 2019a, section 11.3.7). The 2019 ISA concludes that the evidence for $PM_{10-2.5}$-related cardiovascular effects provides only limited support for the biological plausibility of a relationship between short-term $PM_{10–2.5}$ exposure and cardiovascular mortality (U.S. EPA, 2019a, section 11.3.7). Based on the overall evidence, the 2019 ISA concludes that, "this body of evidence is suggestive, but not sufficient to infer, that a causal relationship exists between short-term $PM_{10-2.5}$ exposure and total mortality" (U.S. EPA,

2019a, p. 11-120).

b. Cardiovascular Effects

i. Long-term Exposures

In the 2009 ISA, the evidence describing the relationship between long-term exposure to $PM_{10-2.5}$ and cardiovascular effects was characterized as "inadequate to infer the presence or absence of a causal relationship." The limited number of epidemiologic studies reported contradictory results and experimental evidence demonstrating an effect of $PM_{10-2.5}$ on the cardiovascular system was lacking (U.S. EPA, 2019a, section 6.4).

The evidence relating long-term $PM_{10-2.5}$ exposures to cardiovascular mortality remains limited, with no consistent pattern of associations across studies and, as discussed above, uncertainty stemming from the use of various approaches to estimate $PM_{10-2.5}$ concentrations (U.S. EPA, 2019a, Table 6-70). The evidence for associations with cardiovascular morbidity has grown and, while results across studies are not entirely consistent, some epidemiologic studies report positive associations with ischemic heart disease (IHD) and MI (U.S. EPA, 2019a, Figure 6-34); stroke (U.S. EPA, 2019a, Figure 6-35); atherosclerosis (U.S. EPA, 2019a, section 6.4.5); venous thromboembolism (VTE) (U.S. EPA, 2019a, section 6.4.7); and blood pressure and hypertension (U.S. EPA, 2019a, Section 6.4.6). $PM_{10-2.5}$ cardiovascular mortality effect estimates are often attenuated, but remain positive, in copollutants models that adjust for $PM_{2.5}$. For morbidity outcomes, associations are inconsistent in copollutant models that adjust for $PM_{2.5}$, $NO_2$, and chronic noise pollution (U.S. EPA, 2019a, p. 6-276). The lack of toxicological evidence for long-term $PM_{10-2.5}$ exposures represents a data gap (U.S. EPA, 2019a, section 6.4.10), resulting in the 2019 ISA conclusion that "evidence from experimental animal studies is of insufficient quantity to establish biological plausibility" (U.S. EPA, 2019a, p. 6-277). Based

largely on the observation of positive associations in some epidemiologic studies, the 2019 ISA concludes that "evidence is suggestive of, but not sufficient to infer, a causal relationship between long-term $PM_{10-2.5}$ exposure and cardiovascular effects" (U.S. EPA, 2019a, p. 6-277).

ii. Short-Term Exposures

The 2009 ISA found that the available evidence for short-term $PM_{10-2.5}$ exposure and cardiovascular effects was "suggestive of a causal relationship." This conclusion was based on several epidemiologic studies reporting associations between short-term $PM_{10-2.5}$ exposure and cardiovascular effects, including IHD hospitalizations, supraventricular ectopy, and changes in heart rate variability (HRV). In addition, dust storm events resulting in high concentrations of crustal material were linked to increases in total cardiovascular disease emergency department visits and hospital admissions. However, the 2009 ISA noted the potential for exposure measurement error primarily due to the different methods used across studies to estimate $PM_{10-2.5}$ concentrations and copollutant confounding in these epidemiologic studies. In addition, there was only limited evidence of cardiovascular effects from a small number of experimental studies (e.g. animal toxicological studies and controlled human exposure studies) that examined short-term $PM_{10-2.5}$ exposures (U.S. EPA, 2009a, section 6.2.12.2). In the 2019 ISA, key uncertainties included the potential for exposure measurement error, copollutant confounding, and limited evidence of biological plausibility for cardiovascular effects following inhalation exposure (U.S. EPA, 2019a, section 6.3.13).

The evidence for short-term $PM_{10-2.5}$ exposure and cardiovascular outcomes has expanded since the 2009 ISA, though important uncertainties remain. The 2019 ISA notes that there are a small number of epidemiologic studies reporting positive associations between short-term exposure to $PM_{10-2.5}$ and cardiovascular-related morbidity outcomes. However, the 2019 ISA

notes that there is limited evidence to support that these associations are biologically plausible, or independent of copollutant confounding. The 2019 ISA also concludes that it remains unclear how the approaches used to estimate $PM_{10-2.5}$ concentrations in epidemiologic studies compare amongst one another and subsequently how exposure measurement error varies between each method. Specifically, it is unclear how well-correlated $PM_{10-2.5}$ concentrations are both temporally and spatially across these methods and therefore whether exposure measurement error varies across these methods. Taken together, the 2019 ISA concludes that "the evidence is suggestive of, but not sufficient to infer, a causal relationship between short-term $PM_{10-2.5}$ exposures and cardiovascular effects" (U.S. EPA, 2019a, p. 6-254).

c. Respiratory Effects – Short-term Exposures

Based on a small number of epidemiologic studies observing associations with some respiratory effects and limited evidence from experimental studies to support biological plausibility, the 2009 ISA (U.S. EPA, 2009a) concluded that the relationship between short-term exposure to $PM_{10–2.5}$ and respiratory effects is "suggestive of a causal relationship." Epidemiologic findings were consistent for respiratory infection and combined respiratory-related diseases, but not for COPD. Studies were characterized by overall uncertainty in the exposure assignment approach and limited information regarding potential copollutant confounding. Controlled human exposure studies of short-term $PM_{10–2.5}$ exposures found no lung function decrements and inconsistent evidence for pulmonary inflammation. Animal toxicological studies were limited to those using non-inhalation (e.g., intra-tracheal instillation) routes of $PM_{10–2.5}$ exposure.

Recent epidemiologic findings consistently link $PM_{10–2.5}$ exposure to asthma exacerbation and respiratory mortality, with some evidence that associations remain positive (though

attenuated in some studies of mortality) in copollutant models that include $PM_{2.5}$ or gaseous pollutants. Epidemiologic studies provide limited evidence for positive associations with other respiratory outcomes, including COPD exacerbation, respiratory infection, and combined respiratory-related diseases (U.S. EPA, 2019a, Table 5-36). As noted above for other endpoints, an uncertainty in these epidemiologic studies is the lack of a systematic evaluation of the various methods used to estimate $PM_{10\text{-}2.5}$ concentrations and the resulting uncertainty in the spatial and temporal variability in $PM_{10\text{-}2.5}$ concentrations compared to $PM_{2.5}$ (U.S. EPA, 2019a, sections 2.5.1.2.3 and 3.3.1.1). Specifically, the existing monitoring networks do not provide a great sense of how well correlated concentrations are both spatially and temporally across the $PM_{10\text{-}2.5}$ estimation methods and overall spatial and temporal patterns in $PM_{10\text{-}2.5}$ concentrations. Taken together, the 2019 ISA concludes that "the collective evidence is suggestive of, but not sufficient to infer, a causal relationship between short-term $PM_{10\text{-}2.5}$ exposure and respiratory effects" (U.S. EPA, 2019a, p. 5-270).

d. Cancer – Long-Term Exposures

In the 2012 review, little information was available from studies of cancer following inhalation exposures to $PM_{10–2.5}$. Thus, the 2009 ISA determined the evidence was "inadequate to evaluate the relationship between long-term $PM_{10–2.5}$ exposures and cancer" (U.S. EPA, 2009a). The scientific information evaluated in the 2019 ISA of long-term $PM_{10\text{-}2.5}$ exposure and cancer remains limited, with a few recent epidemiologic studies reporting positive, but imprecise, associations with lung cancer incidence (U.S. EPA, 2019a). Moreover, uncertainty remains in these studies with respect to exposure measurement error due to the use of $PM_{10–2.5}$ predictions that have not been validated by monitored $PM_{10–2.5}$ concentrations (U.S. EPA, 2019a, sections 3.3.2.3 and 10.3.4). Relatively few experimental studies of $PM_{10–2.5}$ have been

conducted, though available studies indicate that $PM_{10–2.5}$ exhibits two key characteristics of carcinogens: genotoxicity and oxidative stress. While limited, such experimental studies provide some evidence of biological plausibility for the findings in a small number of epidemiologic studies (U.S. EPA, 2019a, section 10.3.4).

Taken together, the small number of epidemiologic and experimental studies, along with uncertainty with respect to exposure measurement error, contribute to the determination in the 2019 ISA that, "the evidence is suggestive of, but not sufficient to infer, a causal relationship between long-term $PM_{10-2.5}$ exposure and cancer" (U.S. EPA, 2019a, p. 10-87).

e. Metabolic Effects – Long-Term Exposures

The 2009 ISA did not make a causality determination for $PM_{10-2.5}$-related metabolic effects. One epidemiologic study in the 2019 ISA reports an association between long-term $PM_{10-2.5}$ exposure and incident diabetes, while additional cross-sectional studies report associations with effects on glucose or insulin homeostasis (U.S. EPA, 2019a, section 7.4). As discussed above for other outcomes, uncertainties with the epidemiologic evidence include the potential for copollutant confounding and exposure measurement error due to the different methods used across studies to estimate $PM_{10-2.5}$ concentrations (U.S. EPA, 2019a, Tables 7-14 and 7-15). The evidence base to support the biological plausibility of metabolic effects following $PM_{10-2.5}$ exposures is limited, but a cross-sectional study that investigated biomarkers of insulin resistance and systemic and peripheral inflammation may support a pathway leading to type 2 diabetes (U.S. EPA, 2019a, sections 7.4.1 and 7.4.3). Based on the expanded, though still limited evidence base, the 2019 ISA concludes that, "[o]verall, the evidence is suggestive of, but not sufficient to infer, a causal relationship between [long]-term $PM_{10–2.5}$ exposure and metabolic effects" (U.S. EPA, 2019a, p. 7-56).

f. Nervous System Effects – Long-Term Exposures

The 2009 ISA did not make a causality determination for $PM_{10-2.5}$-related nervous system effects. In the 2019 ISA, available epidemiologic studies report associations between $PM_{10-2.5}$ and impaired cognition and anxiety in adults in longitudinal analyses (U.S. EPA, 2019a, Table 8-25, section 8.4.5). Associations of long-term exposure with neurodevelopmental effects are not consistently reported in children (U.S. EPA, 2019a, sections 8.4.4 and 8.4.5). Uncertainties in these studies include the potential for copollutant confounding, as no studies examined copollutants models (U.S. EPA, 2019a, section 8.4.5), and for exposure measurement error, given the use of various methods to estimate $PM_{10-2.5}$ concentrations (U.S. EPA, 2019a, Table 8-25). In addition, there is limited animal toxicological evidence supporting the biological plausibility of nervous system effects (U.S. EPA, 2019a, sections 8.4.1 and 8.4.5). Overall, the 2019 ISA concludes that, "the evidence is suggestive of, but not sufficient to infer, a causal relationship" between long-term $PM_{10-2.5}$ exposure and nervous system effects (U.S. EPA, 2019a, p. 8-75).

*C. Proposed Conclusions on the Primary $PM_{10}$ Standard*

In reaching proposed conclusions on the current primary $PM_{10}$ standard (presented in section III.C.3), the Administrator has taken into account policy-relevant evidence-based considerations discussed in the PA (summarized in section III.C.2), as well as advice from the CASAC and public comments on the standard received thus far in the reconsideration (section III.C.1). In general, the role of the PA is to help "bridge the gap" between the Agency's assessment of the available evidence, and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the NAAQS. Evidence-based considerations draw upon the EPA's integrated evaluation of the scientific evidence of $PM_{10-2.5}$-related health effects presented in the 2019 ISA (summarized in section III.B above) to address

key policy-relevant questions in the reconsideration.

The approach to reviewing the primary $PM_{10}$ standard is consistent with requirements of the provisions of the CAA related to the review of the NAAQS and how the EPA and the courts have historically interpreted the CAA. As discussed in section I.A above, these provisions require the Administrator to establish primary standards that, in the Administrator's judgment, are requisite (i.e., neither more nor less stringent than necessary) to protect public health with an adequate margin of safety. Consistent with the Agency's approach across all NAAQS reviews, the EPA's approach to informing these judgments is based on a recognition that the available health effects evidence generally reflects a continuum that includes ambient air concentrations for which scientists generally agree that health effects are likely to occur, through lower concentrations at which the likelihood and magnitude of response becomes increasingly uncertain. The CAA does not require the Administrator to establish a primary standard at a zero-risk level or at background concentration levels, but rather at a level that reduces risk sufficiently so as to protect public health, including the health of sensitive groups, with an adequate margin of safety.

The proposed decision on the adequacy of the primary $PM_{10}$ standard described below is a public health policy judgment by the Administrator that draws on the scientific evidence for health effects and judgments about how to consider the uncertainties and limitations that are inherent in the scientific evidence. The four basic elements of the NAAQS (i.e., indicator, averaging time, form, and level) have been considered collectively in evaluating the health protection afforded by the current standard. The Administrator's final decision will additionally consider public comments received on this proposed decision.

1. CASAC Advice in this Reconsideration

The CASAC has provided advice on the adequacy of the current primary $PM_{10}$ standard in the context of its review of the draft PA (Sheppard, 2022a).[106] In this context, the CASAC supported the preliminary conclusion in the draft PA that the evidence reviewed in the 2019 ISA does not call into question the public health protection provided by the current primary $PM_{10}$ standard against $PM_{10-2.5}$ exposures and concurs with the draft PA's overall preliminary conclusion that it is appropriate to consider retaining the current primary $PM_{10}$ standard (Sheppard, 2022a, p. 4 of consensus letter). Additionally, the CASAC concurred that "…at this time, $PM_{10}$ is an appropriate choice as the indicator for $PM_{10-2.5}$" and "that it is important to retain the level of protection afforded by the current $PM_{10}$ standard" (Sheppard, 2022a, p. 4 of consensus letter). The CASAC also recognized uncertainties associated with the scientific evidence, including "compared to $PM_{2.5}$ studies, the more limited number of epidemiology studies with positive statistically significant findings, and the difficulty in extracting the sole contribution of coarse PM to observed adverse health effects" (Sheppard, 2022a, p. 19 of consensus responses).

The CASAC recommended several areas for additional research to reduce uncertainties in the $PM_{10-2.5}$ exposure estimates used in the epidemiologic studies, to evaluate the independence of $PM_{10-2.5}$ health effect associations, to evaluate the biological plausibility of $PM_{10-2.5}$-related effects, and to increase the number of studies examining $PM_{10-2.5}$-related health effects in at-risk populations (Sheppard, 2022a, p. 20 of consensus responses). Furthermore, the

[106] A limited number of public comments have also been received in this reconsideration to date, including comments focused on the draft PA. Of the public comments that addressed the adequacy of the current primary $PM_{10}$ standard, most commenters supported the preliminary conclusion that it is appropriate to consider retaining the current primary $PM_{10}$ standard, without revision. However, one nonprofit organization suggested that the primary $PM_{10}$ standard should be strengthened to a level of 45 $\mu g/m^3$, consistent with the World Health Organization Global Air Quality Guideline (WHO, 2021).

CASAC "recognizes a need for, and supports investment in research and deployment of measurement systems to better characterize $PM_{10-2.5}$" and to "provide information that can improve public health" (Sheppard, 2022a, p. 20 of consensus responses).

2. Evidence-Based Considerations in the Policy Assessment

With regard to the current evidence on health effects associated with long and short--term $PM_{10-2.5}$ exposure health effects, the PA notes that recent epidemiologic studies that continue to report positive associations with mortality and morbidity in cities across North America, Europe, and Asia, where $PM_{10-2.5}$ sources and composition are expected to vary widely (U.S. EPA, 2022b, section 4.3.1). While significant uncertainties remain, as described below and summarized in the PA (U.S. EPA, 2022b, section 4.5), the PA recognizes that this expanded body of evidence has broadened the range of effects that have been linked with $PM_{10-2.5}$ exposures. The uncertainties in the available epidemiologic studies contribute to the determinations in the 2019 ISA that the evidence for short- and long-term exposures to $PM_{10-2.5}$ and cardiovascular effects, cancer, and mortality and long-term $PM_{10-2.5}$ exposures and metabolic effects and nervous system effects is "suggestive of, but not sufficient to infer" causal relationships (U.S. EPA, 2019a; U.S. EPA, 2022b, section 4.3.1). Drawing from this information, the PA concludes that the evidence continues to provide support for maintaining a standard that provides some measure of protection against exposures to $PM_{10-2.5}$, regardless of location, sources of origin, or particle composition (U.S. EPA, 2022b, section 4.5).

With regard to uncertainties, the PA recognizes that the 2019 ISA notes that important uncertainties remain in the evidence base for $PM_{10-2.5}$-related health effects. As summarized in section III.B above and in the PA (U.S. EPA, 2022b, sections 4.3.1 and 4.5). These uncertainties include those related to variability in $PM_{10-2.5}$ exposure estimates used in epidemiologic studies,

in the independence of $PM_{10-2.5}$ health effect associations, and in the biological plausibility of the $PM_{10-2.5}$-related health effects. These uncertainties contribute to the determinations in the 2019 ISA that the evidence for short- and long-term $PM_{10-2.5}$ exposure in key health effect categories is "suggestive of, but not sufficient to infer" causal relationships (U.S. EPA, 2019a). Taking this information into consideration, the PA concludes that, as in previous reviews, such uncertainties raised questions regarding the degree to which additional public health protection would be achieved by revising the existing $PM_{10}$ standard (U.S. EPA, 2022b, section 4.5).

With regard to the indicator for the primary $PM_{10}$ standard, the PA notes that the evidence continues to support retaining the $PM_{10}$ indicator to provide public health protection against $PM_{10-2.5}$-related effects. Consistent with the approaches in previous reviews, a standard with a $PM_{10}$ mass-based indicator, in conjunction with a $PM_{2.5}$ mass-based standard, will result in controlling allowable concentrations of $PM_{10-2.5}$. Given that the use of the $PM_{10}$ indicator does include consideration of both $PM_{2.5}$ and $PM_{10-2.5}$ concentrations, the 2019 ISA provides a comparison of the relative contribution of $PM_{2.5}$ and $PM_{10-2.5}$ to $PM_{10}$ concentrations, finding that the relative contribution of $PM_{2.5}$ and $PM_{10-2.5}$ to $PM_{10}$ concentrations can vary across the U.S. by region and season, with urban locations having a somewhat higher contribution of $PM_{2.5}$ contributing to $PM_{10}$ concentrations than $PM_{10-2.5}$ (U.S. EPA, 2019a, section 2.5.1.1.4, Table 2–7). In these urban locations, where $PM_{2.5}$ concentrations are somewhat higher than in rural locations, the toxicity of the $PM_{10}$ may be higher due to contaminating $PM_{2.5}$. Further, although uncertainties with the evidence persist, the strongest health effects evidence associated with $PM_{10-2.5}$ comes from epidemiologic studies conducted in urban areas. In light of this and consistent with the approaches in previous reviews, the PA concludes that a $PM_{10}$ standard, set at a single unvarying level, will generally result in lower allowable concentrations of $PM_{10-2.5}$ in

urban areas than in nonurban areas. In this way, the $PM_{10}$ indicator will target protection by allowing less $PM_{10-2.5}$ in areas that experience high concentrations of potentially contaminating $PM_{2.5}$. Thus, the evidence continues to support retaining the $PM_{10}$ indicator.

When the above information is taken together, the PA concludes that available evidence does not call into question the adequacy of the public health protection provided by the current primary $PM_{10}$ standard in order to protect against $PM_{10-2.5}$ exposures. Specifically, the PA notes that while the evidence supports maintaining a $PM_{10}$ standard to provide some measure of protection against $PM_{10-2.5}$ exposures, uncertainties in the evidence lead to questions regarding the potential public health implications of revising the existing $PM_{10}$ standard. Thus, the PA concludes that the evidence does not call into question the adequacy of the public health protection afforded by the current primary $PM_{10}$ standard (U.S. EPA, 2022b, section 4.5).

3. Administrator's Proposed Decision on the Current Primary $PM_{10}$ Standard

This section summarizes the Administrator's considerations and proposed conclusions related to the current primary $PM_{10}$ standard and presents his proposed decision to retain that standard, without revision. In establishing primary standards under the Act that are "requisite" to protect the public health with an adequate margin of safety, the Administrator is seeking to establish standards that are neither more nor less stringent than necessary for this purpose. He recognizes that the Act does not require that primary standards be set at a zero-risk level; rather, the NAAQS must be sufficiently protective, but not more stringent than necessary.

Given these requirements, and consistent with the primary $PM_{2.5}$ standards discussed above (section II.C.3), the Administrator's final decision in this reconsideration of the current primary $PM_{10}$ standard will be a public health policy judgment that draws upon the scientific information examining the health effects of $PM_{10-2.5}$ exposures, including how to consider the

range and magnitude of uncertainties inherent in that information. The Administrator recognizes that his final decision will be based on an interpretation of the scientific evidence that neither overstates nor understates its strengths and limitations, nor the appropriate inferences to be drawn.

Consistent with previous reviews, the Administrator first considers the available scientific evidence for $PM_{10-2.5}$-related exposures and health effects, as evaluated in the 2019 ISA. As an initial matter, the Administrator recognizes that the scientific evidence for $PM_{10-2.5}$-related effects available in this reconsideration is the same body of evidence that was available at the time of the 2020 review, as evaluated in the 2019 ISA and summarized in section III.B above. The 2019 ISA concludes that the evidence supports "suggestive of, but not sufficient to infer" causal relationships between short- and long-term exposures to $PM_{10-2.5}$ and cardiovascular effects, cancer, and mortality and long-term $PM_{10-2.5}$ exposures and metabolic effects and nervous system effects (U.S. EPA, 2019a). The Administrator notes that the evidence for several $PM_{10-2.5}$-related health effects has expanded since the completion of the 2009 ISA, but important uncertainties remain. Epidemiologic studies evaluated in the 2019 ISA continue to report positive associations between short-term exposure to $PM_{10-2.5}$ and mortality and morbidity in cities across North America, Europe, and Asia, where $PM_{10-2.5}$ sources and composition are expected to vary widely, but across studies inconsistency remains in the approaches used to estimate $PM_{10-2.5}$ exposures. While the Administrator recognizes that important uncertainties remain, he also recognizes that the expansion in the number of studies evaluating $PM_{10-2.5}$ exposures and health effects since the completion of the 2009 ISA has broadened the range of effects that may be linked with $PM_{10-2.5}$ exposures. The uncertainties in the epidemiologic studies contribute to the determinations in the 2019 ISA that the evidence for short and long-term $PM_{10-}$

$_{2.5}$ exposures and mortality, cardiovascular effects, metabolic effects, nervous system effects, and cancer is "suggestive of, but not sufficient to infer" causal relationships (U.S. EPA, 2019a; U.S. EPA, 2022b, section 4.3.1). Although most of these studies examined $PM_{10-2.5}$ health effect associations in urban areas, some studies have also linked mortality and morbidity with relatively high ambient concentrations of particles of non-urban crustal origin from dust storm events (U.S. EPA, 2019a).

In considering the available evidence, the Administrator recognizes that the evidence continues to provide support for maintaining a standard that provides some measure of protection against exposures to $PM_{10-2.5}$, regardless of location, source of origin, or particle composition, consistent with previous reviews (78 FR 3176, January 15, 2013; 85 FR 82726, December 18, 2020). Drawing from the evidence evaluated in the 2019 ISA and consideration of the scientific evidence in the PA, the Administrator notes that, consistent with previous reviews, the 2019 ISA and the PA highlight a number of uncertainties associated with the evidence, including those related to $PM_{10-2.5}$ exposure estimates used in epidemiologic studies, in the independence of $PM_{10-2.5}$ health effect associations, and in the biological plausibility of the $PM_{10-2.5}$-related effects. These uncertainties contribute to the determinations in the 2019 ISA that the evidence for short-term $PM_{10-2.5}$ exposures and key health effects is "suggestive of, but not sufficient to infer" causal relationships. In considering the available scientific evidence, consistent with approaches employed in past NAAQS reviews, the Administrator places the most weight on evidence supporting "causal" and "likely to be causal" relationships. In so doing, he notes that the available evidence for short-term $PM_{10-2.5}$ exposures and health effects does not support causality determinations of a "causal relationship" or "likely to be causal relationship." Furthermore, the Administrator recognizes that, because of the uncertainties and limitations in the evidence base,

the PA does not include a quantitative assessment of $PM_{10\text{-}2.5}$ exposures and risk that might further inform decisions regarding the adequacy of the current 24-hour primary $PM_{10}$ standard. Therefore, in light of the 2019 ISA conclusions that the evidence supports "suggestive of, but not sufficient to infer" causal relationships, specifically for cardiovascular effects, respiratory effects, cancer, and mortality and short-term exposures to $PM_{10\text{-}2.5}$, and the lack of available quantitative assessments, the Administrator judges that there are substantial uncertainties that raise questions regarding the degree to which additional public health improvements would be achieved by revising the existing $PM_{10}$ standard. Furthermore, the Administrator recognizes that the 2019 ISA also concludes that the evidence supports "suggestive of, but not sufficient to infer" causal relationships for long-term $PM_{10\text{-}2.5}$-exposures and cardiovascular effects, metabolic effects, nervous system effects, cancer, and mortality. However, in considering the available evidence for long-term $PM_{10\text{-}2.5}$ exposures, he notes that there is limited evidence that would support consideration of an annual standard to provide protection against such effects, in conjunction with the current primary 24-hour $PM_{10}$ standard. He preliminarily concludes that the current primary 24-hour $PM_{2.5}$ standard that reduces 24-hour exposures also likely reduces long-term average exposures, and therefore provides some margin of safety against the health effects associated with long-term $PM_{10\text{-}2.5}$ exposures.

In reaching proposed conclusions on adequacy of the current primary 24-hour $PM_{10}$ standard, the Administrator also considers advice from the CASAC. As noted above, the CASAC recognizes uncertainties associated with the scientific evidence, including "compared to $PM_{2.5}$ studies, the more limited number of epidemiology studies with positive statistically significant findings, and the difficulty in extracting the sole contribution of coarse PM to observed adverse health effects" (Sheppard, 2022a, p. 19 of consensus responses). Given these uncertainties, the

CASAC agrees with the PA conclusion that the scientific evidence does not call into question the adequacy of the primary $PM_{10}$ standard and supports consideration of retaining the current standard, noting that "[t]he CASAC supports this decision" (Sheppard, 2022a, p. 4 of consensus letter). Additionally, the CASAC concurred that "…at this time, $PM_{10}$ is an appropriate choice as the indicator for $PM_{10-2.5}$" and "that it is important to retain the level of protection afford by the current $PM_{10}$ standard" (Sheppard, 2022a, p. 4 of consensus letter).

When the above information is taken together, the Administrator proposes to conclude that the available scientific evidence continues to support a $PM_{10}$ standard to provide some measure of protection against $PM_{10-2.5}$ exposures. This proposed conclusion reflects the available evidence for $PM_{10-2.5}$-related health effects, for both short and long-term exposure, as evaluated in the 2019 ISA. However, he also recognizes that important limitations in the evidence remain. Consistent with the decisions in previous reviews, the Administrator proposes to conclude that these limitations lead to considerable uncertainty regarding the potential public health implications of revising the level of the current primary 24-hour $PM_{10}$ standard. Thus, based on his consideration of the evidence and associated uncertainties and limitations for $PM_{10-2.5}$-related health effects, as described above, and his consideration of CASAC advice on the primary $PM_{10}$ standard, the Administrator proposes to retain the current standard, without revision. The Administrator solicits comments on this proposed decision.

Having reached the proposed decision described here based on the interpretation of the $PM_{10-2.5}$-related health effects evidence, as evaluated in the 2019 ISA; the evaluation of policy-relevant aspects of the evidence in the PA; the advice and recommendations from the CASAC; public comments received to date in their reconsideration; and the public health policy judgments described above, the Administrator recognizes that other interpretations, assessments

and judgments might be possible. Therefore, the Administrator solicits comment on the array of issues associated with reconsideration of the primary 24-hour $PM_{10}$ standard, including public health and science policy judgments inherent in his proposed decision, as described above, and the rationales upon which such views are based.

## IV. Communication of Public Health

### *A. Air Quality Index Overview*

Information on the public health implications of ambient concentrations of criteria pollutants is made available primarily by Air Quality Index (AQI) reporting through the EPA's AirNow Web site.[107] The current AQI has been in use since its inception in 1999.[108] It provides useful, timely, and easily understandable information about the daily degree of pollution. The goal of the AQI is to establish a nationally uniform system of indexing pollution concentrations for ozone, carbon monoxide, nitrogen dioxide, PM, and sulfur dioxide. The AQI is recognized internationally as a proven tool to effectively communicate air quality information to the public. In fact, many countries have created similar indices based on the AQI.

The AQI converts an individual pollutant concentration in a community's air to a number on a scale from 0 to 500. Reported AQI values for specific pollutants enable the public to know whether air pollution levels in a particular location are characterized as good (0-50), moderate (51-100), unhealthy for sensitive groups (101- 150), unhealthy (151-200), very unhealthy (201-300), or hazardous (301+). Across criteria pollutants, the AQI index value of 100 typically corresponds to the level of the short-term (e.g., 24-hour, 8-hour, or 1-hour standard) NAAQS for

[107] See *http://www.airnow.gov/*

[108] In 1976, the EPA established a nationally uniform air quality index, then called the Pollutant Standard Index (PSI), for use by State and local agencies on a voluntary basis (41 FR 37660, September 7, 1976; 52 FR 24634, July 1,1987). In August 1999, the EPA adopted revisions to this air quality index (64 FR 42530, August 4, 1999) and renamed the index the AQI.

each pollutant. Below an index value of 100, an intermediate value of 50 is defined either as the level of the annual standard if an annual standard has been established (e.g., $PM_{2.5}$, nitrogen dioxide), a concentration equal to one-half the value of the 24-hour standard used to define an index value of 100 (e.g., carbon monoxide), or a concentration based directly on health effects evidence (e.g., ozone). An AQI value greater than 100 means that a pollutant is in one of the unhealthy categories (i.e., unhealthy for sensitive groups, unhealthy, very unhealthy, or hazardous). An AQI value at or below 100 means that a pollutant concentration is in one of the satisfactory categories (i.e., moderate or good). The scientific evidence on pollutant-related health effects for each NAAQS review evaluated in the ISA[109] support decisions related to pollutant concentrations at which to set the various AQI breakpoints, which delineate the AQI categories for each individual pollutant (i.e., the pollutant concentrations corresponding to index values of 150, 200, 300, and 500). The AQI is reported three ways, all of which are useful and complementary. The daily AQI is reported for the previous day and used to observe trends in community air quality, the AQI forecast helps people plan their outdoor activities for the next day, and the near-real-time AQI, or NowCast AQI, tells people whether it is a good time for outdoor activity.

Historically, state and local agencies have primarily used the AQI to provide general information to the public about air quality and its relationship to public health. For more than two decades, many states and local agencies, as well as the EPA and other Federal agencies, have been developing new and innovative programs and initiatives to provide more information related to air quality and health messaging to the public in a more timely way. These initiatives,

[109] In some NAAQS reviews, there may also be an ISA Supplement or a Provisional Assessment of scientific evidence that becomes available during a review after an ISA is finalized. To the extent that such evidence can inform decisions on the AQI, that information is also considered.

including air quality forecasting, near real-time data reporting through the AirNow Web site, use of data from air quality sensors on the Fire and Smoke Map, and air quality action day programs, provide useful, up-to-date, and timely information to the public about air pollution and its health effects. Such information can help the public learn when their well-being may be compromised, so they can take actions to avoid or to reduce exposures to ambient pollution at concentrations of concern. This information can also encourage the public to take actions that will reduce air pollution on days when concentrations are projected to be of concern to local communities (e.g., air quality action day programs can encourage individuals to drive less or carpool). The EPA and state, local and Tribal agencies recognize that these programs are interrelated with AQI reporting and with the information related to the effects of air pollution on public health that is evaluated through the periodic review, and revision when appropriate, of the NAAQS.

*B. Air Quality Index Category Breakpoints for $PM_{2.5}$*

One purpose of the AQI is to communicate to the public when air quality is poor and thus when they should consider taking actions to reduce their exposures. The higher the AQI value, the higher the level of air pollution and the greater the health concern. In recognition of the scientific information available that is informing the reconsideration of the 2020 final decision on the primary $PM_{2.5}$ standards, including a number of new controlled human exposure and epidemiologic studies published since the completion of the 2009 ISA, as well as additional epidemiologic studies from other peer reviewed documents that evaluate the health effects of wildfire smoke exposure and that can inform the AQI at higher $PM_{2.5}$ concentrations, the EPA proposes to make two sets of changes to the $PM_{2.5}$ sub-index of the AQI. First, the EPA proposes to continue to use the approach used in the revisions to the AQI in 2012 (77 FR 38890, June 29, 2012) of setting the lower breakpoints (50, 100 and 150) to be consistent with the levels of the primary $PM_{2.5}$ annual and 24-hour standards and proposes to revise the lower breakpoints to be

consistent with any changes to the primary $PM_{2.5}$ standards that are part of this reconsideration. Second, the EPA proposes to revise the upper AQI breakpoints (200 and above) and to replace the linear-relationship approach used in 1999 to set these breakpoints, with an approach that more fully considers the $PM_{2.5}$ health effects evidence from controlled human exposure and epidemiologic studies that have become available in the last 20 years. Thus, the EPA considers it appropriate to consider scientific evidence for these purposes beyond the scope of the ISA. More details on these proposed revisions to the AQI are provided below.

Although revisions of the air quality criteria and NAAQS for PM generally prompt changes to the AQI, the AQI is not part of the NAAQS. The AQI is aimed at communicating risks of ambient concentrations which may far exceed the level of the NAAQS. While the AQI was not originally developed to be used as a regulatory tool or for other purposes and EPA does not provide guidance on the use of the AQI for such purposes, the EPA acknowledges that some organizations and entities have identified other uses for the AQI.[110] As such, the EPA is requesting information about how other organizations and entities are applying the AQI. The EPA's goal is to update the $PM_{2.5}$ AQI in conjunction with the Agency's final decisions on the primary annual and 24-hour $PM_{2.5}$ standards, if proposed revisions to such standards are promulgated.

1. Air Quality Index Values of 50, 100 and 150

With respect to the lower AQI breakpoints, the EPA concludes that it is still appropriate to continue to set these breakpoints to be consistent with the primary annual and 24-hour $PM_{2.5}$ standard levels. The lowest AQI value of 50 provides the breakpoint between the "good" and

[110] For example, the Occupational Safety and Health divisions in California, Oregon, and Washington have linked outdoor worker regulations to the upper AQI breakpoints.

"moderate" categories. At and below this concentration, air quality is considered "good" for everyone. Above this concentration, in the "moderate" category, the AQI contains advisories for unusually sensitive individuals. The EPA has historically set this breakpoint at the level of the primary annual $PM_{2.5}$ standard. In doing so, the EPA has recognized that: (1) the annual standard is set to provide protection to the public, including at-risk populations, from $PM_{2.5}$ concentrations which, when experienced on average for a year, have the potential to result in adverse health effects; and that (2) the AQI exposure period represents a shorter exposure period (e.g., 24-hour (or less)) while focusing on the most sensitive individuals. The EPA sees no basis for deviating from this approach in this reconsideration. Thus, the EPA proposes to set the AQI value of 50 at a daily (i.e., 24-hour) average concentration equal to the level of the primary annual $PM_{2.5}$ standard that is promulgated. In this notice, the EPA is proposing to revise the primary annual $PM_{2.5}$ standard level to 9 to 10 $\mu g/m^3$ and soliciting comments on levels down to 8 $\mu g/m^3$ and up to 11 $\mu g/m^3$ (section II.D.3.a).

The historical approach to setting an AQI value of 100, which is the breakpoint between the "moderate" and "unhealthy for sensitive groups" categories, and above which advisories are generated for sensitive groups, is to set it at the same level as the primary 24-hour $PM_{2.5}$ standard. In so doing, the EPA has recognized that the primary 24-hour $PM_{2.5}$ standard is set to provide protection to the public, including at-risk populations, from short-term exposures to $PM_{2.5}$ concentrations which have the potential to result in adverse health effects. Given this, it is appropriate to generate advisories for sensitive groups at concentrations above this level. In the past, state, local, and Tribal air quality agencies have expressed strong support for this approach (78 FR 3086, January 15, 2013). The EPA sees no basis to deviate from this approach in this reconsideration. In this proposal, the EPA is proposing to retain the current primary 24-hour

$PM_{2.5}$ standard with its level of 35 μg/$m^3$ but is taking comment on revising the level of that standard to 25 μg/$m^3$ (section II.D.3.b). Thus, the EPA proposes to retain the AQI value of 100 set at the level of the current primary 24-hour $PM_{2.5}$ standard concentration of 35 μg/$m^3$ (i.e., 24-hour average), but if the level of the 24-hour standard is revised to a different concentration, the EPA is proposing to set the final AQI value of 100 equal to any revised level of the primary 24-hour $PM_{2.5}$ standard.

With respect to an AQI value of 150, which is the breakpoint between the "unhealthy for sensitive groups" and "unhealthy categories," this breakpoint concentration in this reconsideration is based upon the considering the same health effects information, as assessed in the 2019 ISA and ISA Supplement and described in section II above, that informs the proposed decisions on the level of the 24-hour standard and the AQI value of 100. Previously, the Agency has used a proportional adjustment in which the AQI value of 150 was set proportionally to the AQI value of 100. This proportional adjustment inherently recognizes that the available epidemiologic studies provide no evidence of discernible thresholds, below which effects do not occur in either sensitive groups or in the general population, that could inform conclusions regarding concentrations at which to set this breakpoint. Given that the epidemiologic evidence continues to be the most relevant health effects evidence for informing this range of AQI values, the EPA sees no basis to deviate from this approach in this reconsideration. Therefore, the EPA proposes to set an AQI value of 150 proportionally, depending on the breakpoint concentration of the AQI value of 100. This means that if the EPA retains the current primary 24-hour $PM_{2.5}$ standard of 35 μg/$m^3$, we propose to also retain the current AQI value of 150 at a daily (i.e., 24-hour average) concentration of 55 μg/$m^3$. If, however, the EPA revises the level of the primary 24-hour $PM_{2.5}$ standard, we propose to adjust the AQI value of 150 proportional to that revision

(e.g., a 24-hour standard of 30 $\mu g/m^3$ might result in an AQI value for 150 of 45 $\mu g/m^3$).

2. Air Quality Index Values of 200 and Above

In 1999, the EPA established AQI breakpoints for the AQI values of 200 and above (64 FR 42530, August 4, 1999). For this approach the AQI values between 100 and 500 were based on $PM_{2.5}$ concentrations that generally reflected a linear relationship between increasing index values and increasing $PM_{2.5}$ concentrations.[111] It was found that this linear relationship was generally consistent with the health effect evidence, which suggested that as $PM_{2.5}$ concentrations increase, increasingly larger numbers of people are likely to experience serious health effects in this range of $PM_{2.5}$ concentrations (64 FR 42536, August 4, 1999). For the AQI breakpoint of 500, the concentration was based on the method used to establish a previously existing $PM_{10}$ breakpoint that was informed by studies conducted in London using the British Smoke method, which uses a different particle size cutpoint.[112] Due to limited ambient $PM_{2.5}$ monitoring data available at that time, the decision on the 500 breakpoint concentration for $PM_{2.5}$ was based on the stated assumption that PM concentrations measured by the British Smoke method were

[111] The AQI breakpoint at 150 was originally set in 1999 to be linearly related to the concentrations at the 100 and 500 breakpoints but then revised in 2012 to be proportional to the AQI breakpoint concentration at 100 (78 FR 3181, January 15, 2013).

[112] The current AQI value of 500 for $PM_{10}$ was set in 1987 at the concentration of 600 $\mu g/m^3$ based on a 24-hour average, on the basis of increased mortality associated with historical wintertime pollution episodes in London (52 FR 24687 to 24688, July 1, 1987). Particle concentrations during these episodes, measured by the British Smoke method, were in the range of 500 to 1000 $\mu g/m^3$. In the 1987 rulemaking that established the upper bound index value for $PM_{10}$, the EPA cited a generally held opinion that the British Smoke method measures PM with a cutpoint of approximately 4.5 microns (52 FR 24688, July 1, 1987). In establishing this value for $PM_{10}$, the EPA assumed that concentrations of $PM_{10}$, which includes both coarse ($PM_{10-2.5}$) and fine particles ($PM_{2.5}$), during episodes of concern, would be about 100 $\mu g/m^3$ higher than the PM concentration measured in terms of British Smoke (52 FR 24688, July 1, 1987). The $PM_{10}$ upper bound index value of 600 $\mu g/m^3$ was developed by selecting the lower end of the range of concentrations during the historical wintertime pollution episodes in London (500 $\mu g/m^3$) and adding a margin of 100 $\mu g/m^3$ to account for this measurement difference.

approximately equivalent to $PM_{2.5}$ concentrations (64 FR 42530, August 4, 1999). However, the assumption of approximate equivalence between the British Smoke method and the current $PM_{2.5}$ monitoring method is not consistent with the view cited in the 1987 *Federal Register* notice about the $PM_{10}$ AQI value of 500, in which the British Smoke method was noted to have a particle size cutpoint of 4.5 microns (52 FR 24688, July 1, 1987). Given that the British Smoke method has a larger particle size cutpoint than the current $PM_{2.5}$ monitoring method which has a cutpoint of 2.5 microns, a concentration of 500 $\mu g/m^3$ based on the British Smoke method would be equivalent to a lower $PM_{2.5}$ concentration.

As part of this reconsideration, the EPA recognizes that the health effects evidence associated with $PM_{2.5}$ exposure has greatly expanded in recent years. While many of the new studies evaluated in the 2019 ISA focused on examining health effects associated with exposure to lower $PM_{2.5}$ concentrations, there are also several new studies, specifically controlled human exposure studies, that can provide information about health effects at concentrations well above the standard levels. Additionally, there are also studies now available and evaluated in other Agency documents that can inform health effects at higher $PM_{2.5}$ concentrations. Thus, the EPA concludes that it is appropriate to reevaluate the upper AQI breakpoints, taking into account the expanded body of scientific evidence. In particular, because these breakpoints were established in 1999 (64 FR 42530, August 4, 1999), several new epidemiologic studies have become available that provide information about exposures during high pollution events, such as wildfires. Additionally, multiple controlled human exposure studies have become available that provide information about health effects across a range of concentrations. While it remains unclear the exact $PM_{2.5}$ concentrations at which specific health effects occur, the more recent studies do provide more refined information about the concentration range in which these effects

might occur. For example, while human exposure studies generally report only subclinical effects, the consistent observation of these effects in multiple studies can provide an indication of subclinical effects that are on the pathway to more serious health effects as $PM_{2.5}$ concentrations increase above 55 $\mu g/m^3$. These studies provide support for coherence of effects across scientific disciplines and potentially biologically plausible pathways for the overt population-level health effects observed in epidemiologic studies. Therefore, taking into account the short exposure time period in these studies (e.g., 1-6 hours) and that the studies generally do not include at-risk (or sensitive) populations, but rather young, healthy adults, these studies, in conjunction with information from epidemiologic studies, the EPA preliminarily concludes it would be appropriate to be more cautionary and offer advisories to the public for reducing exposures at lower concentrations than recommended with the current AQI breakpoints. Thus, the discussion below focuses on the EPA's proposed revisions to the AQI breakpoints of 200 and above and the EPA's interpretation of the available health effects evidence that supports those proposed revisions.

The AQI value of 200 is the breakpoint between the "unhealthy" and "very unhealthy" categories. At AQI values above 200, the AQI would be providing a health warning that the risk of anyone experiencing a health effect following short-term exposures to these $PM_{2.5}$ concentrations has increased. To inform proposed decisions on this breakpoint, the EPA takes note of studies indicating the potential for respiratory or cardiovascular effects that are associated with more serious health outcomes (e.g., emergency department visits, hospital admissions). The controlled human exposure studies evaluated in the 2009 and 2019 ISAs provide evidence of inflammation as well as cardiovascular effects in healthy subjects at and above 120 $\mu g/m^3$. For example, Ramanathan et al. (2016) observed a transient reduction in antioxidant/anti-

inflammatory function after exposing healthy young subjects to a mean concentration of 150 $\mu g/m^3$ of $PM_{2.5}$ for 2 hours. Urch et al. (2010) also reported increased markers of inflammation when exposing both asthmatic and non-asthmatic subjects to a mean concentration of 140 $\mu g/m^3$ of $PM_{2.5}$ for 3 hours. In studies specifically examining cardiovascular effects, Ghio et al. (2000) and Ghio et al. (2003) exposed healthy subjects to a mean concentration of 120 $\mu g/m^3$ for 2 hours and reported significantly increased levels of fibrinogen, a marker of coagulation that increases during inflammation. Sivagangabalan et al. (2011) exposed healthy subjects to a mean concentration of 150 $\mu g/m^3$ of $PM_{2.5}$ for 2 hours and noted an increased QT interval ($3.4 \pm 1.4$) indicating some evidence for conduction abnormalities, an indicator of possible arrhythmias. Lastly, Brook et al. (2009) reported a transient increase of 2.9 mm Hg in diastolic blood pressure in healthy subjects during the 2-hour exposure to a mean concentration of 148 $\mu g/m^3$ of $PM_{2.5}$.

In addition to epidemiologic studies evaluated in the 2019 ISA that analyzed exposures at ambient $PM_{2.5}$ concentrations, there are a number of recent epidemiologic studies focusing on wildfire smoke that have become available that were evaluated in the EPA's recently released peer-reviewed assessment on wildland fire (U.S. EPA, 2021b). One of these studies, Hutchinson et al. (2018), conducted a bidirectional case-crossover analysis to examine associations between wildfire-specific $PM_{2.5}$ exposure and respiratory-related healthcare encounters (i.e., ED visits, inpatient hospital admissions, and outpatient visits) prior and during the 2007 San Diego wildfires. This study found positive and significant associations to $PM_{2.5}$ exposures and respiratory-related healthcare encounters. Further, during the initial 5-day period of the wildfire event, the study observed that there was evidence of increases in a number of respiratory-related outcomes particularly ED visits for asthma, upper respiratory infection, respiratory symptoms, acute bronchitis, and all respiratory-related visits (Hutchinson et al., 2018), giving the EPA

increased confidence in the association between exposure to $PM_{2.5}$ and respiratory-related outcomes at concentrations experienced during this time period. When examining the air quality during the wildfire event, $PM_{2.5}$ concentrations were highest during the initial five days of the wildfire, with 24-hour average $PM_{2.5}$ concentrations of 89.1 $\mu g/m^3$ across all zip codes and with the highest 24-hour average of 160 $\mu g/m^3$ on the first day (Hutchinson et al., 2018).

When considering this collective body of evidence from controlled human exposure and epidemiologic studies, the Agency proposes to set an AQI value of 200 at a daily (i.e., 24-hour average) concentration of $PM_{2.5}$ of 125 $\mu g/m^3$. This concentration is at the lower end of the concentrations consistently shown to be associated with effects in controlled human exposure studies following short-term exposures (e.g., 2-3 hours) and in young, healthy adults (Ghio et al., 2000; Ghio et al., 2003; Urch et al., 2010; Ramanathan et al., 2016; Sivagangabalan et al., 2011; and Brook et al., 2009) and also within the range of 5-day average and maximum concentrations observed to be associated with respiratory-related outcomes following exposure to wildfire smoke (Hutchinson et al., 2018).

The AQI value of 300 denotes the breakpoint between the "very unhealthy" and "hazardous" categories, and thus marks the beginning of the "hazardous" AQI category. At AQI values above 300, the AQI provides a health warning that everyone is likely to experience effects following short-term exposures to these $PM_{2.5}$ concentrations. To inform decisions on this AQI breakpoint, the EPA takes note of controlled human exposure studies that consistently show subclinical effects which are often associated with more severe cardiovascular outcomes. As discussed above, Brook et al. (2009) reported a transient increase of 2.9 mm Hg in diastolic blood pressure in healthy subjects during the 2-hour exposure to a mean concentration of 148 $\mu g/m^3$ of $PM_{2.5}$. Bellavia et al. (2013) exposed healthy subjects to an average $PM_{2.5}$ concentration

of 242 μg/m$^3$ for 2 hours and reported increased systolic blood pressure (2.53 mm Hg). Tong et al. (2015) exposed healthy subjects to an average $PM_{2.5}$ concentration of 253 μg/m$^3$ for 2 hours and observed a significant increase in diastolic blood pressure (2.1 mm Hg) and a nonsignificant increase in systolic blood pressure (2.5 mm Hg). Lucking et al. (2011) reported impaired vascular function and increased potential for coagulation when exposing healthy subjects to diesel exhaust (DE) with an average $PM_{2.5}$ concentration of 320 μg/m$^3$ for a duration of 1 hour.[113] These studies all provided evidence of impaired vascular function, including vasodilatation impairment and increased thrombus formation, with Tong et al. (2015), Bellavia et al. (2013), Brook et al. (2009) all reporting increases in blood pressure. Additionally, Behbod et al. (2013) reported increased inflammatory markers following a 2-hour exposure to an average $PM_{2.5}$ concentration of 250 μg/m$^3$ in healthy subjects.

In addition to the controlled human exposure studies discussed above, the epidemiologic study conducted by DeFlorio-Barker et al. (2019) examined the relationship between wildfire smoke and cardiopulmonary hospitalizations among adults 65 years of age and older from 2008-2010 in 692 U.S. counties. The authors reported a 2.22% increase in all-cause respiratory hospitalizations on wildfire smoke days for a 10 μg/m$^3$ increase in 24-hour average $PM_{2.5}$ concentrations (DeFlorio-Barker et al., 2019). The maximum 24-hour average concentration in this study on wildfire smoke days was 212.5 μg/m$^3$ (DeFlorio-Barker et al., 2019). In considering this study, the EPA notes the increased probability that even healthy adults experience effects at this maximum exposure concentration, particularly given that this

[113] Although participants in Lucking et al. (2011) were exposed to DE, the authors also conducted analyses using a particle trap, and as noted in the 2019 ISA, this type of study design allows for the assessment of the role of $PM_{2.5}$ on the health effects observed by removing PM from the DE mixture.

maximum concentration is near the exposure concentrations in controlled human exposure studies that consistently reported evidence of impaired vascular function and several that reported increases in blood pressure in healthy adults following 2-hour exposures.

Based on the information above, the EPA proposes to revise the 300 level of the AQI, which marks the beginning of the "hazardous" AQI category, to a concentration that is consistent with the $PM_{2.5}$ concentrations associated with health effects as reported in the controlled human exposure and epidemiologic studies discussed above. Specifically, the Agency proposes to set an AQI value of 300 at a daily (i.e., 24-hour average) $PM_{2.5}$ concentration of 225 $\mu g/m^3$. This concentration falls between the 2-hour average concentrations reported in controlled human exposure studies found to be consistently associated, in healthy adults, with impaired vascular function and/or increases in blood pressure, which can both be a precursor to more severe cardiovascular effects following short-term (1- to 2-hour) exposures, and the maximum 24-hour average $PM_{2.5}$ concentrations on wildfire smoke days reported in the epidemiologic study conducted by DeFlorio-Barker et al. (2019).

Lastly, the EPA is also proposing revisions to the 500 value of the AQI. The 500 value of the AQI is within the "hazardous" category but is specified and used to calculate the slope of the AQI values in the "hazardous category" above and below AQI values of 500. In the past, this breakpoint had a very prominent role in determining the current upper AQI values given that it was used as part of the linear relationship with the concentration at the AQI value of 100 to determine the AQI values of 200 and 300 in 1999 (64 FR 42530, August 4, 1999).

As discussed above, the current breakpoint concentration for the 500 value of the AQI was set in 1999 at a 24-hour average $PM_{2.5}$ concentration of 500 $\mu g/m^3$ and was based on studies conducted in London using the British Smoke method, which used a different particle size

cutpoint and likely overestimated the $PM_{2.5}$ concentration. In looking to improve upon that approach, the EPA considers several recent controlled human exposure studies that observe health effects which are clearly associated with more severe cardiovascular outcomes and note that these seem to follow exposures to high $PM_{2.5}$ concentrations that are well above those typically observed in ambient air. In controlled human exposure studies, Vieira et al. (2016a) and Vieira et al. (2016b) exposed healthy subjects and subjects with heart failure to diesel exhaust (DE) with a mean $PM_{2.5}$ concentration of 325 $\mu g/m^3$ for 21 minutes and reported decreased stroke volume, and increased arterial stiffness (an indicator of endothelial dysfunction) in both healthy and heart failure subjects.[114] Also as discussed above, Lucking et al. (2011) exposed healthy subjects to DE with a mean $PM_{2.5}$ concentration of 320 $\mu g/m^3$ for 1 hour.[115] The types of cardiovascular effects observed in these controlled human exposure studies have been linked with the exacerbation of ischemic heart disease (IHD) and heart failure as well as myocardial infarction (MI) and stroke.

In addition to the controlled human exposure studies discussed above, recent epidemiologic studies examining the relationship between wildfire smoke and respiratory health can also inform proposed decisions on the concentration for the AQI value of 500. As noted earlier in this section, Hutchinson et al. (2018) reported increases in a number of respiratory-related outcomes particularly ED visits for asthma, upper respiratory infection, respiratory symptoms, acute bronchitis, and all respiratory-related visits during the initial 5-day period of the 2007 San Diego fire. During the initial 5-day window, $PM_{2.5}$ concentrations were found to be at

[114] These effects were attenuated when the DE was filtered, to reduce $PM_{2.5}$ concentrations, indicating the effects were likely associated with $PM_{2.5}$ exposure.
[115] When applying a particle trap, $PM_{2.5}$ concentrations were reduced, and effects associated with cardiovascular function including impaired vascular function, as measured by vasodilatation and thrombus formation were attenuated indicating associations with $PM_{2.5}$.

their highest with the 95$^{th}$ percentile of 24-hour average concentrations of 333 µg/m$^3$.

Although studies of short-term (i.e., daily) exposures to wildfire smoke are more informative in considering alternative level for the AQI value of 500 since they mirror the 24-hour exposure timeframe, additional information from epidemiologic studies of longer-term exposures (i.e., over many weeks) during wildfire events can provide supporting information. For example, Orr et al. (2020) conducted a longitudinal study that examined whether exposure to wildfire smoke from a multi-month fire resulted in respiratory effects in subsequent years. The authors conducted respiratory health assessments of adults living in Seeley Lake and Thompson Falls, MT during the 3-month summer wildfire event that occurred in 2017 as well as follow-up visits in each of the two years following the wildfire (Orr et al., 2020). During the 2017 wildfire event (August 1 to September 19, 2017), Orr et al. (2020) reported that many days during the multi-month fire had $PM_{2.5}$ concentrations above 300 µg/m$^3$, resulting in a daily average $PM_{2.5}$ concentration of 220.9 µg/m$^3$ with a maximum $PM_{2.5}$ concentration of 638 µg/m$^3$. This study included full spirometry tests for all study participants during the initial 2017 visit and again in 2018 and 2019 to assess lung function and reported that the average $FEV_1$/FVC decreased significantly in 2018 (71.6% observed; 77.35% predicted) and 2019 (73.4% observed; 76.52% predicted) (Orr et al., 2020). This study suggests that exposure to high $PM_{2.5}$ concentrations during a multi-week fire event may lead to long-term health consequences in the future, such as declines in lung function.

The controlled human exposure studies provide biological plausibility for increases in respiratory-related health care events during the wildfires documented in epidemiologic studies. The collective evidence from controlled human exposure and epidemiologic studies, which includes decreases in stroke volume, increased arterial stiffness, impaired vascular function and

respiratory-related healthcare encounters provide health-based evidence to inform proposed decisions on the level of the AQI value of 500. Given the concentrations observed in these studies, the Agency proposes to revise the AQI value of 500 to a level set at a daily (i.e., 24-hour average) $PM_{2.5}$ concentration of 325 $\mu g/m^3$. This concentration is at or below the lowest concentrations observed in the controlled human exposure studies associated with more severe effects discussed above and also at the low end of the daily concentrations observed in the epidemiologic studies conducted by Hutchinson et al. (2018) and Orr et al. (2020).

3. Summary

Table 1 below summarizes the proposed breakpoints for the $PM_{2.5}$ sub-index.

Table 1 – Proposed Breakpoints for $PM_{2.5}$ Sub-Index

| AQI category | Index values | Current breakpoints ($\mu g/m^3$, 24-hour average) | Proposed breakpoints ($\mu g/m^3$, 24-hour average) |
|---|---|---|---|
| Good | 0-50 | 0.0-12.0 | 0.0-(9.0-10.0) |
| Moderate | 51-100 | 12.1-35.4 | (9.1-10.1)-35.4 |
| Unhealthy for Sensitive Groups | 101-150 | 35.5-55.4 | 35.5-55.4 |
| Unhealthy | 151-200 | 55.5-150.4 | 55.5-125.4 |
| Very Unhealthy | 201-300 | 150.5-250.4 | 125.5-225.4 |
| Hazardous [1] | 301+ | 250.5 | 225.5 |

[1] AQI values between breakpoints are calculated using equation 1 in Appendix G. For AQI values in the hazardous category, AQI values greater than 500 should be calculated using equation 1 and the $PM_{2.5}$ concentration specified for the AQI value of 500.

As discussed above, the EPA recognizes that the health effects evidence associated with $PM_{2.5}$ exposure has greatly expanded in recent years and concludes that the body of scientific evidence supports the need to revise many of the AQI breakpoints. This is particularly true of the

AQI values of 200 and above, where the EPA concludes that the available controlled human exposure and epidemiologic studies support offering advisories to the public for reducing exposures at lower concentrations than recommended with the current AQI breakpoints. However, the EPA also recognizes that there are interpretations and judgments that must be applied in making the determinations of these breakpoints. Thus, the EPA is soliciting comment on the proposed revisions to the AQI described above. In particular, for the AQI values of 50, 100 and 150, the EPA is soliciting comment on the proposed decision to continue to use the approach used in AQI revisions in 2012 (77 FR 38890, June 29, 2012) of setting the lower breakpoints (50, 100, and 150) to be consistent with the levels of the primary annual and 24-hour $PM_{2.5}$ standards and proposed decision to revise the lower breakpoints to be consistent with any changes to the primary $PM_{2.5}$ standards that are part of this reconsideration. With respect to the AQI values of 200 and above, the EPA is soliciting comment on the proposed decision to revise those AQI values, as well as comment on the approach being applied, the health studies viewed as most relevant in these proposed decisions, and the proposed AQI breakpoint concentrations. The EPA also notes that while the newer studies do provide more refined information about the concentration range in which health effects might occur, the evidence continues to support a continuum of effects in concentration exposures in the range of those defined by the upper AQI values, with increasing $PM_{2.5}$ concentrations being associated with increasingly larger numbers of people likely experiencing serious health effects. Given this, the EPA is also soliciting comment on maintaining the linear relationship approach used to set the upper AQI values in 1999 but using a different linear relationship (64 FR 42530, August 4, 1999). For example, the EPA could set the AQI value of 150 based on the primary NAAQS and the AQI value of 300 (which is the breakpoint that identifies the starting concentration for the highest AQI category)

based on the considerations discussed above and using those values to develop a linear relationship for the AQI values for 200 and 500. Under this approach, if the AQI breakpoint for 150 is set at 55.4 $\mu g/m^3$ and the AQI breakpoint for 300 is set at 225.4 $\mu g/m^3$, the AQI breakpoint for 200 would be 112.4 $\mu g/m^3$ and the AQI breakpoint for 500 would be 452.4 $\mu g/m^3$. The EPA solicits comments on whether to use a linear approach for higher breakpoints, the appropriate breakpoints to use for such an approach, and the appropriate values for breakpoints under other approaches, falling within the range of the current breakpoints and the breakpoints identified by these various approaches, as well as to retain and not change the existing breakpoints at this time.

*C. Air Quality Index Category Breakpoints for $PM_{10}$*

The EPA proposes to retain the $PM_{10}$ sub-index of the AQI consistent with the proposed decision to retain the primary $PM_{10}$ standard, and consistent with the health effects information that supports this proposed decision, as discussed in section III.D above.

*D. Air Quality Index Reporting*

With respect to the reporting requirements for the AQI, there have been many technological advances in air quality monitoring and data reporting since the Appendix G to 40 CFR part 58 was last revised in 1999. Federal, state, local and Tribal agencies have used these changes to make health information and air quality data more readily available and easier to access. Given this, it is useful to update the reporting requirements and recommendations to match current practices and ensure the public has the most useful and timely information to take health-protective behaviors.

Currently, Appendix G defines daily reporting as five days per week. When this reporting requirement was originated in 1999 the technology available at that time was not sufficient to calculate and report the AQI more than five days per week without requiring additional staffing

on the weekends. Since that time, advances in technology have allowed for reporting seven days per week automatically without expending additional resources on weekends. As a result, most state, local and Tribal air agencies now report the AQI seven days per a week. Given these technological advances and noting that reporting agencies currently report the AQI seven days per week, the EPA is proposing that state, local and Tribal agencies that report the AQI be required to report it seven days a week, ensuring that the public continues to have access to daily air quality and health information that they can use to take steps to protect their health.

Improvements in monitoring networks and modeling capabilities have also enabled the ability to report the AQI in near real-time. This allows state, local and Tribal air agencies to provide timely air quality information to the public for making health-protective decisions and to help satisfy AQI reporting requirements. The availability of near real-time AQI data also allows for more timely responses by the public when air quality conditions are changing rapidly, such as during wildfire smoke events. Sub-daily reporting of the AQI can be critical when there are rapidly change conditions and/or high pollution events so that the public is able to make informed decisions to protect their health. Many state, local and Tribal air agencies currently report the AQI hourly to ensure that the public has access to accurate and timely information. In recognition of these advances, and to continue to provide for near-real time AQI reporting that the public has come to rely on, the EPA proposes to recommend that state, local and Tribal agencies report the AQI in near-real time. Like air quality forecasting, which also allows the public to make health-protective, near-real time AQI reporting is recommended but not required.

In lieu of or along with reporting the near-real-time AQI directly to the public, most state/local and Tribal agencies submit hourly air quality data to the EPA. The EPA uses this near-real-time data in the National, Interactive and Fire and Smoke maps on the AirNow website,

and to create products for use by weather service providers and the media. Some state, local and Tribal air quality agencies also use these products on their own websites and in their own applications (i.e., the California Air Resources Board uses the data in its California Smoke Spotter application). To continue to ensure the availability of the products that the public and many stakeholders rely upon, the EPA is proposing to recommend that state, local and Tribal air quality agencies submit hourly data to the EPA's air quality database. Submitting hourly data to the EPA for use on the AirNow website and in other products also enables state, local and Tribal air quality agencies to meet the recommendation to report the AQI in near-real-time.

The Agency is updating the reporting requirements and near-real-time reporting and data submission recommendations for the AQI. The Agency is reformatting the question-and-answer format used in Appendix G to align with the current standard formatting used in the Code of Federal Regulations. The EPA is not taking comment on or reopening the language that has merely been moved or rearranged as there are no substantive changes.

Another change the EPA is proposing to make to Appendix G is with regard to Table 2– Breakpoints for the AQI for purposes of clarity. We are proposing to collapse the two rows presented for the Hazardous Category into one. The two rows in the current table specify pollutant concentrations for two AQI ranges within the Hazardous category (301-400 and 401-500), with an intermediate break at 400. This breakpoint of 400, along with those for 200 and 300, were defined and are the historical basis for the Alert, Warning, and Emergency episode levels included in 40 CFR part 51, appendix L, as part of the Prevention of Air Pollution Emergency Episodes program (44 FR 92, May 10, 1979). The 400 breakpoint for all criteria pollutants in the current Table 2 is set at the proportional pollutant concentration approximately halfway between the index values of 300 and 500. In proposing updated AQI breakpoints for

$PM_{2.5}$, the EPA considered adjusting the 400 breakpoint similarly. However, the EPA concluded that collapsing the two rows into a single range (301-500) would provide a more transparent and easy-to-follow presentation of the pollutant concentrations corresponding to the AQI range for the Hazardous category. Moreover, collapsing the Hazardous category into a single row in Table 2 has no substantive effect on the Emergency Episode program in 40 CFR part 51, appendix L. Thus, the EPA is proposing to remove the breakpoint of 400 from the table in Appendix G but this change would not substantively affect the derivation of the AQI for any pollutant.

In addition, the EPA plans to move some information currently in Appendix G into the Technical Assistance Document for the Reporting of Daily Air Quality, or TAD (U.S. EPA, 2018a), so that it can be updated in a more timely manner to reflect current scientific and health effects evidence and current communication methods, thereby assisting state, local and Tribal agencies in providing accurate and timely information to the public. Information that will be moved from Appendix G to the TAD includes the definitions of the sensitive (at-risk) populations for each pollutant. This definition is typically evaluated and updated, as warranted, in most NAAQS reviews, even if the standard is not revised. Generally, if the standard is not revised in a review of the NAAQS, then Appendix G is also not revised. Moving the definitions of sensitive groups to the TAD allows them to be updated even when a NAAQS is not revised to be consistent with the definitions of the sensitive (at-risk) populations identified in the ISA for a NAAQS review. Data calculations for non-required mathematical equations, (i.e., the NowCast), are currently and will continue to be included in the TAD. The EPA works with state, local and Tribal air agencies to modify these calculations as needed, which may not be associated with a NAAQS review. Also, recognizing that the ways that air quality and health information is supplied to the news media and public changes regularly, information about suggested

approaches will be taken out of Appendix G and discussed in the TAD.

## V. Rationale for Proposed Decisions on the Secondary PM Standards

This section presents the rationale for the Administrator's proposed decision that no change to the current secondary PM standards is required at this time to provide requisite protection against the public welfare effects of PM within the scope of this reconsideration (i.e., visibility, climate, and materials effects).[116] This rationale is based on a thorough review of the scientific evidence generally published through December 2017,[117] as presented in the 2019 ISA (U.S. EPA, 2019a), on the non-ecological public welfare effects of PM pertaining to the presence of PM in ambient air, specifically visibility, climate, and materials effects. Additionally, this rationale is based on a thorough evaluation of some studies that became available after the literature cutoff date of the 2019 ISA that could either further inform the adequacy of the current PM NAAQS or address key scientific topics that have evolved since the literature cutoff date for

[116] Consistent with the 2016 Integrated Review Plan (U.S. EPA, 2016), other welfare effects of PM, such as ecological effects, are being considered in the separate, on-going review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM. Accordingly, the public welfare protection provided by the secondary PM standards against ecological effects such as those related to deposition of nitrogen- and sulfur-containing compounds in vulnerable ecosystems is being considered in that separate review. Thus, the Administrator's conclusion in this reconsideration of the 2020 final decision will be focused only and specifically on the adequacy of public welfare protection provided by the secondary PM standards from effects related to visibility, climate, and materials and hereafter "welfare effects" refers to non-ecological welfare effects (i.e., visibility, climate, and materials effects).

[117] In addition to the 2020 review's opening "call for information" (79 FR 71764, December 3, 2014), the 2019 ISA identified and evaluated studies and reports that have undergone scientific peer review and were published or accepted for publication between January 1, 2009 through approximately January 2018 (U.S. EPA, 2019a, p. ES-2). References that are cited in the 2019 ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: *https://hero.epa.gov/hero/particulate-matter*.

the 2019 ISA, generally through March 2021, as presented in the ISA Supplement[118] (U.S. EPA, 2022a). The selection of welfare effects evaluated within the ISA Supplement was based on the causality determinations reported in the 2019 ISA and the subsequent use of scientific evidence in the 2020 PA.[119] Specifically, for welfare effects, the focus within the ISA Supplement is on visibility effects. The ISA Supplement does not include an evaluation of studies on climate or materials effects. The Administrator's rationale also takes into account: (1) the PA evaluation of the policy-relevant information in the 2019 ISA and ISA Supplement and presentation of quantitative analysis of air quality related to visibility impairment; (2) CASAC advice and recommendations, as reflected in discussions of the drafts of the ISA Supplement and PA at public meetings and in the CASAC's letters to the Administrator; and (3) public comments received during the development of these documents.

In presenting the rationale for the Administrator's proposed decision and its foundations, section V.A provides background and introductory information for this reconsideration of the secondary PM standards. It includes background on the 2020 final decision to retain the

[118] As described in more detail in the ISA Supplement, "the scope of this Supplement provides specific criteria for the types of studies considered for inclusion within the Supplement. Specifically, studies must be peer reviewed and published between approximately January 2018 and March 2021" (U.S. EPA, 2022a, section 1.2.2).

[119] As described in section 1.2.1 of the ISA Supplement, "the selection of welfare effects to evaluate within this Supplement is based on the causality determinations reported in the 2019 PM ISA and the subsequent use of scientific evidence in the 2020 PM PA. The 2019 PM ISA concluded a *causal relationship* for each of the welfare effects categories evaluated (i.e., visibility, climate effects, and materials effects). While the 2020 PM PA considered the broader set of evidence for these effects, for climate effects and material effects, it concluded that there remained 'substantial uncertainties with regard to the quantitative relationships with PM concentrations and concentration patterns that limit[ed] [the] ability to quantitatively assess the public welfare protection provided by the standards from these effects (U.S. EPA, 2020a). Given these uncertainties and limitations, the basis of the discussion on conclusions regarding the secondary standards in the 2020 PM PA primarily focused on visibility effects. Therefore, this Supplement focuses only on visibility effects in evaluating newly available scientific information and is limited to studies conducted in the U.S. and Canada" (U.S. EPA, 2022a, section 1.2.1).

secondary PM standards (section V.A.1) and also describes the general approach for this reconsideration (section V.A.2). Section V.B summarizes the key aspects of the currently available evidence and quantitative information for PM-related visibility impairment and section V.C summarizes the available information for other PM-related welfare effects. Section V.D presents the Administrator's proposed conclusions on the current secondary PM standards (V.D.III), drawing on both evidence- and quantitative information-based considerations (section V.D.1) and advice from the CASAC (V.D.2).

*A. General Approach*

This reconsideration of the 2020 final decision on the secondary PM standards relies on the EPA's assessments of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgments regarding secondary standards that are requisite to protect the public welfare from known or anticipated adverse effects associated with the pollutant's presence in the ambient air. The EPA's assessments are primarily documented in the 2019 ISA, ISA Supplement, and PA, all of which have received CASAC review and public comment (83 FR 53471, October 23, 2018; 83 FR 55529, November 6, 2018; 85 FR 4655, January 27, 2020; 86 FR 52673, September 22, 2021; 86 FR 54186, September 30, 2021; 86 FR 56263, October 8, 2021; 87 FR 958, January 7, 2022; 87 FR 22207, April 14, 2022; 87 FR 31965, May 26, 2022). In bridging the gap between the scientific assessments of the 2019 ISA and ISA Supplement and the judgments required of the Administrator in determining whether the current standards provide the requisite public welfare protection, the PA evaluates policy implications of the evaluation of the current evidence in the 2019 ISA and ISA Supplement, and the quantitative information documented in the PA. In evaluating the public welfare protection afforded by the current standards against PM-related effects within the scope of this reconsideration, the four basic elements of the NAAQS (indicator, averaging time, level, and form) are considered

collectively.

The final decision on the adequacy of the current secondary standards is a public welfare policy judgment to be made by the Administrator. In reaching conclusions with regard to the standard, the decision will draw on the scientific information and analyses about welfare effects, and associated public welfare significance, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This approach is based on the recognition that the available evidence generally reflects a continuum that includes ambient air exposures at which scientists agree that effects are likely to occur through lower levels at which the likelihood and magnitude of responses become increasingly uncertain. This approach is consistent with the requirements of the provisions of the Clean Air Act related to the review of NAAQS and with how the EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish secondary standards that, in the judgment of the Administrator, are requisite to protect public welfare from known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect the public welfare from known or anticipated adverse effects.

The subsections below provide background and introductory information. Background on the 2020 decision to retain the current standards, including the rationale for that decision, for non-visibility effects and visibility effects is summarized in sections V.A.1.a and V.A.1.b below, respectively. This is followed, in section V.A.2, by an overview of the general approach for the reconsideration of the 2020 final decision. Following this introductory section and subsections,

the subsequent sections summarize current information and analyses, including that newly available in this reconsideration. The Administrator's proposed conclusions on the secondary PM standards, based on the current information, are provided in section V.D.3.

1. Background on the Current Standards

The current secondary PM standards were affirmed in 2020 based on the scientific and technical information available at that time, as well as the Administrator's judgments regarding the available welfare effects evidence, the appropriate degree of public welfare protection for the existing standards, and available air quality information on visibility impairment that may be allowed by such a standard (85 FR 82684, December 18, 2020). With the 2020 decision, the Administrator retained the secondary 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$, the annual $PM_{2.5}$ standard, with its level of 15.0 $\mu g/m^3$, and the 24-hour $PM_{10}$ standard, with its level of 150 $\mu g/m^3$. The subsections below focus on the key considerations, and the Administrator's conclusions, for climate and materials effects (section V.A.1.a) and visibility effects (section V.A.2.b) in the 2020 review.

a. Non-Visibility Effects

In light of the robust evidence base, the 2019 ISA concluded there to be causal relationships between PM and climate effects and materials effects (U.S. EPA, 2019a, sections 13.3.9 and 13.4.2). The 2020 final decision was based on a thorough review in the 2019 ISA of the scientific information on PM-induced climate and materials effects. The decision also took into account: (1) assessments in the 2020 PA of the most policy-relevant information in the 2019 ISA regarding evidence of adverse effects of PM to climate and materials, (2) uncertainties in the available evidence to inform a quantitative assessment of PM-related climate and materials effects, (3) CASAC advice and recommendations, and (4) public comments received during the

development of these documents and on the proposal notice.

Consistent with the general approach routinely employed in NAAQS reviews, the initial consideration in the 2020 review of the secondary standards was with regard to the adequacy of protection provided by the existing standards. Key aspects of the consideration are summarized in section V.A.1.a.i below.

i. Considerations Regarding Adequacy of the Existing Standards for Non-Visibility Effects in the 2020 Review

In considering non-visibility welfare effects in the 2020 review, as discussed above, the Administrator concluded that, while it is important to maintain an appropriate degree of control of fine and coarse particles to address non-visibility welfare effects, "it is generally appropriate to retain the existing standards and that there is insufficient information to establish any distinct secondary PM standards to address climate and materials effects of PM" (85 FR 82744, December 18, 2020).

With regard to climate, the Administrator recognized that there were a number of improvements and refinements to climate models since the 2012 review. However, while the evidence continued to support a causal relationship between PM and climate effects, the Administrator noted that significant limitations continued to exist related to quantifying the contributions of direct and indirect effects of PM and PM components on climate forcing (U.S. EPA, 2020a, sections 5.2.2.1.1 and 5.4). He also recognized that the models continued to exhibit considerable variability in estimates of PM-related climate impacts at regional scales (e.g., ~100 km) as compared to simulations at global scales. Therefore, the resulting uncertainty led the Administrator to conclude that the available scientific information in the 2020 review remained insufficient to quantify climate impacts associated with particular concentrations of PM in

ambient air (U.S. EPA, 2020a, section 5.2.2.2.1) or to evaluate or consider a level of PM air quality in the U.S. to protect against climate effects and that there was insufficient information available to base a national ambient standard on climate impacts (85 FR 82744, December 18, 2020).

With regard to materials effects, the Administrator noted that the evidence available in the 2019 ISA continued to support a causal relationship between materials effects and PM deposition (U.S. EPA, 2019a, section 13.4). He recognized that the deposition of fine and coarse particles to materials can lead to physical damage and/or impaired aesthetic qualities. Particles can contribute to materials damage by adding to the natural weathering processes and by promoting the corrosion of metals, the degradation of building materials, and the weakening of material components. While some new information was available in the 2019 ISA, the information was from studies primarily conducted outside of the U.S. in areas where PM concentrations in ambient air are higher than those observed in the U.S. (U.S. EPA, 2020a, section 13.4). Additionally, the information assessed in the 2019 ISA did not support quantitative analyses of PM-related materials effects in the 2020 review (U.S. EPA, 2020a, section 5.2.2.2.2). Given the limited amount of information available and its inherent uncertainties and limitations, the Administrator concluded that he was unable to relate soiling or damage to specific levels of PM in ambient air or to evaluate or consider a level of air quality to protect against such materials effects, and that there was insufficient information available to support a distinct national ambient standard based on materials effects (85 FR 82744, December 18, 2020).

In the 2020 review, the CASAC agreed with the 2020 PA conclusions that, while these effects are important, "the available evidence does not call into question the protection afforded by the current secondary PM standards" and recommended that the secondary standards "should

be retained" (Cox, 2019b, p. 3 of letter). In reaching a final decision in the 2020 review, for all of the reasons discussed above and recognizing the CASAC conclusion that the evidence provided support for retaining the current secondary PM standards, the Administrator concluded that it was appropriate to retain the existing secondary PM standards, without revision. For climate and materials effects, this conclusion reflected his judgment that, although it remains important to maintain secondary $PM_{2.5}$ and $PM_{10}$ standards to provide some degree of control over long- and short-term concentrations of both fine and coarse particles, there was insufficient information to establish distinct secondary PM standards to address non-visibility PM-related welfare effects (85 FR 82744, December 18, 2020).

b. Visibility Effects

The 2019 ISA concluded that, "the evidence is sufficient to conclude that a causal relationship exists between PM and visibility impairment" (U.S. EPA, 2019a, section 13.2.6). The 2020 decision on the adequacy of the secondary standards with regard to visibility effects was a public welfare policy judgment made by the Administrator, which drew upon the available scientific evidence for PM-related visibility effects and on analyses of visibility impairment, as well as judgments about the appropriate weight to place on the range of uncertainties inherent in the evidence and analyses. The 2020 final decision was based on a thorough review in the 2019 ISA of the scientific information on PM-related visibility effects. The decision also took into account: (1) assessments in the 2020 PA of the most policy-relevant information in the 2019 ISA regarding evidence of adverse effects of PM on visibility; (2) air quality analyses of the $PM_{2.5}$ visibility index and design values based on the form and averaging time of the existing secondary 24-hour $PM_{2.5}$ standard; (3) CASAC advice and recommendations; and (4) public comments received during the development of these documents and on the 2020 proposal notice.

Consistent with the general approach routinely employed in NAAQS reviews, the initial consideration in the 2020 review of the secondary PM standards was with regard to the adequacy of the protection provided by the then-existing standards. Key aspects of that consideration are summarized in section V.A.1.b.i below.

i. Consideration Regarding the Adequacy of the Existing Standards for Visibility Effects in the 2020 Review

In considering the visibility effects in the 2020 review, the Administrator noted the long-standing body of evidence for PM-related visibility impairment. This evidence, which is based on the fundamental relationship between light extinction and PM mass, demonstrated that ambient PM can impair visibility in both urban and remote areas, and had changed very little since the 2012 review (U.S. EPA, 2019a, section 13.1; U.S. EPA, 2009a, section 9.2.5). The evidence related to public perception of visibility impairment was from studies from four areas in North America.[120] These studies provided information to inform our understanding of levels of visibility impairment that the public judged to be "acceptable" (U.S. EPA, 2010a; 85 FR 24131, April 30, 2020). In considering these public preference studies, the Administrator noted that, as described in the 2019 ISA, no new visibility studies had been conducted in the U.S. and there was little newly available information with regard to acceptable levels of visibility impairment in the U.S. The Administrator recognized that visibility impairment can have implications for people's enjoyment of daily activities and their overall well-being, and therefore, considered the

[120] Preference studies were available in four urban areas. Three western preference studies were available, including one in Denver, Colorado (Ely et al., 1991), one in the lower Fraser River valley near Vancouver, British Columbia, Canada (Pryor, 1996), and one in Phoenix, Arizona (BBC Research & Consulting, 2003). A pilot focus group study was also conducted for Washington, DC (Abt Associates, 2001), and a replicate study with 26 participants was also conducted for Washington, DC (Smith and Howell, 2009). More details about these studies are available in Appendix D.

degree to which the current secondary standards protect against PM-related visibility impairment.

Consistent with the 2012 review, in the 2020 review, the Administrator first concluded that a target level of protection for a secondary PM standard is most appropriately defined in terms of a visibility index that directly takes into account the factors (i.e., species composition and relative humidity) that influence the relationship between $PM_{2.5}$ in ambient air and PM-related visibility impairment. In defining a target level of protection, the Administrator considered the specific aspects of such an index, including the appropriate indicator, averaging time, form and level (78 FR 82742-82744, December 18, 2020).

First, with regard to indicator, the Administrator noted that in the 2012 review, the EPA used an index based on estimates of light extinction by $PM_{2.5}$ components calculated using an adjusted version of the IMPROVE algorithm, which allows the estimation of the light extinction using routinely monitored components of $PM_{2.5}$ and $PM_{10-2.5}$, along with estimates of relative humidity. The Administrator recognized that, while there have been some revisions to the IMPROVE algorithm since the time of the 2012 review, our fundamental understanding of the relationship between PM in ambient air and light extinction had changed little and the various IMPROVE algorithms appropriately reflected this relationship across the U.S. In the absence of a monitoring network for direct measurement of light extinction, he concluded that a calculated light extinction indicator that utilizes the IMPROVE algorithms continued to provide a reasonable basis for defining a target level of protection against PM-related visibility impairment (78 FR 82742-82744, December 18, 2020).

In further defining the characteristics of a visibility index, the Administrator next considered the appropriate averaging time, form, and level of the index. Given the available

scientific information the review, and in considering the CASAC's advice and public comments, the Administrator concluded that, consistent with the decision in the 2012 review, a visibility index with a 24-hour averaging time and a form based on the 3-year average of annual 90$^{th}$ percentile values remained reasonable. With regard to the averaging time and form of such an index, the Administrator noted analyses conducted in the last review that demonstrated relatively strong correlations between 24-hour and subdaily (i.e., 4-hour average) $PM_{2.5}$ light extinction (78 FR 3226, January 15, 2013), indicating that a 24-hour averaging time is an appropriate surrogate for the subdaily time periods of the perception of PM-related visibility impairment and the relevant exposure periods for segments of the viewing public. This decision in the 2020 review also recognized that a 24-hour averaging time may be less influenced by atypical conditions and/or atypical instrument performance (78 FR 3226, January 15, 2013). The Administrator recognized that there was no new information to support updated analyses of this nature, and therefore, he believed these analyses continued to provide support for consideration of a 24-hour averaging time for a visibility index in this review. With regard to the statistical form of the index, the Administrator noted that, consistent with the 2012 review: (1) a multi-year percentile form offers greater stability from the occasional effect of interannual meteorological variability (78 FR 3198, January 15, 2013; U.S. EPA, 2011, p. 4–58); (2) a 90$^{th}$ percentile represents the median of the distribution of the 20 percent worst visibility days, which are targeted in Federal Class I areas by the Regional Haze Program; and (3) public preference studies did not provide information to identify a different target than that identified for Federal Class I areas (U.S. EPA, 2011, p. 4-59). Therefore, the Administrator judged that a visibility index based on estimates of light extinction, with a 24-hour averaging time and a 90$^{th}$ percentile form, averaged over three years, remained appropriate (78 FR 82742-82744, December 18, 2020).

With regard to the level of a visibility index, consistent with the 2012 review, the Administrator judged that it was appropriate to establish a target level of protection of 30 deciviews (dv),[121] [122] reflecting the upper end of the range of visibility impairment judged to be acceptable by at least 50% of study participants in the available public preference studies (78 FR 3226, January 15, 2013). The 2011 PA identified a range of levels from 20 to 30 dv based on the responses in the public preference studies available at that time (U.S. EPA, 2011, section 4.3.4). At the time of the 2012 review, the Administrator noted a number of uncertainties and limitations in public preference studies, including the small number of stated preference studies available, the relatively small number of study participants, the extent to which the study participants may not be representative of the broader study area population in some of the studies, and the variations in the specific materials and methods used in each study. In considering the available preference studies, with their inherent uncertainties and limitations, the prior Administrator concluded that the substantial degree of variability and uncertainty in the public preference studies should be reflected in a target level of protection based on the upper end of the range of candidate protection levels (CPLs).

Given that there were no new preference studies available in the 2020 review, the Administrator's judgments were based on the same studies, with the same range of levels, available in the 2012 review. As identified in the 2020 PA (U.S. EPA, 2020a, section 5.5), there were a number of limitations and uncertainties associated with these studies, including the following:

[121] Deciview (dv) refers to a scale for characterizing visibility that is defined directly in terms of light extinction. The deciview scale is frequently used in the scientific and regulatory literature on visibility.

[122] For comparison, 20 dv, 25 dv, and 30 dv are equivalent to 64, 112, and 191 megameters ($Mm^{-1}$), respectively.

- Available studies may not represent the full range of preferences for visibility in the U.S. population, particularly given the potential variability in preferences based on the conditions commonly encountered and the scenes being viewed.
- Available preference studies were conducted 15 to 30 years ago and may not accurately represent the current day preferences of people in the U.S.
- The variety of methods used in the preference studies may potentially influence the responses as to what level of impairment is deemed acceptable.
- Factors that are not captured in the methods of the preference studies, such as the time of day when light extinction is the greatest or the frequency of impairment episodes, may influence people's judgment on acceptable visibility (U.S. EPA, 2020a, section 5.2.1.1).

Therefore, in considering the scientific information, with its uncertainties and limitations, as well as public comments on the level of the target level of protection against visibility impairment, the Administrator concluded that it was appropriate to again use a level of 30 dv for the visibility index (78 FR 82742-82744, December 18, 2020).

Having concluded that the protection provided by a standard defined in terms of a $PM_{2.5}$ visibility index, with a 24-hour averaging time, and a $90^{th}$ percentile form, averaged over 3 years, set at a level of 30 dv, was requisite to protect public welfare with regard to visual air quality, the Administrator next considered the degree of protection from visibility impairment afforded by the existing suite of secondary PM standards.

In this context, the Administrator considered the updated analyses of visibility impairment presented in the 2020 PA (U.S. EPA, 2020a, section 5.2.1.2), which reflected a number of improvements since the 2012 review. Specifically, the updated analyses examined multiple versions of the IMPROVE equation, including the version incorporating revisions since

the time of the 2012 review. These updated analyses provided a further understanding of how variation in the inputs to the algorithms affect the estimates of light extinction (U.S. EPA, 2020a, Appendix D). Additionally, for a subset of monitoring sites with available $PM_{10-2.5}$ data, the updated analyses better characterized the influence of coarse PM on light extinction than in the 2012 review (U.S. EPA, 2020a, section 5.2.1.2).

The results of the updated analyses in the 2020 PA were consistent with those from the 2012 review. Regardless of which version of the IMPROVE equation was used, the analyses demonstrated that, based on 2015-2017 data, the 3-year visibility metric was at or below about 30 dv in all areas meeting the current 24-hour $PM_{2.5}$ standard, and below 25 dv in most of those areas. In locations with available $PM_{10-2.5}$ monitoring, which met both the current 24-hour secondary $PM_{2.5}$ and $PM_{10}$ standards, 3-year visibility index metrics were at or below 30 dv regardless of whether the coarse fraction was included as an input to the algorithm for estimating light extinction (U.S. EPA, 2020a, section 5.2.1.2). While the inclusion of the coarse fraction had a relatively modest impact on the estimates of light extinction, the Administrator recognized the continued importance of the $PM_{10}$ standard given the potential for larger impacts on light extinction in areas with higher coarse particle concentrations, which were not included in the analyses in the 2020 PA due to a lack of available data (U.S. EPA, 2019a, section 13.2.4.1; U.S. EPA, 2020a, section 5.2.1.2). He noted that the air quality analyses showed that all areas meeting the existing 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$, had visual air quality at least as good as 30 dv, based on the visibility index. Thus, the secondary 24-hour $PM_{2.5}$ standard would likely be controlling relative to a 24-hour visibility index set at a level of 30 dv. Additionally, areas would be unlikely to exceed the target level of protection for visibility of 30 dv without also exceeding the existing secondary 24-hour $PM_{2.5}$ standard. Thus, the Administrator judged

that the 24-hour $PM_{2.5}$ standard provided sufficient protection in all areas against the effects of visibility impairment, i.e., that the existing 24-hour $PM_{2.5}$ standard would provide at least the target level of protection for visual air quality of 30 dv which he judged appropriate (78 FR 82742-82744, December 18, 2020).

2. General Approach and Key Issues in this Reconsideration of the 2020 Final Decision

To evaluate whether it is appropriate to consider retaining the current secondary PM standards, or whether consideration of revision is appropriate, the EPA has adopted an approach in this reconsideration that builds upon the general approach used in past reviews and reflects the body of evidence and information now available. Accordingly, the approach in this reconsideration takes into consideration the approaches used in past reviews, including the substantial assessments and evaluations performed in those reviews, and also takes into account the more recent scientific information and air quality data now available to inform understanding of the key policy-relevant issues in the reconsideration. As summarized above, the Administrator's decisions in the 2020 review were based on an integration of PM welfare effects information with the judgments on the public welfare significance of key effects, policy judgments as to when the standard is requisite, consideration of CASAC advice, and consideration of public comments.

Similarly, in this reconsideration, we draw on the current information from studies of PM-related visibility effects, quantitative analyses of PM-related visibility impairment, and information from studies of non-visibility welfare effects. In so doing, we consider both the information available at the time of the 2012 and 2020 reviews and information more recently available, including that which has been critically analyzed and characterized in the 2019 ISA

and ISA Supplement[123] for visibility, climate, and materials effects. The evaluations in the PA, of the potential implications of various aspects of the scientific evidence in the 2019 ISA and ISA Supplement (building on prior such assessments), augmented by the quantitative air quality, exposure or risk-based information, are also considered along with the associated uncertainties and limitations.

*B. Overview of Welfare Effects Evidence*

The information summarized here is based on the scientific assessment of the welfare effects evidence available in this reconsideration; this assessment is documented in the 2019 ISA and ISA Supplement and its policy implications are further discussed in the PA. While the 2019 ISA provides the broad scientific foundation for this reconsideration, we recognize that additional literature has become available since the cutoff date of the 2019 ISA that expands the body of evidence related to visibility effects that can inform the Administrator's judgment on the adequacy of the current secondary PM standards. As such, the ISA Supplement builds on the information in the 2019 ISA with a targeted identification and evaluation of new scientific information regarding visibility effects. As described in the ISA Supplement and the PA, the selection of welfare effects to evaluate within the ISA Supplement were based on the causality determinations reported in the 2019 ISA and the subsequent use of scientific evidence in the 2020 PA (U.S. EPA, 2019a, section 1.2; U.S. EPA, 2022a, section 1.4.2). The ISA Supplement

[123] As noted above and described in detail in section 1.4.2 of the PA, the ISA Supplement focuses on a thorough evaluation of some studies that became available after the literature cutoff date of the 2019 ISA that could either further inform the adequacy of the current PM NAAQS or address key scientific topics that have evolved since the literature cutoff date for the 2019 ISA. The selection of the welfare effects to evaluate within the ISA Supplement were based on the causality determinations reported in the 2019 ISA and the subsequent use of scientific evidence in the 2020 PA. Specifically, for welfare effects, the focus within the ISA Supplement is on visibility effects. The ISA Supplement does not include an evaluation of studies on climate or materials effects.

focuses on U.S. and Canadian studies that provide new information on public preferences for visibility impairment and/or developed new methodologies or conducted quantitative analyses of light extinction (U.S. EPA, 2022a, section 1.2). Such studies of visibility effects and quantitative relationships between visibility impairment and PM in ambient air were considered to be of greatest utility in informing the Administrator's conclusions on the adequacy of the current secondary PM standards. The visibility effects evidence presented within the 2019 ISA, along with the targeted identification and evaluation of new scientific information in the ISA Supplement, provides the scientific basis for the reconsideration of the 2020 final decision on the secondary PM standards for visibility effects. For climate and materials effects, the 2020 PA concluded that there were substantial uncertainties associated with the quantitative relationships with PM concentrations and the concentration patterns that limited the ability to quantitatively assess the public welfare protection provided by the standards from these effects. Therefore, the evaluation of the information related to these effects draws heavily from the 2019 ISA and 2020 PA. The subsections below briefly summarize the nature of PM-related visibility (section V.B.1.a), climate (section V.B.1.b), and materials (section V.B.1.c) effects.

1. Nature of Effects

Visibility impairment can have implications for people's enjoyment of daily activities and for their overall sense of well-being (U.S. EPA, 2009a, section 9.2). The strongest evidence for PM-related visibility impairment comes from the fundamental relationship between light extinction and PM mass (U.S. EPA, 2009a), which confirms a well-established "causal relationship exists between PM and visibility impairment" (U.S. EPA, 2009a, p. 2-28). Beyond its effects on visibility, the 2009 ISA also identified a causal relationship "between PM and climate effects, including both direct effects of radiative forcing and indirect effects that involve

cloud and feedbacks that influence precipitation formation and cloud lifetimes" (U.S. EPA, 2009a, p. 2-29). The evidence also supports a causal relationship between PM and effects on materials, including soiling effects and materials damage (U.S. EPA, 2009a, p. 2-31).

The evidence available in this reconsideration is consistent with the evidence available at the time of the 2012 and 2020 reviews and supports the conclusions of causal relationships between PM and visibility, climate, and materials effects (U.S. EPA, 2019a, chapter 13). Evidence newly available in this reconsideration augments the previously available evidence of the relationship between PM and visibility impairment (U.S. EPA, 2019a, section 13.2; U.S. EPA, 2022a, section 4), climate effects (U.S. EPA, 2019a, section 13.3), and materials effects (U.S. EPA, 2019a, section 13.4).

a. Visibility

Visibility refers to the visual quality of a human's view with respect to color rendition and contrast definition. It is the ability to perceive landscape form, colors, and textures. Visibility involves optical and psychophysical properties involving human perception, judgment, and interpretation. Light between the observer and the object can be scattered into or out of the sight path and absorbed by PM or gases in the sight path. Consistent with conclusions of causality in the 2012 and 2020 reviews, the 2019 ISA concludes that "the evidence is sufficient to conclude that a causal relationship exists between PM and visibility impairment" (U.S. EPA, 2019a, section 13.2.6). These conclusions are based on the strong and consistent evidence that ambient PM can impair visibility in both urban and remote areas (U.S. EPA, 2019a, section 13.1; U.S. EPA, 2009a, section 9.2.5).

The fundamental relationship between light extinction and PM mass, and the EPA's understanding of this relationship, has changed little since the 2009 ISA (U.S. EPA, 2009a). The

combined effect of light scattering and absorption by particles and gases is characterized as light extinction, i.e., the fraction of light that is scattered or absorbed per unit of distance in the atmosphere.[124] Light extinction is measured in units of 1/distance, which is often expressed in the technical literature as visibility per megameter (abbreviated $Mm^{-1}$). Higher values of light extinction (usually given in units of $Mm^{-1}$ or dv) correspond to lower visibility. When PM is present in the air, its contribution to light extinction is typically much greater than that of gases (U.S. EPA, 2019a, section 13.2.1). The impact of PM on light scattering depends on particle size and composition, as well as relative humidity. All particles scatter light, as described by the Mie theory, which relates light scattering to particle size, shape, and index of refraction (U.S. EPA, 2019a, section 13.2.3; Mie, 1908, Van de Hulst, 1981). Fine particles scatter more light than coarse particles on a per unit mass basis and include sulfates, nitrates, organics, light-absorbing carbon, and soil (Malm et al., 1994). Hygroscopic particles like ammonium sulfate, ammonium nitrate, and sea salt increase in size as relative humidity increases, leading to increased light scattering (U.S. EPA, 2019a, section 13.2.3).

As at the time of the 2012 and 2020 reviews, direct measurements of PM light extinction, scattering, and absorption continue to be considered more accurate for quantifying visibility than PM mass-based estimates because measurements do not depend on assumptions about particle characteristics (e.g., size, shape, density, component mixture, etc.) (U.S. EPA, 2019a, section 13.2.2.2). Measurements of light extinction can be made with high time resolution, allowing for

[124] All particles scatter light and, although a larger particle scatters more light than a similarly shaped smaller particle of the same composition, the light scattered per unit of mass is greatest for particles with diameters from ~0.3-1.0 μm (U.S. EPA, 2009a, section 2.5.1; U.S. EPA, 2019a, section 13.2.1). Particles with hygroscopic components (e.g., particulate sulfate and nitrate) contribute more to light extinction at higher relative humidity than at lower relative humidity because they change size in the atmosphere in response to relative humidity.

characterization of subdaily temporal patterns of visibility impairment. A number of measurement methods have been used for visibility impairment (e.g., transmissometers, integrating nephelometers, teleradiometers, telephotometers, and photography and photographic modeling), although each of these methods has its own strengths and limitations (U.S. EPA, 2019a, Table 13-1). While some recent research confirms and adds to the body of knowledge regarding direct measurements as is described in the 2019 ISA and ISA Supplement, no major new developments have been made with these measurement methods since prior reviews (U.S. EPA, 2019a, section 13.2.2.2; U.S. EPA, 2022a, section 4.2).

In the absence of a robust monitoring network for the routine measurement of light extinction across the U.S., estimation of light extinction based on existing PM monitoring can be used. The theoretical relationship between light extinction and PM characteristics, as derived from Mie theory (U.S. EPA, 2019a, Equation 13.5), can be used to estimate light extinction by combining mass scattering efficiencies of particles with particle concentrations (U.S. EPA, 2019a, section 13.2.3; U.S. EPA, 2009a, sections 9.2.2.2 and 9.2.3.1). This estimation of light extinction is consistent with the method used in previous reviews. The algorithm used to estimate light extinction, known as the IMPROVE algorithm,[125] provides for the estimation of light extinction ($b_{ext}$), in units of $Mm^{-1}$, using routinely monitored components of fine ($PM_{2.5}$) and coarse ($PM_{10-2.5}$) PM. Relative humidity data are also needed to estimate the contribution by liquid water that is in solution with the hygroscopic components of PM. To estimate each component's contribution to light extinction, their concentrations are multiplied by extinction

[125] The algorithm is referred to as the IMPROVE algorithm as it was developed specifically to use monitoring data generated at IMPROVE network sites and with equipment specifically designed to support the IMPROVE program and was evaluated using IMPROVE optical measurements at the subset of monitoring sites that make those measurements (Malm et al., 1994).

coefficients and are additionally multiplied by a water growth factor that accounts for their expansion with moisture. Both the extinction efficiency coefficients and water growth factors of the IMPROVE algorithm have been developed by a combination of empirical assessment and theoretical calculation using particle size distributions associated with each of the major aerosol components (U.S. EPA, 2019a, sections 13.2.3.1 and 13.2.3.3).

At the time of the 2012 review, two versions of the IMPROVE algorithm were available in the literature – the *original IMPROVE algorithm* (Lowenthal and Kumar, 2004, Malm and Hand, 2007, Ryan et al., 2005) and the *revised IMPROVE algorithm* (Pitchford et al., 2007). As described in detail in the PA (U.S. EPA, 2022b, section 5.3.1.1) and the 2019 ISA (U.S. EPA, 2019a, section 13.2.3), the algorithm has been further evaluated and refined since the time of the 2012 review (Lowenthal and Kumar, 2016), particularly for PM characteristics and relative humidity in remote areas. All three versions of the IMPROVE algorithm were considered in evaluating visibility impairment in this reconsideration.

Consistent with the evidence available at the time of the 2012 and 2020 reviews, our understanding of public perception of visibility impairment comes from visibility preference studies conducted in four areas in North America.[126] The detailed methodology for these studies are described in the PA (U.S. EPA, 2022b, section 5.3.1.1), the 2019 ISA (U.S. EPA, 2019a), and the 2009 ISA (U.S. EPA, 2019a). In summary, the study participants were queried regarding multiple images that were either photographs of the same location and scenery that had been taken on different days on which measured extinction data were available or digitized

[126] Preference studies were available in four urban areas in the last review: Denver, Colorado (Ely et al., 1991), Vancouver, British Columbia, Canada (Pryor, 1996), Phoenix, Arizona (BBC Research & Consulting, 2003), and Washington, DC (Abt Associates, 2001; Smith and Howell, 2009).

photographs onto which a uniform "haze" had been superimposed. Results of the studies indicated a wide range of judgments on what study participants considered to be acceptable visibility across the different study areas, depending on the setting depicted in each photograph. Based on the results of the four cities, a range encompassing the $PM_{2.5}$ visibility index values from images that were judged to be acceptable by at least 50 percent of study participants across all four of the urban preference studies was identified (U.S. EPA, 2010a, p. 4-24; U.S. EPA, 2020a, Figure 5-2). Much lower visibility (considerably more haze resulting in higher values of light extinction) was considered acceptable in Washington, DC, than was in Denver, and 30 dv reflected the level of impairment that was determined to be "acceptable" by at least 50 percent of study participants (78 FR 3226-3227, January 15, 2013).

Since the completion of the 2009 and 2019 ISAs, there has been only one public preference study that has become available in the U.S. This study uses images of the Grand Canyon, AZ, described in the ISA Supplement (U.S. EPA, 2022a). The Grand Canyon study, conducted by Malm et al. (2019), has a similar study design to that used in the public preference studies discussed above; however, there are several important differences that make it difficult to directly compare the results of the Malm et al. (2019) study with other public preference studies. As an initial matter, the Grand Canyon study was conducted in a Federal Class I area, as opposed to in an urban area, with a scene depicted in the photographs that did not include urban features.[127] We recognize that public preferences with respect to visibility in Federal Class 1 areas may well differ from visibility preferences in urban areas and other contexts, although

[127] The Grand Canyon study used a single scene looking west down the canyon with a small landscape feature of a 100-km-distant mountain (Mount Trumbull), along with other closer landscape features. The scenes presented in the previously available visibility preference studies are presented in more detail in Table D-9 in the PA (U.S. EPA, 2022b, Appendix D).

there is currently a lack of information to on such questions. Further, the Malm et al. (2019) study also used a much lower range of superimposed "haze" than the preference studies discussed above.[128] It is unclear whether the participant preferences are a function in part of the range of potential values presented, such that the participant preferences for the Grand Canyon were generally lower[129] than the other preference studies in part because of the lower range of superimposed "haze" for the images in that study, or if their preferences would vary if presented with images with a range of superimposed "haze" more comparable to the levels used in the other studies (i.e., more "haze" superimposed on the images).

The Malm et al. (2019) study also explored alternate methods for evaluating "acceptable" levels of visual air quality from the preference studies, including the use of scene-specific visibility indices as potential indicators of visibility levels as perceived by the observer (Malm et al., 2019). In addition to measures of atmospheric haze, such as atmospheric extinction, used in previously available preference studies, other indices for visual air quality include color and achromatic contrast of single landscape figures, average and equivalent contrast of an entire scene, edge detection algorithms such as the Sobel index, and just-noticeable difference or change indexes. The results reported by Malm et al. (2019) suggest that scene-dependent metrics, such as contrast, may be useful alternate predictors of preference levels compared to universal metrics like light extinction (U.S. EPA, 2022a, section 4.2.1). This is because extinction alone is not a measure of "haze," but of light attenuation per unit distance, and visible "haze" is

[128] The Grand Canyon study superimposed light extinction ranging from 3 dv to 20 dv on the image slides shown to participants compared to the previously available preference studies. In those studies, the visibility ranges presented were as low as 9 dv and as high as 45 dv. The visibility ranges presented in the previously available visibility preference studies are described in more detail in Table D-9 in the PA (U.S. EPA, 2022b, Appendix D).
[129] In the Grand Canyon study, the level of impairment that was determined to be "acceptable" by at least 50 percent of study participants was 7 dv (Malm et al., 2019).

dependent on both light extinction and distance to a landscape feature (U.S. EPA, 2022a, section 4.2.1). However, there are very few studies available that use scene-dependent metrics (i.e., contrast) to evaluate public preference information, which makes it difficult to evaluate them as an alternative to the light extinction approach.

b. Climate

The available evidence continues to support the conclusion of a causal relationship between PM and climate effects (U.S. EPA, 2019a, section 13.3.9). Since the 2012 review, climate impacts have been extensively studied and recent research reinforces and strengthens the evidence evaluated in the 2009 ISA. Recent evidence provides greater specificity about the details of radiative forcing effects[130] and increases the understanding of additional climate impacts driven by PM radiative effects. The Intergovernmental Panel on Climate Change (IPCC) assesses the role of anthropogenic activity in past and future climate change, and since the completion of the 2009 ISA, has issued the Fifth IPCC Assessment Report (AR5; IPCC, 2013) which summarizes any key scientific advances in understanding the climate effects of PM since the previous report. As in the 2009 ISA, the 2019 ISA draws substantially on the IPCC report to summarize climate effects. As discussed in more detail in the PA (U.S. EPA, 2022b, section 5.3.2.1.1), the general conclusions are similar between the IPCC AR4 and AR5 reports with regard to effects of PM on global climate. Consistent with the evidence available in the 2012 review, the key components, including sulfate, nitrate, organic carbon (OC), black carbon (BC),

[130] Radiative forcing (RF) for a given atmospheric constituent is defined as the perturbation in net radiative flux, at the tropopause (or the top of the atmosphere) caused by that constituent, in watts per square meter ($Wm^{-2}$), after allowing for temperatures in the stratosphere to adjust to the perturbation but holding all other climate responses constant, including surface and tropospheric temperatures (Fiore et al., 2015; Myhre et al., 2013). A positive forcing indicates net energy trapped in the Earth system and suggests warming of the Earth's surface, whereas a negative forcing indicates net loss of energy and suggests cooling (U.S. EPA, 2019a, section 13.3.2.2).

and dust, that contribute to climate processes vary in their reflectivity, forcing efficiencies, and direction of forcing. Since the completion of the 2009 ISA, the evidence base has expanded with respect to the mechanisms of climate responses and feedbacks to PM radiative forcing; however, the recently published literature assessed in the 2019 ISA does not reduce the considerable uncertainties that continue to exist related these mechanisms.

As described in the PA (U.S. EPA, 2022b, section 5.3.2.1.1), PM has a very heterogeneous distribution globally and patterns of forcing tend to correlate with PM loading, with the greatest forcings centralized over continental regions. The climate response to this PM forcing, however, is more complicated since the perturbation to one climate variable (e.g., temperature, cloud cover, precipitation) can lead to a cascade of effects on other variables. While the initial PM radiative forcing may be concentrated regionally, the eventual climate response can be much broader spatially or be concentrated in remote regions, and may be quite complex, affecting multiple climate variables with possible differences in the direction of the forcing in different regions or for different variables (U.S. EPA, 2019a, section 13.3.6). The complex climate system interactions lead to variation among climate models, which have suggested a range of factors which can influence large-scale meteorological processes and may affect temperature, including local feedback effects involving soil moisture and cloud cover, changes in the hygroscopicity of the PM, and interactions with clouds (U.S. EPA, 2019a, section 13.3.7). However, there remains insufficient evidence to related climate effects to specific PM levels in ambient air or to establish a quantitative relationship between PM and climate effects, particularly at a regional scale. Further research is needed to better characterize the effects of PM on regional climate in the U.S. before PM climate effects can be quantified.

c. Materials

Consistent with the evidence assessed in the 2009 ISA, the available evidence continues to support the conclusion that there is a causal relationship between PM deposition and materials effects. Effects of deposited PM, particularly sulfates and nitrates, to materials include both physical damage and impaired aesthetic qualities, generally involving soiling and/or corrosion (U.S. EPA, 2019a, section 13.4.2). Because of their electrolytic, hygroscopic, and acidic properties and their ability to sorb corrosive gases, particles contribute to materials damage by adding to the effects of natural weathering processes, by potentially promoting or accelerating the corrosion of metals, degradation of painted surfaces, deterioration of building materials, and weakening of material components.[131] There is a limited amount of recently available data for consideration in this review from studies primarily conducted outside of the U.S. on buildings and other items of cultural heritage. However, these studies involved concentrations of PM in ambient air greater than those typically observed in the U.S. (U.S. EPA, 2019a, section 13.4).

Building on the evidence available in the 2009 ISA, and as described in detail in the PA (U.S. EPA, 2022b, section 5.3.2.1.2) and in the 2019 ISA (U.S. EPA, 2019a, section 13.4), research has progressed on (1) the theoretical understanding of soiling of items of cultural heritage; (2) the quantification of degradation rates and further characterization of factors that influence damage of stone materials; (3) materials damage from PM components besides sulfate and black carbon and atmospheric gases besides $SO_2$; (4) methods for evaluating soiling of materials by PM mixtures; (5) PM-attributable damage to other materials, including glass and photovoltaic panels; (6) development of dose-response relationships for soiling of building

[131] As discussed in the 2019 ISA (U.S. EPA, 2019a, section 13.4.1), corrosion typically involves reactions of acidic PM (i.e., acidic sulfate or nitrate) with material surfaces, but gases like $SO_2$ and nitric acid ($HNO_3$) also contribute. Because "the impacts of gaseous and particulate N and S wet deposition cannot be clearly distinguished" (U.S. EPA, 2019a, p. 13-1), the assessment of the evidence in the 2019 ISA considers the combined impacts.

materials; and (7) damage functions to quantify material decay as a function of pollutant type and load. While the evidence of PM-related materials effects has expanded somewhat since the completion of the 2009 ISA, there remains insufficient evidence to relate soiling or damage to specific PM levels in ambient air or to establish a quantitative relationship between PM and materials degradation. The recent evidence assessed in the 2019 ISA is generally similar to the evidence available in the 2009 ISA, including associated limitations and uncertainties and a lack of evidence to inform quantitative relationships between PM and materials effects, therefore leading to similar conclusions about the PM-related effects on materials.

C. Summary of Air Quality and Quantitative Information

Beyond the consideration of the scientific evidence, as discussed in section V.B above, quantitative analyses of PM air quality, when available, can also inform conclusions on the adequacy of the public welfare protection provided by the current secondary PM standards.

1. Visibility Effects

In the 2012 and 2020 reviews, quantitative analyses for PM-related visibility effects focused on daily visibility impairment, given the short-term nature of PM-related visibility effects. The evidence and information available in this reconsideration continues to provide support for the short-term (i.e., hourly or daily) nature of PM-related visibility impairment. As such, the quantitative analyses presented in the PA continue to focus on daily visibility impairment and utilize a two-phase assessment approach for visibility impairment, consistent with the approaches taken in past reviews. First, the PA considers the appropriateness of the elements (indicator, averaging time, form, and level) of the visibility index for providing protection against PM-related visibility effects. Second, recent air quality was used to evaluate the relationship between the current secondary 24-hour $PM_{2.5}$ standard and the visibility index.

The information available since the 2012 review includes an updated equation for estimating light extinction, summarized in the PA (U.S. EPA, 2022b, section 5.3.1.1) and described in the 2019 ISA (U.S. EPA, 2019a, section 13.2.3.3), as well as more recent air monitoring data, that together allow for development of an updated assessment of PM-related visibility impairment in study locations in the U.S.

a. Target Level of Protection in Terms of a $PM_{2.5}$ Visibility Index

In evaluating the adequacy of the current secondary PM standards, the PA first evaluates the appropriateness of the elements (indicator, averaging time, form, and level) identified for a distinct secondary standard to protect against visibility effects. In previous reviews, the visibility index was set at a level of 30 dv, with estimated light extinction as the indicator, a 24-hour averaging time, and a $90^{th}$ percentile form, averaged over three years.

With regard to an indicator for the visibility index, the PA recognizes the lack of availability of methods and an established network for directly measuring light extinction (U.S. EPA, 2022b, section 5.3.1.1). Therefore, consistent with previous reviews, the PA concludes that a visibility index based on estimates of light extinction by $PM_{2.5}$ components derived from an adjusted version of the original IMPROVE algorithm to be the most appropriate indicator for the visibility index in this reconsideration. As described in section 5.3.1.1 of the PA, the IMPROVE algorithm estimates light extinction using routinely monitored components of $PM_{2.5}$ and $PM_{10-2.5}$, along with estimates of relative humidity (U.S. EPA, 2022b, section 5.3.1.1).

With regard to averaging time, the PA notes that the evidence continues to provide support for the short-term nature of PM-related visibility effects. Given that there is no new information available regarding the time periods during which visibility impairment occurs or public preferences related to specific time periods for visibility impairment, the PA concludes

that it is appropriate to continue to focus on daily visibility impairment. In so doing, the PA relies on analyses that were conducted in the 2012 review that showed relatively strong correlations between 24-hour and sub-daily (i.e., 4-hour average) $PM_{2.5}$ light extinction that indicated that a 24-hour averaging time is an appropriate surrogate for the sub-daily time periods relevant for visual perception (U.S. EPA, 2011, Figures G-4 and G-5; Frank, 2012). These analyses continue to provide support for a 24-hour averaging time for the visibility index in this reconsideration. Consistent with previous reviews, the PA also notes that the 24-hour averaging time may be less influenced by atypical conditions and/or atypical instrument performance than a sub-daily averaging time (85 FR 82740, December 18, 2020; 78 FR 3226, January 15, 2013).

With regard to the form for the visibility index, the available information continues to provide support for a 3-year average of annual $90^{th}$ percentile values. Given that there is no new information to inform selection of an alternate form, as in previous reviews, the PA notes that the 3-year average form provides stability from the occasional effect of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year (85 FR 82741, December 18, 2020; 78 FR 3198, January 15, 2013; U.S. EPA, 2011, p. 4-58). In so doing, the PA considers the evaluation in the 2010 Urban-Focused Visibility Assessment (UFVA) of three different statistical forms: $90^{th}$, $95^{th}$, and $98^{th}$ percentiles (U.S. EPA, 2010a, Chapter 4). In considering this evaluation of statistical forms from the 2010 UFVA, consistent with the 2011 PA, the PA notes that the Regional Haze Program targets the 20 percent most impaired days for visibility improvements in visual air quality in Federal Class I areas and that the median of the distribution of these 20 percent most impaired days would be the $90^{th}$ percentile. The 2011 PA also noted that strategies that are implemented so that 90 percent of days would have visual air quality that is at or below the level of the visibility index would reasonably be expected to lead to

improvements in visual air quality for the 20 percent most impaired days. Additionally, as in the 2011 PA, the PA recognizes that the available public preference studies do not address frequency of occurrence of different levels of visibility (U.S. EPA, 2022b, section 5.3.1.2). Therefore, the analyses and consideration for the form of a visibility index from the 2011 PA continue to provide support for a 90$^{th}$ percentile form, averaged across three years, in defining the characteristics of a visibility index in this reconsideration.

With regard to the level for the visibility index, the PA recognizes that there is an additional public preference study (Malm et al., 2019) available in this reconsideration. As noted above, however, this study differs from the previously available public preference studies in several ways which makes it difficult to integrate this newly available study with the previously available studies. Most significantly, this study was evaluated public preferences for visibility in the Grand Canyon, perhaps the most notable Class I area in the country for visibility purposes. Therefore, the PA concludes that the Grand Canyon study is not directly comparable to the other available preferences studies and public preferences of visibility impairment in the Malm et al. (2019)are not appropriate to consider in identifying a range of levels for the target level of protection against visibility impairment for this reconsideration of the secondary PM NAAQS.

Therefore, the PA continues to rely on the same studies[132] and the range of 20 to 30 dv identified from those studies in previous reviews. With regard to selecting the appropriate target level of protection for visibility impairment within this range, the PA notes that in previous reviews, a level at the upper end of the range (i.e., 30 dv) was selected given the uncertainties

[132] As noted above, the available public preference studies include those conducted in Denver, Colorado (Ely et al., 1991), Vancouver, British Columbia, Canada (Pryor, 1996), Phoenix, Arizona (BBC Research & Consulting, 2003), and Washington, DC (Abt Associates, 2001; Smith and Howell, 2009).

and limitations associated with the public preference studies (U.S. EPA, 2022b, section 5.3.1.1). However, the PA also recognizes that (1) the degree of protection provided by a secondary PM NAAQS is not determined solely by any one element of the standard but by all elements (i.e., indicator, averaging time, form, and level) being considered together, and (2) decisions regarding the adequacy of the current secondary standards is a public welfare policy judgment to be made by the Administrator. As such, the Administrator may judge that a target level of protection below the upper end of the range (i.e., less than 30 dv) is appropriate, depending on his public welfare policy judgments, which draw upon the available scientific evidence for PM-related visibility effects and on analyses of visibility impairment, as well as judgments about the appropriate weight to place on the range of uncertainties inherent in the evidence and analyses.

In considering the available public preference studies, consistent with past reviews, the PA concludes that it is reasonable to consider a range of 20 to 30 dv for selecting a target level of protection, including a high value of 30 dv, a midpoint value of 25 dv, and a low value of 20 dv. A target level of protection at or in the upper end of the range would focus on the Washington, DC, preference study results (Abt Associates, 2001; Smith and Howell, 2009) which identified 30 dv as the level of impairment that was determined to be "acceptable" by at least 50 percent of study participants. The public preferences of visibility impairment in the Washington, DC, study are likely to be generally representative of urban areas that do not have valued scenic elements (e.g., mountains) in the distant background. This would be more representative of areas in the middle of the country and many areas in the eastern U.S., as well as possibly some areas in the western U.S.

A target level of protection in the middle of the range would be most closely associated with the level of impairment that was determined to be "acceptable" by at least 50 percent of

study participants in the Phoenix, AZ, study (BBC Research & Consulting, 2003), which was 24.3 dv. This study, while methodologically similar to the other public preference studies, included participants that were selected as a representative sample of the Phoenix area population[133] and used computer-generated images to depict specific uniform visibility impairment conditions. This study yielded the best results of the four public preference studies in terms of the least noisy preference results and the most representative selection of participants. Therefore, based on this study, the use of 25 dv to represent a midpoint within the range of target levels protection is well supported.

A target level of protection at or just above the lower end of the range would focus on the Denver, CO, study, but may not be as strongly supported as higher levels within the range (Ely et al., 1991). Older studies, such as those conducted in Denver, CO (Ely et al., 1991), and British Columbia, Canada (Pryor, 1996), used photographs that were taken at different times of the day and on different days to capture a range of light extinction levels needed for the preference studies. Compared to studies that used computer-generated images (i.e., those in Phoenix, AZ, and Washington, DC) there was more variability in scene appearance in these older studies that could affect preference rating and includes uncertainties associated with using ambient measurements to represent sight path-averaged light extinction values rather than superimposing a computer-generated amount of haze onto the images. When using photographs, the intrinsic appearance of the scene can change due to meteorological conditions (i.e., shadow patterns and

[133] The other preference studies did not include populations that were necessarily representative of the population in the area for which the images being judged. For example, in the Denver, CO, study, participants were from intact groups (i.e., those who were meeting for other reasons) and were asked to provide a period of time during a regularly scheduled meeting to participate in the study (Ely et al., 1991). As another example, in the British Columbia, Canada, study, participants were recruited from undergraduate and graduate students enrolled in classes at the University of British Columbia's Department of Geography (Pryor, 1996).

cloud conditions) and spatial variations in ambient air quality that can result in ambient light extinction measurement not being representative of the sight-path-averaged light extinction. Computer-generated images, such as those generated with WinHaze, do not introduce such uncertainties, as the same base photograph is used (i.e., there is no intrinsic change in scene appearance) and the modeled haze that is superimposed on the photograph is determined based on uniform light extinction throughout the scene.

In addition to differences in preferences that may arise from photographs versus computer-generated images, urban visibility preference may differ by location, and such differences may arise from differences in the cityscape scene that is depicted in the images. These differences are related to the perceived value of objects and scenes that are included in the image, as objects at a greater distance have a greater sensitivity to perceived visibility changes as light extinction is changed compared to similar scenes with objects at shorter distances. For example, a person (regardless of their location) evaluating visibility in an image with more scenic elements such as mountains or natural views may value better visibility conditions in these images compared to the same level of visibility impairment in an image that only depicts urban features such as buildings and roads. That is, if a person was shown the same level of visibility impairment in two images depicting different scenes – one with mountains in the background and urban features in the foreground and one with no mountains in the background and nearby buildings in the image without mountains in the distance – may find the amount of haze to be unacceptable in the image with the mountains in the distance because of a greater perceived value of viewing the mountains, while finding the amount of haze to be acceptable in the image with the buildings because of a lesser value of viewing the cityscape or an expectation that such urban areas may generally have higher levels of haze in general. This is consistent

when comparing the differences between the Denver, CO, study results (which found the 50% acceptance criteria occurred at the best visual air quality levels among the four cities) and the Washington, DC, results (which found the 50% acceptability criteria occurred at the worst visual air quality levels among the four cities). These results may occur because the most prominent and picturesque feature of the cityscape of Denver is the visible snow-covered mountains in the distance, while the prominent and picturesque features of the Washington, DC, cityscape are buildings relatively nearby without prominent and/or values scenic features that are more distant. Given these variabilities in preferences it is unclear to what extent, the available evidence provides strong support for a target level of protection at the lower end of the range. Future studies that reduce sources of noisiness and uncertainty in the results could provide more information that would support selection of a target level of protection at or just above the lower end of the range.

Taken together, the PA concludes that available information continues to support a visibility index with estimated light extinction as the indicator, a 24-hour averaging time, and a $90^{th}$ percentile form, averaged over three years, with a level within the range of 20 to 30 dv.

b. Relationship between the $PM_{2.5}$ Visibility Index and the Current Secondary 24-Hour $PM_{2.5}$ Standard

The PA presents quantitative analyses based on recent air quality that evaluate the relationship between recent air quality and calculated light extinction. As in previous reviews, these analyses explored this relationship as an estimate of visibility impairment in terms of the 24-hour $PM_{2.5}$ standard and the visibility index. Generally, the results of the updated analyses are similar to those based on the data available at the time of the 2012 and 2020 reviews (U.S. EPA, 2022b, section 5.3.1.2). As discussed in section V.C.1.a above, the PA concludes that the

available evidence continues to support a visibility index with estimated light extinction as the indicator, a 24-hour averaging time, and a 90$^{th}$ percentile form, averaged over three years, with a level within the range of 20 to 30 dv. These analyses evaluate visibility impairment in the U.S. under recent air quality conditions, particularly those conditions that meet the current standards, and the relative influence of various factors on light extinction. Given the relationship of visibility with short-term PM, we focus particularly on the short-term PM standards.[134] Compared to the 2012 review, updated analyses incorporate several refinements, including (1) the evaluation of three versions of the IMPROVE equation to calculate light extinction (U.S. EPA, 2022b, Appendix D, Equations D-1 through D-3) in order to better understand the influence of variability in equation inputs;[135] (2) the use of 24-hour relative humidity data, rather than monthly average relative humidity as was used in the 2012 review (U.S. EPA, 2022b, section 5.3.1.2, Appendix D); and (3) the inclusion of the coarse fraction in the estimation of light extinction (U.S. EPA, 2022b, section 5.3.1.2, Appendix D). The analyses in the

[134] The analyses presented in the PA focus on the visibility index and the current secondary 24-hour $PM_{2.5}$ standard with a level of 35 $\mu g/m^3$. However, we recognize that all three secondary PM standards influence the PM concentrations associated with the air quality distribution. As noted in section V.A.1 above, the current secondary PM standards include the 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$, the annual $PM_{2.5}$ standard, with its level of 15.0 $\mu g/m^3$, and the 24-hour $PM_{10}$ standard, with its level of 150 $\mu g/m^3$. With regard to the annual $PM_{2.5}$ standard, we note that all 60 areas included in the analyses meet the current secondary annual PM standard (U.S. EPA, 2022b, Table D-7).

[135] While the $PM_{2.5}$ monitoring network has an increasing number of continuous FEM monitors reporting hourly $PM_{2.5}$ mass concentrations, there continue to be data quality uncertainties associated with providing hourly $PM_{2.5}$ mass and component measurements that could be input into IMPROVE equation calculations for sub-daily visibility impairment estimates. As detailed in the PA, there are uncertainties associated with the precision and bias of 24-hour $PM_{2.5}$ measurements (U.S. EPA, 2022b, p. 2-18), as well as to the fractional uncertainty associated with 24-hour PM component measurements (U.S. EPA, 2022b, p. 2-21). Given the uncertainties present when evaluating data quality on a 24-hour basis, the uncertainty associated with sub-daily measurements may be even greater. Therefore, the inputs to these light extinction calculations are based on 24-hour average measurements of $PM_{2.5}$ mass and components, rather than sub-daily information.

reconsideration are updated from the 2012 and 2020 reviews and include 60 monitoring sites that measure $PM_{2.5}$ and $PM_{10}$ and are geographically distributed across the U.S. in both urban and rural areas (U.S. EPA, 2022b, Appendix D, Figure D-1).

When light extinction was calculated using the revised IMPROVE equation, in areas that meet the current 24-hour $PM_{2.5}$ standard for the 2017-2019 time period, all sites have light extinction estimates at or below 26 dv (U.S. EPA, 2022b, Figure 5-3). For the four locations that exceed the current 24-hour $PM_{2.5}$ standard, light extinction estimates range from 22 dv to 27 dv (U.S. EPA, 2022b, Figure 5-3). These findings are consistent with the findings of the analyses using the same IMPROVE equation in the 2012 review with data from 102 sites with data from 2008-2010 and in the 2020 review with data from 67 sites with data from 2015-2017. The analyses presented in the PA indicate similar findings to those from the analyses in the 2012 and 2020 reviews, i.e., the updated quantitative analysis shows that the 3-year visibility metric was no higher than 30 dv[136] at sites meeting the current secondary PM standards, and at most such sites the 3-year visibility index values are much lower (e.g., an average of 20 dv across the 60 sites).[137]

When light extinction was calculated using the revised IMPROVE equation,[138] the resulting 3-year visibility metrics are nearly identical to light extinction estimates calculated using the original IMPROVE equation (U.S. EPA, 2022b, Figure 5-4), but some sites are just

[136] A 3-year visibility metric with a level of 30 dv would be at the upper end of the range of levels identified from the public preference studies.
[137] When light extinction is calculated using the original IMPROVE equation, all 60 sites have 3-year visibility metrics below 30 dv, 58 sites are at or below 25 dv, and 26 sites are at or below 20 dv (see U.S. EPA, 2022b, Appendix D, Table D-3).
[138] As described in more detail in the PA, the revised IMPROVE equation divides PM components into smaller and larger sizes of particles in $PM_{2.5}$, with separate mass scattering efficiencies and hygroscopic growth functions for each size category (U.S. EPA, 2022b, section 5.3.1.1).

slightly higher. Using the revised IMPROVE equation, for those sites that meet the current 24-hour $PM_{2.5}$ standard, the 3-year visibility metric is at or below 26 dv. For the four locations that exceed the current 24-hour $PM_{2.5}$ standard, light extinction estimates range from 22 dv to 29 dv (U.S. EPA, 2022b, Figure 5-4). These results are similar to those for light extinction calculated using the original IMPROVE equation,[139] and those from previous reviews.

When light extinction was calculated using the refined equation from Lowenthal and Kumar (2016), the resulting 3-year visibility metrics are slightly higher at all sites compared to light extinction estimates calculated using the original IMPROVE equation (U.S. EPA, 2022b, Figure 5-5).[140] These higher estimates are to be expected, given the higher OC multiplier included in the IMPROVE equation from Lowenthal and Kumar (2016), which reflects the use of data from remote areas with higher concentrations of organic PM when validating the equation. As such, it is important to note that the Lowenthal and Kumar (2016) version of the equation may overestimate light extinction in non-remote areas, including the urban areas in the updated analyses in this reconsideration.

Nevertheless, when light extinction is calculated using the Lowenthal and Kumar (2016) equation for those sites that meet the current 24-hour $PM_{2.5}$ standard, the 3-year visibility metric is generally at or below 28 dv. For those sites that exceed the current 24-hour $PM_{2.5}$ standard, three of these sites have a 3-year visibility metric ranging between 26 dv and 30 dv, while one

[139] When light extinction is calculated using the revised IMPROVE equation, all 60 sites have 3-year visibility metrics below 30 dv, 56 sites are at or below 25 dv, and 26 sites are at or below 20 dv (see U.S. EPA, 2022b, Appendix D, Table D-3).

[140] When light extinction is calculated using the Lowenthal and Kumar IMPROVE equation, 59 sites have 3-year visibility metrics below 30 dv, 45 sites are at or below 25 dv, and 15 sites are at or below 20 dv. The one site with a 3-year visibility metric of 32 dv exceeds the secondary 24-hour $PM_{2.5}$ standard, with a design value of 56 $\mu g/m^3$ (see U.S. EPA, 2022b, Appendix D, Table D-3).

site in Fresno, California that exceeds the current 24-hour $PM_{2.5}$ standard and has a 3-year visibility index value of 32 dv (compared to 29 dv when light extinction is calculated with the original IMPROVE equation) (see U.S. EPA, 2022b, Appendix D, Table D-3). At this site, it is likely that the 3-year visibility metric using the Lowenthal and Kumar (2016) equation would be below 30 dv if $PM_{2.5}$ concentrations were reduced such that the 24-hour $PM_{2.5}$ level of 35 $\mu g/m^3$ was attained.

In considering visibility impairment under recent air quality conditions, the PA recognizes that the differences in the inputs to equations estimating light extinction can influence the resulting values. For example, given the varying chemical composition of emissions from different sources, the 2.1 multiplier in the Lowenthal and Kumar (2016) equation may not be appropriate for all source types. At the time of the 2012 review, the EPA judged that a 1.6 multiplier for converting OC to OM was more appropriate, for the purposes of estimating visibility index at sites across the U.S., than the 1.4 or 1.8 multipliers used in the original and revised IMPROVE equations, respectively. A multiplier of 1.8 or 2.1 would account for the more aged and oxygenated organic PM that tends to be found in more remote regions than in urban regions, whereas a multiplier of 1.4 may underestimate the contribution of organic PM found in remote regions when estimating light extinction (78 FR 3206, January 15, 2013; U.S. EPA, 2012, p. IV-5). The available scientific information and results of the air quality analyses indicate that it may be appropriate to select inputs to the IMPROVE equation (e.g., the multiplier for OC to OM) on a regional basis rather than a national basis when calculating light extinction. This is especially true when comparing sites with localized PM sources (such as sites in urban or industrial areas) to sites with PM derived largely from biogenic precursor emissions (that contribute to widespread secondary organic aerosol formation), such as those in the southeastern

U.S. The PA notes, however, that conditions involving PM from such different sources have not been well studied in the context of applying a multiplier to estimate light extinction, contributing uncertainty to estimates of light extinction for such conditions.

At the time of the 2012 review, the EPA noted that $PM_{2.5}$ is the size fraction of PM responsible for most of the visibility impairment in urban areas (77 FR 38980, June 29, 2012). Data available at the time of the 2012 review suggested that, generally, $PM_{10\text{-}2.5}$ was a minor contributor to visibility impairment most of the time (U.S. EPA, 2010a) although the coarse fraction may be a major contributor in some areas in the desert southwestern region of the U.S. Moreover, at the time of the 2012 review, there were few data available from $PM_{10\text{-}2.5}$ monitors to quantify the contribution of coarse PM to calculated light extinction. Since that time, an expansion in $PM_{10\text{-}2.5}$ monitoring efforts has increased the availability of data for use in estimating light extinction with both $PM_{2.5}$ and $PM_{10\text{-}2.5}$ concentrations included as inputs in the equations. The analysis in the 2020 review addressed light extinction at 20 of the 67 $PM_{2.5}$ sites where collocated $PM_{10\text{-}2.5}$ monitoring data were available. Since the 2020 review, $PM_{10\text{-}2.5}$ monitoring data are available at more locations and the analyses presented in the PA include those for light extinction estimated with coarse and fine PM at all 60 sites. Generally, the contribution of the coarse fraction to light extinction at these sites is minimal, contributing less than 1 dv to the 3-year visibility metric (U.S. EPA, 2020a, section 5.2.1.2). However, the PA notes that in the updated quantitative analyses, only a few sites were in locations that would be expected to have high concentrations of coarse PM, such as the Southwest. These results are consistent with those in the analyses in the 2019 ISA, which found that mass scattering from $PM_{10–2.5}$ was relatively small (less than 10%) in the eastern and northwestern U.S., whereas mass scattering was much larger in the Southwest (more than 20%) particularly in southern Arizona

and New Mexico (U.S. EPA, 2019a, section 13.2.4.1, p. 13-36).

Overall, the findings of these updated quantitative analyses are generally consistent with those in the 2012 and 2020 reviews. The 3-year visibility metric was generally below 26 dv in most areas that meet the current 24-hour $PM_{2.5}$ standard. Small differences in the 3-year visibility metric were observed between the variations of the IMPROVE equation, which may suggest that it may be more appropriate to use one version over another in different regions of the U.S. based on PM characteristics such as particle size and composition to more accurately estimate light extinction.

2. Non-Visibility Effects

Consistent with the evidence available at the time of the 2012 and 2020 reviews, and as described in detail in the PA (U.S. EPA, 2022b, section 5.3.2.2), the data remain insufficient to conduct quantitative analyses for PM effects on climate and materials. For PM-related climate effects, as explained in more detail in the PA (U.S. EPA, 2022b, section 5.3.2.1.1), our understanding of PM-related climate effects is still limited by significant key uncertainties. The recently available evidence does not appreciably improve our understanding of the spatial and temporal heterogeneity of PM components that contribute to climate forcing (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). Significant uncertainties also persist related to quantifying the contributions of PM and PM components to the direct and indirect effects on climate forcing, such as changes to the pattern of rainfall, changes to wind patterns, and effects on vertical mixing in the atmosphere (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). Additionally, while improvements have been made to climate models since the completion of the 2009 ISA, the models continue to exhibit variability in estimates of the PM-related climate effects on regional scales (e.g., ~100 km) compared to simulations at the global scale (U.S. EPA, 2022b, sections

5.3.2.1.1 and 5.5). While our understanding of climate forcing on a global scale is somewhat expanded since the 2012 review, significant limitations remain to quantifying potential adverse PM-related climate effects in the U.S. and how they would vary in response to incremental changes in PM concentrations across the U.S. As such, while recent research is available on climate forcing on a global scale, the remaining limitations and uncertainties are significant, and the recent global scale research does not translate directly for use at regional spatial scales. Therefore, the evidence does not provide a clear understanding at the necessary spatial scales for quantifying the relationship between PM mass in ambient air and the associated climate-related effects in the U.S. that would be necessary for informing consideration of a national PM standard on climate in this reconsideration (U.S. EPA, 2022b, section 5.3.2.2.1; U.S. EPA, 2019a, section 13.3).

For PM-related materials effects, as explained in more detail in the PA (U.S. EPA, 2022b, section 5.3.2.1.2), the available evidence has been somewhat expanded to include additional information about the soiling process and the types of materials impacted by PM. This evidence provides some limited information to inform dose-response relationships and damage functions associated with PM, although most of these studies were conducted outside of the U.S. where PM concentrations in ambient air are typically above those observed in the U.S. (U.S. EPA, 2022b, section 5.3.2.1.2; U.S. EPA, 2019a, section 13.4). The evidence on materials effects characterized in the 2019 ISA also includes studies examining effects of PM on the energy efficiency of solar panels and passive cooling building materials, although the evidence remains insufficient to establish quantitative relationships between PM in ambient air and these or other materials effects (U.S. EPA, 2022b, section 5.3.2.1.2). While the available evidence assessed in the 2019 ISA is somewhat expanded since the time of the 2012 review, quantitative relationships

have not been established for PM-related soiling and corrosion and frequency of cleaning or repair that further the understanding of the public welfare implications of materials effects (U.S. EPA, 2022b, section 5.3.2.2.2; U.S. EPA, 2019a, section 13.4). Therefore, there is insufficient information to inform quantitative analyses assessing materials effects to inform consideration of a national PM standard on materials in this reconsideration (U.S. EPA, 2022b, section 5.3.2.2.2; U.S. EPA, 2019a, section 13.4).

D. Proposed Conclusions on the Secondary PM Standards

In reaching proposed conclusions on the current secondary PM standards (presented in section IV.D.3), the Administrator has taken into account policy-relevant evidence- and quantitative information-based considerations discussed in the PA (summarized in section IV.D.2), as well as advice from the CASAC and public comment on the standards received thus far in the reconsideration (section IV.D.1). In general, the role of the PA is to help "bridge the gap" between the Agency's assessment of the current evidence and quantitative analyses, and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the NAAQS. Evidence-based considerations draw upon the EPA's integrated assessment of the scientific evidence of PM-related welfare effects presented in the 2019 ISA and ISA Supplement (summarized in section V.B above) to address key policy-relevant questions in the reconsideration. Similarly, the quantitative information-based considerations (summarized in section V.C above) focused on the potential for PM-related welfare effects under recent air quality conditions for the purposes of addressing the policy-relevant questions.

This approach to reviewing the secondary standards is consistent with the requirements of the provisions of the CAA related to the review of the NAAQS and with how the EPA and the courts have historically interpreted the CAA. As discussed in section I.A above, these provisions

require the Administrator to establish secondary standards that, in the Administrator's judgment, are requisite (i.e., neither more nor less stringent than necessary) to protect the public welfare from known or anticipated adverse effects associated with the presence of the pollutant in ambient air. Consistent with the Agency's approach across all NAAQS reviews, the EPA's approach to informing these judgments is based on a recognition that the available welfare effects evidence generally reflects a continuum that includes ambient air exposures for which scientists generally agree that effects are likely to occur through lower levels at which the likelihood and magnitude of response become increasingly uncertain. The CAA does not require the Administrator to establish secondary standards at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect the public welfare from known or anticipated adverse effects.

The proposed decision on the adequacy of the current secondary standards described below is a public welfare policy judgment by the Administrator that draws upon the scientific evidence for the relevant welfare effects, quantitative analyses of air quality, as available, and judgments about how to consider the uncertainties and limitations that are inherent in the scientific evidence and quantitative analyses. The four basic elements of the NAAQS (i.e., indicator, averaging time, form, and level) have been considered collectively in evaluating the public welfare protection afforded by the current standard against PM-related visibility, climate and materials effects. The Administrator's final decision will additionally consider public comments received on this proposed decision.

1. CASAC Advice in this Reconsideration

The CASAC provided its advice regarding the current secondary standards in the context

of its review of the draft PA (Sheppard, 2022a).[141] In its comments on the draft PA, the CASAC first recognized the scientific evidence is sufficient to support a causal relationship between PM and visibility effects, climate effects and materials effects.

With regard to visibility effects, the CASAC recognized that the identification of a target level of protection for the visibility index is based on a limited number of studies and suggested that "additional region- and view-specific visibility preference studies and data analyses are needed to support a more refined visibility target" (Sheppard, 2022a, p. 21 of consensus responses). While the CASAC did not recommend revising either the target level of protection for the visibility index or the level of the current 24-hour $PM_{2.5}$ standard, they did state that a visibility index of 30 deciviews "needs to be justified" and "[i]f a value of 20-25 deciviews is deemed to be an appropriate visibility target level of protection, then a secondary 24-hour $PM_{2.5}$ standard in the range of 25-35 $\mu g/m^3$ should be considered" (Sheppard, 2022a, p. 21 of consensus responses).

The CASAC also recognized the limited availability of monitoring methods and networks for directly measuring light extinction. As such, they suggest that "[a] more extensive technical evaluation of the alternatives for visibility indicators and practical measurement methods (including the necessity for a visibility FRM) is need for future reviews" (Sheppard, 2022a, p. 22 of consensus letter). The majority of the CASAC "recommend[ed] that an FRM for a directly

[141] A limited number of public comments have also been received in this reconsideration to date, including comments focused on the draft PA. Of those public comments that addressed the adequacy of the secondary PM standards, the majority of commenters support the preliminary conclusion that it is appropriate to consider retaining the current secondary PM standards, without revision. These commenters generally cite to a lack of newly available evidence and information that would inform consideration of alternative secondary PM standards to protect against PM-related effects on visibility, climate, and materials. One commenter, however, supported the revision of the secondary PM standards to provide additional protection against PM-related visibility effects.

measured $PM_{2.5}$ light extinction indicator be developed" to inform the consideration of the protection afforded by the secondary PM standards against visibility impairment, the minority of the CASAC "believe that a light extinction FRM is not necessary to set a secondary standard protective of visibility" (Sheppard, 2022a, p. 22 of consensus responses).

With regard to climate and materials effects, the CASAC noted that substantial uncertainties remain in the scientific evidence for these effects. The CASAC suggested a number of areas for future research to further inform our understanding of these effects, including more climate-related research and research that would allow for quantitative assessment of the relationship between materials effects and PM in ambient air.

2. Evidence- and Quantitative Information-Based Considerations in the Policy Assessment

The secondary PM standards include the 24-hour $PM_{2.5}$ standard, with its level of 35 $\mu g/m^3$ as the $98^{th}$ percentile, averaged over three years; the annual $PM_{2.5}$ standard, with its level of 15.0 $\mu g/m^3$ as the annual mean, averaged over three years; and the 24-hour $PM_{10}$ standard, with its level of 150 $\mu g/m^3$, not to be exceeded more than once per year on average over three years. Together, these standards provide protection against both long-term average and short-term peak PM concentrations. For example, the 24-hour $PM_{2.5}$ standard is most effective at limiting peak 24-hour $PM_{2.5}$ concentrations, but in doing so, also has an effect on annual average $PM_{2.5}$ concentrations. Additionally, the annual standard is most effective in controlling "typical" or average $PM_{2.5}$ concentrations, but also provides some measure of protection against peak exposures.

The PA considers the degree to which the available scientific evidence and quantitative information supports or calls into question the adequacy of the protection afforded by the current secondary PM standards. In doing so, the PA considers the evidence assessed in the 2019 ISA

and ISA Supplement, including the extent to which the evidence for PM-related visibility impairment, climate effects, or materials effects alters key conclusions from the 2020 review. The PA also considers quantitative analyses of visibility impairment and the extent to which they may indicate different conclusions from those in the 2020 review regarding the degree of protection from adverse effects provided by the current secondary standards.

Consistent with the approaches used in previous reviews, the quantitative analyses in the PA utilized a two-phase assessment for visibility impairment. First, the PA considered the appropriateness of the elements (indicator, averaging time, form, and level) of the visibility index for providing protection against PM-related visibility effects. Second, the PA evaluated the relationship between the current secondary 24-hour $PM_{2.5}$ standard and the visibility index.

With regard to the appropriateness of the visibility index and its target level of protection against PM-related visibility effects, the PA notes that there is limited information available in this reconsideration beyond that available in previous reviews to inform conclusions on the elements (indicator, averaging time, form, and level) of the visibility index (described in more detail in section V.C.1.a above). In considering the available information, the PA concludes that the available information continues to support a visibility index with estimated light extinction as the indicator, a 24-hour averaging time, and a $90^{th}$ percentile form, averaged over three years, with a level within the range of 20 to 30 dv.

With regard to the relationship between the current secondary 24-hour $PM_{2.5}$ standard and the visibility index, the PA presents updated analyses based on recent air quality information, with a focus on locations meeting the current secondary 24-hour $PM_{2.5}$ and $PM_{10}$ standards. In the absence of advances in the monitoring methods for directly measuring light extinction, and given the lack of a robust monitoring network for the routine measurement of light extinction

across the U.S. (section V.B.1.a), as in previous reviews, the PA analyses use calculated light extinction to estimate PM-related visibility impairment (U.S. EPA, 2022b, section 5.3.1.2). Compared to the 2012 review, updated analyses incorporate several refinements. These include (1) the evaluation of three versions of the IMPROVE equation to calculate light extinction (U.S. EPA, 2022b, Appendix D, Equations D-1 through D-3) in order to better understand the influence of variability in equation inputs;[142] (2) the use of 24-hour relative humidity data, rather than monthly average relative humidity as was used in the 2012 review (U.S. EPA, 2022b, section 5.3.1.2, Appendix D); and (3) the inclusion of the coarse fraction in the estimation of light extinction (U.S. EPA, 2022b, section 5.3.1.2, Appendix D). The PA's updated analyses include 60 monitoring sites that measure $PM_{2.5}$ and $PM_{10}$ that are geographically distributed across the U.S. in both urban and rural areas (U.S. EPA, 2022b, Appendix D, Figure D-1).[143]

In areas that meet the current 24-hour $PM_{2.5}$ standard for the 2017-2019 time period, all sites have light extinction estimates at or below 26 dv using the original and revised IMPROVE equations (U.S. EPA, 2022b, section 5.3.1.2). In addition, the four locations that exceeds the current 24-hour $PM_{2.5}$ standard have light extinction estimates that range from 22 to 27 dv when using the original IMPROVE equation (U.S. EPA, 2022b, Figure 5-3) and from 22 to 29 dv when using the revised IMPROVE equation (U.S. EPA, 2022b, Figure 5-4). The analyses

[142] While the $PM_{2.5}$ monitoring network has an increasing number of continuous FEM monitors reporting hourly $PM_{2.5}$ mass concentrations, there continue to be data quality uncertainties associated with providing hourly $PM_{2.5}$ mass and component measurements that could be input into IMPROVE equation calculations for sub-daily visibility impairment estimates. Therefore, the inputs to these light extinction calculations are based on 24-hour average measurements of $PM_{2.5}$ mass and components, rather than sub-daily information.

[143] These sites are those that have a valid 24-hour $PM_{2.5}$ design value for the 2015-2017 period and met strict criteria for PM species for this analysis, based on 24-hour average $PM_{2.5}$ and $PM_{10-2.5}$ mass and component data that were available from monitors in the IMPROVE network, CSN, and NCore Multipollutant Monitoring Network (U.S. EPA, 2022b, Appendix D).

presented in the PA indicate similar findings to those from the analyses in the 2012 and 2020 reviews, i.e., the updated quantitative analysis shows that the 3-year visibility metric was no higher than 30 dv (the upper end of the range of target levels of protection) at sites meeting the current secondary PM standards, and at most such sites the 3-year visibility index values are much lower (e.g., an average of 20 dv across the 60 sites).[144]

When light extinction is calculated using the updated IMPROVE equation from Lowenthal and Kumar (2016), the resulting 3-year visibility metrics are slightly higher at all sites compared to light extinction calculated using the original and revised IMPROVE equations (U.S. EPA, 2022b, Figure 5-5). The slightly higher estimates of light extinction are consistent with the higher OC multiplier included in the IMPROVE equation from Lowenthal and Kumar (2016), reflecting the use of data from remote areas with higher concentrations of organic PM when validating that equation. As such, it is important to note that the Lowenthal and Kumar (2016) version of the IMPROVE equation may overestimate light extinction in non-remote areas, including in the urban areas included in the analyses presented in the PA.

Nevertheless, when light extinction is calculated using the Lowenthal and Kumar (2016) equation for those sites that meet the current 24-hour $PM_{2.5}$ standard, the 3-year visibility metric is generally at or below 28 dv.[145] For the sites that exceed the current 24-hour $PM_{2.5}$ standard,

[144] As noted above in section V.1.C.b, when light extinction is calculated using the original IMPROVE equation, all 60 sites have 3-year visibility metrics below 30 dv, 58 sites are at or below 25 dv, and 26 sites are at or below 20 dv (see U.S. EPA, 2022b, Appendix D, Table D-3). When light extinction is calculated using the revised IMPROVE equation, all 60 sites have 3-year visibility metrics below 30 dv, 56 sites are at or below 25 dv, and 26 sites are at or below 20 dv (see U.S. EPA, 2022b, Appendix D, Table D-3).

[145] As noted above in section V.1.C.b, when light extinction is calculated using the Lowenthal and Kumar IMPROVE equation, 59 sites have 3-year visibility metrics below 30 dv, 45 sites are at or below 25 dv, and 15 sites are at or below 20 dv. The one site with a 3-year visibility metric of 32 dv exceeds the secondary 24-hour $PM_{2.5}$ standard, with a design value of 56 $\mu g/m^3$ (see U.S. EPA, 2022b, Appendix D, Table D-3).

three of the sites have a 3-year visibility metric ranging between 26 dv and 30 dv, while one site in Fresno, California that exceeds the current 24-hour $PM_{2.5}$ standard has a 3-year visibility index value of 32 dv (compared to 29 dv when light extinction is calculated with the original IMPROVE equation) (see U.S. EPA, 2022b, Appendix D, Table D-3). At this site, it is likely that the 3-year visibility metric using the Lowenthal and Kumar (2016) equation would be below 30 dv if $PM_{2.5}$ concentrations were reduced such that the 24-hour $PM_{2.5}$ level of 35 $\mu g/m^3$ was attained.

In the 2012 review, the EPA noted that $PM_{2.5}$ is the size fraction of PM responsible for most of the visibility impairment in urban areas (77 FR 38980, June 29, 2012). Data available at the time of the 2012 review suggested that $PM_{10-2.5}$ is often a minor contributor to visibility impairment (U.S. EPA, 2010a), though it may make a larger contribution in some areas in the desert southwestern region of the U.S. However, at the time of the 2012 review, there were few data available from $PM_{10-2.5}$ monitors to quantify the contribution of coarse PM to calculated light extinction. Since that time, an expansion in $PM_{10-2.5}$ monitoring efforts has increased the availability of data for use in estimating light extinction with both $PM_{2.5}$ and $PM_{10-2.5}$ concentrations included as inputs in the equations. The analysis in the 2020 review addressed light extinction at 20 of the 67 $PM_{2.5}$ sites where collocated $PM_{10-2.5}$ monitoring data were available. Since the 2020 review, $PM_{10-2.5}$ monitoring data are available at more locations and the analyses presented in the PA include those for light extinction estimated with coarse and fine PM at all 60 sites. Generally, the contribution of the coarse fraction to light extinction at these sites is minimal, contributing less than 1 dv to the 3-year visibility metric, as assessed and presented in the 2020 PA (U.S. EPA, 2020a, section 5.2.1.2). However, the PA notes that in the updated quantitative analyses, only a few sites were in locations that would be expected to have high

concentrations of coarse PM, such as the Southwest. These results are consistent with those in the analyses in the 2019 ISA, which found that mass scattering from $PM_{10–2.5}$ was relatively small (less than 10%) in the eastern and northwestern U.S., whereas mass scattering was much larger in the Southwest (more than 20%) particularly in southern Arizona and New Mexico (U.S. EPA, 2019a, section 13.2.4.1, p. 13-36).

In summary, the findings of these updated quantitative analyses are generally consistent with those in the 2012 and 2020 reviews. The 3-year visibility metric was generally below 26 dv in most areas that meet the current 24-hour $PM_{2.5}$ standard when light extinction is calculated using the original and revised IMPROVE equations, and generally at or below 28 dv when using the Lowenthal and Kumar (2016) equation to estimate light extinction. Small differences in the 3-year visibility metric were observed between the variations of the IMPROVE equation. When light extinction is calculated using the revised IMPROVE equation, there is a generally ±1-2 dv at the study locations compared to light extinction calculated using the original IMPROVE equation (U.S. EPA, 2022b, Appendix D, Table D-3). When light extinction is calculated using the Lowenthal and Kumar (2016) equation, the difference compared to using either the original or revised IMPROVE equation generally ranges from no difference to up to 4 dv greater in areas that meet the current secondary 24-hour $PM_{2.5}$ standard (U.S. EPA, 2022b, Appendix D, Table D-3). As noted in previous reviews, a change of 1 to 2 dv in light extinction under many viewing conditions will be perceived as a small, but noticeable, change in the appearance of a scene, regardless of the initial amount of visibility impairment (U.S. EPA, 2004a; U.S. EPA, 2010a). Given that there is more variability when estimating light extinction using the Lowenthal and Kumar (2016) IMPROVE equation compared to the original or revised IMPROVE equations, it is important to recognize that the PA notes that the Lowenthal and Kumar (2016) equation may

not be appropriate for all locations and source types. For example, the larger multiplier used in the Lowenthal and Kumar (2016) may be more appropriate for estimating light extinction in more remote areas where there is more aged and oxygenated organic PM compared to in urban areas. As such, the PA recognizes that one version of the IMPROVE equation is not necessarily more accurate or precise in estimating light extinction, and that differences in locations may support the selection of inputs to the IMPROVE equation or of the appropriate IMPROVE equation to estimate light extinction on a regional basis rather than on a national basis. Overall, regardless of the IMPROVE equation that is used to estimate light extinction, in areas that meet the current 24-hour $PM_{2.5}$ standards, the 3-year visibility metric is at or below 28 dv, which is in the upper range of levels for the target level of protection identified from the public preference studies (i.e., 20 to 30 dv). In fact, even in areas that exceed the secondary 24-hour $PM_{2.5}$ standard, and regardless of the IMPROVE equation that is used to calculate light extinction, all study locations have 3-year visibility index values at or below 30 dv, which is the upper end of the range of target levels of protection.

With regard to PM-related climate effects, the PA recognizes that while the evidence base has expanded since the completion of the 2009 ISA, the recent evidence has not appreciably improved the understanding of the spatial and temporal heterogeneity of PM components that contribute to climate forcing (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). Despite continuing research, there are still significant limitations in quantifying the contributions of PM and PM components to the direct and indirect effects on climate forcing (e.g., changes to the pattern of rainfall, changes to wind patterns, effects on vertical mixing in the atmosphere) (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). In addition, while a number of improvements and refinements have been made to climate models since the 2012 review, these models continue to exhibit

variability in estimates of the PM-related climate effects on regional scales (e.g., ~100 km) compared to simulations at the global scale (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). While recent research has added to the understanding of climate forcing on a global scale, there remain significant limitations to quantifying potential adverse effects from PM on climate in the U.S. and how they would vary in response to incremental changes in PM concentrations in the U.S. Overall, the PA recognizes that while new research is available on climate forcing on a global scale, the remaining uncertainties and limitations are significant, and the new global scale research does not translate directly to use at regional spatial scales. Thus, the evidence does not provide a clear understanding at the spatial scales needed for the NAAQS of a quantitative relationship between concentrations of PM mass in ambient air and the associated climate-related effects (U.S. EPA, 2022b, sections 5.3.2.2.1 and 5.5). The PA concludes that the evidence does not call into question the adequacy of the current secondary PM standards for climate effects.

With regard to materials effects, the PA notes the availability of recent evidence in this reconsideration related to the soiling process and the types of materials that are affected. Such evidence provides some limited information to inform dose-response relationships and damage functions associated with PM, though most recent studies have been conducted outside the U.S. in areas where PM concentrations in ambient air are higher than those observed in the U.S. (U.S. EPA, 2022b, section 5.3.2.1.2; U.S. EPA, 2019a, section 13.4). The recent evidence includes studies examining PM-related effects on the energy efficiency of solar panels and passive cooling building materials, though there remains insufficient evidence to establish quantitative relationships between PM in ambient air and these or other materials effects (U.S. EPA, 2022b, section 5.3.2.1.2). While recent research has expanded the body of evidence for PM-related materials effects, the PA recognizes the lack of information to inform quantitative analyses assessing materials effects or the potential public welfare implications of such effects (U.S. EPA,

2022b, section 5.3.2.2.2). Thus, the PA concludes that the evidence does not call into question the adequacy of the current secondary PM standards for materials effects.

Overall, the PA recognizes that the newly available welfare effects evidence, critically assessed in the 2019 ISA as part of the full body of evidence, and visibility effects evidence, assessed in the ISA Supplement, reaffirms the conclusions on the visibility, climate, and materials effects of PM as recognized in the 2012 and 2020 reviews (U.S. EPA, 2022b, sections 5.3.1.1., 5.3.2.1, and 5.5). Further, there is a general consistency of the currently available evidence with the evidence that was available in previous reviews, including with regard to key aspects of the decision to retain the standards in the 2012 and 2020 reviews (U.S. EPA, 2022b, sections 5.3.1.1, 5.3.2.1, and 5.5). The quantitative analyses for visibility impairment for recent air quality conditions indicate that estimated light extinction in areas meeting the current secondary 24-hour $PM_{2.5}$ standards have a 3-year visibility index at or below 30 dv (i.e., the upper end of the range of target levels of protection identified in the 2012 and 2020 reviews) and most areas have 3-year visibility index values at or below the midpoint of the range of target levels of protection (i.e., 25 dv) (U.S. EPA, 2022b, sections 5.3.1.2 and 5.5). Collectively, the PA finds that the evidence and quantitative information-based considerations support consideration of retaining the current secondary PM standards, without revision (U.S. EPA, 2022b, section 5.5).

3. Administrator's Proposed Decision on the Current Secondary PM Standards

This section summarizes the Administrator's considerations and conclusions related to the current secondary $PM_{2.5}$ and $PM_{10}$ standards and presents his proposed decision that no change is required for those standards at this time. The CAA provisions require the Administrator to establish secondary standards that, in the judgment of the Administrator, are

requisite to protect public welfare from known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect the public welfare from known or anticipated adverse effects. The final decision on the adequacy of the current secondary standards is a public welfare policy judgment to be made by the Administrator. The decision should draw on the scientific information and analyses about welfare effects, and associated public welfare significance, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This approach is based on the recognition that the available evidence generally reflects a continuum that includes ambient air exposures at which scientists agree that effects are likely to occur through lower levels at which the likelihood and magnitude of responses become increasingly uncertain. This approach is consistent with the requirements of the provisions of the Clean Air Act related to the review of NAAQS and with how the EPA and the courts have historically interpreted the Act.

Given these requirements, the Administrator's final decision in this reconsideration will be a public welfare policy judgment that draws upon the scientific and technical information examining PM-related visibility impairment, climate effects and materials effects, including how to consider the range and magnitude of uncertainties inherent in that information. The Administrator recognizes that his final decision will be based on an interpretation of the scientific evidence and technical analyses that neither overstates nor understates their strengths and limitations, nor the appropriate inferences to be drawn.

As an initial matter in considering the secondary standards, the Administrator notes the

longstanding body of evidence for PM-related visibility impairment. As in previous reviews, this evidence continues to demonstrate a causal relationship between ambient PM and effects on visibility (U.S. EPA, 2019a, section 13.2). The Administrator recognizes that visibility impairment can have implications for people's enjoyment of daily activities and for their overall sense of well-being. Therefore, as in previous reviews, he considers the degree to which the current secondary standards protect against PM-related visibility impairment. In so doing, and consistent with previous reviews, the Administrator considers the protection provided by the current secondary standards against PM-related visibility impairment in conjunction with the Regional Haze Program as a means of achieving appropriate levels of protection against PM-related visibility impairment in urban, suburban, rural, and Federal Class I areas across the country. Programs implemented to meet the secondary PM NAAQS, along with the requirements of the Regional Haze Program established for protecting against visibility impairment in Class I areas, would be expected to improve visual air quality across all areas.

In addition, the Administrator notes that the Regional Haze Program was established by Congress specifically to achieve "the prevention of any future, and the remedying of existing, impairment of visibility in mandatory Class I areas, which impairment results from man-made air pollution," and that Congress established a long-term program to achieve that goal (CAA section 169A). The Administrator finds that in adopting section 169A, Congress set a goal of eliminating anthropogenic visibility impairment at Class I areas, as well as a framework for achieving that goal which extends well beyond the planning process and timeframe for attaining secondary NAAQS. Thus, recognizing that the Regional Haze Program will continue to contribute to reductions in visibility impairment in Class I areas, the Administrator proposes to conclude that addressing visibility impairment in Class I areas is beyond the scope of the secondary PM

NAAQS and that setting the secondary PM NAAQS at a level that would remedy visibility impairment in Class I areas would result in standards that are more stringent than is requisite.

In further considering what standards are requisite to protect against adverse public welfare effects from visibility impairment, the Administrator adopts an approach consistent with the approach used in previous reviews (section V.A.1.b). That is, he first identifies an appropriate target level of protection in terms of a PM visibility index that accounts for the factors that influence the relationship between particles in the ambient air and visibility (i.e., size fraction, species composition, and relative humidity). He then considers air quality analyses examining the relationship between this PM visibility index and the current secondary 24-hour $PM_{2.5}$ standard in locations meeting the current 24-hour $PM_{2.5}$ and $PM_{10}$ standards (U.S. EPA, 2022b, section 5.3.1.2).

To identify a target level of protection, the Administrator first considers the characteristics of the visibility index and defines its elements (indicator, averaging time, form, and level). With regard to the indicator for the visibility index, the Administrator recognizes that there is a lack of availability of methods and an established network for directly measuring light extinction, consistent with the conclusions reached in the PA (U.S. EPA, 2022b, section 5.3.1.1) and with the CASAC's recommendation for additional research on direct measurement methods for light extinction (Sheppard, 2022a, p. 21 of consensus responses). He notes that in the 2012 and 2020 reviews, given the lack of such monitoring data, the EPA used an index based on estimates of light extinction by $PM_{2.5}$ components calculated using an adjusted version of the original IMPROVE algorithm. As described above (sections V.B.1.a and V.D.2), this algorithm allows the estimation of light extinction using routinely monitored components of $PM_{2.5}$ and

$PM_{10-2.5}$,[146] along with estimates of relative humidity. While revisions have been made to the IMPROVE algorithm since the 2012 review (U.S. EPA, 2022b, section 5.3.1.1), the Administrator recognizes that our fundamental understanding of the relationship between ambient PM and light extinction has changed little since the 2012 review. He further recognizes that the results of the quantitative analyses in the PA that examined three versions of the IMPROVE equation indicate that there are very small differences in estimates of light extinction between the equations, and that it is not always clear that one version of the IMPROVE equation is more appropriate for estimating light extinction across the U.S. than other versions of the IMPROVE equation. He does, however, recognize that the PA suggests that it may be appropriate to select inputs to the IMPROVE equation (e.g., the multiplier for OC to OM) on a regional basis rather than a national basis when calculating light extinction (U.S. EPA, 2022b, section 5.3.1.2), and he further notes the CASAC's recognition that PM-visibility relationships are region specific (Sheppard, 2022a, p. 21 of consensus responses). In the absence of a robust monitoring network to directly measure light extinction (sections V.B.1.a and V.D.2), he preliminarily judges that estimated light extinction, as calculated using one or more versions of the IMPROVE algorithms, continues to be the most appropriate indicator for the visibility index in this reconsideration.

In further defining the characteristics of a visibility index based on estimates of light extinction, the Administrator considers the appropriate averaging time, form, and level of the index. With regard to the averaging time and form, the Administrator notes that in previous reviews, a 24-hour averaging time was selected and the form was defined as the 3-year average

[146] In the 2012 review, the focus was on $PM_{2.5}$ components given their prominent role in PM-related visibility impairment in urban areas and the limited data available for $PM_{10-2.5}$ (77 FR 38980, June 29, 2012; U.S. EPA, 2022b, section 5.3.1.2).

of annual 90th percentile values. The Administrator recognizes that the evidence available in this reconsideration and described in the PA continue to provide support for the short-term nature of PM-related visibility effects. In so doing, he relies on analyses of 24-hour and sub-daily $PM_{2.5}$ light extinction to inform his conclusions on averaging time. The Administrator notes that there are strong correlations between 24-hour and sub-daily (i.e., 4-hour average) $PM_{2.5}$ light extinction), indicating that a 24-hour averaging time is an appropriate surrogate for the sub-daily time periods relevant for visual perception (U.S. EPA, 2011, Appendix G, section G.4). He further recognizes that the longer averaging time may be less influenced by atypical conditions and/or atypical instrument performance. Considering this information, and noting that the CASAC did not provide advice or recommendations with regard to the averaging time of the visibility index, the Administrator preliminarily judges that it the 24-hour averaging time continues to be appropriate for the visibility index.

With regard to the form of the visibility index, the Administrator notes that consistent with the approach taken in other NAAQS, including the current secondary 24-hour $PM_{2.5}$ NAAQS, a multi-year percentile form offers greater stability to the air quality management process by reducing the possibility that statistically unusual indicator values will lead to transient violations of the standard. Using a 3-year average provides stability from the occasional effects of inter-annual meteorological variability that can result in unusually high pollution levels for a particular year (U.S. EPA, 2011, p. 4-58). In considering the percentile that would be appropriate with the 3-year average, the Administrator first notes that the Regional Haze Program targets the 20% most impaired days for improvements in visual air quality in Class I areas.[147] Based on

[147] As noted above, the Administrator views the Regional Haze Program as a complement to the secondary PM NAAQS, and thus takes into consideration its approach to improving visibility in considering how to address visibility outside of Class I areas.

analyses examining 90th, 95th, and 98th percentile forms, the Administrator preliminarily judges that a focus similar to the Regional Haze Program focused on improving the 20% most impaired days suggest that the 90th percentile, which represents the median of the 20% most impaired days, such that 90% of days have visual air quality that is at or below the target level of protection of the visibility index, would be reasonably expected to lead to improvements in visual air quality for the 20% most impaired days (U.S. EPA, 2011, p. 4-59). In the analyses of percentiles, the results suggest that a higher percentile value could have the effect of limiting the occurrence of days with peak PM-related light extinction in areas outside of Federal Class I areas to a greater degree. However, the Administrator preliminarily concludes that it is appropriate to balance concerns about focusing on the group of most impaired days with concerns about focusing on the days with peak visibility impairment. Additionally, the Administrator notes that the CASAC did not provide advice or recommendations related to the form of the visibility index. Therefore, the Administrator preliminarily judges that it remains appropriate to define a visibility index in terms of a 24-hour averaging time and a form based on the 3-year average of annual 90th percentile values.

With regard to the level of the visibility index, the Administrator first notes that the information that is available regarding the range of levels of visibility impairment judged to be acceptable by at least 50% of study participants in the visibility preference studies is largely the same as was in previous reviews.[148] As such, the Administrator notes that the PA identifies a range of 20 to 30 dv as appropriate for considering the level for the visibility index. Furthermore, the Administrator notes that a level at the upper end of the range (i.e., 30 dv) was selected for the

[148] For reasons stated above, the Administrator does not find it appropriate to use the most recent preference study (Malm et al., 2019) for purposes of identifying a target level of protection for the visibility index.

2012 and 2020 reviews, given the uncertainties and limitations associated with the public preference studies (U.S. EPA, 2022b, section 5.3.1.1). In considering the available public preference studies and the range of target levels of protection derived from the studies, the Administrator notes that, while methodologically similar, the studies have inherent differences that impact the responses from the study participants. He notes that the images used to evaluate public preferences differed significantly depending on geographical location, and that public preferences for visual air quality can vary depending on the scenic elements depicted in the images. He also recognizes that the older studies (i.e., those in Denver, CO, and British Columbia, Canada) used photographs, paired with ambient measurements of light extinction, as opposed to the computer-generated images in more recent studies (i.e., those in Phoenix, AZ, and Washington, DC), which introduces more variability in scene appearance that can influence preferences. Furthermore, the distances of objects depicted in the images can influence the perceived visibility changes, as objects at a greater distance have more sensitivity to changes in visibility impairment compared to those at shorter distances. The Administrator recognizes that these differences, and the uncertainties and limitations that result from them, are important to consider when identifying a target level of protection for the visibility index, particularly in identifying the appropriate level of protection that would be neither more nor less stringent than necessary for a national standard.

In addition to the methodological differences across the public preferences studies, the Administrator takes note of the uncertainties and limitations associated with the studies and discussed in the PA. In particular, the Administrator notes that available studies may not capture the full range of visibility preferences in the U.S. population, particularly given the potential for preferences to vary based on the visibility conditions commonly encountered and the types of

scenes being viewed and factors that are not captured by the methods used in available preference studies may influence people's judgments on acceptable visibility, including the duration of visibility impairment, the time of day during which light extinction is greatest, and the frequency of episodes of visibility impairment (U.S. EPA, 2022b, section 5.3.1.1).

In considering the appropriate target level of protection for the visibility index, the Administrator also takes note of the CASAC's advice. Specifically, he notes that the CASAC recognizes that such a judgment is based on a limited number of visibility preference studies, with studies conducted in the western U.S. reporting public preferences for visibility impairment associated with the lower end of the range of levels, while studies conducted in the eastern U.S. reporting public preferences associated with the upper end of the range. While the CASAC did not specifically recommend a level for the visibility index, they did state that a visibility index of 30 deciviews "needs to be justified" (Sheppard, 2022a, p. 21 of consensus responses). In considering the available information and the CASAC's advice, the Administrator notes that the public preference studies were conducted in several geographical areas across the U.S., and while they provide insight to regional preferences for visibility impairment, none of these studies identify a specific level of visibility impairment that would be perceived as "acceptable" or "unacceptable" across the whole U.S. population. The Administrator notes that there have long been significant questions about how to set a national standard for visibility that is not overprotective for some areas of the U.S. In establishing the Regional Haze Program to improve visibility in Class I areas, Congress noted that "as a matter of equity, the national ambient air quality standards cannot be revised to adequately protect visibility in all areas of the country." H.R. Rep. 95-294 at 205. Similarly, in the 1997 review, the Administrator at that time noted significant differences in visibility in the eastern U.S. compared to the western U.S. due to

background conditions, found that a standard set to protect against visibility impairment nationwide would be significantly overprotective and not justified for some parts of the country, and concluded it was appropriate to rely on the Regional Haze Program in conjunction with the secondary PM NAAQS to achieve the requisite degree of protection from visibility impairment (62 FR 38652, July 18, 1997). For the reasons noted above, the Administrator is not seeking to set a standard that would eliminate visibility impairment in Class I areas, but significant uncertainties remain regarding how to judge visibility impairment across the entire range of daily outdoor activities for Americans across the country. Thus, the Administrator recognizes that there are substantial uncertainties and limitations in the public preference studies that should be considered when selecting a target level of protection for the visibility index. The Administrator proposes to conclude that the uncertainties and variability inherent in the public preference studies warrant setting a higher target level of protection than if the underlying methods and results from the public preference studies were more consistent. In so doing, the Administrator first preliminarily judges that, consistent with similar judgments in past reviews, it is appropriate to recognize that the secondary 24-hour $PM_{2.5}$ standard is intended to address visibility impairment across a wide range of regions and circumstances, and that the current standard works in conjunction with the Regional Haze Program to improve visibility, and therefore, it is appropriate to establish a target level of protection based on the upper end of the range of levels. In considering the information available in this reconsideration and the CASAC's advice, the Administrator proposes to conclude that the protection provided by a visibility index based on estimated light extinction, a 24-hour averaging time, and a $90^{th}$ percentile form, averaged over 3 years, set at a level of 30 dv (the upper end of the range of levels) would be requisite to protect public welfare with regard to visibility impairment.

Having provisionally concluded that it remains appropriate in this reconsideration to define the target level of protection in terms of a visibility index based on estimated light extinction as described above (i.e., with a 24-hour averaging time; a 3-year, 90$^{th}$ percentile form; and a level of 30 dv), the Administrator next considers the degree of protection from visibility impairment afforded by the existing secondary standards. He considers the updated analyses of PM-related visibility impairment presented in the PA (U.S. EPA, 2022b, section 5.3.1.2), which reflect several improvements over the 2012 review. Specifically, the updated analyses examine multiple versions of the IMPROVE algorithm, including the version incorporating revisions since the 2012 review (section V.B.1.a). This approach provides an improved understanding of how variation in equation inputs impacts calculated light extinction (U.S. EPA, 2022b, Appendix D). In addition, all of the sites included in the analyses had $PM_{10-2.5}$ data available, which allows for better characterization of the influence of the coarse fraction on light extinction (U.S. EPA, 2022b, section 5.3.1.2).

The Administrator notes that the results of these updated analyses are consistent with the results from the 2012 and 2020 reviews. Regardless of the IMPROVE equation used, these analyses demonstrate that the 3-year visibility metric is at or below 28 dv in all areas meeting the current 24-hour $PM_{2.5}$ standard (section V.C.1.b). Given the results of these analyses, the Administrator concludes that the updated scientific evidence and technical information support the adequacy of the current secondary $PM_{2.5}$ and $PM_{10}$ standards to protect against PM-related visibility impairment. While the inclusion of the coarse fraction had a relatively modest impact on calculated light extinction in the analyses presented in the PA, he nevertheless recognizes the continued importance of the $PM_{10}$ standard given the potential for larger impacts in locations with higher coarse particle concentrations, such as in the southwestern U.S., for which only a

few sites met the criteria for inclusion in the analyses in the PA (U.S. EPA, 2019a, section 13.2.4.1; U.S. EPA, 2022b, section 5.3.1.2).

With regard to the adequacy of the secondary 24-hour $PM_{2.5}$ standard, the Administrator notes that the CASAC stated that "[i]f a value of 20-25 deciviews is deemed to be an appropriate visibility target level of protection, then a secondary 24-hour $PM_{2.5}$ standard in the range of 25-35 $\mu g/m^3$ should be considered" (Sheppard, 2022a, p. 21 of consensus responses). The Administrator recognizes that the CASAC recommended the Administrator provide additional justification for a visibility index target of 30 dv but did not specifically recommend that he choose an alternative level for the visibility index. The Administrator has considered the CASAC's advice, together with the available scientific evidence and quantitative information in reaching his proposed conclusions. The Administrator recognizes conclusions regarding the appropriate weight to place on the scientific and technical information examining PM-related visibility impairment including how to consider the range and magnitude of uncertainties inherent in that information is a public welfare policy judgment left to the Administrator. As such, the Administrator notes his conclusion on the appropriate visibility index (i.e., with a 24-hour averaging time; a 3-year, $90^{th}$ percentile form; and a level of 30 dv) and his conclusions regarding the quantitative analyses of the relationship between the visibility index and the current secondary 24-hour $PM_{2.5}$ standard. In so doing, he proposes to conclude that the current secondary standards provide requisite protection against PM-related visibility effects. With respect to non-visibility welfare effects, the Administrator considers the evidence for PM-related impacts on climate and on materials and concludes that it is generally appropriate to retain the existing secondary standards and that it is not appropriate to establish any distinct secondary PM standards to address non-visibility PM-related welfare effects. With regard to climate, he

recognizes that a number of improvements and refinements have been made to climate models since the time of the 2012 review. However, despite continuing research and the strong evidence supporting a causal relationship with climate effects (U.S. EPA, 2019a, section 13.3.9), the Administrator notes that there are still significant limitations in quantifying the contributions of the direct and indirect effects of PM and PM components on climate forcing (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). He also recognizes that models continue to exhibit considerable variability in estimates of PM-related climate impacts at regional scales (e.g., ~100 km), compared to simulations at the global scale (U.S. EPA, 2022b, sections 5.3.2.1.1 and 5.5). The resulting uncertainty leads the Administrator to preliminarily conclude that the scientific information available in this reconsideration remains insufficient to quantify, with confidence, the impacts of ambient PM on climate in the U.S. (U.S. EPA, 2022b, section 5.3.2.2.1) and that there is insufficient information at this time to base a national ambient standard on climate impacts.

With respect to materials effects, the Administrator notes that the available evidence continues to support the conclusion that there is a causal relationship with PM deposition (U.S. EPA, 2019a, section 13.4). He recognizes that deposition of particles in the fine or coarse fractions can result in physical damage and/or impaired aesthetic qualities. Particles can contribute to materials damage by adding to the effects of natural weathering processes and by promoting the corrosion of metals, the degradation of painted surfaces, the deterioration of building materials, and the weakening of material components. While some recent evidence on materials effects of PM is available in the 2019 ISA, the Administrator notes that this evidence is primarily from studies conducted outside of the U.S. in areas where PM concentrations in ambient air are higher than those observed in the U.S. (U.S. EPA, 2019a, section 13.4). Given

the limited amount of information on the quantitative relationships between PM and materials effects in the U.S., and uncertainties in the degree to which those effects could be adverse to the public welfare, the Administrator preliminarily judges that the scientific information available in this reconsideration remains insufficient to quantify, with confidence, the public welfare impacts of ambient PM on materials and that there is insufficient information at this time to support a distinct national ambient standard based on materials impacts.

Taken together, the Administrator proposes to conclude that the scientific and technical information for PM-related visibility impairment, climate impacts, and materials effects, with its attendant uncertainties and limitations, supports the current level of protection provided by the secondary PM standards as being requisite to protect against known and anticipated adverse effects on public welfare. For visibility impairment, this proposed conclusion reflects his consideration of the evidence for PM-related light extinction, together with his consideration of updated analyses of the protection provided by the current secondary $PM_{2.5}$ and $PM_{10}$ standards. For climate and materials effects, this conclusion reflects his preliminary judgment that, although it remains important to maintain secondary $PM_{2.5}$ and $PM_{10}$ standards to provide some degree of control over long- and short-term concentrations of both fine and coarse particles, it is generally appropriate not to change the existing secondary standards and that it is not appropriate to establish any distinct secondary PM standards to address PM-related climate and materials effects at this time. As such, the Administrator recognizes that current suite of secondary standards (i.e., the 24-hour $PM_{2.5}$, 24-hour $PM_{10}$, and annual $PM_{2.5}$ standards) together provide such control for both fine and coarse particles and long- and short-term visibility and non-

visibility (e.g., climate and materials)[149] effects related to PM in ambient air. His proposed conclusions on the secondary standards are consistent with advice from the CASAC, which noted substantial uncertainties remain in the scientific evidence for climate and materials effects. Thus, based on his consideration of the evidence and analyses for PM-related welfare effects, as described above, and his consideration of CASAC advice on the secondary standards, the Administrator proposes not to change those standards (i.e., the current 24-hour and annual $PM_{2.5}$ standards, 24-hour $PM_{10}$ standard) at this time. The Administrator solicits comments on this proposed conclusion.

The Administrator additionally recognizes that the available evidence on visibility impairment generally reflects a continuum and that the public preference studies did not identify a specific level of visibility impairment that would be perceived as "acceptable" or "unacceptable" across the whole U.S. population. However, he notes a judgment of a target level of protection, below 30 dv and down to 25 dv, could be supported if more weight was put on the public preference study performed in the Phoenix, AZ, study (BBC Research & Consulting, 2003), which yielded the best results of the four public preference studies in terms of the least noisy preference results and the most representative selection of participants. While the Administrator notes that CASAC did not recommend revising the level of the current 24-hour $PM_{2.5}$ standard, the Administrator recognizes that, should an alternative level be considered for the visibility index, that the CASAC recommends also considering revisions to the secondary 24-hour $PM_{2.5}$ standard (Sheppard, 2022a, p. 21 of consensus responses). Thus, the Administrator solicits comment on the appropriateness of a target level of protection for visibility below 30 dv

[149] As noted earlier, other welfare effects of PM, such as ecological effects, are being considered in the separate, on-going review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM.

and down as low as 25 dv, and of revising the level of the current secondary 24-hour $PM_{2.5}$ standard to a level as low as 25 $\mu g/m^3$. Any comments on such revisions should include an explanation of the basis for the commenters' views.

*E. Proposed Decisions on the Secondary PM Standards*

Taking the above considerations into account, upon reconsidering the public welfare protection provided by the current secondary PM standards for the known and anticipated adverse effects within the scope of this reconsideration, in light of the currently available scientific evidence and quantitative information, the Administrator proposes not to change the current secondary PM standards at this time. In the Administrator's preliminary judgment, such a suite of secondary PM standards and the rationale supporting not revising the current standards are reasonably judged to reflect the appropriate consideration of the strength of the available evidence and other information and their associated uncertainties and the advice of CASAC.

The Administrator recognizes that the final suite of standards will reflect his ultimate judgment in the final rulemaking, and in the on-going review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM, as to the suite of secondary PM standards that are requisite to protect the public welfare from known or anticipated adverse effects associated with the pollutant's presence in the ambient air. The final judgment to be made by the Administrator will appropriately consider the requirement for standards that are neither more nor less stringent than necessary and will recognize that the CAA does not require that secondary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect the public welfare from known or anticipated adverse effects.

The Administrator also solicits comment on whether it would be appropriate to revise the current secondary 24-hour $PM_{2.5}$ standard, in conjunction with considering a lower target level of protection for the visibility index below 30 dv, and as low as 25 dv. The Administrator takes note

that, while the CASAC did not recommend changes to the current level of 35 $\mu g/m^3$ for the secondary 24-hour $PM_{2.5}$ standard, they indicated that alternative levels should be considered if a lower target level of protection (i.e., lower than 30 dv) for the visibility index was judged to be appropriate. Thus, the Administrator additionally solicits comment on the appropriateness of revising the level of the current secondary 24-hour $PM_{2.5}$ standard to a level as low as 25 $\mu g/m^3$. Any comments on such revisions should include an explanation of the basis for the commenters' views.

Having reached the proposed decision described here based on interpretation of the welfare effects evidence for this reconsideration, as assessed in the 2019 ISA and ISA Supplement, and the quantitative analyses of visibility impairment in the PA; the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA; the advice and recommendations from the CASAC; public comments received to date in this reconsideration; and the public welfare policy judgments described above, the Administrator recognizes that other interpretations, assessments and judgments might be possible. Therefore, the Administrator solicits comment on the array of issues associated with reconsideration of the secondary PM standards, including public welfare and science policy judgments inherent in his proposed decision, as described above, and the rationales upon which such views are based.

## VI. Interpretation of the NAAQS for PM

### *A. Proposed Amendments to Appendix K: Interpretation of the NAAQS for Particulate Matter*

The EPA proposes to revise Appendix K to make the $PM_{10}$ data handling procedures for the 24-hour $PM_{10}$ standards specified in 40 CFR 50.6 more consistent with those for other NAAQS pollutants and to codify existing practices. The proposed revisions, which describe site-level computations, site-to-site combinations, and daily validity requirements are discussed in more detail below.

1. Updating design value calculations to be on a site-level basis

First, the EPA proposes to require $PM_{10}$ design values be calculated on a site-level basis. Past practice has been to calculate a monitor-level design value for each individual $PM_{10}$ monitor when more than one monitor is located at a single site; however, this practice is inconsistent with the data handling for $PM_{2.5}$ and several other NAAQS pollutants. This inconsistency with $PM_{2.5}$ has led to public confusion about the applicable $PM_{10}$ design value and data completeness criteria at a site because operators are more accustomed to site-level monitoring requirements. To resolve this confusion, the EPA believes it would be appropriate to identify a single design value for each site; the EPA is proposing an analytic approach to combine data collected from multiple $PM_{10}$ monitors collocated at a site to obtain a single set of daily $PM_{10}$ concentration data for that site. This proposal to move from monitor-level to site-level $PM_{10}$ design values is supported by the high level of consistency in the measurement data obtained across the various federal reference and equivalent $PM_{10}$ monitoring instruments currently in operation (U.S. EPA, 2009a, section 3.4.1.1).

The proposed approach would provide for monitoring agencies to designate in their annual network plan one monitor as the primary monitor for each site.[150] Once a primary monitor has been determined for a site, missing daily $PM_{10}$ concentrations for the primary monitor would be substituted from any other monitors located at the site. In the event of two or more monitors operating at the same site, missing daily $PM_{10}$ concentrations for the primary monitor would be substituted with daily values averaged across the other collocated monitors. The EPA notes that at the time of this proposal, there were more than 100 sites nationwide with two or more

[150] In the absence of a primary monitor designation, the primary monitor would default to the monitor with the most complete daily dataset in each year.

monitors operating simultaneously.

This proposed approach for combining data across collocated monitors at a site is consistent with the existing approach described in Appendix N to Part 50 for the current $PM_{2.5}$ NAAQS. The EPA invites public comment on the scientific validity of combining data across $PM_{10}$ monitors and the merits of the proposed approach for combining data across multiple $PM_{10}$ monitors collocated at a site.

2. Codifying site combinations to maintain a continuous data record

Second, and complementary to the first proposed revision described above, the EPA proposes to maintain the existing practice of combining data from nearby monitoring sites to determine a valid design value, known as a "site combination." Site combinations typically involve situations where one site closes and another begins monitoring a short distance away within a few days, and the monitoring agency wishes to combine the data from the two sites to maintain a continuous data record. The EPA Regional offices have approved over ten site combinations for $PM_{10}$ since the promulgation of the 1987 $PM_{10}$ NAAQS; these will be considered approved site combinations if these revisions are promulgated.

Relatedly, the EPA proposes to maintain the existing practice of allowing monitoring agencies to submit site combination requests to the appropriate Regional Administrator through the EPA's Air Quality System (AQS) database. Site combinations may be approved by the Regional Administrator after they determine that the measured air quality concentrations do not differ substantially between the two sites. To make this determination for a requested site combination, the Regional Administrator may request additional information from the Agency including detailed information on the locations and distance between the two sites, levels of ambient concentrations measured at the two sites, and local emissions or meteorology data. To

improve transparency, the EPA will make records of all approved site combinations available in the AQS database and will update design value calculations in AQS when approved site combinations are implemented. The EPA invites public comment on the merits of the proposed process for approving site combinations to obtain valid design values for the $PM_{10}$ NAAQS.

3. Clarifying daily validity requirements for continuous monitors

Third, the EPA proposes to maintain the existing practice of considering daily averages to be valid if at least 75 percent of the hourly averages (i.e., 18 hourly values) for the 24-hour period are available unless a substitution test can show validity on days with seven or more missing hours.

*B. Proposed Amendments to Appendix N: Interpretation of the NAAQS for $PM_{2.5}$*

The EPA proposes to revise Appendix N by updating references to the proposed revision(s) of the standards and changing data handling provisions related to combining data from nearby monitoring sites to codify existing practices that are currently being implemented as EPA standard operating procedures.

1. Updating references to the proposed revision(s) of the standards

The EPA proposes to maintain the existing practice of combining data from nearby monitoring sites to determine a valid design value, known as a "site combination." Site combinations typically involve situations where one site closes and another begins monitoring a short distance away within a few days, and the monitoring agency wishes to combine the data from the two sites to maintain a continuous data record. The EPA Regional offices have approved over 40 site combinations for $PM_{2.5}$ since the promulgation of the 1997 $PM_{2.5}$ NAAQS; these will be considered approved site combinations if these revisions are promulgated.

2. Codifying site combinations to maintain a continuous data record

Relatedly, the EPA proposes to maintain the existing practice of allowing monitoring

agencies to submit site combination requests to the appropriate Regional Administrator through the EPA's Air Quality System (AQS) database. Site combinations may be approved by the Regional Administrator after they determine that the measured air quality concentrations do not differ substantially between the two sites. To make this determination for a requested site combination, the Regional Administrator may request additional information from the Agency including detailed information on the locations and distance between the two sites, levels of ambient concentrations measured at the two sites, and local emissions or meteorology data. To improve transparency, the EPA will make records of all approved site combinations available in the AQS database and will update design value calculations in AQS when approved site combinations are implemented. The EPA invites public comment on the merits of the proposed process for approving site combinations to obtain valid design values for the $PM_{2.5}$ NAAQS.

## VII. Proposed Amendments to Ambient Monitoring and Quality Assurance Requirements

The EPA is proposing revisions to ambient air monitoring requirements for PM to improve the usefulness of and appropriateness of data used in regulatory decision making. These proposed changes focus on ambient monitoring requirements found in 40 CFR Part 50 (Appendix L), Part 53, and Part 58 with associated appendices (A, B, C, D, and E). These proposed changes include addressing updates in the approval of reference and equivalent methods, updates in quality assurance statistical calculations to account for lower concentration measurements, updates to support improvements in PM methods, a revision to the $PM_{2.5}$ network design to account for at-risk populations, and updates to the Probe and Monitoring Path Siting Criteria for NAAQS pollutants.

The EPA last completed revisions to PM ambient air monitoring regulations as a part of the PM NAAQS review completed in 2012 (78 FR 3085, January 15, 2013). This final

rulemaking included revisions to ensure the suite of standards for PM provide requisite protection of public health and welfare as well as corresponding revisions to the data handling conventions for PM and to the ambient air monitoring, reporting, and network design requirements. Other pollutant-specific monitoring updates have occurred in conjunction with revisions to the NAAQS. In such cases, the monitoring revisions were typically finalized as part of the final rulemaking for the NAAQS.[151] Specific proposed changes are described below.

*A. Proposed Amendment in 40 CFR Part 50 (Appendix L): Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere – addition of the Tisch cyclone as an approved second stage separator.*

The EPA is proposing a technical change to Appendix L to include the addition of an alternative $PM_{2.5}$ particle size separator to that of the WINS and the VSCC size separators. The new separator is the TE-PM2.5C cyclone manufactured by Tisch Environmental Inc., Cleves, Ohio, and has been shown to have performance equivalent to that of the originally specified WINS impactor with regards to aerodynamic cutpoint and $PM_{2.5}$ concentration measurement. In addition, the new TE-PM2.5C has a service interval comparable to the VSCC separator and is significantly longer than the service interval for the WINS. Generally, the TE-PM2.5C is also physically interchangeable with the WINS and VSCC where both are manufactured for the same sampler. The proposal would allow the WINS, VSCC, or TE-PM2.5C to be used in a $PM_{2.5}$ FRM sampler. As is the case for the WINS and VSCC, the TE-PM2.5C is now also an approved size separator for candidate $PM_{2.5}$ FEMs. Currently, the EPA has designated one $PM_{2.5}$ sampler configured with TE-PM2.5C separator as a Class II $PM_{2.5}$ equivalent method and one as a $PM_{10-2.5}$ equivalent method. Upon promulgation of this proposed change to Appendix L, these instruments would be redesignated as $PM_{2.5}$ and $PM_{10-2.5}$ FRMs, respectively. Owners of such

[151] Links to the NAAQS final rules are available at: *https://www.epa.gov/criteria-air-pollutants*.

samplers would contact the sampler manufacturer to receive a new reference method label for the samplers.

*B. Proposed Amendments to Ambient Air Monitoring Reference and Equivalent Methods in 40 CFR Part 53*

The EPA is proposing clarifications to the regulations associated with submittal of candidate FRM and FEM applications for review by the EPA. Revisions are also proposed in instances where current regulatory specifications are no longer pertinent and require updating. In addition, the EPA has compiled a list of noted minor errors to correct in regulations associated with the testing requirements and acceptance criteria for federal reference methods (FRMs) and federal equivalent methods (FEMs) in Part 53. These errors are typically not associated with the content of Federal Register documents but often relate to transcription errors and typographical errors in the electronic CFR (eCFR) and printed versions of the CFR.

1. Update to program title and delivery address for FRM and FEM Application and Modification Requests

The EPA is proposing to update the name of the program and delivery address for the EPA review of FRM and FEM Applications and Modification Requests (§53.4). These revisions are due solely to organizational changes and do not affect the structure or role of the Reference and Equivalent Methods Designation Program in reviewing new FRM and FEM application requests and requests to modify existing designated instruments.

2. Requests for delivery of a candidate FRM or FEM instrument

As part of the current applicant review process, §53.4(d) allows the EPA to request only candidate $PM_{2.5}$ FRMs and Class II or Class III equivalent methods for test purposes. The EPA proposes to revise this section to allow the EPA to request any candidate FRM, FEM, or a designated FRM or FEM associated with a Modification Request, regardless of NAAQS

pollutant type or metric.

3. Amendments to requirements for submission of materials in §53.4(b)(7) for language and format

The EPA proposes to amend §53.4(b)(7) of 40 CFR, which specifies the format(s) in which all submissions must be received, to specify that all written application materials must be submitted to the EPA in English in MS Word format and that submitted data must be submitted in MS Excel format.

4. Amendment to designation of reference and equivalent methods

The EPA proposes to clarify the terms of new FRM and FEM methods (§53.8(a)) to ensure that candidate samplers and analyzers are not publicly announced, marketed, or sold as FRMs until the EPA's approval has been formally announced in the *Federal Register*.

5. Amendment to one test field campaign requirement for Class III $PM_{2.5}$ FEMs

Field comparability tests for candidate Class III $PM_{2.5}$ FEMs include the requirement that a total of five field campaigns must be conducted at four separate sites: A, B, C, and D. The Site D specifications of §53.35(b)(1)(ii)(D) require that the site "…shall be in a large city east of the Mississippi River, having characteristically high sulfate concentrations and high humidity levels." However, dramatic decreases in ambient sulfate concentration make it difficult for applicants to routinely meet the high sulfate concentration requirement. Therefore, the EPA proposes to revise the Site D specifications to read "…shall be in a large city east of the Mississippi River, having characteristically high humidity levels."

6. Amendment to use of monodisperse aerosol generator

Wind tunnel evaluation of candidate $PM_{10}$ inlets and evaluation of candidate $PM_{2.5}$ fractionators under static conditions requires the generation and use of monodisperse calibration

aerosols of specified aerodynamic sizes. In the current regulations (§53.61(g)), the TSI Incorporated Vibrating Orifice Aerosol Generator (VOAG) is the only approved monodisperse generator for this purpose. However, TSI Incorporated no longer manufacturers nor supports the VOAG. Therefore, the EPA proposes to add a commercially available monodisperse aerosol generator—the Model 1520 Flow-Focusing Monodisperse Aerosol Generator, MSP Corporation, Shoreview, MN–to the list of approved generators for this purpose.

7. Corrections to 40 CFR Part 53 (Reference and Equivalent Methods)

Certain provisions of §53.14, Modification of a reference or equivalent method, incorrectly state an EPA response deadline of 30 days for receipt of modification materials in response to an EPA notice. Per a 2015 amendment, (80 FR 65460, 65416; October. 26, 2015), all EPA response deadlines for modifications of reference or equivalent methods are 90 days from day of receipt.

The EPA proposes corrections to the following tables: Table A-1 to Subpart A of Part 53 - Summary of Applicable Requirements for Reference and Equivalent Methods for Air Monitoring of Criteria Pollutants identifies the applicable 40 CFR part 50 appendices and 40 CFR part 53 subparts for each criteria pollutant. The four rows in the section for $PM_{10-2.5}$ erroneously do not include the footnote instruction that the aforementioned pollutant alternative Class III requirements may be substituted in regard to Part 50 Appendix O - Reference Method for the Determination of Coarse Particulate Matter as $PM_{10-2.5}$ in the Atmosphere.

Table B-1 $SO_2$ states the interference equivalent for each interferent is ±0.005 ppm for both the standard- and lower-range limits, with the exception of nitric oxide (NO) for the lower-range limit per note 4. When testing the lower range of $SO_2$, the limit for NO is ±0.003 ppm, therefore an incorrect lower limit (±0.0003) is currently stated in note 4 for this exception to the

$SO_2$ lower-range limit.

The EPA proposes corrections to the following figures: After the EPA received an inquiry regarding the interaction of NO and $O_3$, the EPA investigated the interferent testing requirements stated by 40 CFR part 53, Subpart B. The EPA has determined that during the 2011 $SO_2$ amendment and subsequent 2015 $O_3$ amendment, several typographical errors were introduced into Table B-3, the most significant of which is the omission of note 3, which instructs the applicant to not mix the pollutant with the interferent. Additionally, Appendix A to Subpart B of Part 53 provides figures depicting optional forms for reporting test results. Figure B-3 lists an incorrect formula: the lower detectible limit section is missing the proper operator in the LDL calculation formula and Figure B-5 lists an incorrect calculation metric: there is a typesetting error in the calculation of the standard deviation. The EPA proposes to correct the typesetting errors.

The EPA proposes correcting typesetting errors in several formulas provided throughout §53.43.

*C. Proposed Changes to 40 CFR Part 58 (Ambient Air Quality Surveillance)*

1. Quality Assurance Requirements for Monitors Used in Evaluations for National Ambient Air Quality Standards

The EPA has evaluated the quality system as part of the PM NAAQS reconsideration and identified several areas that could be improved in light of lower average ambient $PM_{2.5}$ concentrations across the country and the proposed more revised primary annual $PM_{2.5}$ NAAQS described in section II above. Thus, we assessed $PM_{2.5}$ concentration data across a range of values to determine if any changes were warranted to their use in the statistics used to evaluate the data qualify in the $PM_{2.5}$ network. This section describes that work and any proposed changes as a result. Other changes proposed in this section include clarifications and other improvements

that will better assist with the consistency and operations of quality assurance programs.

a. Quality System Requirements

The EPA has reconsidered the Appendix A, 2.3.1.1 goal for acceptable measurement uncertainty for automated and manual $PM_{2.5}$ methods currently stated as an upper 90 percent confidence limit for the coefficient of variation (CV) of 10 percent and ±10 percent for total bias. The average $PM_{2.5}$ concentrations across the nation have steadily declined since the promulgation of the first $PM_{2.5}$ standard (U.S. EPA, 2022, section 2.3). As ambient concentrations decrease, the bias is inflated using the current bias statistic in 4.2.5. The EPA has developed a new bias statistic to minimize the effect of low $PM_{2.5}$ concentrations on bias and is proposing to revise section 4.2.5 to implement this new bias statistic. The EPA has concluded that with this change to the bias statistic, the coefficient of variation (CV) of 10 percent and ±10 percent for total bias is still an acceptable goal for estimating total bias in the networks. The technical justification and background for this change is documented in a technical memorandum to the docket for this rulemaking titled Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network.[152]

The EPA is proposing to update and clarify ambient air monitoring requirements found in Appendix A, section 2.6.1 pertaining to EPA Protocol Gas standards used for ambient air monitoring and the Ambient Air Protocol Gas Verification Program. Appendix A would be revised to clarify that in order to participate in the Ambient Air Protocol Gas Verification Program, producers of Protocol Gases must adhere to the requirements of 40 CFR 75.21(g), and

[152] Noah, G. (2022). Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA-HQ-OAR-2015-0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

only regulatory ambient air monitoring programs may submit cylinders for assay verification to the EPA Ambient Air Protocol Gas Verification Program. The EPA is proposing to include an allowable uncertainty of ±2.0 percent for EPA Protocol Gas standards used in ambient air monitoring. This allowable uncertainty limit would match the existing limit set by the EPA's continuous emission monitoring program found in Part 75, Appendix A, Section 5.1.4(b) and would make the EPA's regulations of quality assurance of ambient air monitors more uniform and consistent.

b. Measurement Quality Check Requirements

The EPA is proposing to remove section 3.1.2.2 from Appendix A. This provision in the quality assurance requirements for ambient air monitoring allows for $NO_2$ compressed gas standards to be used to generate audit standards. However, $NO_2$ compressed gas standards are not currently designated by the EPA's Office of Research and Development (ORD) as an EPA Protocol Gas Standard. As such, this provision conflicts with paragraph 2.6.1 of Appendix A that requires that any standard used for generating test atmospheres be an EPA Protocol Gas Standard. The EPA is aware that there is a need for $NO_2$ compressed gas standards for direct read $NO_2$ monitoring methods. If these $NO_2$ compressed gas standards can, in the future, be proven to be stable and approvable as EPA Protocol Gas Standards, the EPA will consider restoring this provision to Appendix A.

The EPA is proposing to revise the requirement in section 3.1.3.3 pertaining to the validation of the gaseous cylinders used for the National Performance Audit Program (NPAP). The EPA proposes to change the requirement for annual verification to the ORD-recommended certification periods for standards identified in Table 2-3 of the EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (Appendix A, 6.0(4). These ORD-

recommended periods are based on the periods for which similar gas mixtures over specific concentration ranges have been shown to be stable, as documented in the peer-reviewed literature or in concentration stability data submitted by NIST and specialty gas producers and reviewed by the EPA. In effect, this would decrease the cost and burden on the Protocol Gas Verification Program (PGVP), which performs these verifications annually. The EPA anticipates this will also decrease the delay in returning tanks back to the auditors. This would provide auditors with longer periods with valid certifications to perform audits without annual interruptions for the verification process.

The EPA is proposing to adjust the minimum value required by Appendix A, section 3.2.4 to be considered valid sample pairs for the $PM_{2.5}$ Performance Evaluation Program (PEP) from 3 $\mu g/m^3$ to 2 $\mu g/m^3$. As discussed above, ambient $PM_{2.5}$ concentrations have decreased, and many samples being collected now are below the 3 $\mu g/m^3$ threshold and deemed invalid for purposes of a valid audit sample. Therefore, decreasing this threshold from 3 $\mu g/m^3$ to 2 $\mu g/m^3$ would increase the number of valid PEP sample pairs collected, which would reduce the number of re-audits that need to be performed to compensate for invalid sample pairs. Inclusion of values down to 2 $\mu g/m^3$ would represent the concentrations occurring in routine monitoring operations and are included in annual mean concentrations of the networks. Reducing the number of re-audits would reduce audit costs to monitoring organizations while better representing the data in the networks. The technical justification and background for this change is documented in a technical memorandum to the docket for this rulemaking titled Task 16 on PEP/NPAP Task

Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network.[153]

c. Calculations for Data Quality Assessments

The EPA is proposing to update the Appendix A, section 4.2.1, Equation 6 and Equation 7 for calculating the *Collocated Quality Control Sampler Precision Estimate for $PM_{10}$, $PM_{2.5}$ and Pb.* The proposed changes are

Equation 6

$$d_i = \frac{X_i - Y_i}{(X_i + Y_i)/2} \cdot 100$$

to

$$t_i = \frac{X_i - Y_i}{\sqrt{(X_i + Y_i)/2}} \times 100$$

and

Equation 7

$$CV = \sqrt{\frac{n \cdot \sum_{i=1}^{n} d_i^2 - \left(\sum_{i=1}^{n} d_i\right)^2}{2n(n-1)}} \cdot \sqrt{\frac{n-1}{X^2_{0.1,n-1}}}$$

to

$$CV90_{NAQQS} = 100 * \sqrt{\frac{k \times \sum_{i=1}^{k} t_i^2 - \left(\sum_{i=1}^{k} t_i\right)^2}{2k(k-1)}} \times \sqrt{\frac{k-1}{NAAQS\ Concentration * X^2_{0.1,k-1}}}$$

[153] Noah, G. (2022). Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA-HQ-OAR-2015-0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

These new statistics are designed to address the inflated precision values that result from using these calculations to compare low concentrations that are now observed in the networks. The current precision estimate uses a relative percent difference (RPD) when comparing two collocated samplers. As the two numbers used in the comparison get smaller, the statistic generally produces a result that is inflated. A precision statistic calculated for low-concentration data may show poor agreement even if the nominal values are relatively close to each other. By using the square root in the denominator in these statistics, the variability is more constant across all concentrations thereby reducing the inflated effect. The EPA believes this proposed change would provide the correct context for considering inflated RPDs when calculating the bias estimate. The technical justification and background for this change is documented in a technical memorandum to the docket for this rulemaking titled Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network.[154]

The EPA is proposing to update the Appendix A, 4.2.5, Equation 8 calculation for the Performance Evaluation Programs Bias Estimate for $PM_{2.5}$ from

$$100 * \frac{\sum_{i=1}^{n} d_i}{n} \quad \text{where} \quad d_i = \frac{meas - audit}{audit} \times 100$$

to

$$100 * \frac{\sum_{i=1}^{n} s_i}{n\sqrt{NAAQS\ concentration}} \quad \text{where} \quad s_i = \frac{meas - audit}{\sqrt{audit}} \times 100$$

Again, because the average ambient PM concentrations across the nation have steadily

[154] Noah, G. (2022). Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA-HQ-OAR-2015-0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

declined since the promulgation of the $PM_{2.5}$ standard, the current method of calculation may not be appropriate for determining bias for these lower ambient concentrations and newer sampling methodologies. The current bias estimate uses a percent difference (PD), referenced in Appendix A, section 4.1.1, when comparing an audit sampler against a routine sampler. As the two numbers used in the comparison get smaller, the statistic generally produces a result that is inflated. A bias statistic calculated for low-concentration data may show poor agreement even if the nominal values are relatively close to each other. This may be misleading when trying to assess bias and summarizing data to be used in decision making. The EPA believes this proposed change would provide the correct context for considering inflated RPDs when calculating the bias estimate. The technical justification and background for this change is documented in a technical memorandum to the docket for this rulemaking titled Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network.[155]

d. References

The EPA proposes to update the references and hyperlinks in Appendix A, section 6. Several of the reference documents have been updated and the web locations have changed. This proposal provides accuracy in identifying and locating essential supporting documentation so that historical documents that do not represent current practices are not used. The EPA believes that it is important that interested parties—especially ambient air monitoring organizations and stakeholders—have the most current materials that provide clarifications and guidance on the interpretation of the regulations.

[155] Noah, G. (2022). Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA-HQ-OAR-2015-0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

The EPA is also proposing to add a footnote to Table A-1 of Appendix A to Part 58 - Minimum Data Assessment Requirements for NAAQS Related Criteria Pollutant Monitors. The proposed footnote would clarify the allowable time (i.e., every two weeks, once a month, once a quarter, once every 6 months, or distributed over all 4 quarters depending on the check) between checks and encourage monitoring organizations to perform data assessments at regular intervals. The EPA believes this proposal is appropriate because the current stipulation is unclear regarding the specified interval for required verifications. For example, under the current flow rate verification for $PM_{10}$ (low vol.), $PM_{2.5}$, and Pb-$PM_{10}$, a flow check could be performed on April 1 and not checked again until May 31, leaving approximately two months between checks. Following this practice would leave large intervals of time between verifications, and if a check fails using the described practice, an unacceptably large data loss could result. Also, a check could be performed on the last day of a QC check interval and then on the first day of the following interval, with only a day or two between checks. This is not the intended practice for QC measures that are meant to ensure equipment is continually operating properly over an operational period. For this reason, the EPA is proposing to clarify the allowable time between checks.

2. Quality Assurance Requirements for Prevention of Significant Deterioration (PSD) Air Monitoring

This section on Quality Assurance Requirements for Prevention of Significant Deterioration (PSD) Air Monitoring was developed in parallel to the proposed changes associated with Appendix A. Thus, this section includes similar detail and proposed changes for evaluating quality system statistics for $PM_{2.5}$, clarifications, and other improvements that will better assist with the consistency and operations of quality assurance programs for PSD.

a. Quality System Requirements

The EPA has reconsidered the Appendix A, section 2.3.1.1 goal for acceptable measurement uncertainty for automated and manual $PM_{2.5}$ methods currently stated as an upper 90 percent confidence limit for the CV of 10 percent and ±10 percent for total bias. The average PM concentrations across the nation have steadily declined since the promulgation of the first $PM_{2.5}$ standard (U.S. EPA, 2022, section 2.3). As ambient concentrations decrease, the bias is inflated using the current bias statistic in section 4.2.5. Using a new statistic to replace the existing statistic in section 4.2.5 developed to eliminate the effect of low concentrations on bias, the EPA has concluded that the coefficient of variation (CV) of 10 percent and ±10 percent for total bias is still an acceptable goal for estimating total bias in the networks. The technical justification and background for this change is documented in a technical memorandum to the docket for this rulemaking titled Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network.[156]

The EPA is proposing to update and clarify ambient air monitoring requirements found in Appendix A, section 2.6.1 pertaining to EPA Protocol Gas standards used for ambient air monitoring and the Ambient Air Protocol Gas Verification Program. Appendix A would be revised to clarify that in order to participate in the Ambient Air Protocol Gas Verification Program, producers of Protocol Gases must adhere to the requirements of 40 CFR section 75.21(g), and only regulatory ambient air monitoring programs may submit cylinders for assay verification to the EPA Ambient Air Protocol Gas Verification Program. The EPA is proposing

[156] Noah, G. (2022). Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA-HQ-OAR-2015-0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

to include an allowable uncertainty of ±2.0 percent for EPA Protocol Gas standards used in ambient air monitoring. This allowable uncertainty limit would match the existing limit set by the EPA's continuous emission monitoring program found in Part 75, Appendix A, Section 5.1.4(b) and would make the EPA's regulations more uniform and consistent.

b. Measurement Quality Check Requirements

The EPA is proposing to remove section 3.1.2.2 from Appendix A. This provision in the quality assurance requirements for ambient air monitoring allows for $NO_2$ compressed gas standards to be used to generate audit standards. However, $NO_2$ compressed gas standards are not currently designated by the EPA's ORD as an EPA Protocol Gas Standard. As such, this provision conflicts with paragraph 2.6.1 of Appendix A that requires that any standard used for generating test atmospheres be an EPA Protocol Gas Standard. The EPA is aware that there is a need for $NO_2$ compressed gas standards for direct read $NO_2$ monitoring methods. If these $NO_2$ compressed gas standards can, in the future, be proven to be stable and approvable as EPA Protocol Gas Standards, the EPA will consider restoring this provision to Appendix A.

The EPA is proposing to revise the requirement in section 3.1.3.3 pertaining to the validation of the gaseous cylinders used for the NPAP. The EPA proposes to change the requirement for annual verification to the ORD-recommended certification periods for standards identified in Table 2-3 of the EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (Appendix A, 6.0(4)). These ORD-recommended periods are based on the periods for which similar gas mixtures over specific concentration ranges have been shown to be stable, as documented in the peer-reviewed literature or in concentration stability data submitted by NIST and specialty gas producers and reviewed by the EPA. In effect, this would decrease the cost and burden on the PGVP, which performs these verifications annually. The EPA anticipates

this will also decrease the delay in returning tanks back to the auditors. This would provide auditors with longer periods with valid certifications to perform audits without annual interruptions for the verification process.

The EPA is proposing to adjust the minimum value required by Appendix A, section 3.2.4 to be considered valid sample pairs for the $PM_{2.5}$ Performance Evaluation Program (PEP) from 3 $\mu g/m^3$ to 2 $\mu g/m^3$. As discussed above, ambient $PM_{2.5}$ concentrations have decreased, and many samples being collected now are below the 3 $\mu g/m^3$ threshold and deemed invalid for purposes of a valid audit sample. Therefore, decreasing this threshold from 3 $\mu g/m^3$ to 2 $\mu g/m^3$ would increase the number of valid PEP sample pairs collected, which would reduce the number of re-audits that need to be performed to compensate for invalid sample pairs. Inclusion of values down to 2 $\mu g/m^3$ would represent the concentrations occurring in routine monitoring operations and are included in annual mean concentrations of the networks. Reducing the number of re-audits would reduce audit costs to monitoring organizations while better representing the data in the networks. The technical justification and background for this change is documented in a technical memorandum to the docket for this rulemaking titled Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network.[157]

c. Calculations for Data Quality Assessments

The EPA is proposing to update the Appendix A, section 4.2.5, Equation 8 calculation for the Performance Evaluation Programs Bias Estimate for $PM_{2.5}$ from

[157] Noah, G. (2022). Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA-HQ-OAR-2015-0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

$$100 * \frac{\sum_{i=1}^{n} d_i}{n} \quad \text{where} \quad d_i = \frac{meas - audit}{audit} \times 100$$

to

$$100 * \frac{\sum_{i=1}^{n} s_i}{n\sqrt{NAAQS\ concentration}} \quad \text{where} \quad s_i = \frac{meas - audit}{\sqrt{audit}} \times 100$$

Again, because the average ambient PM concentrations across the nation have steadily declined since the promulgation of the $PM_{2.5}$ standard, the current method of calculation may not be appropriate for determining bias for these lower ambient concentrations and newer sampling methodologies. The current bias estimate uses a PD, referenced in Appendix A, section 4.1.1, when comparing an audit sampler against a routine sampler. As the two numbers used in the comparison get smaller, the statistic generally produces a result that is inflated. A bias statistic calculated for low-concentration data may show poor agreement even if the nominal values are relatively close to each other. This may be misleading when trying to assess bias and summarizing data to be used in making decisions. The EPA believes this proposed change would provide the correct context for considering inflated RPDs when calculating the bias estimate. The technical justification and background for this change is documented in a technical memorandum to the docket for this rulemaking titled Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network.[158]

d. References

The EPA proposes to update the references and hyperlinks in Appendix A, section 6.

[158] Noah, G. (2022). Task 16 on PEP/NPAP Task Order: Bias and Precision DQOs for the $PM_{2.5}$ Ambient Air Monitoring Network. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA-HQ-OAR-2015-0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

Several of the reference documents have been updated and the web locations have changed. This proposal provides accuracy in identifying and locating essential supporting documentation so that historical documents that do not represent current practices are not used. The EPA believes that it is important that interested parties—especially ambient air monitoring organizations and stakeholders—have the most current materials that provide clarifications and guidance on the interpretation of the regulations.

The EPA is also proposing to add a footnote to Table A-1 of Appendix A to Part 58 - Minimum Data Assessment Requirements for NAAQS Related Criteria Pollutant Monitors. The proposed footnote would clarify the allowable time (i.e., every two weeks, once a month, once a quarter, once every six months, or distributed over all four quarters depending on the check) between checks and encourage monitoring organizations to perform data assessments at regular intervals. The EPA believes this proposal is appropriate because the current stipulation is unclear regarding the specified interval for required verifications. For example, under the current flow rate verification for $PM_{10}$ (low vol.), $PM_{2.5}$, and Pb-$PM_{10}$, a flow check could be performed on April 1 and not checked again until May 31, leaving approximately two months between checks. Following this practice would leave large intervals of time between verifications, and if a check fails using the described practice, an unacceptably large data loss could result. Also, a check could be performed on the last day of a QC check interval and then on the first day of the following interval, with only a day or two between checks. This is not the intended practice for quality control measures that are meant to ensure equipment is continually operating properly over an operational period. For this reason, the EPA is proposing to clarify the allowable time between checks.

3. Proposed Amendments to PM Ambient Air Quality Methodology

a. Proposal to revoke Approved Regional Methods (ARMs)

The EPA is proposing to remove provisions for approval and use of Approved Regional Methods (ARMs) throughout parts 50 and 58 of the CFR. ARMs are continuous $PM_{2.5}$ methods that have been approved specifically within a State or local air agency monitoring network for purposes of comparison to the NAAQS and to meet other monitoring objectives. However, at this time, there are no approved ARMs, nor does the EPA anticipate any will be requested. There are, however, more than a dozen approved FEMs for $PM_{2.5}$. These approved FEMs are eligible for comparison to the NAAQS and to meet other monitoring objectives.

The EPA first proposed a process to approve and use ARMs in January of 2006 (71 FR 2709, January 17, 2006). At that time, there were no approved continuous $PM_{2.5}$ methods available to compare to the NAAQS. The hope was that approved ARMs would quickly start the use of $PM_{2.5}$ continuous methods that worked well in monitoring agency networks, since the benefits of regulatory-grade automated methods were not available at that time to air agency programs. It was hoped that the benefits of automated $PM_{2.5}$ methods – including real-time data reporting of $PM_{2.5}$ to support forecasting and reporting of the AQI while also providing a regulatory dataset eligible for comparison to the $PM_{2.5}$ NAAQS – would encourage the development of ARMs. The idea to encourage ARMs was conceived following review of data across the country demonstrating that some agencies were achieving acceptable data comparability with their $PM_{2.5}$ methods compared to collocated FRMs; however, those methods did not necessarily provide consistent data across the country. At that time, there were no approved $PM_{2.5}$ continuous FEMs and it was unclear how soon any might be approved. However, by March 2008, the EPA's Reference and Equivalent Methods program had approved the first $PM_{2.5}$ continuous FEM (73 FR 13224, March 12, 2008). Over the next eight years, an

additional 12 $PM_{2.5}$ continuous FEMs were approved. With many commercially available $PM_{2.5}$ continuous FEMs available to air agencies, almost all agencies soon began implementing one or more $PM_{2.5}$ FEMs in their network. By 2020, monitoring agencies were reporting $PM_{2.5}$ continuous FEM data from 660 sites across the country (U.S. EPA, 2022, section 2.2.3.1). Therefore, with a large and growing network of $PM_{2.5}$ continuous FEMs and no approved applications for ARMs in the 16 years that this provision has been available, the EPA is proposing to remove this provision, including any related language, and to instead rely on the existing network of approved $PM_{2.5}$ FEMs and future approved FEMs. The EPA notes that although references to ARMs occur across part 50 and part 58, the EPA is not reopening the substance of the provisions where these references occur and is only proposing regulatory text for these provisions for the purpose of removing the reference to ARMs.

b. Proposal for Calibration of PM Federal Equivalent Methods (FEMs)

The EPA is proposing to modify its specifications for PM FEMs described in Appendix C to Part 58. Specifically, the EPA is proposing that valid State, local, and Tribal air monitoring data generated in routine networks and submitted to the EPA may be used to improve the PM concentration measurement performance of approved FEMs. This approach, initiated by instrument manufacturers, would be implemented as a national solution in factory calibrations of approved FEMs through a firmware update. This would apply to any PM FEM methods (i.e., $PM_{10}$, $PM_{2.5}$, and $PM_{10\text{-}2.5}$). The EPA is proposing this modification because there are some approved PM FEMs that are not currently meeting measurement quality objectives (MQOs) when evaluating data nationally (U.S. EPA, 2022, section 2.2.3.1) meaning that an update to a factory calibration may be appropriate; however, there is not a clearly defined process to update the calibration of an FEM. While there are several types of data available to use as the reference

for such updates (e.g., routinely operated FRMs, audit program FRMs, and chemical speciation sampler data), we are proposing to use routinely operated State, local, and Tribal FRMs as the basis of comparison upon which to calibrate FEMs. The goal of updating factory calibrations would be to increase the number of routinely operating FEMs meeting MQOs across the networks in which they are operated. The EPA has received input from CASAC (Sheppard, 2022, p. 2 of consensus responses) and State, local, and Tribal agencies (NACAA Monitoring Committee 01/20/22; AAPCA Ambient Monitoring Committee 01/26/2022; Tribal air quality professionals call on 02/17/22), all of which expressed strong interest in improving FEM data comparability to collocated FRMs. While there are other approaches that could improve data comparability between PM FEMs and collocated FRMs, The EPA believes that this approach represents the most reliable approach to update FEM factory calibrations, since the existing FRM network data that meets MQOs would be used to set updated factory calibrations. While the Agency is proposing to add this language to more expressly define a process to update factory calibrations of approved PM FEMs, the EPA believes that the existing rules for updating approved FRMs and FEMs found at 40 CFR 53.14 may also continue to be utilized for this purpose as appropriate. This section allows instrument manufactures to submit to the EPA a "Modification of a reference or equivalent method." Submitting a modification request may be appropriate to ensure an approved FEM continues to meet the 40 CFR 53.9, "Conditions of designation". Specifically, 40 CFR 53.9(c) requires that, "Any analyzer, $PM_{10}$ sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as part of an FRM or FEM shall function within the limits of the performance specifications referred to in 53.20(a), 53.30(a), 53.35, 53.50, or 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in § 53.4(b)(3)." Thus, instrument manufactures are

encouraged to seek improvements to their approved FEM methods as needed to continue to meet data quality needs as operated across the network. Instrument manufactures have an option to pursue that now and may have an additional option in the future should we finalize this proposal for calibration of PM FEMs.

In the PA (U.S. EPA, 2022b, section 2.2.3.1), the EPA analyzed the quality of data from FRM samplers and continuous $PM_{2.5}$ FEM monitors operating in routine networks to determine whether they meet the MQOs for $PM_{2.5}$ FRMs and FEMs (40 CFR Part 58, Appendix A, section 2.3.1.1): "Measurement Uncertainty for Automated and Manual $PM_{2.5}$ Methods. The goal for acceptable measurement uncertainty is defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 10 percent and ±10 percent for total bias." When aggregating data across the country, all $PM_{2.5}$ FRMs meet the MQOs for these methods. But of $PM_{2.5}$ continuous FEMs aggregated across the country, some meet the MQOs, and others do not.

One of the major challenges to ensuring uniform data from PM methods is that there are no accepted standards against which to calibrate PM methods. This was discussed in the 2004 Air Quality Criteria for Particulate Matter (U.S. EPA, 2004b). PM reference methods typically include the design and performance requirements set forth in the 40 CFR Part 50. This is a contrast to FRMs and FEMs for gaseous NAAQS pollutants for which there are accepted calibration standards; in the case of ozone, there is even a standard reference photometer that can be used to calibrate approved methods in the field or laboratory. For PM monitoring methods, in the absence of accepted calibration standards, acceptable data quality is determined by comparing to other PM FRMs. One challenge to comparing to other PM FRMs during the initial field testing for purposes of FEM approval is that the dataset will in almost all cases be substantially more limited than what's available in routine networks once deployed. Thus, we

seek to encourage instrument manufacturers of approved FEMs to evaluate data in routine networks and consider improvements to their FEM calibration, as needed.

The EPA is proposing to use routine and collocated FRM data operated by State, local and Tribal agencies as the basis to update factory calibrations. Routine State, local and tribal agency FRM data form the largest portion of the monitored air quality data used in epidemiologic studies that are being used to inform proposed decisions regarding the adequacy of the public health protection afforded by the primary $PM_{2.5}$ NAAQS, as discussed in section II above. While the EPA is proposing to use routine FRM data, there are other reference datasets that could be considered. For example, the agency has an FRM audit program[159] operated by independent operators and laboratories. This program is highly valuable to the success of the $PM_{2.5}$ monitoring program by providing independent data to assess the quality of routinely operated FRMs and FEMs. If we used the audit program data as the basis for calibrating continuous monitors, we would lose the ability to collect independent data from audit monitors to assess the operation of routine monitors. Therefore, by using routinely operated FRMs to calibrate continuous FEMs, the Agency will continue to maintain the independence of the FRM audit program to assess the quality of routinely operated FRM and continuous FEM data. The EPA also has chemical speciation data available at sites where the Chemical Speciation Network (CSN) or IMPROVE samplers are operated; however, these samplers use technologies that operate at different flow rates and with different-size selective devices than approved FRMs, and neither of these programs use FRMs as the basis to collect samples. Therefore, while CSN and IMPROVE data can be useful to help determine the aerosol chemistry of $PM_{2.5}$ and may provide additional validation of collocated FRM or FEM data, by themselves these data are not

[159] See: *https://www.epa.gov/amtic/national-pm25-performance-evaluation-program*

appropriate to update factory calibration of continuous FEMs.

The EPA proposes to direct instrument companies and other interested stakeholders to the EPA's Air Quality System (AQS) database[160] to access the valid routine network data that the Agency proposes to allow for use in updating factory calibration of continuous FEMs. There are several ways to obtain data from the AQS database, and many do not require registration. For example, daily processed datasets by year are publicly available at the web site of "Pre-Generated Data Fields."[161] The data utilized would need to be valid PM FRM and FEM data that are collocated and aligned to the same date. For example, for $PM_{2.5}$ mass concentrations, there are files by year for "$PM_{2.5}$ FRM/FEM Mass" identified with a parameter code of 88101. This information, already aggregated to daily data, represent the time-period of midnight-to-midnight local standard time. While any years of data may be considered, instrument companies should normally use at least two years of recent data where we are past the certification period for the previous-year data, which is May 1st of each year. Including at least two years of data is intended to address cases where one of the years may have high or low air quality concentrations. Data in the current year and previous year when we are not past the May 1st certification date can be considered to test data with a correction established from a previous year or more than one year. If multiple factors are included, any new statistical correction or corrections should be based on one or more calendar years, with independent testing of that data on another year or more that was not used to develop the equation(s).

The EPA also encourages instrument companies to consider and implement all the ways to optimize $PM_{2.5}$ FEMs. This may include, but is not limited to, whether a method's data can be

[160] See: *https://www.epa.gov/aqs*
[161] See: *https://aqs.epa.gov/aqsweb/airdata/download_files.html*

improved by operating the FEM inside an HVAC-controlled shelter or outside with minimal or no HVAC control; optimizing heating of the airstream to avoid condensation while retaining semi-volatile PM captured on the FRM; and any specialized guidance or training that may help monitoring agencies optimize their data quality and comparability to collocated FRMs. Other options might include updates to unique coefficients used in the factory calibration such as the density of the aerosol, where applicable. Such changes would normally need to be approved by the EPA according to existing rules found at 40 CFR 53.14.

Another challenge to consider is how to deal with potential outliers that may exist in the validated State, local, and Tribal agency network data available from AQS that would be used to establish new factory calibrations. One of the reasons to use data from the AQS database is that there are tens of thousands of collocated data pairs available that include many of the approved continuous $PM_{2.5}$ FEMs. Having a large data set will diminish the effect of any one or more outliers. However, acknowledging that the goal of this proposed change is to update factory calibrations to increase the number of routinely operating FEMs meeting MQOs across the networks in which they are operated, we propose that instrument companies may, but are not required to, check for and exclude any potential outliers. Additionally, we propose that the range of data may be limited to those concentrations that are within the normal operating ranges of most sites, but this is not required. This approach, for example, could include 24-hour average $PM_{2.5}$ concentrations up to the level of the primary 24-hour $PM_{2.5}$ NAAQS or some percentile above that level (e.g., 125% of the 24-hour NAAQS). The rationale for this is that there are very few sites with routine concentrations above the level of the primary 24-hour $PM_{2.5}$ NAAQS, and the establishment of any equation with this data would need to be constructed carefully to avoid having data below the primary annual $PM_{2.5}$ NAAQS drive the coefficients used above the level

of the primary 24-hour $PM_{2.5}$ NAAQS.

Ideally, the geographic coverage of the data used in establishing a new factory calibration would be national in scope; however, instrument companies can only use the data that is available. For widely used $PM_{2.5}$ FEMs, this will not be an issue, but for less-operated $PM_{2.5}$ FEMs, there may be limitations in the geographic scope of data produced. Another challenge may be a large grouping of sites in one part of the country that drives development of an equation used across all networks. Instrument companies may limit the use of sites with large groupings in one or more geographical area so that the data are more geographically representative across the network so long as there is a reasonable rationale as to why data from certain sites are not being included. With a new factory calibration available, instrument companies will need to test the performance of the updated calibration across a variety of sites. Testing of an updated factory calibration can be accomplished by utilizing a different year or years other than the time-period used to establish the revised factory calibration or a subset of data across all years. Testing should also include the range of sites in which the method is used.

Building off the geographic location of the sites in which an updated factory calibration is tested with previously collected data, the EPA considered what performance level should be acceptable. Ideally, an updated factory calibration would work such that a significantly larger number of, or all, individual sites operating with the updated factory calibration would meet the MQOs. However, due to several complicating factors such as seasonal changes in temperature and humidity, elevation, differences in aerosol composition, and differences in concentration between more polluted urban sites and relatively cleaner rural sites (some of which read well below the proposed revisions to the level of the primary annual $PM_{2.5}$ NAAQS discussed in section II above), the EPA should not expect that every site will necessarily meet the MQOs.

Therefore, the goal of this proposal is to increase the number of routinely operating FEMs meeting MQOs across the networks in which they are operated, especially for sites near the level of the NAAQS proposed elsewhere in this proposal. Since there are multiple MQOs to consider, the EPA proposes to place the most attention on improvements to the bias MQO goal because this statistic will likely have the most influence on improving the resultant data collected. In attempting to address this goal, instrument companies may be interested in testing their original data used in field studies of their candidate FEMs with an updated factory calibration. While this could be a useful exercise to understand the sensitivity of the original and any updated factory calibration, the EPA proposes not to require meeting the performance criteria of the original field testing as a condition of approving an updated factory calibration.

Regarding how frequently factory calibrations should be updated, the EPA believes it would be most appropriate to not define a specific time-period for updates. Rather, updates should be based on the available of quality data being produced across the network. Monitoring agencies routinely check their data comparability to collocated FRMs, including as part of annual data certification where an AMP-256 report describing data quality is included as part of the certification package (§ 58.15(c)). In addition, monitoring agencies typically provide a more thorough review of their networks and accompanying data quality as part of the five-year assessments due to the EPA pursuant to 40 CFR 58.10(d).

Another important aspect to implementing updated factory calibrations is the treatment of data already collected under the original factory calibration. There are two time periods to consider. First, there is the time-period before the EPA approves an updated to a factory calibration. We propose that data collected prior to an approved update to a factory calibration be allowed to remain as measured based on the factory calibration that was approved at the time the

data was collected. Second, there is the time-period between when an updated factory calibration is approved by the EPA and when that updated calibration is implemented in the field. While ideally, this time-period would be short, there may be reasons why some agencies and the sites they run cannot easily update the firmware with the updated factory calibration. We solicit comment on how to handle these situations and whether there should be an allowance to correct such data.

The EPA sought early input from State, local, and Tribal monitoring agencies (NACAA Monitoring Committee 01/20/22; AAPCA Ambient Monitoring Committee 01/26/2022; Tribal air quality professionals call on 02/17/22) regarding how best to address the issue of some $PM_{2.5}$ FEMs having bias issues. Many monitoring agencies identified that they strongly favor a national solution that can be accomplished and implemented through a firmware upgrade or similar resolution that is consistent with the approach described above. One State suggested that the EPA should consider and allow site-by-site corrections between FRM and collocated FEMs with ongoing collocation at a 1:6 sample frequency for FRMs. The rationale for site-by-site corrections was that there are differences in the types of aerosol composition and concentration between urban and rural locations and having site-by-site corrections would ensure that each type of location is individually calibrated to a collocated FRM rather than to a consistent factory calibration that may average out any differences. In contrast, other monitoring agencies expressed concern about the challenges of implementing a site-by-site approach, especially for those agencies who stated that they would not be able to redeploy the FRMs that would be necessary to perform the site-by-site corrections in their networks for reasons including no longer having FRMs, not having staff available to support and operate the FRMs, and no longer have gravimetric laboratory capacity to support a larger inventory of FRMs operating in their

networks.

The CASAC also provided input on the FEM bias issue. As part of their review of the draft PA, the CASAC stated that "the FEM bias needs to be addressed to make the FRMs and FEMs more comparable" (Sheppard, 2022a, p. 2 of consensus responses). The CASAC offered two options for the EPA to consider. "One option would be to allow states to develop correction factors for co-located FRMs and FEMs. These correction factors could be used to adjust FEM concentrations downward (or upward) to be comparable to FRMs. Another option would be for the EPA to revise the 'equivalency box' (EB) criteria used to judge whether the bias of a new continuous $PM_{2.5}$ monitor relative to an FRM is acceptable during field testing" (Sheppard, 2022a, p. 2 of consensus responses). The CASAC's first option is consistent with the input received during early input described above. The EPA believes that the second option should be considered in future reviews of the PM NAAQS to help establish updated goals for data quality from $PM_{2.5}$ FEMs. The existing network of commercially available $PM_{2.5}$ FRMs and some of the continuous FEMs are already meeting the MQOs at the existing concentrations, which are at or below the proposed revisions to the level of the primary annual $PM_{2.5}$ NAAQS discussed in section II above. However, the EPA recognizes that not all $PM_{2.5}$ FEMs are meeting MQOs and, therefore, the EPA intends to address improvements to existing FEMs that are not meeting MQOs as described above.

In attempting to address the comparability of $PM_{2.5}$ FEMs to collocated FRMs through our proposal to allow updates to factory calibrations, the EPA recognizes that other potential solutions do not need to be mutually exclusive. That is, there can be multiple approaches to improve the comparability of $PM_{2.5}$ FRMs to continuous FEMs. Therefore, the EPA solicits comment on additional ways to improve $PM_{2.5}$ data comparability between $PM_{2.5}$ FRMs and

collocated continuous FEMs.

The EPA encourages early dialogue with instrument companies considering an update to any part (e.g., hardware, software, and/or firmware revision) of an approved FEM designation. Dialogue with the EPA as well as applications by instrument manufactures can be initiated by contacting the EPA ORD's Reference and Equivalent (R&E) Methods Designation program. The contact information for this can be found at 40 CFR 53.4, "Applications for reference or equivalent method determinations."

In summary, the EPA is proposing that valid State, local, and Tribal air monitoring data generated in routine networks and submitted to the EPA may be used to update factory calibrations included as part of approved FEMs. This approach, initiated by instrument manufacturers, subject to EPA approval, would be implemented as a national solution in factory calibrations of approved FEMs through a firmware update. This would apply to any PM FEM methods (i.e., $PM_{10}$, $PM_{2.5}$, and $PM_{10-2.5}$). As part of this process, the EPA proposes that a range of data based on the most representative concentrations up to all available concentrations may be used in developing and testing a new factory calibration, that a representative set of geographic locations can be used, that outliers may be included or not included, that a new factory calibration should be developed using data from at least two years and tested on a separate year(s) of data, that updates to factory calibrations can occur as often as needed, and should be evaluated by monitoring agencies as part of routine data assessments such as during certification of data and five year assessments, that the EPA recognizes only data from existing operating sites is available, and that an updated factory calibration does not have to work with the original field study data submitted that led to the designation as an FEM. The EPA solicits input on this approach and any alternatives that would lead to more sites meeting the bias MQO with

automated FEMs, especially for those sites that are near the level of the primary annual $PM_{2.5}$ NAAQS, as proposed to be revised in section II above.

4. Proposed Amendment to the $PM_{2.5}$ Monitoring Network Design Criteria to address At-Risk Communities

To enhance protection of air quality in communities subject to disproportionate air pollution risk, particularly in light of the proposed range for a revised $PM_{2.5}$ annual standard, the EPA proposes to modify our $PM_{2.5}$ monitoring network design criteria to include an environmental justice factor that accounts for proximity of populations at increased risk of adverse health effects from $PM_{2.5}$ exposures to sources of concern. Specifically, the EPA proposes to modify our existing requirement (40 CFR Part 58, Appendix D, section 4.7.1(b)(3)): "For areas with additional required SLAMS, a monitoring station is to be sited in an area of poor air quality," to additionally address at-risk communities with a focus on anticipated exposures from local sources of emissions. The scientific evidence evaluated in the 2019 ISA and ISA Supplement indicates that sub-populations at potentially greater risk from $PM_{2.5}$ exposures include: children, lower socioeconomic status (SES)[162] populations, minority populations (particularly Black populations), and people with certain preexisting diseases (particularly cardiovascular disease and asthma). The EPA is proposing that communities with relatively higher proportions of sub-populations at greater risk from $PM_{2.5}$ exposure within the jurisdiction of a state or local monitoring agency should be considered "at-risk communities" for these purposes.

The $PM_{2.5}$ network design criteria has led to a robust national network of $PM_{2.5}$

[162] SES is a composite measure that includes metrics such as income, occupation, and education, and can play a role in populations' access to healthy environments and healthcare.

monitoring stations. These monitoring stations are largely in Core-Based Statistical Areas (CBSAs)[163] across the country that include many $PM_{2.5}$ monitor sites in at-risk communities. Many of the epidemiologic studies evaluated in the 2019 ISA and ISA Supplement, including those that provide evidence of disparities in $PM_{2.5}$ exposure and health risk in minority populations and low SES populations, often use data from these existing $PM_{2.5}$ monitoring sites. However, we anticipate that if the level of the annual NAAQS is lowered, characterizing localized air quality issues may become even more important around local emission sources. The EPA believes that adding a network design requirement to specifically locate monitors in at-risk communities will improve our characterization of exposures for at-risk communities where localized air quality issues may exist. Requiring the siting of $PM_{2.5}$ monitoring stations in at-risk communities allows other methods to be operated alongside $PM_{2.5}$ measurements to support multiple monitoring objectives (40 CFR part 58, Appendix D, section 1.1). The EPA believes that it is appropriate to formalize the monitoring network's characterization of $PM_{2.5}$ concentrations in communities at increased risk, to provide these areas with the level of protection intended with the $PM_{2.5}$ NAAQS. The addition of this requirement will also lead to enhanced local data that will allow regulatory air quality agencies to assist communities to reduce exposures and to help inform future implementation and reviews of the NAAQS.

As described in section II.B.2 above and in more detail in the PA (U.S. EPA, 2022b, section 3.3.2), the public health implications of health effects associated with $PM_{2.5}$ in ambient

[163] CBSAs - Metropolitan and Micropolitan Statistical Areas are collectively referred to as Core-Based Statistical Areas. Metropolitan statistical areas have at least one urbanized area of 50,000 or more population, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties. Micropolitan statistical areas are a set of statistical areas that have at least one urban cluster of at least 10,000 but less than 50,000 population, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties.

air are dependent on the type and severity of effects, as well as the size of the population affected and whether there are populations and/or lifestages at increased risk of a $PM_{2.5}$-related health effect. The 2019 ISA cites extensive evidence indicating that "both the general population as well as specific populations and lifestages are at risk for $PM_{2.5}$-related health effects" (U.S. EPA, 2019, p. 12-1). Factors that may contribute to increased risk of $PM_{2.5}$-related health effects include lifestage, pre-existing diseases (cardiovascular disease and respiratory disease), race/ethnicity, and socioeconomic status. The increased risk faced by these sub-populations raises environmental justice[164] concerns. Section II of this preamble, section 12.5 of the 2019 ISA (U.S. EPA, 2019a) and section 3.3.3 of the ISA Supplement (U.S. EPA, 2022a) provide extensive discussion on the evidence for disparities in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risks of these sub-populations.

Consistent with the requirement of the Clean Air Act to protect sensitive sub-populations, the EPA is particularly concerned with protecting sub-populations identified as being at higher risk of adverse health effects from $PM_{2.5}$ exposure in the 2019 ISA, ISA Supplement and PA (U.S. EPA, 2019a; U.S. EPA, 2022a; U.S. EPA, 2022b). The EPA finds it appropriate to better characterize the localized air quality in communities with relatively higher proportions of these sub-populations to ensure these sub-populations receive the intended level of protection of a revised NAAQS proposed earlier in section II. Thus, the EPA is proposing to modify the $PM_{2.5}$ ambient monitoring network design criteria to add a provision pertaining to sub-populations

[164] The EPA defines environmental justice as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. The EPA further defines the term fair treatment to mean that "no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies."

identified as at increased risk for $PM_{2.5}$ exposures and health risks associated with $PM_{2.5}$ ("at-risk communities").

An enhanced network should include representation of at-risk communities who live near emission sources of concern such as, but not limited to, major ports, rail yards, airports, industrial areas, or major transportation corridors. The EPA finds it appropriate, in light of the evidence of increased risk to these communities, to better characterize exposures given proximity to local sources of concern. For example, the EPA believes it is worthwhile to characterize localized ambient concentrations occurring when there are emission sources located in a part of a metropolitan area that are different than the design value[165] site of the same metropolitan area. Thus, while there may be sites with higher overall maximum concentrations in another part of the same metropolitan area, those sites are covered by our long-standing existing requirement that monitors be placed "…in the area of expected maximum concentration" [§58, Appendix D, Section 4.7.1(b)(1)].

$PM_{2.5}$ concentrations have generally trended down when averaged across all monitoring sites over the last two decades since $PM_{2.5}$ measurements commenced nationally in 1999.[166] This downward trend has resulted in lower background concentrations being measured upwind of urban areas; however, the impact of local emissions on $PM_{2.5}$ may not be known if there is not a requirement to monitor ambient air in these areas. For example, the presence of new local sources of fine particle air pollution proximate to at-risk communities, such as significant increases in heavy duty truck traffic since monitors were originally sited, should be taken into

[165] Design value is defined in § 58.1 - Definitions. Design value means the calculated concentration according to the applicable appendix of part 50 of this chapter for the highest site in an attainment or nonattainment area.
[166] See: *https://www.epa.gov/air-trends/particulate-matter-pm25-trends*

consideration. As explained in the PA (U.S. EPA, 2022b), measured $PM_{2.5}$ at near-road monitoring stations include an increment relative to other sites in the same CBSA. The near-road sites will complement any new or moved sites located to specifically address at-risk communities near sources of concern. We anticipate the significance of local emissions may increase if, as proposed, the level of the annual $PM_{2.5}$ NAAQS is lowered. Thus, the EPA seeks to support communities with at-risk populations in proximity to local sources of concern so that they have access to $PM_{2.5}$ NAAQS-comparable data to ensure compliance with the $PM_{2.5}$ NAAQS and for other data uses.

To successfully select and deploy an ambient air monitoring station, monitoring agencies must comply with the requirements of the EPA network design criteria (40 CFR part 58, Appendix D, section 4.7), consider input from the community and other interested stakeholders, and then overlay the requirements and input with logistically available options in the neighborhoods they intend to monitor. Often, monitoring agencies partner with schools and other government agencies that have access to property in a neighborhood so that the desired monitoring stations can be sited, deployed, and maintained. Locating monitoring stations in neighborhoods should be done in a way that provides a good representation of the particulate matter exposures of the communities in which they are located. Alternatively, monitoring stations can be located directly next to emission sources of concern. However, these locations, known as "source-oriented" sites, may not necessarily represent the exposures in community or the effect of a multitude of emissions that can impact a neighborhood.

To ensure monitoring sites are appropriately representing exposure in at-risk communities, we propose that sites represent "area-wide" air quality near local sources of concern. Sites representing "area-wide" air quality are those monitors sited at neighborhood,

urban, and regional scales, as well as those monitors sited at either micro- or middle-scale that are identified as being representative of many such locations in the same MSA[167]. Most existing as well as new or moved sites are expected to be neighborhood-scale, which means that the monitoring stations would typically represent conditions throughout some reasonably homogeneous urban sub-region with dimensions of a few kilometers [Part 58, Appendix D, section 4.7.1(c)(3)]. Additionally, as described in §58.30, sites representing "area-wide" air quality have a long-standing applicability to both the annual and 24-hour $PM_{2.5}$ NAAQS. Siting in a community representing "area-wide" air quality as proposed is consistent with other network design objectives pursuant to which we locate monitors where people live, work, and play.

The types of sites that are minimally required as part of the $PM_{2.5}$ network design are associated with two geopolitical levels: MSAs and states. The minimum number and type of sites that are required within an MSA are a function of the population of the MSA, based on the latest available information from the Census Bureau, and the design value of the existing network of $PM_{2.5}$ sites reported for that MSA. MSAs with design values at or above 85% of any $PM_{2.5}$ NAAQS are required to operate one more site than those MSAs with values that are less than 85% of any $PM_{2.5}$ NAAQS (40 CFR part 58, Appendix D, Table D-5). Each MSA required to operate at least one monitoring station is to site the monitor at neighborhood or larger scale in an area of expected maximum concentration. MSAs with a population of 1 million or more are required to operate a $PM_{2.5}$ monitor at a $NO_2$ near-road station in the same MSA. Thus, according to Table D-5 of Appendix D to Part 58, only those MSAs with a population of greater than 1 million with the most recent 3-year design value greater than or equal to 85% of any $PM_{2.5}$

[167] Metropolitan Statistical Area (MSA) means a CBSA associated with at least one urbanized area of 50,000 population or greater. The central-county, plus adjacent counties with a high degree of integration, comprise the area.

NAAQS are required to operate at least three $PM_{2.5}$ monitoring stations. Since one of these sites would be the site in the area of expected maximum concentration, which most often will be the design value site, and the other the near-road site, only the third location would not address either of those two requirements.

The requirement for a third monitoring station in a MSA, where it exists, would take on the revised network design requirement to address at-risk communities near sources of concern. Many existing sites in the area of expected maximum concentration or near-road sites that are located in at-risk communities. Thus, having multiple sites located in at-risk communities may be appropriate so long as each siting criteria is achieved. Also, while we are proposing this modification to our network design criteria, we recognize that the number of monitors to support key monitoring objectives, including addressing at-risk communities, could go well beyond what is currently minimally required. Many monitoring agencies already operate more monitoring sites than are minimally required and we expect this to continue in considering siting monitors in at-risk communities. Thus, the existing and robust network of almost 1,000 $PM_{2.5}$ sites nationally will continue to protect all populations at the level of the NAAQS discussed in section II of this proposal, by always having at least one site in the area of expected maximum concentration for each CBSA where monitoring is required. Many existing and a few new sites will form an important sub-component of the $PM_{2.5}$ network by characterizing air quality in at-risk communities, particularly with respect to sources of concern.

Monitoring requirements applicable at the state level include measuring regional background and regional transport (40 CFR part 58, Appendix D, section 4.7.3). These required sites at the state level are largely located in rural areas and may include use of IMPROVE samplers or continuous $PM_{2.5}$ monitors. The sites required at the state level complement sites

required at the MSA level. Together the sites already required at the state level combined with existing siting requirements at the MSA level as well as the proposed revisions described herein to address at-risk communities will achieve several monitoring objectives, including comparison to the NAAQS and AQI. The availability of data from regional background and regional transport sites compared to data from design value sites already allow for calculating incremental exposure in communities with the highest design value location. With the proposed addition of a siting requirement for at-risk communities and the use of data from these sites compared to select regional background and regional transport sites as well as other sites in the same MSA, we can assess the incremental burden of exposure from local emissions to at-risk communities.

In addition to using data from the robust network of almost 1,000 $PM_{2.5}$ sites for NAAQS and AQI purposes, having a stable network of long-term sites is especially valuable for trends and as an input to long term health and epidemiology studies that support reviews of the PM NAAQS. Therefore, while we are proposing to add a $PM_{2.5}$ network design criteria to address at-risk communities, many sites are likely already in valuable locations meeting one of the existing network design criteria (i.e., being in an area-wide area of expected maximum concentration or collocated with near-road sites) and supporting multiple monitoring objectives. Also, in many communities there may already be sites meeting the network design criteria we are proposing for at-risk communities. Thus, acknowledging the value of having long-term data from a consistent set of network sites, on balance the EPA believes that the movement of sites should be minimized, especially in MSA's with a small number of sites. However, a small number of new

sites[168] are expected to be required due to the existing minimum monitoring requirements (Table D-5 of Appendix D to Part 58) and the revised primary annual $PM_{2.5}$ NAAQS proposed in section II of this proposal. Also, sites do on occasion need to move due to loss of leases, no longer meeting siting criteria, or other reasons. For any of these cases, we believe it is appropriate to include prioritizing establishing sites in at-risk communities near sources of concern, should new sites be established, or existing locations be lost, and replacement sites need to be identified. Therefore, the EPA proposes that annual monitoring network plans [40 CFR 58.10(a)(1)] that include the few newly required sites and five-year assessments [40 CFR 58.10(d)] include a provision to examine the ability of existing and proposed sites to support air quality characterization for areas with at-risk populations in the community and the objective discussed herein.

Assessing and prioritizing at-risk communities for monitoring can be accomplished through several approaches. The most critical aspect of prioritizing which communities to monitor is their representation of the at-risk populations described earlier in this section. The other major consideration is whether the community is near source(s) of concern. While many CBSA's have one or more sources of concern described above, some CBSA's will not have the level of emissions from sources of concern that result in an elevated level of measured $PM_{2.5}$ concentrations in surrounding communities. Since one of our other siting criteria to "..be in the area of expected concentration" [§58, Appendix D, Section 4.7.1(b)(1)] ensures there is a monitoring site in the community with the highest exposure in each CBSA with a monitoring

[168] Gantt, B. (2022). Analyses of Minimally Required $PM_{2.5}$ Sites Under Alternative NAAQS. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA-HQ-OAR-2015-0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

requirement, on balance the EPA believes we should include being in an at-risk community for CBSAs with a third site requirement when there are no sources of concern identified in a CBSA or such sources do exist but are not expected to lead to elevated levels of measured $PM_{2.5}$ concentrations.

To identify at-risk communities to consider for the proposed monitoring requirement, tools such as the EPA's EJSCREEN[169] are available. The EPA solicits comment on other tools and/or datasets that can could be utilized to identify the at-risk communities described above. With information on at-risk communities, monitoring agencies need data that can best inform where there may be elevated levels of exposures from sources of concern. While we use FRMs and FEMs to determine compliance with the NAAQS, there are several additional datasets available that may be useful in evaluating the potential for elevated levels of exposure to communities near sources of concern. Potential datasets include non-regulatory data (CSN, IMPROVE, and AQI non-regulatory $PM_{2.5}$ continuous monitors), modelling data – which utilizes emission inventory and meteorological data, emerging sensor networks such as used in the EPA's AirNow fire and smoke map[170], and satellites – which measure radiance and with computational algorithms are then used to estimate $PM_{2.5}$ from aerosol optical depth (AOD). The 2019 ISA and PA (U.S. EPA, 2019a; U.S. EPA, 2022b) include details on each these, except for the AirNow fire and smoke map, which first became operational in 2020. Each of these datasets have advantages and disadvantages, especially when attempting to determine exposure concentrations for the averaging times of the $PM_{2.5}$ NAAQS described in section II (i.e., annual NAAQS and 24-hour NAAQS). The EPA solicits comment on datasets most useful to identify

[169] See: *https://www.epa.gov/ejscreen*
[170] See: *https://fire.airnow.gov/*

communities with high exposures for $PM_{2.5}$ NAAQS (i.e., annual or 24-hour), including any discussion on limitations or advantages of the dataset of interest. The EPA is soliciting comment on the use of these datasets for the purpose of identifying communities where the proposed monitoring requirement would apply and not for the purpose of satisfying the proposed monitoring requirement.

The monitoring methods appropriate for use at these proposed sites are FRMs and automated continuous FEMs. These are the methods that are eligible to compare to the $PM_{2.5}$ NAAQS, which will be the primary objective for collecting this data. There are several other monitoring objectives that would benefit from use of automated continuous FEMs. For example, having hourly data available from automated continuous FEMs would allow sites to provide data in near-real time to support forecasting and near real-time reporting of the AQI. Automated continuous methods are also useful to support evaluation of other methods such as low-cost sensors. When used in combination with on-site wind speed and wind direction measurements, automated FEMs can provide useful pollution roses indicating the origin of emissions that affect a community. Additionally, when collocated with continuous carbon methods such as an aethalometer, automated FEMs can help identify potential local carbon sources contributing to increased exposure in the community. The EPA and the CASAC worked collaboratively in 2010 (Russell and Samet, 2010) to define a list of measurements that would be useful to implement in the near-road environment, and a subset of these measurements may additionally be of value to characterize the exposure in at-risk communities. While either FRMs or automated FEMs may be used at a site for comparison to the $PM_{2.5}$ NAAQS, the EPA encourages use of automated continuous FEMs at sites in at-risk communities.

Although there are only a few new sites required,[171] plus any potentially moved sites in cases where a site lease is lost, EPA believes we should build upon our existing regulatory process for selecting and approving these sites (40 CFR 58.10). For example, the timeline to implement the proposed $PM_{2.5}$ sites in at-risk communities should allow monitoring agencies enough time for communities and other interested parties to provide their input regarding moving or adding new sites, while also minimally disrupting ongoing operations of monitoring agency programs. Another important factor is to ensure all existing $PM_{2.5}$ sites have data available for comparison to a revised $PM_{2.5}$ NAAQS, which is discussed in section II of this proposal. With a final rule from this proposal expected in 2023, we believe it would be appropriate to provide at least 12 months from the effective date of a final rule for monitoring agencies to initiate planning to implement these measures by seeking input from communities and other interested parties, and to consider revisions to their $PM_{2.5}$ networks or explain how the existing network meets the objectives of this proposed modification. Thus, the EPA proposes that monitoring agencies identify their initial approach to the question of whether any new or moved sites are needed and to identify the potential communities in which the agencies are considering adding monitoring, if applicable, as well as identifying how they intend to meet the proposed revised criteria for $PM_{2.5}$ network design to address at-risk communities. These aspects that will potentially affect the siting of new and moved sites should be addressed in the agencies' annual monitoring network plans due to each applicable EPA Regional office no later than July 1, 2024 (40 CFR 58.10). Specifics on the resulting proposed new or moved sites for $PM_{2.5}$ network design to address at-

[171] Gantt, B. (2022). Analyses of Minimally Required $PM_{2.5}$ Sites Under Alternative NAAQS. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA-HQ-OAR-2015-0072). Available at: *https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072*.

risk communities would need to be detailed in the annual monitoring network plans due to each applicable EPA Regional office no later than July 1, 2025 (40 CFR 58.10). We are proposing that any new or moved sites would be required to be implemented and fully operational no later than 24 months from the date of approval of a plan or January 1, 2027, whichever comes first, but the EPA solicits comment on whether less time is needed (e.g., 12 months from plan approval and/or January 1, 2026).

In summary, the EPA is proposing to modify our $PM_{2.5}$ network design criteria to include an environmental justice factor to address at-risk communities with a focus on exposures from sources of concern. While this proposal would require that sites be located in at-risk communities, particularly those whose air quality is potentially affected by local sources of concern, such sites should still meet the requirement for being considered "area-wide" air quality. Specific areas of interest we seek comment on include how to identify at-risk communities, the sources of concern important to consider, the datasets to identify communities with high exposures, and the most useful measurements to collocate with $PM_{2.5}$ in at-risk communities. The EPA seeks comment on these areas of interest as well as the proposed modification of our $PM_{2.5}$ network design objectives and implementation as described herein.

5. Proposed Revisions to Probe and Monitoring Path Siting Criteria

The EPA is proposing changes to monitoring requirements in the subpart Appendix E—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring. Since 2006, multiple rule revisions were made to establish siting requirements for $PM_{10–2.5}$ and $O_3$ monitoring sites (71 FR 2748, January 17, 2006), Near-Road $NO_2$ monitoring sites (75 FR 6535, February 9, 2010), Near-Road CO monitoring sites (76 FR 54342, August 31, 2011), and Near-Road $PM_{2.5}$ monitoring sites (78 FR 3285, January 15, 2013). Through these multiple revisions

to the regulatory text, some requirements were inadvertently omitted, and, over time, the clarity of this Appendix was reduced through these omissions that, in a few instances, led to unintended and conflicting regulatory requirements. The EPA proposes to reinstate portions of previous Probe and Monitoring Path Siting Criteria Requirements from previous rulemaking where appropriate to restore the original intent. The proposed changes that affect the overall Appendix follow, while those specific to the various sections of the Appendix will be addressed under a specific section heading. The EPA notes that the entire regulatory text section for Appendix E is being reprinted with this proposal because this section is being reorganized for clarity in addition to being selectively revised as described in detail below. The EPA is soliciting comment on the specific provisions of Appendix E proposed for revision. However, there are a number of provisions that are being reprinted in the regulatory text solely for clarity to assist the public in understanding the changes being proposed and reconciling requirements between different portions of the regulation text; the EPA is not soliciting comment on those provisions and considers changes to those provisions to be beyond the scope of this proposed rulemaking.

a. Providing Separate Section for Open Path Monitoring Requirements

The current Appendix E regulation combines open path monitor siting requirements with requirements for siting samplers and monitors that utilize probe inlets. While this approach allowed the EPA to promulgate an abbreviated regulation for probe-siting requirements, the EPA now has determined that the clarity of the requirements for each monitoring method type has been diminished by this combination. As such, the EPA is proposing to relocate all open path monitor siting criteria requirements to a separate section in this Appendix. Providing separate sections for these distinct monitoring method types will allow the EPA to more clearly articulate minimum technical siting requirements for each. Further rationale for creating these separate

sections is that the regulatory monitoring community has not submitted to AQS measurement results from open path monitors since 2009. Because these open path monitoring methods are rarely used for monitoring to compare to the NAAQS, the EPA believes that moving the open path siting criteria to their own section will make clearer the probe siting criteria for the ambient air monitoring methods that are now most commonly utilized by monitoring organizations.

b. Amending Distance Precision for Spacing Offsets

The EPA proposes to require that when rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures. The EPA proposes to communicate this rounding requirement in the regulatory text using footnotes in Table E-1, Table E-2, and Table E-3 of the current regulation.

c. Clarifying Summary Table of Probe Siting Criteria

To provide additional specificity and flexibility to the summary table for probe siting criteria (see current Table E-4 in Appendix E), the EPA proposes to change the ">" (greater than) symbols to "≥" (greater than or equal to) symbols. This minor revision will more clearly express the EPA's intent that the distance offsets provided in the current Table E-4 in Appendix E are acceptable for NAAQS compliance monitoring.

d. Adding Flexibility for the Spacing from Minor Sources

Current requirements for the spacing of probe inlets and monitoring paths from minor sources of $SO_2$ and $NO_2$ stipulate that the probe inlets and monitoring paths must be away from these minor sources (see current section 3(b) in Appendix E). The EPA proposes to clarify and provide flexibility by changing this requirement to a goal. The EPA proposes to replace the "must" in this regulation with a "should". As stated in Section 1(c) of the current rule, a "must" defines a requirement while a "should" specifies a goal. Since the current rule does not specify

how far the probe must be spaced from such minor sources, the EPA proposes that a "should" in this regulation is more appropriate. Minor sources can have adverse impacts on the representativeness of the ambient pollutant concentrations sampled by the probe inlet. As such, the EPA recommends that sites with these minor sources be avoided whenever practicable and probe inlets spaced as far from these minor sources as possible when alternative monitoring stations are not suitable.

e. Amendments and Clarification for the Spacing from Obstructions and Trees

The EPA proposes to clarify and redefine that the minimum arc required to be free of obstructions for a probe inlet or monitoring path is 270 degrees. Currently this portion of the regulation (see current section 4(b) of Appendix E) specifies 180 degrees as this minimum arc. However, this requirement is inconsistent with the requirement found in footnote 5 of Table E-4 in Appendix E that specifies the probe inlet or monitoring path must have unrestricted airflow of 270 degrees around the probe and 180 degrees for the arc is only allowed if the probe is on the side of a building or a wall. These inconsistent regulatory requirements were introduced in the 2006 rulemaking when the 270-degree requirement was omitted from the regulation text of section 4(b) (see 71 FR 61236, October 17, 2006).

There are also inconsistent requirements in the current regulation regarding the spacing of probe inlets from the driplines of trees. Section 5(a) of Appendix E requires the probe inlet must be no closer than 10 meters to the driplines of any trees, while footnote 3 of Table E-4 of the Appendix E qualifies that this minimum 10-meter offset is only required when the tree also acts as an obstruction.

f. Reinstating Minimum 270-Degree Arc and Clarifying 180-Degree Arc in Regulatory Text

The EPA proposes to correct identified inconsistencies in this regulation by reinstating

the 270-degree requirement in section 4(b) of Appendix E. Additionally, the EPA proposes to further clarify this regulation by stating that the continuous 180-degree minimum arc of unrestricted airflow provision is reserved for monitors sited on the side of a building or a wall to comply with network design criteria requirements specified in Appendix D of part 58. Examples include CO monitoring in urbanized areas that relies on monitoring in street canyons and near-road monitoring where a continuous arc of 270 degrees of unrestricted airflow is not routinely possible given limited monitor siting options.

g. Clarification on Obstacles that Act as an Obstruction

The EPA proposes to clarify the definitions of "obstructions" and "obstacles" in the regulatory text (see section 4 of the current Appendix E). While obstacles should be avoided as much as is practicable, logistical constraints may dictate that some obstacles are present within the vicinity of the monitoring probe inlet. Obstructions to the air flow of the probe inlet are those obstacles that are horizontally closer than twice the vertical distance the obstacle protrudes above the probe inlet and can be reasonably thought to scavenge reactive gases or to restrict the airflow for any pollutant. The EPA does not generally consider objects or obstacles such as flag poles or site towers for $NO_y$ convertors or towers for meteorological sensors, etc. to be obstructions.

h. Amending and Clarifying the 10-meter Tree Dripline Requirement

The EPA proposes to reconcile the conflicting requirements in section 5(a) and Table E-4, footnote 3 of the current regulation by deleting the qualification in footnote 3 of Table E-4 to require that the probe inlet must always be no closer than 10 meters to the tree dripline. The EPA also proposes to reinstate the goal that was omitted from section 5(a) during previous rule revisions, that monitor probe inlets should be at least 20 meters from the driplines of trees. Additionally, the EPA proposes to clarify section 5(a) of the current regulation by adding that

when the tree or group of trees is considered an obstruction, then the regulatory requirements of section 4(a) apply.

i. Amending Spacing Requirement for Microscale Monitoring

To obtain representative ambient air monitoring measurements for source-oriented and microscale air monitoring stations, it is important to have unobstructed airflow between the monitor's probe inlet and the source under investigation. This reasoning was used by the EPA when near-road $NO_2$ monitoring stations were required to have an unobstructed airflow between the monitor probe and the outside nearest edge of the traffic lane (see current section 4(d) of this regulation). To assist in further clarifying the monitoring siting criteria for the spacing from obstructions and spacing from trees, the EPA proposes to change from a goal to a requirement that microscale sites for any pollutant shall have no trees or shrubs blocking the line-of-sight fetch between the monitor's probe inlet and the source under investigation. The EPA proposes to communicate this requirement by changing the "should" to a "shall" in the regulatory text of section 5(c). The EPA does not consider small obstacles such as shrubs that are below this fetch to adversely impact the representativeness of the air quality measurements results. This proposed revision of section 4(d) will bring more consistency to Appendix E.

j. Amending Waiver Provisions

The EPA believes the effects of any requirements in this proposal that may be considered to be new are minor. While we are attempting to clarify probe and siting criteria as part of our monitoring regulations, the Agency fully intends to maintain waiver provisions that exist in the regulation for these siting criteria (see current section 10). For cases where long-term trend sites or monitors that determine the design value for their area cannot reasonably meet these regulatory siting requirements, the EPA encourages monitoring organizations to work with their

respective EPA Regional Offices to determine if a waiver from these siting criteria is appropriate.

Even though the current regulation adequately and clearly identifies which monitoring situations are eligible for the EPA to consider waiving the requirements for probe-siting criteria (see current section 10), these waiver provisions are silent regarding how long an approved waiver remains in force and effect. Environmental conditions (e.g., airflow due to changes in growth of trees, shrubs, construction of buildings or other obstructions) around monitoring stations are prone to change over time. As such, the EPA has identified that previously approved waivers should be periodically reevaluated to ensure that the conditions upon which the original waiver was approved still exist and that the siting conditions have not degraded to an unacceptable level. The EPA proposes to modify section 10.3 of the current regulation to state that waivers from the probe-siting criteria must be renewed minimally every 5 years. Ideally, sites needing a waiver renewal should be inspected by the EPA such as during a Technical Systems Audit (TSA) typically conducted at a subset of sites within each Primary Quality Assurance Organization (PQAO) every three years. However, virtual inspections may also be acceptable using documentation such as photos and traffic counts. Dates for the most recent approval of a waiver must then be included in the applicable network assessment and annual monitoring network plan. The EPA proposes to revise 58.10(b)(10) of the regulation to maintain consistency in the regulation text for probe siting criteria requirements and annual monitoring network plans. This proposal leverages the existing annual assessment requirements found in parts 58.10(a)(1) and 58.10(d).

k. Broadening of Acceptable Probe Materials

The current regulatory specifications for acceptable probe materials for sampling reactive

gases are limited to borosilicate glass, FEP, or their equivalent (see section 9 of the regulation). The EPA's selection of "or its equivalent" in the current regulatory text was intended to allow flexibility to monitoring organizations when selecting suitable sampling train materials. In practice, however, this text has resulted in potentially suitable materials not being used for sampling trains due to concerns that the material may not meet these regulatory requirements. The current requirements for acceptable probe materials were promulgated in 1979. Since 1979, several potential alternatives to borosilicate glass and FEP were developed and are commercially available.

Because some of these alternative materials have advantages over the currently approved materials (e.g., cost and durability), the EPA has received numerous inquiries from monitoring organizations regarding the regulatory suitability of these materials. Monitoring organizations have expressed particular interest in the potential use of PVDF (polyvinylidene fluoride) which is marketed under the registered tradename of Kynar® by Arkema Inc. (Colombes, France). In response to these inquiries, the EPA's Office of Research and Development (ORD) recently designed and conducted a laboratory study to determine the transport efficiency of $O_3$, $SO_2$, $NO_2$, and CO through several candidate tubing materials (Johnson, 2022). Based on these tests results, the EPA is proposing to revise Section 9 of the current regulation to add PVDF, PTFE, and PFA to the list of approved materials for efficiently transporting gaseous criteria pollutants. The EPA also proposes to clarify that the residence-time criteria for sampling reactive gas through these approved materials applies to all $O_3$, $SO_2$, and $NO_2$ monitors. In conjunction with the previously approved borosilicate glass and FEP materials, including these three new materials would provide monitoring organizations with a wider variety of efficient sampling and transport materials needed for conducting NAAQS compliance monitoring.

The EPA has also studied and approved the use of Nafion™ upstream of ozone analyzers to minimize measurement bias associated with high ambient RH levels (U.S. EPA, 2020b). Minimal loss of ozone occurred in these systems as long as the Nafion™ system was conditioned beforehand. Nafion™ is composed primarily of PTFE and can be considered equivalent to PTFE. It has been shown in ORD's recent tests described above to exhibit virtually no loss of ozone at 20 second residence times.

*D. Taking Comment on Incorporating data from Next Generation Technologies*

1. Background on use of FRM and FEM monitors

The EPA approves FRM and FEM monitors for criteria pollutant measurements in the *Federal Register* after careful review of applications describing extensive testing of the methods operation and performance. The siting of these monitors across State, local, and Tribal networks is subject to detailed requirements for network design detailed in Appendix D to 40 CFR part 58 with probe and siting criteria described in Appendix E for 40 CFR part 58. The operation of these monitors is subject to extensive quality assurance requirements detailed in Appendix A to 40 CFR part 58, which ensures data quality statistics are produced to inform the quality of the data needed to ensure regulatory grade decisions are made with data of known quality. The EPA believes these requirements are important for ensuring the degree of accurate and precise data which is appropriate for regulatory decision-making, particularly decisions about attainment or nonattainment of the NAAQS. However, the EPA also recognizes that the capital and operating costs of these monitors is substantial, which requires the EPA and states to prioritize where monitors should be deployed. The EPA recognizes that making use of broader air quality data sets which are less expensive can provide important benefits, even if the EPA does not consider those datasets suitable for all regulatory purposes. In some circumstances in the past, for

example, the EPA has used non-FRM monitoring to inform decisions about the boundaries of a nonattainment area, although the data was not sufficient to support a finding that an area was in nonattainment. Likewise, the EPA has incorporated sensor data into its fire and smoke map for the purpose of informing the public of potential imminent health risks, even though that data would not be comparable to the NAAQS for purposes of determining attainment. There are multiple uses of air quality data and the EPA believes there may be additional opportunities to develop broader air quality datasets which provide benefits to the EPA and the public even where the data is not from FRM/FEM monitors and is not suitable for comparison to the NAAQS.

2. Next Generation Technologies: Data Considerations

The EPA and our State, local, and Tribal partners in cooperation with other Federal Agencies have made great strides in integrating data from routine air monitoring methods with data from next generation technologies to address emerging air quality issues. For example, the EPA and USFS, in consultation with other partners, launched the publicly available AirNow Fire and Smoke Map,[172] which has received over 26 million page views since its release in July 2020. This fire and smoke map has been an invaluable tool for the public, providing refined spatial information on current Air Quality Index (AQI) conditions, fire and smoke plumes locations, actions for communities to take based on local air quality, and links to Smoke Forecast Outlooks developed by specially trained air resource advisors. Data are brought together from multiple systems including permanent and temporary $PM_{2.5}$ continuous monitoring sites, sensors, and satellite derived fire and smoke data. With the success of the fire and smoke map and a robust and growing network of $PM_{2.5}$ continuous FEMs and sensor network data, as well as existing and

[172] See: *https://fire.airnow.gov*

future satellites products, the EPA is interested in considering further enhancements to the evolution of data products to meet new and emerging non-regulatory air quality data needs. Below we describe each of the major data sets, their advantages, and any challenges to their use. We then solicit input on additional approaches and/or products to incorporating data from next generation technologies that can help address important non-regulatory air quality data needs.

3. $PM_{2.5}$ continuous FEMs

As described in the PA, State, local, and Tribal monitoring agencies are using an increasing number of $PM_{2.5}$ continuous FEMs. These methods are primarily deployed to meet two monitoring objectives: first, to compare to the NAAQS, and second, to report and support forecasting of the AQI. $PM_{2.5}$ continuous FEMs have some key advantages over FRMs, most notably that they provide automated hourly measurement of $PM_{2.5}$ available in near real time. The continuous $PM_{2.5}$ data are reported as soon as practicable after the end of each hour, usually within 5-10 minutes, and are used in multiple applications of real-time data such as such as by State, local, and Tribal web sites[173,174], the EPA's AirNow web site, and national media outlets. Recent improvements in the availability and exchange of near real-time data through a dedicated AirNow Application Programming Interface (API) allow for efficient exchange of data between the EPA, other federal agencies, and commercial data providers such as low-cost sensor networks. The efficient exchange of data through the AirNow API was a key advancement in the successful implementation of the EPA AirNow's fire and smoke map. The $PM_{2.5}$ continuous FEM data are critical to "ground truthing" other datasets such as sensors and satellites for two important reasons. First, $PM_{2.5}$ continuous FEMs are subject to extensive regulatory-grade

[173] See: *https://www.airnow.gov/partners/state-and-local-partners/*
[174] See: *https://www.airnow.gov/partners/tribal-partners/*

quality assurance and quality control as required by Appendix A to 40 CFR Part 58. Second, $PM_{2.5}$ continuous FEMs are located in accordance with strict siting criteria according to Appendix E to 40 CFR Part 58. The siting criteria assure that measured data represent ambient air at ground level where people are breathing and are thus exposed to particle pollution. The EPA and State, local, and Tribal agencies are working to upgrade many existing FRM-only sites with $PM_{2.5}$ continuous FEMs through use of American Rescue Plan funds.[175] Despite these investments, there are major challenges to monitoring agencies' ability to have enough trained and available staff to support their regulatory monitoring networks, especially in remote locations, and to have the capital resources to implement new monitoring stations. So, while there may be some improvements to the existing network of almost 1,000 $PM_{2.5}$ regulatory-grade monitoring stations, regulatory instruments will not produce data everywhere that it is desired. Thus, the integration of $PM_{2.5}$ continuous FEMs with other datasets is an important opportunity to address existing and emerging air quality data needs for non-regulatory purposes.

4. $PM_{2.5}$ satellite products

Satellite-based instruments provide measurements of radiance that can be used to calculate the aerosol optical depth (AOD) of the atmosphere. For over a decade, satellite AOD values have been used in models that incorporate multiple datasets to predict surface level $PM_{2.5}$ concentrations over the U.S. (hereafter, satellite-$PM_{2.5}$). Despite some heterogeneity in performance under varying conditions, the satellite-$PM_{2.5}$ datasets have significantly advanced in terms of accuracy in recent years (Di et al., 2019; van Donkelaar et al., 2019; Zhang and Kondragunta, 2021). The EPA is using satellite-$PM_{2.5}$ datasets in a variety of contexts. Satellite-$PM_{2.5}$ data was included in a comparative analysis of hybrid modeling methods in the PA (U.S.

[175] See: *https://www.epa.gov/arp/enhanced-air-quality-monitoring-funding-under-arp*

EPA, 2022b). The EPA is also working with NASA and NOAA to use satellite-$PM_{2.5}$ in the AirNow system.[176] The EPA also uses satellite AOD and many other satellite data products in the development of our photochemical modeling platforms that are used in regulatory and policy assessments both by the EPA and by our State and local partners.

Each satellite data product has its own strengths and limitations. One strength is the spatial coverage, which can be once-a-day globally for polar orbiting satellites or over a fixed field of view continuously for geostationary satellites. Satellite-$PM_{2.5}$ data has the limitation that it is not a direct measurement of $PM_{2.5}$ concentrations, but rather is derived through a model that connects the total column AOD to surface $PM_{2.5}$. In addition, the satellite products are only capable of making daytime measurements because they rely on sunlight. In fact, most satellite-$PM_{2.5}$ data products use the surface monitor network as an input. As such, the satellite-$PM_{2.5}$ data does not substitute for a ground-based monitor; rather it complements the monitor network. The EPA continues to explore ways to use the wealth of data from satellites to address important air quality questions consistent with their strengths and limitations.

5. Use of air sensors

The term "air sensor" is a simplified way of referring to a class of technology that has expanded on the market in recent years and has common traits of directly reading a pollutant in the air, being smaller in size, and often sold at lower prices that support a wider number of monitoring locations than possible in the past. As explained on the EPA's Air Sensor Toolbox website,[177] air sensor monitors that are lower in cost, portable, and generally easier to operate

[176] The EPA provided an update on the Health and Air Quality Applied Scientist Team (HAQAST) AirNow Project at the NASA HAQAST meeting in Texas in June 2022. For more information, see: *https://haqast.org/haqast-houston-june-1-2/*.
[177] See: *https://www.epa.gov/air-sensor-toolbox*

than regulatory-grade monitors are widely used in the United States to understand air quality conditions. Many refer to this class of technology as "low-cost air sensors," "air sensor devices," or "air quality sensors." Potential uses for these non-regulatory air sensor technologies include, but are not limited to, science education, supplementing regulatory air quality measurements, conducting research, measuring local air quality to better understand sources of pollution, locating leaks at industrial facilities, and emergency response.

The growth in use of sensors included in the EPA's fire and smoke map provides a platform to build upon. There are thousands of PM sensors whose data are coordinated and overlaid with routine and temporary $PM_{2.5}$ continuous monitors as well as satellite-derived data on fires and smoke. Sensors offer an opportunity to supplement higher-cost regulatory monitoring to provide data for the non-regulatory uses as described above. However, there are several challenges to using sensors. Each commercially available PM sensor appears to have its own data quality challenges depending on season, aerosol encountered, and meteorological conditions (typically temperature and relative humidity). The EPA has gone to considerable length to ensure the $PM_{2.5}$ sensor data on the fire and smoke map have a correction available with collocated FRMs and FEMs.[178] This was possible due to the large number of air sensors that are the same make and model located across the country. Thus, an important challenge for the use of sensors is the spatial richness in sensor networks needed to make integrating the dataset with other monitoring data viable. Even with corrected sensor data in hand, publicly shared sensor data lacks reliability and accountability for ensuring that basic siting criteria are met. Sensors are often installed by members of the public who share data to the sensor network,

[178] See: *https://www.epa.gov/research-states/airnow-fire-and-smoke-map-extension-us-wide-correction-purpleair-pm25-sensors*

which is generally understood as implicitly representing that the sensor is located in ambient air although, in fact, the sensor may be located inside a home or next to a highly localized source of emissions such as the flue of a home heating system. In areas with many reporting sensors, these concerns about siting may be lessened through site-to site comparison of data; however, the absence of any confirmed information about siting presents challenges for use of sensor data.

6. Summary

The near real-time integration of data from $PM_{2.5}$ continuous monitors, sensors, and satellites has been proven through use of the EPA's fire and smoke map. This mapping product is possible though the use of API's where data sets are automatically shared on pre-specified computer servers. Given the success of the fire and smoke map, the EPA is interested in pursuing additional approaches and/or products that can help address important non-regulatory air quality data needs. Therefore, the EPA solicits comment on the most important data uses and data sets to consider in future products. Such approaches and/or products could utilize historical or near real-time data. For example, what are the advantages and disadvantages of using existing data and tools to identify PM hot spots across an area of interest? Could satellite data or a combined surface layer ($PM_{2.5}$ FRM and FEM data, sensor data, and satellite data) be useful in siting regulatory monitors? Could combined surfaces layers be useful in determining the boundaries of nonattainment areas? Could combined surface layers be useful in exploring potential emission sources to consider in SIP planning? To what extent would requirements for data formats, units, or timescales of interest need to evolve to best address these needs? What other datasets should the EPA consider merging with the data sets listed above to help better inform air quality management, including prioritizing network investments for potential new sites such as in at risk communities described elsewhere in this proposal? The EPA seeks input and prioritization on

each of these questions to help improve the utility of data to better support air quality management to improve public health and the environment.

## VIII. Clean Air Act Implementation Requirements for the PM NAAQS

The proposed revision to the primary annual $PM_{2.5}$ NAAQS discussed in section II above, if finalized, would trigger a process under which states[179] will make recommendations to the Administrator regarding area designations. States also will be required to review their existing section 110 infrastructure state implementation plans and modify them if necessary to implement a revised NAAQS. A revised primary annual $PM_{2.5}$ NAAQS will need to be incorporated into the implementation of applicable air permitting requirements and the transportation conformity and general conformity processes, and states will need to review existing regulations for these programs that already cover $PM_{2.5}$ to determine the extent to which any changes are needed. This section provides background information for understanding the possible implications of the proposed NAAQS changes and describes the EPA's plans for providing states guidance needed to assist their implementation efforts. This section also describes existing EPA interpretations of CAA requirements and other EPA guidance relevant to implementation of a revised $PM_{2.5}$ NAAQS. Given the strong scientific evidence for disparities in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risk among certain populations (as discussed in section II of this notice), the EPA included in its 2016 $PM_{2.5}$ State Implementation Plan (SIP) Requirements Rule (which was written to be applicable for any future NAAQS revisions) included a number of key recommendations for states to advance environmental justice through their attainment planning process. In addition, as discussed throughout this section, environmental justice considerations

[179] This and all subsequent references to "state" are meant to include state, local and tribal agencies responsible for the implementation of a $PM_{2.5}$ control program.

are evaluated with regard to the several specific program elements of the overall implementation process. State and local air agencies have a critically important role in implementing the NAAQS, including this proposed $PM_{2.5}$ NAAQS, should it become finalized. Given the information provided in this proposed rulemaking, state and local air agencies are encouraged to begin to consider how they might develop implementation plans that encourage early emission reductions as well as emission reductions that facilitate or amplify reductions affecting overburdened communities. The public is encouraged to share information on this important topic and although this rulemaking is not requesting comment specifically on this topic, information on this topic may be submitted for informational purposes to the docket for this proposed rulemaking. The EPA may consider whether additional guidance on the topic of environmental justice and $PM_{2.5}$ implementation is appropriate, beyond what is already included in the existing $PM_{2.5}$ SIP Requirements Rule. The EPA encourages air agencies and other stakeholders to review the existing $PM_{2.5}$ SIP Requirements Rule and the information provided therein regarding environmental justice considerations in $PM_{2.5}$ air planning. To be clear, nothing in the above text should be interpreted as seeking comment in this proposal on any aspect of the 2016 $PM_{2.5}$ SIP Requirements Rule.

With respect to the topics covered in this section, the EPA welcomes the public to provide input to the Agency through comments. However, because these issues are not relevant to the establishment of a revised primary annual $PM_{2.5}$ NAAQS, and because no specific revisions are proposed for the regulations implementing the $PM_{2.5}$ NAAQS (i.e., 40 CFR 51, subpart Z), the EPA does not expect to respond to these comments in the final action on this proposal (nor is it required to do so).

*A. Designation of Areas*

After the EPA establishes or revises a NAAQS, the CAA requires the EPA and the states

to take steps to ensure that the new or revised NAAQS is met. The first step, known as the initial area designations, involves identifying areas of the country that either meet or do not meet the new or revised NAAQS, along with the nearby areas contributing to the violations.

Section 107(d)(1) of the CAA states that, "By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 109, the Governor of each state shall … submit to the Administrator a list of all areas (or portions thereof) in the State" and that making recommendations for whether the EPA should designate those areas as nonattainment, attainment, or unclassifiable.[180] The CAA provides the EPA discretion to require states to submit their designations recommendations within a reasonable amount of time not exceeding 1 year. The CAA also stipulates that "the Administrator may not require the Governor to submit the required list sooner than 120 days after promulgating a new or revised national ambient air quality standard." Section 107(d)(1)(B)(i) further provides, "Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) … as expeditiously as practicable, but in no case later than 2 years from the date of promulgation. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations." With respect to the NAAQS setting process, courts have interpreted the term "promulgation" to be signature and widespread dissemination of a final rule.[181] One way the EPA intends to account for environmental justice in the implementation process is to promptly issue designations in accordance with the statutory requirements to ensure

[180] While the CAA says "designating" with respect to the Governor's letter, in the full context of the CAA section it is clear that the Governor actually makes a recommendation to which the EPA must respond via a specified process if the EPA does not accept it.
[181] API v. Costle, 609 F.2d 20 (D.C. Cir. 1979)

expeditious public health protections for all populations, including those currently experiencing disparities in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risk.

If the EPA agrees with the designation recommendation of the state, then it may proceed to promulgate the designations for such areas. If, however, the EPA disagrees with the state's recommendation, then the EPA may elect to make modifications to the recommended designations. By no later than 120 days prior to promulgating the final designations, the EPA is required to notify states of any intended modifications to the designations of any areas or portions thereof, including the boundaries of areas, as the EPA may deem necessary. States then have an opportunity to comment on the EPA's tentative designation decision. If a state elects not to provide designation recommendations, then the EPA must timely promulgate the designation that it deems appropriate. While section 107(d) of the CAA specifically addresses the designations process for states, the EPA intends to follow the same process for tribes to the extent practicable, pursuant to section 301(d) of the CAA regarding tribal authority, and the Tribal Authority Rule (63 FR 7254, February 12, 1998). To provide clarity and consistency in doing so, the EPA issued a guidance memorandum to our Regional Offices on working with tribes during the designations process (Page, 2011a).

Monitoring data are currently available from numerous existing $PM_{2.5}$ Federal Equivalent Methods (FEM) and Federal Reference Methods (FRM) sites to determine compliance with the proposed revised $PM_{2.5}$ primary annual NAAQS. As discussed in section II above, the EPA is proposing to: (1) revise the level of the primary annual $PM_{2.5}$ standard and retain the current primary 24-hour $PM_{2.5}$ standard (section II.D.3); and (2) not change the current secondary annual and 24-hour $PM_{2.5}$ standards at this time (section V.D.3). Consistent with the process used in previous area designations efforts, the EPA will evaluate each area on a case-by-case basis

considering the specific facts and circumstances unique to the area[182] to support area boundaries decisions for the revised standard. Section 107(d) explicitly requires that the EPA designate as nonattainment not only the area that is violating the pertinent standard, but also those nearby areas that contribute to the violation in the violating area. For the reason noted earlier, the EPA believes it is important to consider environment justice within the framework of this area-specific analysis. Consistent with past practice, the EPA expects to address issues relevant to area designations more fully in a separate designations-specific memorandum around the time of promulgation of any revised $PM_{2.5}$ NAAQS.[183] Examples of issues that may be included in the separate designations-specific memorandum may include, but are not limited to, exceptional events demonstrations for wildfire and/or prescribed fires on wildland, factors to consider in identifying appropriate designations for areas and boundaries, among other relevant topics. For informational purposes, the public can comment on the process and schedule for the initial area designations and nonattainment boundary setting effort associated with a new or revised $PM_{2.5}$ NAAQS. As noted above, the EPA does not expect to respond to these comments in the final regulatory action establishing the NAAQS.

As in past iterations of the $PM_{2.5}$ NAAQS, the EPA intends to make the designations for any revised NAAQS based on the most recent 3 years of complete and valid air quality data. Accordingly, the EPA recommends that states base their initial designation recommendations on the most current available 3 years of complete and valid air quality data. The EPA intends to use

[182] The EPA has historically used area-specific analyses to support nonattainment area boundary recommendations and final boundary determinations by evaluating factors such as air quality data, emissions and emissions-related data (e.g., population density and degree of urbanization, traffic and commuting patterns), meteorology, geography/topography, and jurisdictional boundaries. We expect to follow a similar process when establishing area designations for any new or revised $PM_{2.5}$ NAAQS.

[183] *https://www3.epa.gov/pmdesignations/2012standards/docs/april2013guidance.pdf*

available air quality data from the current $PM_{2.5}$ mass and speciation monitoring networks and other technical information. The EPA will then base the final designations on 3 consecutive years of certified air quality monitoring data, likely 2021-2023.[184]

In some areas, state or tribal air agencies may have flagged air quality data for certain days in the Air Quality System due to potential impacts from exceptional events (i.e., such as wildfires or high wind dust storms). Air quality concentrations on such days may affect the calculation of design values for regulatory air monitoring sites in determining whether such sites may violate the revised $PM_{2.5}$ NAAQS, and therefore could influence the initial area designations for this revised NAAQS. Under the 2016 Exceptional Events Rule (see "Treatment of Data Influenced by Exceptional Events; Final Rule," 81 FR 68216, October 3, 2016), an air agency may submit to the EPA a demonstration with supporting information and analyses for each monitor and day the air agency claims should be excluded from design value calculations for regulatory purposes. The EPA has provided a number of tools to assist air agencies in preparing their demonstrations[185] and will continue to work with air agencies as they identify, prepare and submit exceptional events demonstrations. The EPA recognizes that some areas and stakeholders may be concerned about wildfire and prescribed fire related impacts to designations and/or other forthcoming actions of regulatory significance for which a state may want to submit an exceptional events demonstration. The EPA has already issued guidance addressing development of exceptional events demonstrations for both wildfire and prescribed fires on wildland. Existing

[184] In certain circumstances in which the Administrator has insufficient information to promulgate area designations within 2 years from the promulgation of a new or revised NAAQS, CAA section 107(d)(1)(B)(i) provides the EPA may extend the designations schedule by up to 1 year.

[185] *See* EPA's Exceptional Events homepage at *https://www.epa.gov/air-quality-analysis/treatment-air-quality-data-influenced-exceptional-events-homepage-exceptional*.

guidance and other tools are available on the EPA's website identified above. The air agency is required to follow the exceptional events demonstration submission deadlines that are identified in Table 2 to 40 CFR 50.14(c)(2)(vi) – "Schedule for Initial Notification and Demonstration Submission for Data Influenced by Exceptional Events for Use in Initial Area Designations." Further, the EPA has notified states of areas subject to mitigation plan provisions. Within 2 years of the notification, if the air agency has not submitted a required mitigation plan, the EPA will not concur with the air agency's request to exclude data until the required plan is submitted and verified.

As noted earlier, the EPA intends to provide designation guidance to the states and tribes around the time of the promulgation of a revised NAAQS, to assist in formulating these recommendations. With regard to the area designations process, if, after evaluating the state recommendations in light of the technical factors, the Administrator intends to modify any state area recommendation, the EPA will notify the appropriate state Governor no later than 120 days prior to making final designations decisions. A state that believes the Administrator's intended modification is inappropriate will have the opportunity to demonstrate to the EPA why it believes its original recommendation (or a revised recommendation) is more appropriate before final designations are promulgated. The Administrator will take any additional input from the state into account in making final designation decisions. If the Administrator departs from the stated intentions in the initial 120-day notification letter in a way that does not match the most recently received recommendation from the Governor (or tribe) as of the date of the final designation, the Administrator will provide an additional 120-day notification letter notifying the Governor of such modifications. The EPA invites preliminary comment on all aspects of the designation process at this time, which the Agency will consider in developing any updated

guidance.

*B. Section 110(a)(1) and (2) Infrastructure SIP Requirements*

The CAA directs states to address basic SIP requirements to implement, maintain, and enforce the NAAQS. Under CAA sections 110(a)(1) and (2), states are required to have state implementation plans that provide the necessary air quality management infrastructure including, among other things, enforceable emissions limitations, an ambient monitoring program, an enforcement program, air quality modeling capabilities, and adequate personnel, resources, and legal authority. After the EPA promulgates a new or revised NAAQS, states are required to make a new SIP submission to establish that they meet the necessary structural requirements for such new or revised NAAQS or make changes to do so. The EPA refers to this type of SIP submission as an "infrastructure SIP submission." Under CAA sections 110(a)(1), all states are required to make these infrastructure SIP submissions within 3 years after promulgation of a new or revised primary standard. While the CAA authorizes the EPA to set a shorter time for states to make these SIP submissions, the EPA does not currently intend to do so.

Under CAA section 110(a)(1) and (2), states are required to make SIP submissions that address a number of requirements pertaining to implementation, maintenance, and enforcement of a new or revised NAAQS. The specific subsections in CAA section 110(a)(2) require states to address a number of requirements, as applicable: (A) Emissions limits and other control measures, (B) Ambient air quality monitoring/data system, (C) Programs for enforcement of control measures and for construction or modification of stationary sources, (D)(i) Interstate pollution transport; and (D)(ii) Interstate and international pollution abatement, (E) Adequate resources and authority, conflict of interest, and oversight of local governments and regional agencies, (F) Stationary source monitoring and reporting, (G) Emergency episodes, (H) SIP revisions, (I) Plan revisions for nonattainment areas, (J) Consultation with government officials,

public notification, PSD and visibility protection, (K) Air quality modeling and submission of modeling data, (L) Permitting fees, and (M) Consultation and participation by affected local entities. These requirements apply to all SIP submissions in general, but the EPA has provided specific guidance to states concerning its interpretation of these requirements in the specific context of infrastructure SIP submissions for a new or revised NAAQS (Page, 2013).

The EPA interprets the CAA such that two elements identified in section 110(a)(2) are not subject to the 3-year submission deadline of section 110(a)(1) and thus states are not required to address them in the context of an infrastructure SIP submission. The elements pertain to part D, in title I of the CAA, which addresses plan requirements for nonattainment areas. Therefore, for the reasons explained below, the following section 110(a)(2) elements are considered by the EPA to be outside the scope of infrastructure SIP actions: (1) the portion of section 110(a)(2)(C), programs for enforcement of control measures and for construction or modification of stationary sources that applies to permit programs applicable in designated nonattainment areas, (known as "nonattainment new source review") under part D; and (2) section 110(a)(2)(I), which requires a SIP submission pursuant to part D, in its entirety. The EPA does not expect states to address the requirement for a new or revised NAAQS in the infrastructure SIP submissions to include regulations or emissions limits developed specifically for attaining the relevant standard in areas designated nonattainment for the proposed revised $PM_{2.5}$ NAAQS. States will be required to submit infrastructure SIP submissions for a revised $PM_{2.5}$ NAAQS before they are required to submit nonattainment plan SIP submissions to demonstrate attainment with the same NAAQS. States are required to submit nonattainment plans to provide for attainment and maintenance of a revised $PM_{2.5}$ NAAQS within 18 months from the effective date of nonattainment area designations as required under CAA section 189(a)(2)(B). The EPA reviews and acts upon these

later SIP submissions through a separate process. For this reason, the EPA does not expect states to address new nonattainment area emissions controls per section 110(a)(2)(I) in their infrastructure SIP submissions.

One of the required infrastructure SIP elements is that each state's SIP must contain adequate provisions to prohibit, consistent with the provisions of title I of the CAA, emissions from within the state that will significantly contribute to nonattainment in, or interfere with maintenance by, any other state of the primary or secondary NAAQS.[186] This element is often referred to as the "good neighbor" or "interstate transport" provision.[187] The provision has two prongs: significant contribution to nonattainment (prong 1) and interference with maintenance (prong 2). The EPA and states must give independent significance to prong 1 and prong 2 when evaluating downwind air quality problems under CAA section 110(a)(2)(D)(i)(I).[188] Further, case law has established that the EPA and states must implement requirements to meet interstate transport obligations in alignment with the applicable statutory attainment schedule of the downwind areas impacted by upwind-state emissions.[189] Thus, the EPA anticipates that states will need to address interstate transport obligations associated with any revised PM NAAQS, if finalized, in alignment with the provisions of subpart 4 of part D of the CAA, as discussed in more detail in section VIII.C below. Specifically, states must implement any measures required to address interstate transport obligations as expeditiously as practicable and no later than the next statutory attainment date, i.e., for this NAAQS revision, if finalized, as expeditiously as

[186] CAA section 110(a)(2)(D)(i)(I)
[187] CAA section 110(a)(2)(D)(i)(II) also addresses certain interstate effects that states must address and thus is also sometimes referred to as relating to "interstate transport."
[188] *See North Carolina v. EPA*, 531 F.3d 896, 909-11 (D.C. Cir. 2008).
[189] *See id.* 911-13. *See also Wisconsin v. EPA,* 938 F.3d 303, 313-20 (D.C. Cir. 2019); *Maryland v. EPA*, 958 F.3d 1185, 1203-04 (D.C. Cir. 2020).

practicable but no later than the end of the sixth calendar year following nonattainment area designations. *See* CAA section 188(c).

The EPA anticipates developing further information and coordinating with states with respect to the requirements of CAA section 110(a)(2)(D)(i)(I) for implementation of any revised PM NAAQS. We note that states may elect to make SIP submissions that address certain infrastructure SIP elements separately from the others. In recent years, due in part to the complexity of addressing interstate transport obligations, some states have found it efficient to make SIP submissions to address the interstate transport provisions separately from other infrastructure SIP elements.

It is the responsibility of each state to review its air quality management program's existing SIP provisions in light of each new or revised NAAQS to determine if any revisions are necessary to implement a new or revised NAAQS. Most states have revised and updated their SIPs in recent years to address requirements associated with other revised NAAQS. For some states, it may be the case that for a number of infrastructure elements, the state may believe it already has adequate state regulations already adopted and approved into the SIP to address a particular requirement with respect to any revised $PM_{2.5}$ NAAQS. For such portions of the state's infrastructure SIP submission, the state may provide an explanation of how its existing SIP provisions are adequate.

If a state determines that existing SIP-approved provisions are adequate in light of the revised $PM_{2.5}$ NAAQS with respect to a given infrastructure SIP element (or sub-element), then the state may make a SIP submission "certifying" that the existing SIP contains provisions that

address those requirements of the specific section 110(a)(2) infrastructure elements.[190] In the case of such a certification submission, the state does not have to include a copy of the relevant provision (e.g., rule or statute) itself. Rather, the state in its infrastructure SIP submission may provide citations to the SIP-approved state statutes, regulations, or non-regulatory measures, as appropriate, which meet the relevant CAA requirement. Like any other SIP submission, that state can make such a certification only after it has provided reasonable notice and opportunity for public hearing. This "reasonable notice and opportunity for public hearing" requirement for infrastructure SIP submissions is to meet the requirements of CAA sections 110(a), and section 110(l). Under the EPA's regulations at 40 CFR part 51, if a public hearing is held, an infrastructure SIP submittal must include a certification by the state that the public hearing was held in accordance with the EPA's procedural requirements for public hearings. See 40 CFR part 51, appendix V, paragraph 2.1(g), and see 40 CFR 51.102.

In consultation with its EPA Regional office, a state should follow all applicable EPA regulations governing infrastructure SIP submissions in 40 CFR part 51 - e.g., subpart I (Review of New Sources and Modifications), subpart J (Ambient Air Quality Surveillance), subpart K (Source Surveillance), subpart L (Legal Authority), subpart M (Intergovernmental Consultation), subpart O (Miscellaneous Plan Content Requirements), subpart P (Protection of Visibility), and subpart Q (Reports). For the EPA's general criteria for infrastructure SIP submissions, refer to 40 CFR part 51, Appendix V, Criteria for Determining the Completeness of Plan Submissions. The EPA recommends that states electronically submit their infrastructure SIPs to the EPA through the State Plan Electronic Collaboration System (SPeCS),[191] an online system available through

[190] A “certification” approach would not be appropriate for the interstate pollution control requirements of CAA section 110(a)(2)(D)(i).
[191] *https://cdx.epa.gov/*

the EPA's Central Data Exchange.

*C. Implementing any Revised $PM_{2.5}$ NAAQS in Nonattainment Areas*

Part D of the CAA describes the various program requirements that apply to nonattainment areas for different NAAQS. Section 172 (found in subpart 1 of part D) includes general SIP requirements, and sections 188-190 (found in subpart 4 of part D) include SIP requirements that specifically govern implementation for the $PM_{10}$ and $PM_{2.5}$ NAAQS. All $PM_{2.5}$ nonattainment areas are initially classified as Moderate per CAA section 188(a). Under section 189(a)(2), states are required to submit attainment plan SIP submissions to the EPA within 18 months of the effective date of area designations. These plans need to show how the nonattainment area will attain the primary $PM_{2.5}$ standards "as expeditiously as practicable," but presumptively by no later than the end of the 6$^{th}$ calendar year after the effective date of designations. For example, if the EPA finalizes nonattainment designations for a revised $PM_{2.5}$ NAAQS in 2024, then the outermost statutory Moderate area attainment date would be December 31, 2030. If the state fails to attain the standard by the end of the 6$^{th}$ calendar year after the effective date of designations, the EPA is required to reclassify the area to Serious, and the state then must attain the standard by the end of the 10$^{th}$ calendar year after the effective date of designations (e.g., December 31, 2034).

On August 24, 2016, the EPA issued a detailed SIP Requirements Rule for implementing the $PM_{2.5}$ NAAQS (81 FR 58010, August 24, 2016) ($PM_{2.5}$ SIP Requirements Rule). It provides guidance and establishes additional regulatory requirements for states regarding development of attainment plans for nonattainment areas for the 1997, 2006, and 2012 revisions of the $PM_{2.5}$ NAAQS. The EPA also intended this implementation rule to apply to nonattainment areas designated pursuant to any future revisions of the $PM_{2.5}$ NAAQS. The rule covers a number of SIP requirements for nonattainment areas, including a nonattainment area emissions inventory,

policies regarding $PM_{2.5}$ precursor pollutants (i.e., $SO_2$, NOx, VOC, and ammonia), control strategies (such as reasonably available control measures and reasonably available control technology), air quality modeling, attainment demonstrations, reasonable further progress requirements, quantitative milestones, and contingency measures. Guidance provided in the $PM_{2.5}$ SIP Requirements Rule is supplemented by other EPA guidance documents, including guidance on emissions inventory development (80 FR 8787, February 19, 2015; U.S. EPA, 2017), optional $PM_{2.5}$ precursor demonstrations (U.S. EPA, 2019b),[192] and guidance on air quality modeling for meeting air quality goals for the ozone and $PM_{2.5}$ NAAQS and regional haze program (U.S. EPA, 2018b).

Under the basic approach outlined in the $PM_{2.5}$ SIP Requirements Rule, a state would first develop an updated emissions inventory of sources and emissions activities in the nonattainment area. It would then use air quality modeling or other tools to estimate the air quality improvement that can be expected in the nonattainment area by the attainment year due to enforceable and existing "on the books" federal, state, and local emissions reduction measures. The state also would work with the regulated community and other stakeholders to evaluate potential control measures for emissions sources and activities in the nonattainment area, and identify the additional reasonably available control measures (RACM) and reasonably available control technology (RACT) that can be implemented by these sources in order to attain the standard as expeditiously as practicable, but no later than by the end of the 6$^{th}$ calendar year after the effective date of designations.

The evaluation of air quality improvement associated with potential future emissions

[192] Provides guidance on developing demonstrations under section 189(e) intended to show that a certain $PM_{2.5}$ precursor in a particular nonattainment area does not significantly contribute to $PM_{2.5}$ concentrations that exceed the standard.

reductions is commonly performed with sophisticated air quality modeling tools. Given that fine particle concentrations are affected both by regionally-transported pollutants (e.g., $SO_2$ and $NO_x$ emissions from power plants) and emissions of direct $PM_{2.5}$ and other pollutants from local sources in the nonattainment area (e.g., steel mills, rail yards, highway mobile sources), the EPA recommends the use of regional photochemical models (such as CMAQ and CAMx), in combination with source-oriented dispersion models (such as AERMOD), as needed, to develop $PM_{2.5}$ attainment strategies for any revised $PM_{2.5}$ NAAQS. The EPA SIP modeling guidance provides details on the development of attainment demonstrations, and the EPA will continue to assist air agencies in modeling and technical analyses (80 FR 8787, February 19, 2015; U.S. EPA, 2017).

The $PM_{2.5}$ SIP Requirements Rule provides recommendations to states regarding when and how to consider environmental justice in the context of $PM_{2.5}$ attainment planning. Some of the considerations for states include: (1) identifying areas with overburdened communities where more ambient monitoring may be warranted; (2) targeting emissions reductions that may be needed to attain the $PM_{2.5}$ NAAQS; and (3) increasing opportunities for meaningful involvement for overburdened populations (80 FR 58010, 58136, August 25, 2016). The EPA expects states to consider these and other factors as part of their SIP development process.

The $PM_{2.5}$ SIP Requirements Rule outlines some examples of how states can implement these recommendations.[193] For instance, states can use modeling and screening tools to better understand where sources of $PM_{2.5}$ or $PM_{2.5}$ precursor emissions are located and identify areas that may be candidates for additional ambient monitoring. Furthermore, once these target areas

[193] For more information on the EPA's recommendations and examples, *see* 81 FR 58010, 58137, August 24, 2016.

are identified, states can prioritize direct $PM_{2.5}$ or $PM_{2.5}$ precursor control measures and enforcement strategies in these areas to reduce ambient $PM_{2.5}$ and achieve the NAAQS. The EPA recognizes that states have flexibility under the CAA to concentrate state resources on controlling sources of $PM_{2.5}$ emissions that directly and adversely affect certain populations currently experiencing disparities in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risk, thereby maximizing health benefits for those populations. Moreover, states can establish opportunities to bolster meaningful involvement in a number of ways, such as communicating with communities with disparities in exposures and risks in appropriate languages and developing enhanced notice-and-comment opportunities for those communities.

As previously mentioned, the 2016 $PM_{2.5}$ SIP Requirements Rule is structured in such a way that it provides guidance and regulatory requirements for remaining nonattainment areas for the 1997, 2006, and 2012 revisions of the $PM_{2.5}$ NAAQS, as well as for nonattainment areas designated pursuant to any future revisions of the $PM_{2.5}$ NAAQS. Thus, the EPA is not proposing changes to the current $PM_{2.5}$ SIP Requirements Rule in this proposed rulemaking, and therefore is not requesting comment on that rule.

*D. Implementing the Primary and Secondary $PM_{10}$ NAAQS*

As summarized in sections III.C.3 and III.D.3 above, the EPA is proposing to retain the current primary and secondary 24-hour $PM_{10}$ standards to protect against the health effects associated with short-term exposures to thoracic coarse particles and against the welfare effects considered in this reconsideration (i.e., visibility, climate, and materials effects). The EPA intends to retain the existing implementation strategy for meeting the CAA requirements for the $PM_{10}$ NAAQS. States and emissions sources should continue to follow the existing guidance and regulations for implementing the current standards.

*E. Prevention of Significant Deterioration and Nonattainment New Source Review Programs*

*for the Proposed Revised Primary Annual $PM_{2.5}$ NAAQS*

The CAA, at parts C and D of title I, contains preconstruction review and permitting programs applicable to new major stationary sources and major modifications of existing major sources. The preconstruction review of each new major stationary source and major modification applies on a pollutant-specific basis, and the requirements that apply for each pollutant depend on whether the area in which the source is situated is designated as attainment (or unclassifiable) or nonattainment for that pollutant. In areas designated attainment or unclassifiable for a pollutant, the Prevention of Significant Deterioration (PSD) requirements under part C apply to construction at major sources. In areas designated nonattainment for a pollutant, the Nonattainment New Source Review (NNSR) requirements under part D apply to major source construction. Collectively, those two sets of permit requirements are commonly referred to as the "major New Source Review" or "major NSR" programs.

Until the EPA designates an area with respect to the proposed revised $PM_{2.5}$ NAAQS, the NSR provisions applicable under an area's designation for the 1997, 2006, and 2012 $PM_{2.5}$ NAAQS would continue to apply. *See* 40 CFR 51.166(i)(2) and 52.21(i)(2). That is, for areas designated as attainment/unclassifiable for the 1997, 2006, and 2012 $PM_{2.5}$ NAAQS, PSD will apply to new major stationary sources and major modifications that trigger major source permitting requirements for $PM_{2.5}$. For areas designated nonattainment for the 1997, 2006, or 2012 $PM_{2.5}$ NAAQS, NNSR requirements will apply for new major stationary sources and major modifications that trigger major source permitting requirements for $PM_{2.5}$. When the new designations for the proposed revised $PM_{2.5}$ NAAQS, if finalized, become effective, those designations will further inform whether PSD or NNSR applies to $PM_{2.5}$ in a particular area. New major sources and major modifications will be subject to the PSD program requirements for $PM_{2.5}$ if they are located in an area that does not have a current nonattainment designation under

CAA section 107 for $PM_{2.5}$.[194]

The EPA has assessed the proposed revision of the level of the primary annual $PM_{2.5}$ NAAQS and is not proposing any changes to the NSR program regulations as part of this proposal to revise the $PM_{2.5}$ NAAQS. Sources and reviewing authorities will be able to use existing NSR regulatory provisions. Under the PSD program, the applicant must demonstrate that the new or modified source emissions increase does not cause or contribute to a NAAQS violation. In 2017, the EPA revised the *Guideline on Air Quality Models* (published as Appendix W to 40 CFR part 41) to address primary and secondary $PM_{2.5}$ impacts in making this demonstration and has since provided associated technical guidance, models and tools, such as the recent "Final Guidance for Ozone and Fine Particulate Matter Permit Modeling" (July 29, 2022).[195] The EPA will consider whether changes or updates to PSD program guidance or associated tools are warranted as a result of the proposed revision to the primary annual $PM_{2.5}$ NAAQS, should it be finalized, and would communicate such changes through separate action(s) following promulgation of a revised standard.

The statutory requirements for a PSD permit program set forth under part C of title I of

[194] 40 CFR 51.166(i)(2) and 52.21(i)(2)

[195] On July 29, 2022, the EPA issued "Final Guidance for Ozone and Fine Particulate Matter Permit Modeling," available at https://www.epa.gov/system/files/documents/2022-07/Guidance_for_O3_PM25_Permit_Modeling.pdf. This guidance provides the EPA's recommendations for how a stationary source seeking a PSD permit may demonstrate that it will not cause or contribute to a violation of the National Ambient Air Quality Standards for Ozone and $PM_{2.5}$ and PSD increments for $PM_{2.5}$, as required under Section 165(a)(3) of the Clean Air Act and 40 CFR sections 51.166(k) and 52.21(k). The EPA has also previously issued two technical guidance documents for use in conducting these demonstrations: "Guidance on the Development of Modeled Emission Rates for Precursors (MERPs) as a Tier 1 Demonstration Tool for Ozone and $PM_{2.5}$ under the PSD Permitting Program," available at *https://www.epa.gov/sites/default/files/2020-09/documents/epa-454_r-19-003.pdf*, and "Guidance on the Use of Models for Assessing the Impacts of Emissions from Single Sources on the Secondarily Formed Pollutants: Ozone and $PM_{2.5}$," available at *https://www.epa.gov/sites/default/files/2020-09/documents/epa-454_r-16-005.pdf.*

the CAA (sections 160 through 169) are addressed by the EPA's PSD regulations found at 40 CFR 51.166 (minimum requirements for an approvable PSD SIP) and 40 CFR 52.21 (PSD permitting program for permits issued under the EPA's federal permitting authority). These regulations already apply for $PM_{2.5}$ in areas that have been designated attainment or unclassifiable for $PM_{2.5}$ whenever a proposed new major source or major modification triggers PSD requirements for $PM_{2.5}$.

For PSD, a "major stationary source" is one with the potential to emit 250 tons per year (tpy) or more of any regulated NSR pollutant, unless the new or modified source is classified under a list of 28 source categories contained in the statutory definition of "major emitting facility" in section 169(1) of the CAA. For those 28 source categories, a "major stationary source" is one with the potential to emit 100 tpy or more of any regulated NSR pollutant. A "major modification" is a physical change or a change in the method of operation of an existing major stationary source that results, first, in a significant emissions increase of a regulated NSR pollutant and, second, in a significant net emissions increase of that pollutant. See 40 CFR 51.166(b)(2)(i), 40 CFR 52.21(b)(2)(i). The EPA PSD regulations define the term "regulated NSR pollutant" to include any pollutant for which a NAAQS has been promulgated and any pollutant identified in the EPA regulations as a constituent or precursor to such pollutant. See 40 CFR 51.166(b)(49), 40 CFR 52.21(b)(50). These regulations identify $SO_2$ and $NO_X$ as precursors to $PM_{2.5}$ in all attainment and unclassifiable areas. See 40 CFR 51.166(b)(49)(i), 40 CFR 52.21(b)(50)(i). Thus, for $PM_{2.5}$, the PSD program currently requires the review and control of

emissions of direct $PM_{2.5}$ emissions and $SO_2$ and $NO_X$ (as precursors to $PM_{2.5}$), as applicable.[196] Among other things, for each regulated NSR pollutant emitted or increased in a significant amount, the PSD program requires a new major stationary source or a major modification to apply the "best available control technology" (BACT) and to conduct an air quality impact analysis to demonstrate that the proposed major stationary source or major modification will not cause or contribute to a violation of any NAAQS or PSD increment.[197] See CAA section 165(a)(3)–(4), 40 CFR 51.166(j)–(k), 40 CFR 52.21(j)–(k). The PSD requirements may also include, in appropriate cases, an analysis of potential adverse impacts on Class I areas. See CAA section 162(a) and 165, 40 CFR 51.166(p); 40 CFR 52.21(p)).[198] The EPA has developed the Guideline on Air Quality Models and other documents to, among other things, provide methods

[196] Sulfur dioxide is a precursor to $PM_{2.5}$ in all attainment and unclassifiable areas. $NO_X$ is presumed to be a precursor to $PM_{2.5}$ in all attainment and unclassifiable areas, unless a state or the EPA demonstrates that emissions of $NO_X$ from sources in a specific area are not a significant contributor to that area's ambient $PM_{2.5}$ concentrations. VOC is presumed not to be a precursor to $PM_{2.5}$ in any attainment or unclassifiable area, unless a state or the EPA demonstrates that emissions of VOC from sources in a specific area are a significant contributor to that area's ambient $PM_{2.5}$ concentrations.

[197] By establishing the maximum allowable level of ambient pollutant concentration increase in a particular area, an increment defines "significant deterioration" of air quality in that area. Increments are defined by the CAA as maximum allowable increases in ambient air concentrations above a baseline concentration and are specified in the PSD regulations by pollutant and area classification (Class I, II and III). 40 CFR 51.166(c), 40 CFR 52.21(c); 75 FR 64864; October 20, 2010.

[198] Congress established certain Class I areas in section 162(a) of the CAA, including international parks, national wilderness areas, and national parks that meet certain criteria. Such Class I areas, known as mandatory federal Class I areas, are afforded special protection under the CAA. In addition, states and tribal governments may establish Class I areas within their own political jurisdictions to provide similar special air quality protection.

and guidance for demonstrating compliance with the $PM_{2.5}$ NAAQS and PSD increments for $PM_{2.5}$.[199]

The EPA has historically interpreted the requirement for an air quality impact analysis under CAA section 165(a)(3) and the implementing regulations to include a requirement to demonstrate that emissions from the proposed facility will not cause or contribute to a violation of any NAAQS that is in effect as of the date a PSD permit is issued, except to the extent that a pending permit application was subject to grandfathering provisions that the EPA had established through rulemaking. The EPA is not proposing such provisions for this action. In past NAAQS revision rules, including the 2012 $PM_{2.5}$ NAAQS (78 FR 3086, January 15, 2013) and 2015 Ozone NAAQS (80 FR 65292, October 26, 2015), the EPA included limited grandfathering provisions that exempted certain pending PSD permit actions (those that had reached a particular stage in the permitting process at the time the revised NAAQS was promulgated or became effective) from the requirement to demonstrate that the proposed emissions increases would not cause or contribute to a violation of the revised NAAQS. In August 2019, the U.S. Court of Appeals for the D.C. Circuit vacated the grandfathering provision in the PSD rules applicable to the 2015 Ozone NAAQS, finding that the provision contradicted "Congress's 'express policy choice' not to allow construction which will 'cause or contribute to' nonattainment of 'any' effective NAAQS, regardless of when they are adopted or when a permit was completed."

[199] *See* 40 CFR part 51, Appendix W; 82 FR 5182, January 17, 2017; *See also* U.S. EPA, 2021c. The EPA provided an initial version of the same guidance for public comment on February 10, 2020. Upon consideration of the comments received, and consistent with Executive Order 13990, the EPA revised the initial draft guidance and posted the revised version for additional public comment.

Murray Energy Corp. v. EPA, 936 F.3d 597, 627 (D.C. Cir. 2019).[200] Based on that court decision, the EPA is not proposing any grandfathering provision for this proposed $PM_{2.5}$ NAAQS revision, if finalized. Accordingly, PSD permits issued on or after the effective date of any final revised $PM_{2.5}$ NAAQS would require a demonstration that the proposed emissions increases would not cause or contribute to a violation of the revised $PM_{2.5}$ NAAQS.

The EPA anticipates that, if this rule is finalized as proposed, the existing $PM_{2.5}$ air quality in some areas will not be in attainment of the new revised primary annual $PM_{2.5}$ NAAQS, and that these areas will be designated as "nonattainment" at a later date, consistent with the designation process described in the preceding sections. However, until such nonattainment designation occurs, proposed new major sources and major modifications located in any area currently designated attainment or unclassifiable for $PM_{2.5}$ will continue to be subject to the PSD program requirements for $PM_{2.5}$.[201] This raises the question as to how a source can be issued a PSD permit in light of known existing ambient violations of the revised NAAQS. Section 165(a)(3)(B) of the CAA states that a proposed source may not construct unless it demonstrates that it will not cause or contribute to a violation of any NAAQS. This statutory requirement is implemented through a provision contained in the PSD regulations at 40 CFR 51.166(k) and

[200] While the specifics of this case involved the 2015 ozone NAAQS, the case was based upon an interpretation of CAA section 165(a) and therefore applies equally to any PSD grandfathering for a new or revised NAAQS.

[201] Any proposed major stationary source or major modification triggering PSD requirements for $PM_{2.5}$ that does not receive its PSD permit by the effective date of a new nonattainment designation for the area where the source would locate would then be required to satisfy applicable NNSR preconstruction permit requirements for $PM_{2.5}$.

52.21(k).[202] If a source cannot make this demonstration, or if its initial air quality impact analysis shows that the source's impact would cause or contribute to a violation, a PSD permit may not be issued unless the permit applicant compensates for the adverse impact that would otherwise cause or contribute to a violation of the NAAQS. While the PSD regulations do not explicitly specify remedial actions that a prospective source can take to address such a situation, the EPA has historically recognized in regulations, and through other actions, that sources applying for PSD permits may utilize offsets as part of the required PSD demonstration under CAA section 165(a)(3)(B).[203]

Part D of title I of the CAA includes preconstruction review and permitting requirements applicable to new major stationary sources and major modifications located in areas designated nonattainment for a pollutant for which a NAAQS has been established (i.e., a criteria pollutant). The relevant part D requirements are typically referred to as the NNSR program. The EPA's regulations for the NNSR programs are contained in 40 CFR 51.165, 52.24 and part 51, Appendix S. Specifically, the EPA has developed minimum program requirements for an NNSR program that is approvable in a SIP, and those requirements, which include requirements for $PM_{2.5}$, are contained in 40 CFR 51.165. In addition, 40 CFR part 51, Appendix S contains

[202] 40 CFR 51.166(k) requires that SIPs shall "provide that the owner or operator of the proposed source or modification shall demonstrate that allowable emission increases from the proposed source or modification, in conjunction with all other applicable emissions increases or reductions (including secondary emissions), would not cause or contribute to air pollution in violation of: (i) Any national ambient air quality standard in any air quality control region; or (ii) Any applicable maximum allowable increase over the baseline concentration in any area.

[203] *See*, *e.g.*, Page, 2010 ; 44 FR 3274, 3278, January 16, 1979; See also *In re Interpower of New York, Inc.*, 5 E.A.D. 130, 141 (EAB 1994) (describing an EPA Region 2 PSD permit that relied in part on offsets to demonstrate the source would not cause or contribute to a violation of the NAAQS). 52 FR 24634, 24684, July 1, 1987; 78 FR 3085, 3261–62, Jan. 15, 2013. The EPA has recognized the ability of sources to obtain offsets in the context of PSD though the PSD provisions of the Act do not expressly reference offsets as the NNSR provisions of the Act do. *See* 80 FR 65292, 65441, October 26, 2015.

requirements constituting an interim NNSR program. This program enables NNSR permitting in nonattainment areas by states that lack a SIP-approved NNSR permitting program during the time between the date of the relevant designation and the date that the EPA approves into the SIP a NNSR program. *See* 40 CFR part 51, Appendix S, Part I; 40 CFR 52.24(k).

For NNSR, "major stationary source" is generally defined as a source with the potential to emit at least 100 tpy of the regulated NSR pollutant for which the area is designated nonattainment. In some cases, however, the CAA and the NNSR regulations define "major stationary source" for NNSR in terms of a lower rate dependent on the pollutant and degree of nonattainment in the area. For $PM_{2.5}$, in addition to the general threshold level of 100 tpy, a lower major source threshold of 70 tpy applies in Serious $PM_{2.5}$ nonattainment areas pursuant to subpart 4 of part D, title I of the CAA. *See* 40 CFR 51.165(a)(1)(iv)(A)(*1*)(*vii*) and (*viii*); 40 CFR part 51, Appendix S, II.A.4.(i)(a)(7) and (8).

Under the NNSR program, direct $PM_{2.5}$ emissions and emissions of each $PM_{2.5}$ precursor are reviewed separately in accordance with the applicable major source threshold. For example, the threshold for Serious $PM_{2.5}$ nonattainment areas is 70 tpy of direct $PM_{2.5}$, as well as for the $PM_{2.5}$ precursors $SO_2$, $NO_X$, VOC, and ammonia.[204] See 40 CFR 51.165(a)(1)(iv)(A)(1)(vii) and (viii); 40 CFR part 51, Appendix S, II.A.4.(i)(a)(7) and (8). For modifications, NNSR applies to proposed physical changes or changes in the method of operation of an existing stationary source where (1) the source is major for the nonattainment pollutant (or a precursor for that pollutant) and (2) the physical change or change in the method of operation of a major stationary source

[204] All recognized precursors to $PM_{2.5}$ are regulated as precursors for NNSR. *See* 40 CFR 51.165(a)(1)(xxxvii)(C)(*2*). No significant emission rate is established by the EPA for ammonia, and states are required to define "significant" for ammonia for their respective areas unless the state pursues the optional precursor demonstration to exclude ammonia from planning requirements. *See* 40 CFR 51.165(a)(1)(x)(F); 40 CFR 51.165(a)(13).

results, first, in a significant emissions increase of a regulated NSR pollutant and, second, in a significant net emissions increase of that same nonattainment pollutant (or same precursor for that pollutant). *See* 40 CFR 51.165(a)(1)(v)(A); 40 CFR part 51, Appendix S, II.A.5.(i).

For example, to qualify as a major modification for $SO_2$ (as a $PM_{2.5}$ precursor) in a moderate $PM_{2.5}$ nonattainment area, the existing source would have to have the potential to emit 100 tpy or more of $SO_2$, and the project would have to result in an increase in $SO_2$ emissions of 40 tpy or more. See 40 CFR 51.165(a)(1)(x)(A). New major stationary sources and major modifications for $PM_{2.5}$ subject to NNSR must comply with the "lowest achievable emission rate" (LAER) as defined in the CAA and NNSR rules, as well as performing other analyses as required under section 173 of the CAA.

Following the promulgation of any revised NAAQS for $PM_{2.5}$, some new nonattainment areas for $PM_{2.5}$ may result. Where a state does not have an NNSR program or where the current NNSR program does not apply to $PM_{2.5}$, that state will be required to submit the necessary SIP revisions to ensure that new major stationary sources and major modifications for $PM_{2.5}$ undergo preconstruction review pursuant to the NNSR program. States are required to submit nonattainment plans to provide for attainment and maintenance of a revised $PM_{2.5}$ NAAQS within 18 months from the effective date of nonattainment area designations as required under CAA section 189(a)(2)(B). Therefore, states whose existing NNSR program requirements, if any, cannot be interpreted to apply to the revised primary annual $PM_{2.5}$ NAAQS at that time will be allowed to issue the necessary permits in accordance with the applicable nonattainment permitting requirements contained in 40 CFR part 51, Appendix S, which would apply to the revised $PM_{2.5}$ NAAQS upon its effective date. *See* 73 FR 28321, 28340, May 16, 2008.

Finally, the EPA recommends that, where appropriate, PSD and NNSR permitting

authorities assess impacts to communities with environmental justice concerns. For example, this may include conducting a demographic analysis to inform development of a plan for community outreach and engagement, conducting a cumulative emissions impact analysis,[205] or considering the environmental and social costs imposed on the impacted community when conducting an alternative sites analysis.[206] Another option could be improving the understanding of the potential impact of minor sources by generating an emissions inventory for such minor sources, including sources that are not currently required to report emissions, to generate options on how emissions can be reduced in the target area. *See* 81 FR 58010, 58137. The EPA anticipates developing further information and consulting with permitting authorities on how to best address environmental justice in the permitting process.

*F. Transportation Conformity Program*

Transportation conformity is required under CAA section 176(c) to ensure that transportation plans, transportation improvement programs (TIPs) and federally supported highway and transit projects will not cause or contribute to any new air quality violation, increase the frequency or severity of any existing violation, or delay timely attainment or any required interim emissions reductions or other milestones. Transportation conformity applies to areas that are designated as nonattainment or nonattainment areas that have been redesignated to attainment with an approved CAA section 175A maintenance plan (i.e., maintenance areas) for

[205] The permitting authority may conduct a cumulative analysis of the projected $PM_{2.5}$ emissions from all emission units at the proposed facility and $PM_{2.5}$ emissions from nearby facilities, to provide a more complete assessment of the ambient air impacts of the proposed facility on affected communities. See 40 CFR Part 51, Appendix W, section 9.2.3.

[206] Section 173(a)(5) of the CAA requires for an NNSR permit "an analysis of alternative sites, sizes, production processes, and environmental control techniques for such proposed source [that] demonstrates that benefits of the proposed source significantly outweigh the environmental and social costs imposed as a result of its location, construction, or modification." This requirement is referred to as the "alternative sites analysis."

transportation-related criteria pollutants: carbon monoxide, ozone, $NO_2$, $PM_{2.5}$, and $PM_{10}$. Transportation conformity for any new or revised NAAQS for $PM_{2.5}$ does not apply until one year after the effective date of the nonattainment designation for that NAAQS. *See* CAA section 176(c)(6) and 40 CFR 93.102(d)). The EPA's Transportation Conformity Rule[207] establishes the criteria and procedures for determining whether transportation activities conform to the SIP. The EPA is not proposing changes to the transportation conformity rule in this proposed rulemaking. The EPA notes that the transportation conformity rule already addresses the $PM_{2.5}$ and $PM_{10}$ NAAQS. However, in the future, the EPA will review the need to issue or revise guidance describing how the current conformity rule applies in nonattainment and maintenance areas for any new or revised primary or secondary PM NAAQS, as needed.

*G. General Conformity Program*

The general conformity program implements CAA section 176(c) and requires that Federal agencies do not adopt, accept, approve, or fund activities that are not consistent with state air quality goals. General conformity applies to any federal action (e.g., funding, licensing, permitting, or approving) if 1) the action takes place in a nonattainment or maintenance area for any of the criteria pollutants and 2) it is not a Federal Highway Administration (FHWA) or Federal Transit Administration (FTA) project as defined in 40 CFR 93.101 (these projects are covered under the transportation conformity program described above).

The EPA's General Conformity Rule[208] establishes the criteria and procedures for determining if a federal action conforms to the applicable attainment plan. General conformity for any revised $PM_{2.5}$ NAAQS does not apply until one year after the effective date of the nonattainment designation for that NAAQS. The EPA is not proposing changes to the general

[207] 40 CFR part 93, subpart A
[208] 40 CFR 93.150 to 93.165

conformity rule in this proposed rulemaking. The EPA notes that the general conformity rule already addresses the $PM_{2.5}$ and $PM_{10}$ NAAQS.

## IX. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket. The EPA prepared an illustrative analysis of the potential costs and benefits associated with this action. This analysis is contained in the document, "Regulatory Impact Analysis for the Proposed Reconsideration of the National Ambient Air Quality Standards for Particulate Matter," which is available in the Regulatory Impact Analysis (RIA) docket (EPA–HQ–OAR–2019-0587) and briefly summarized below. The RIA estimates the costs and monetized human health benefits in 2032, after implementing existing and expected regulations and assessing emissions reductions to meet the current annual and 24-hour particulate matter NAAQS (12/35 $\mu g/m^3$), associated with applying national control strategies for the proposed annual and 24-hour alternative standard levels of 10/35 $\mu g/m^3$ and 9/35 $\mu g/m^3$, as well as the following two more stringent alternative standard levels: (1) an alternative annual standard level of 8 $\mu g/m^3$ in combination with the current 24-hour standard (i.e., 8/35 $\mu g/m^3$), and (2) an alternative 24-hour standard level of 30 $\mu g/m^3$ in combination with the proposed annual standard level of 10 $\mu g/m^3$ (i.e., 10/30 $\mu g/m^3$). . Table 2 provides a summary of the estimated monetized benefits, costs, and net benefits associated with applying national control strategies toward reaching alternative standard levels. However, the CAA and judicial

decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising NAAQS, although such factors may be considered in the development of state plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered in issuing this proposed rule.

Table 2 – Estimated Monetized Benefits, Costs, and Net Benefits of the Illustrative Control Strategies Applied Toward the Primary Alternative Annual and Daily Standard Levels of 10/35 $\mu g/m^3$, 10/30 $\mu g/m^3$, 9/35 $\mu g/m^3$, and 8/35 $\mu g/m^3$ in 2032 for the U.S. (millions of 2017$)

| | **10/35** | **10/30** | **9/35** | **8/35** |
|---|---|---|---|---|
| Benefits[a] | $8,500 and $17,000 | $9,600 and $20,000 | $21,000 and $43,000 | $46,000 and $95,000 |
| Costs[b] | $95 | $260 | $390 | $1,800 |
| Net Benefits | $8,400 and $17,000 | $9,300 and $19,000 | $20,000 and $43,000 | $44,000 and $93,000 |

Notes: Rows may not appear to add correctly due to rounding. We focus results to provide a snapshot of costs and benefits in 2032, using the best available information to approximate social costs and social benefits recognizing uncertainties and limitations in those estimates. The estimated costs and monetized human health benefits associated with applying national control strategies do not fully account for all the emissions reductions needed to reach the proposed and more stringent alternative standard levels for some standard levels analyzed.

[a] We assume that there is a cessation lag between the change in PM exposures and the total realization of changes in mortality effects. Specifically, we assume that some of the incidences of premature mortality related to $PM_{2.5}$ exposures occur in a distributed fashion over the 20 years following exposure, which affects the valuation of mortality benefits at different discount rates. Similarly, we assume there is a cessation lag between the change in PM exposures and both the development and diagnosis of lung cancer. The benefits are associated with two point estimates from two different epidemiologic studies, and we present the benefits calculated at a real discount rate of 3 percent. The benefits exclude additional health and welfare benefits that could not be quantified.

[b] The costs are annualized using a 7 percent interest rate.

*B. Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA. There are no information collection requirements directly associated with a proposed decision to revise or retain a NAAQS under section 109 of the CAA.

*C. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Rather, this proposed rule establishes national standards for allowable concentrations of PM in ambient air as required by section 109 of the CAA. See also *American Trucking*

*Associations v. EPA*, 175 F.3d 1027, 1044-45 (D.C. Cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities), rev'd in part on other grounds, *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001).

*D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain any unfunded mandate as described in the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531—1538, and does not significantly or uniquely affect small governments. Furthermore, as indicated previously, in setting a NAAQS the EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards, although such factors may be considered to a degree in the development of state plans to implement the standards. See also *American Trucking Associations* v. *EPA,* 175 F. 3d at 1043 (noting that because the EPA is precluded from considering costs of implementation in establishing NAAQS, preparation of the RIA pursuant to the Unfunded Mandates Reform Act would not furnish any information that the court could consider in reviewing the NAAQS).

The EPA acknowledges, however, that if corresponding revisions to associated SIP requirements and air quality surveillance requirements are proposed at a later time, those revisions might result in such effects. Any such effects would be addressed as appropriate if and when such revisions are proposed.

*E. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. However, the EPA recognizes that states will have a substantial interest in this action and any future revisions to associated requirements.

*F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes as tribes are not obligated to adopt or implement any NAAQS. In addition, tribes are not obligated to conduct ambient monitoring for PM or to adopt the ambient monitoring requirements of 40 CFR part 58. Thus, Executive Order 13175 does not apply to this action. However, consistent with the *EPA Policy on Consultation and Coordination with Indian Tribes*, the EPA will offer government-to-government consultation with tribes as requested.

*G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is subject to Executive Order 13045 because it is an economically significant regulatory action as defined by Executive Order 12866, and the EPA believes that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. The Policy on Children's Health also applies to this action. Accordingly, we have evaluated the environmental health or safety effects of PM exposures on children. The protection offered by these standards may be especially important for children because childhood represents a lifestage associated with increased susceptibility to PM-related health effects. Because children have been identified as a susceptible population, we have carefully evaluated the environmental health effects of exposure to PM pollution among children. Children make up a substantial fraction of the U.S. population, and often have unique factors that contribute to their increased risk of experiencing a health effect due to exposures to ambient air pollutants because of their continuous growth and development. As described in the 2019 Integrated Science Assessment, children may be particularly at risk for health effects related to ambient air $PM_{2.5}$ exposures compared with adults because they have (1) a developing respiratory system, (2) increased

ventilation rates relative to body mass compared with adults, and (3) an increased proportion of oral breathing, particularly in boys, relative to adults. More detailed information on the evaluation of the scientific evidence and policy considerations pertaining to children, including an explanation for why the Administrator judges the proposed standards to be requisite to protect public health, including the health of children, with an adequate margin of safety, are contained in sections II.B and II.D of this preamble. Copies of all documents have been placed in the public docket for this action.

*H. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution or Use*

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this action is to propose to revise the primary annual $PM_{2.5}$ NAAQS and to retain the primary 24-hour $PM_{2.5}$ NAAQS, primary $PM_{10}$ NAAQS, and secondary PM NAAQS. The action does not prescribe specific pollution control strategies by which these ambient standards and monitoring revisions will be met. Such strategies will be developed by states on a case-by-case basis, and the EPA cannot predict whether the control options selected by states will include regulations on energy suppliers, distributors, or users. Thus, the EPA concludes that this proposal does not constitute a significant energy action as defined in Executive Order 13211.

*I. National Technology Transfer and Advancement Act (NTTAA)*

This action involves technical standards. The EPA proposes to use the current indicators for fine ($PM_{2.5}$) and coarse ($PM_{10}$) particles. The indicator for fine particles is measured using the Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere (appendix L to 40 CFR part 50), which is known as the $PM_{2.5}$ FRM, and the indicator for coarse particles is measured using the Reference Method for the Determination of Particulate Matter as

$PM_{10}$ in the Atmosphere (appendix J to 40 CFR part 50), which is known as the $PM_{10}$ FRM.

To the extent feasible, the EPA employs a Performance-Based Measurement System (PBMS), which does not require the use of specific, prescribed analytic methods. The PBMS is defined as a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner. It is intended to be more flexible and cost effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. Though the FRM defines the particular specifications for ambient monitors, there is some variability with regard to how monitors measure PM, depending on the type and size of PM and environmental conditions. Therefore, it is not practically possible to fully define the FRM in performance terms to account for this variability. Nevertheless, our approach in the past has resulted in multiple brands of monitors being approved as FRM for PM, and we expect this to continue. Also, the FRMs described in 40 CFR part 50 and the equivalency criteria described in 40 CFR part 53, constitute a performance-based measurement system for PM, since methods that meet the field testing and performance criteria can be approved as FEMs. Since finalized in 2006 (71 FR 61236, October 17, 2006) the new field and performance criteria for approval of $PM_{2.5}$ continuous FEMs has resulted in the approval of 13 approved FEMs. In summary, for measurement of $PM_{2.5}$ and $PM_{10}$, the EPA relies on both FRMs and FEMs, with FEMs relying on a PBMS approach for their approval. The EPA is not precluding the use of any other method, whether it constitutes a voluntary consensus standard or not, as long as it meets the specified performance criteria.

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA believes that this action does **not** have disproportionately high and adverse

human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this assessment is contained in sections II.B.2, II.C.1, II.C.3, II.D.2, and II.D. of this preamble and also in the 2019 Integrated Science Assessment, Supplement to the 2019 Integrated Science Assessment, and Policy Assessment. The EPA has carefully evaluated the potential impacts on minority populations and low SES populations as discussed in sections II.B.2, II.C.1, II.C.3, II.D.2, and II.D.3 of the Supplemental Information section. The Integrated Science Assessment, Supplement to the Integrated Science Assessment, and Policy Assessment contain the evaluation of the scientific evidence, quantitative risk analyses and policy considerations that pertain to these populations. These documents are available as described in the Supplementary Information section of this preamble and copies of all documents have been placed in the public docket for this action.

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**List of Subjects**

**40 CFR Part 50**

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

**40 CFR Part 53**

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

**40 CFR Part 58**

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

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Dated:

_____

**Michael S. Regan**,
*Administrator*.

For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is proposed to be amended as follows:

## PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

1. The authority citation for part 50 continues to read as follows:

**Authority**: 42 U.S.C. 7401 *et seq.*

2. Add § 50.20 to read as follows:

### § 50.20 National primary ambient air quality standards for $PM_{2.5}$.

(a) The national primary ambient air quality standards for $PM_{2.5}$ are [9.0 to 10.0] micrograms per cubic meter ($\mu g/m^3$) annual arithmetic mean concentration and 35 $\mu g/m^3$ 24-hour average concentration measured in the ambient air as $PM_{2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers) by either:

(1) A reference method based on Appendix L of this part and designated in accordance with part 53 of this chapter; or

(2) An equivalent method designated in accordance with part 53 of this chapter.

(b) The primary annual $PM_{2.5}$ standard is met when the annual arithmetic mean concentration, as determined in accordance with Appendix N of this part, is less than or equal to [9.0 to 10.0] $\mu g/m^3$.

(c) The primary 24-hour $PM_{2.5}$ standard is met when the $98^{th}$ percentile 24-hour concentration, as determined in accordance with Appendix N of this part, is less than or equal to 35 $\mu g/m^3$.

3. Amend Appendix K to part 50 as follows:

a. In section 1.0, by revising paragraph (b);

b. In section 2.3, by adding a new paragraph (d); and

c. In section 3.0, by adding new paragraphs (a) and (b).

The revisions and additions read as follows.

**Appendix K to Part 50 - Interpretation of the National Ambient Air Quality Standards for Particulate Matter**

**1.0 General**

* * * * *

(b) The terms used in this appendix are defined as follows:

*Average* refers to the arithmetic mean of the estimated number of exceedances per year, as per section 3.1.

*Collocated monitors* refer to two or more air measurement instruments for the same parameter (e.g., $PM_{10}$ mass) operated at the same site location, and whose placement is consistent with part 53 of this chapter. For purposes of considering a combined site record in this appendix, when two or more monitors are operated at the same site, one monitor is designated as the "primary" monitor with any additional monitors designated as "collocated." It is implicit in these appendix procedures that the primary monitor and collocated monitor(s) are all reference or equivalent methods; however, it is not a requirement that the primary and collocated monitors utilize the same specific sampling and analysis method.

*Combined site data record* is the data set used for performing computations in this appendix and represents data for the primary monitors augmented with data from collocated monitors according to the procedure specified in section 3.0(a) of this appendix.

*Daily value for $PM_{10}$* refers to the 24-hour average concentration of $PM_{10}$ calculated or measured from midnight to midnight (local time).

*Exceedance* means a daily value that is above the level of the 24-hour standard after rounding to the nearest 10 $\mu g/m^3$ (i.e., values ending in 5 or greater are to be rounded up).

*Expected annual value* is the number approached when the annual values from an increasing number of years are averaged, in the absence of long-term trends in emissions or meteorological conditions.

*Primary monitors* are suitable monitors designated by a state or local agency in their annual network plan as the default data source for creating a combined site data record. If there is only one suitable monitor at a particular site location, then it is presumed to be a primary monitor.

*Year* refers to a calendar year.

* * * * *

**2.3 Data Requirements**

* * * * *

(d) 24-hour average concentrations will be computed from submitted hourly $PM_{10}$ concentration data for each corresponding day of the year and the result will be stored in the first, or start, hour (*i.e.*, midnight, hour '0') of the 24-hour period. A 24-hour average concentration shall be considered valid if at least 75 percent of the hourly averages (*i.e.*, 18 hourly values) for the 24-hour period are available. In the event that fewer than all 24 hourly average concentrations are available (*i.e.*, fewer than 24 but at least 18), the 24-hour average concentration shall be computed on the basis of the hours available using the number of available hours within the 24-hour period as the divisor (*e.g.*, the divisor is 19 if 19 hourly values are available). 24-hour periods with seven or more missing hours shall also be considered for computations in this appendix if, after substituting zero for all missing hourly concentrations, the resulting 24-hour

average daily value exceeds the level of the 24-hour standard specified in 40 CFR 50.6 after rounding to the nearest 10 $\mu g/m^3$.

* * * * *

**3.0 Computational Equations for the 24-Hour Standards**

(a) All computations shown in this appendix shall be implemented on a site-level basis. Site level concentration data shall be processed as follows:

(1) The default dataset for $PM_{10}$ mass concentrations for a site shall consist of the measured concentrations recorded from the designated primary monitor(s). All daily values produced by the primary monitor are considered part of the site record.

(2) If a daily value is not produced by the primary monitor for a particular day, but a value is available from a single collocated monitor, then that collocated monitor value shall be considered part of the combined site data record. If daily value data is available from two or more collocated monitors, the average of those collocated values shall be used as the daily value. The data record resulting from this procedure is referred to as the "combined site data record."

(b) In certain circumstances, including but not limited to site closures or relocations, data from two nearby sites may be combined into a single site data record for the purpose of calculating a valid design value. The appropriate Regional Administrator may approve such combinations if the Regional Administrator determines that the measured concentrations do not differ substantially between the two sites, taking into consideration factors such as distance between sites, spatial and temporal patterns in air quality, local emissions and meteorology, jurisdictional boundaries, and terrain features.

* * * * *

4. Amend Appendix L to Part 50 by:

a. Revising section 7.3.4; and

b. Adding paragraph 7.3.4.5.

The revision and addition read as follows:

**Appendix L to Part 50 - Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere**

* * * * *

7.3.4 ***Particle size separator.*** The sampler shall be configured with one of the three alternative particle size separators described in this section. One separator is an impactor-type separator (WINS impactor) described in sections 7.3.4.1, 7.3.4.2, and 7.3.4.3 of this appendix. One alternative separator is a cyclone-type separator (VSCC$^{TM}$) described in section 7.3.4.4 of this appendix. The other alternative separator is also a cyclone-type separator (TE-PM2.5C) described in section 7.3.4.5 of this appendix.

* * *

7.3.4.5 A second cyclone-type separator is identified as a Tisch TE-PM2.5C Cyclone particle size separator specified as part of EPA-designated reference method RFPS-1014-219 (80 FR 32114, June 5, 2015) and as manufactured by Tisch Environmental Incorporated, 145 S. Miami Avenue, Village of Cleves, Ohio 45002.

* * * * *

5. Amend Appendix N to Part 50 as follows:

a. In section 1.0, revise paragraph (a); and

b. In section 3.0(d), add paragraph (3); and

c. In section 4.1, revise paragraph (a); and

d. In section 4.2, revise paragraph (a).

The addition and revisions read as follows.

**Appendix N to Part 50 - Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$**

**1.0 General**

(a) This appendix explains the data handling conventions and computations necessary for determining when the national ambient air quality standards (NAAQS) for $PM_{2.5}$ are met, specifically the primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS specified in §§ 50.7, 50.13, 50.18, and 50.20. $PM_{2.5}$ is defined, in general terms, as particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers. $PM_{2.5}$ mass concentrations are measured in the ambient air by a Federal Reference Method (FRM) based on appendix L of this part, as applicable, and designated in accordance with part 53 of this chapter or by a Federal Equivalent Method (FEM) designated in accordance with part 53 of this chapter. Only those FRM and FEM measurements that are derived in accordance with part 58 of this chapter (i.e., that are deemed "suitable") shall be used in comparisons with the $PM_{2.5}$ NAAQS. The data handling and computation procedures to be used to construct annual and 24-hour NAAQS metrics from reported $PM_{2.5}$ mass concentrations, and the associated instructions for comparing these calculated metrics to the levels of the $PM_{2.5}$ NAAQS, are specified in sections 2.0, 3.0, and 4.0 of this appendix.

* * * * *

**3.0 Requirements for Data Use and Data Reporting for Comparisons with the NAAQS for $PM_{2.5}$**

* * * * *

(d) * * *

(3) In certain circumstances, including but not limited to site closures or relocations, data from two nearby sites may be combined into a single site data record for the purpose of calculating a valid design value. The appropriate Regional Administrator may approve such site combinations if the Regional Administrator determines that the measured concentrations do not differ substantially between the two sites, taking into consideration factors such as distance between sites, spatial and temporal patterns in air quality, local emissions and meteorology, jurisdictional boundaries, and terrain features.

* * * * *

**4.1 Annual $PM_{2.5}$ NAAQS**

(a) Levels of the primary and secondary annual $PM_{2.5}$ National Ambient Air Quality Standards are specified in §§ 50.7, 50.13, 50.18, and 50.20 as applicable.

* * * * *

**4.2 Twenty-four-hour $PM_{2.5}$ NAAQS**

(a) Levels of the primary and secondary 24-hour $PM_{2.5}$ National Ambient Air Quality Standards are specified in §§ 50.7, 50.13, 50.18, and 50.20 as applicable.

* * * * *

**PART 53— AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT METHODS**

6. The authority citation for Part 53 continues to read as follows:

**Authority:**

**Authority:** Sec. 301(a) of the Clean Air Act (42 U.S.C. 1857g(a)), as amended by sec. 15(c)(2) of Pub. L. 91-604, 84

Stat. 1713, unless otherwise noted.

**Subpart A [Amended]**

7. Amend §53.4 by:

a. Revising paragraph (a);

b. Adding paragraph (b)(7); and

c. Revising paragraph (d).

The revisions and addition read as follows:

**§ 53.4 Applications for reference or equivalent method determinations.**

(a) Applications for FRM or FEM determinations and Modification Requests of existing designated instruments shall be submitted to: Director, Center for Environmental Measurement and Modeling, Reference and Equivalent Methods Designation Program (MD-205-03), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711 (Commercial Delivery Address: 4930 Old Page Road, Durham, North Carolina 27703.)

* * * * *

(b) (7) All written materials for new FRM and FEM applications and Modification Requests must be submitted in English in MS Word format. For any calibration certificates originally written in a non-English language, the original non-English version of the certificate must be submitted to EPA along with a version of the certificate translated to English. All laboratory and field data associated with new FRM and FEM applications and Modification Requests must be submitted in MS Excel format. All worksheets in MS Excel must be unprotected to enable full inspection as part of the application review process.

* * * * *

(d) For candidate reference or equivalent methods or for designated instruments that are the subject of a Modification Request, the applicant, if requested by EPA, shall provide to EPA a representative sampler or analyzer for test purposes. The sampler or analyzer shall be shipped FOB destination to Director, Center for Environmental Measurements and Modeling, Reference and Equivalent Methods Designation Program (MD D205-03), U.S Environmental Protection Agency, 4930 Old Page Road, Durham, North Carolina, 27703, scheduled to arrive concurrently with or within 30 days of the arrival of the other application materials. This sampler or analyzer may be subjected to various tests that EPA determines to be necessary or appropriate under §53.5(f), and such tests may include special tests not described in this part. If the instrument submitted under this paragraph malfunctions, becomes inoperative, or fails to perform as represented in the application before the necessary EPA testing is completed, the applicant shall be afforded the opportunity to repair or replace the device at no cost to the EPA. Upon completion of EPA testing, the sampler or analyzer submitted under this paragraph shall be repacked by EPA for return shipment to the applicant, using the same packing materials used for shipping the instrument to EPA unless alternative packing is provided by the applicant. Arrangements for, and the cost of, return shipment shall be the responsibility of the applicant. The EPA does not warrant or assume any liability for the condition of the sampler or analyzer upon return to the applicant.

* * * * *

8. Section 53.8(a) is revised to read:

**§ 53.8 Designation of reference and equivalent methods.**

(a) A candidate method determined by the Administrator to satisfy the applicable requirements of this part shall be designated as a FRM or FEM (as applicable) by and upon publication of a

notice of the designation in the *Federal Register*. Applicants shall not publicly announce, market, or sell the candidate sampler and analyzer as an approved FRM or FEM (as applicable) until the *Federal Register* notice has been published.

* * * * *

9. Amend §53.14 by

a. Revising paragraphs (c)(4), (5) and (6) to read as follows:

**§ 53.14 Modification of a reference or equivalent method.**

* * * * *

(c) * * *

(4) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 90-day period shall commence upon receipt of the additional information).

(5) Send notice to the applicant that additional tests are necessary and specify which tests are necessary and how they shall be interpreted (in such cases, the 90-day period shall commence upon receipt of the additional test data).

(6) Send notice to the applicant that additional tests will be conducted by the Administrator and specify the reasons for and the nature of the additional tests (in such cases, the 90-day period shall commence 1 calendar day after the additional tests are completed).

* * * * *

10. Revise Table A-1 to Subpart A of Part 53 to read as follows:

**TABLE A–1 TO SUBPART A OF PART 53—SUMMARY OF APPLICABLE REQUIREMENTS FOR REFERENCE AND EQUIVALENT METHODS FOR AIR MONITORING OF CRITERIA POLLUTANTS**

| Pollutant | Reference or equivalent | Manual or automated | Applicable part 50 appendix | Applicable subparts of part 53 | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | A | B | C | D | E | F |
| $SO_2$..... | Reference..... | Manual ..... | A–2 | | | | | | |
| | | Automated ..... | A–1 | ✓ | ✓ | | | | |
| | Equivalent..... | Manual ..... | A–1 | ✓ | | ✓ | | | |
| | | Automated ..... | A–1 | ✓ | ✓ | ✓ | | | |
| CO..... | Reference ..... | Automated ..... | C | ✓ | ✓ | | | | |
| | Equivalent..... | Manual ..... | C | ✓ | | ✓ | | | |
| | | Automated ..... | C | ✓ | ✓ | ✓ | | | |
| $O_3$..... | Reference ..... | Automated ..... | D | ✓ | ✓ | | | | |
| | Equivalent..... | Manual ..... | D | ✓ | | ✓ | | | |
| | | Automated ..... | D | ✓ | ✓ | ✓ | | | |
| $NO_2$ ..... | Reference ..... | Automated ..... | F | ✓ | ✓ | | | | |
| | Equivalent ..... | Manual ..... | F | ✓ | | ✓ | | | |
| | | Automated ..... | F | ✓ | ✓ | ✓ | | | |
| Pb ..... | Reference ..... | Manual ..... | G | | | | | | |
| | Equivalent ..... | Manual ..... | G | ✓ | | ✓ | | | |
| | | Automated ..... | G | ✓ | | ✓ | | | |
| $PM_{10}$-Pb ... | Reference ..... | Manual ..... | Q | | | | | | |
| | Equivalent..... | Manual ..... | Q | ✓ | | ✓ | | | |
| | | Automated ..... | Q | ✓ | | ✓ | | | |
| $PM_{10}$ ..... | Reference ..... | Manual ..... | J | ✓ | | | ✓ | | |
| | Equivalent..... | Manual ..... | J | ✓ | | ✓ | ✓ | | |
| | | Automated..... | J | ✓ | | ✓ | ✓ | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| $PM_{2.5}$..... | Reference ..... | Manual ..... | L | ✓ | | | | ✓ | |
| | Equivalent Class I | Manual ..... | L | ✓ | | ✓ | | ✓ | |
| | Equivalent Class II | Manual ..... | L[1] | ✓ | | ✓[2] | | ✓ | ✓[1,2] |
| | Equivalent Class III | Automated..... | L[1] | ✓ | | ✓ | | ✓ | ✓[1] |
| $PM_{10-2.5}$..... | Reference ..... | Manual ..... | L, O[2] | ✓ | | | | ✓ | |
| | Equivalent Class I | Manual ..... | L, O[2] | ✓ | | ✓ | | ✓ | |
| | Equivalent Class II | Manual ..... | L, O[2] | ✓ | | ✓[2] | | ✓ | ✓[1,2] |
| | Equivalent Class III | Automated..... | L[1], O[1,2] | ✓ | | ✓ | | ✓ | ✓[1] |
| 1 Some requirements may apply, based on the nature of each particular candidate method, as determined by the Administrator.<br>2 Alternative Class III requirements may be substituted. | | | | | | | | | |

**Subpart B [Amended]**

11. Amend Table B-1 to Subpart B of Part 53 by revising Note 4 to read as follows:

**Table B-1 to Subpart B of Part 53- Performance Limit Specifications for Automated Methods**

* * * * *

"[4] For nitric oxide interference for the $SO_2$ UVF method, interference equivalent is ±0.003 ppm for the lower range."

12. Revise Table B-3 to Subpart B of Part 53 to read as follows:

**Table B-3 to Subpart B of Part 53 - Interferent Test Concentration, [1] Parts per Million**

| Pollutant | Analyzer type[2] | Hydro-chloric acid | Ammonia | Hydrogen sulfide | Sulfur dioxide | Nitrogen dioxide | Nitric oxide | Carbon dioxide | Ethylene | Ozone | M-xylene | Water vapor | Carbon monoxide | Methane | Ethane | Naphthalene |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| $SO_2$ | Ultraviolet fluorescence | | | [5] 0.1 | [4] 0.14 | 0.5 | 0.5 | | | 0.5 | 0.2 | 20,000 | | | | [6] 0.05 |
| $SO_2$ | Flame photometric | | | 0.01 | [4] 0.14 | | | 750 | | | | [3] 20,000 | 50 | | | |

| Pollutant | Analyzer type[2] | Hydro-chloric acid | Ammonia | Hydrogen sulfide | Sulfur dioxide | Nitrogen dioxide | Nitric oxide | Carbon dioxide | Ethylene | Ozone | M-xylene | Water vapor | Carbon monoxide | Methane | Ethane | Naphthalene |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| $SO_2$ | Gas chromatography | | | 0.1 | [4] 0.14 | | | 750 | | | | [3] 20,000 | 50 | | | |
| $SO_2$ | Spectrophotometric-wet chemical (pararosanaline) | 0.2 | 0.1 | 0.1 | [4] 0.14 | 0.5 | | 750 | | 0.5 | | | | | | |
| $SO_2$ | Electrochemical | 0.2 | 0.1 | 0.1 | [4] 0.14 | 0.5 | 0.5 | | 0.2 | 0.5 | | [3] 20,000 | | | | |
| $SO_2$ | Conductivity | 0.2 | 0.1 | | [4] 0.14 | 0.5 | | 750 | | | | | | | | |
| $SO_2$ | Spectrophotometric-gas phase, including DOAS | | | | [4] 0.14 | 0.5 | 0.5 | | | 0.5 | 0.2 | | | | | |
| $O_3$ | Ethylene Chemiluminescence | | | [3] 0.1 | | | | 750 | | [4] 0.08 | | [3] 20,000 | | | | |
| $O_3$ | NO-chemilumescence | | | [3] 0.1 | | 0.5 | | 750 | | [4] 0.08 | | [3] 20,000 | | | | |
| $O_3$ | Electrochemical | | [3] 0.1 | | 0.5 | 0.5 | | | | [4] 0.08 | | [3] 20,000 | | | | |
| $O_3$ | Spectrophotometric-wet chemical (potassium iodide) | | [3] 0.1 | | 0.5 | 0.5 | [3] 0.5 | | | [4] 0.08 | | | | | | |
| $O_3$ | Spectrophotometric-gas phase, including ultraviolet absorption and DOAS | | | | 0.5 | 0.5 | [3] 0.5 | | | [4] 0.08 | 0.02 | 20,000 | | | | |
| CO | Non-dispersive Infrared | | | | | | | 750 | | | | 20,000 | [4] 10 | | | |
| CO | Gas chromatography with flame ionization detector | | | | | | | | | | | 20,000 | [4] 10 | | 0.5 | |
| CO | Electrochemical | | | | | | 0.5 | | 0.2 | | | 20,000 | [4] 10 | | | |
| CO | Catalytic combustion-thermal detection | | 0.1 | | | | | 750 | 0.2 | | | 20,000 | [4] 10 | 5.0 | 0.5 | |
| CO | IR fluorescence | | | | | | | 750 | | | | 20,000 | [4] 10 | | 0.5 | |
| CO | Mercury replacement-UV photometric | | | | | | | | 0.2 | | | | [4] 10 | | 0.5 | |
| $NO_2$ | Chemiluminescent | | [3] 0.1 | | 0.5 | [4] 0.1 | 0.5 | | | | | 20,000 | | | | |
| $NO_2$ | Spectrophotometric-wet chemical (azo-dye reaction) | | | | 0.5 | [4] 0.1 | 0.5 | 750 | | 0.5 | | | | | | |
| $NO_2$ | Electrochemical | 0.2 | [3] 0.1 | | 0.5 | [4] 0.1 | 0.5 | 750 | | 0.5 | | 20,000 | 50 | | | |
| $NO_2$ | Spectrophotometric-gas phase | | [3] 0.1 | | 0.5 | [4] 0.1 | 0.5 | | | 0.5 | | 20,000 | 50 | | | |

[1] Concentrations of interferent listed must be prepared and controlled to ±10 percent of the stated value.

| Pollutant | Analyzer type[2] | Hydro-chloric acid | Ammonia | Hydrogen sulfide | Sulfur dioxide | Nitrogen dioxide | Nitric oxide | Carbon dioxide | Ethylene | Ozone | M-xylene | Water vapor | Carbon monoxide | Methane | Ethane | Naphthalene |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

[2] Analyzer types not listed will be considered by the Administrator as special cases.
[3] Do not mix interferent with the pollutant.
[4] Concentration of pollutant used for test. These pollutant concentrations must be prepared to ±10 percent of the stated value.
[5] If candidate method utilizes an elevated-temperature scrubber for removal of aromatic hydrocarbons, perform this interference test.
[6] If naphthalene test concentration cannot be accurately quantified, remove the scrubber, use a test concentration that causes a full-scale response, reattach the scrubber, and evaluate response for interference.

* * * * *

13. In Appendix A to Subpart B of Part 53, revise Figures B-3 and B-5 as follows:

Appendix A to Subpart B of Part 53 - Optional Forms for Reporting Test Results

* * * * *

**LDL and INTERFERENCE TEST DATA**

Applicant_____ Date_____

Analyzer_____ Pollutant_____

| TEST PARAMETER | | READING or CALCULATION | TEST NUMBER | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| LOWER DETECTABLE LIMIT | | $B_Z$ | | | | | | | | | | | | | | | |
| | | $B_L$ | | | | | | | | | | | | | | | |
| | | LDL = $B_L - B_Z$ | | | | | | | | | | | | | | | |
| INTER-FERENCE EQUIV-ALENT | 1 | $R_1$ | | | | | | | | | | | | | | | |
| | | $R_{i1}$ | | | | | | | | | | | | | | | |
| | | $IE = R_{i1} - R_1$ | | | | | | | | | | | | | | | |
| | 2 | $R_2$ | | | | | | | | | | | | | | | |
| | | $R_{i2}$ | | | | | | | | | | | | | | | |
| | | $IE = R_{i2} - R_2$ | | | | | | | | | | | | | | | |
| | 3* | $R_3$ | | | | | | | | | | | | | | | |
| | | $R_{i3}$ | | | | | | | | | | | | | | | |
| | | $IE = R_{i3} - R_3$ | | | | | | | | | | | | | | | |
| | 4* | $R_4$ | | | | | | | | | | | | | | | |
| | | $R_{i4}$ | | | | | | | | | | | | | | | |
| | | $IE = R_{i4} - R_4$ | | | | | | | | | | | | | | | |
| | 5* | $R_5$ | | | | | | | | | | | | | | | |
| | | $R_{i5}$ | | | | | | | | | | | | | | | |
| | | $IE = R_{i5} - R_5$ | | | | | | | | | | | | | | | |
| | TOTAL* | $\sum_{i=1}^{n} \lvert IE_i \rvert$ | | | | | | | | | | | | | | | |

*If required.

Figure B-3
Form for test data and calculations for lower detectable limit (LDL) and interference equivalent (IE)
(see § 53.23(c) and (d)).

* * * * *

**CALCULATION OF ZERO DRIFT, SPAN DRIFT, AND PRECISION**

Applicant_____ Date_____

Analyzer_____ Pollutant_____

| TEST PARAMETER | | CALCULATION | TEST DAY (n) | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| ZERO DRIFT | 12 HOUR | $12ZD = C_{max} - C_{min}$ | | | | | | | | | | | | | | | |
| | 24 HOUR | $Z = (L_1 + L_2)/2$ | | | | | | | | | | | | | | | |
| | | $24ZD = Z_n - Z_{n-1}$ | | | | | | | | | | | | | | | |
| | | $24ZD = Z'_n - Z'_{n-1}$ | | | | | | | | | | | | | | | |
| SPAN DRIFT | 24 HOUR | $S_n = \frac{1}{6}\sum_{i=7}^{12} P_i$ | | | | | | | | | | | | | | | |
| | | $SD_n = \frac{S_n - S_{n-1}}{S_{n-1}} \times 100\%$ | | | | | | | | | | | | | | | |
| | | $SD_n = \frac{S_n - S'_{n-1}}{S'_{n-1}} \times 100\%$ | | | | | | | | | | | | | | | |
| PREC-ISION | 20% URL ($P_{20}$) | P20 = % STANDARD DEVIATION of ($P_1 \ldots P_6$) | | | | | | | | | | | | | | | |
| | 80% URL ($P_{80}$) | P20 = % STANDARD DEVIATION of ($P_7 \ldots P_{12}$) | | | | | | | | | | | | | | | |

Figure B-5
Form for calculating zero drift, span drift and precision (see §53.23(e)).

* * * * *

## Subpart C [Amended]

14. Revise §53.35(b)(1)(ii)(D) to read as follows:

## § 53.35 Test procedure for Class II and Class III methods for $PM_{2.5}$ and $PM_{10-2.5}$.

* * * * *

(b) ***

(1) ***

(ii) ***

(D) Site D shall be in a large city east of the Mississippi River, having characteristically high humidity levels.

* * * * *

15. Revise Table C-4 to Subpart C of Part 53 to read as follows:

| TABLE C-4 TO SUBPART C OF PART 53 —TEST SPECIFICATIONS FOR $PM_{10}$, $PM_{2.5}$ AND $PM_{10-2.5}$ CANDIDATE EQUIVALENT METHODS | | | | | | |
|---|---|---|---|---|---|---|
| **Specification** | **$PM_{10}$** | **$PM_{2.5}$** | | | **$PM_{10-2.5}$** | |
| | | **Class I** | **Class II** | **Class III** | **Class II** | **Class III** |
| Acceptable concentration range ($R_j$), $\mu g/m^3$. | 5-300 | 3-200 | 3-200 | 3-200 | 3-200 | 3-200 |
| Minimum number of test sites. | 2 | 1 | 2 | 4 | 2 | 4 |
| Minimum number of candidate method samplers or analyzers per site. | 3 | 3 | 3[1] | 3[1] | 3[1] | 3[1] |
| Number of reference method samplers per site. | 3 | 3 | 3[1] | 3[1] | 3[1] | 3[1] |
| Minimum number of acceptable sample sets per site for $PM_{10}$ methods: | | | | | | |
| $R_j < 20$ $\mu g/m^3$ ..... | 3 | | | | | |
| $R_j > 20$ $\mu g/m^3$ ..... | 3 | | | | | |
| Total ..... | 10 | | | | | |
| Minimum number of acceptable sample sets per site for $PM_{2.5}$ and $PM_{10-2.5}$ candidate equivalent methods: | | | | | | |
| $R_j < 15$ $\mu g/m^3$ for 24-hr or $R_j < 8$ $\mu g/m^3$ for 48-hr samples. | | 3 | 3 | 3 | 3 | 3 |
| Rj > 15 $\mu g/m^3$ for 24-hr or $R_j > 8$ $\mu g/m^3$ for 48-hr samples. | | 3 | 3 | 3 | 3 | 3 |
| Each season ..... | | 10 | 23 | 23 | 23 | 23 |
| Total, each site ..... | | 10 | 23 | 23 (46 for two-season sites) | 23 | 23 (46 for two- |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | season sites) |
| Precision of replicate reference method measurements, $P_{Rj}$ or $RP_{Rj}$, respectively; RP for Class II or III $PM_{2.5}$ or $PM_{10–2.5}$, maximum. | 5 μg/m$^3$ or 7%. | 2 μg/m$^3$ or 5%. | 10%[2] ... | 10%[2] ... | 10%[2] ... | 10%[2] ... |
| Precision of $PM_{2.5}$ or $PM_{10–2.5}$ candidate method, CP, each site. | | | 10%[2] ... | 15%[2] ... | 15%[2] ... | 15%[2] ... |
| Slope of regression relationship. | 1 ±0.10 | 1 ±0.05 | 1 ±0.10 | 1 ±0.10 | 1 ±0.10 | 1 ±0.12 |
| Intercept of regression relationship, μg/m$^3$. | 0 ±5 ..... | 0 ±1 ..... | Between: 13.55 – (15.05 × slope), but not less than – 1.5; and 16.56 – (15.05 × slope), but not more than +1.5 | Between: 15.05 – (17.32 × slope), but not less than – 2.0; and 15.05 – (13.20 × slope), but not more than +2.0 | Between: 62.05 – (70.5 × slope), but not less than – 3.5; and 78.95 – (70.5 × slope), but not more than +3.5 | Between: 70.50 – (82.93 × slope), but not less than – 7.0; and 70.50 – (61.16 × slope), but not more than +7.0 |
| Correlation of reference method and candidate method measurements. | ≥ 0.97 | ≥ 0.97 | ≥ 0.93—for CCV ≤ 0.4;<br>≥ 0.85 + 0.2 × CCV—for 0.4 ≤ CCV ≤ 0.5;<br>≥ 0.95—for CCV ≥ 0.5 | | | |
| 1 Some missing daily measurement values may be permitted; see test procedure.<br>2 Calculated as the root mean square over all measurement sets. | | | | | | |

**Subpart D [Amended]**

16. Amend §53.43(a)(2)(xvi) and (c)(2)(iv)by revising the formulas to read as follows:

**§53.43 Test procedures.**

**(a)** ***

**(2)** ***

**(xvi)** ***

$$CV_E = \left. \sqrt{\frac{\sum_{i=1}^{n} E^2(i) - \frac{1}{n}\left(\sum_{i=1}^{n} E\,(i)\right)^2}{n-1}} \right/ \bar{E}$$

* * * * *

(c) ***

(2) ***

(iv) ***

$$Pj = \sqrt{\frac{\sum_{i=1}^{3} C^2(i)(j) - \frac{1}{3}\left(\sum_{i=1}^{3} C\,(i)(j)\right)^2}{2}}$$

* * * * *

$$RP_j = \ 100\%\ x \sqrt{\frac{\sum_{i=1}^{3} C^2(i)\ (j) - \frac{1}{3}\left(\sum_{i=1}^{3} C\ (i)(j)\right)^2}{2}} \Bigg/ \overline{C}_{(j)}$$

* * * * *

**Subpart E [Amended]**

17. In § 53.51(d), revise paragraph (2) to read as follows:

**§ 53.51 Demonstration of compliance with design specifications and manufacturing and test requirements.**

* * * * *

(d) * * *

(2) VSCC and TE-PM2.5C separators. For samplers and monitors utilizing the BGI VSCC or Tisch TE-PM2.5C particle size separators specified in appendix L of paragraphs 7.3.4.4 and 7.3.4.5, respectively, the respective manufacturers shall identify the critical dimensions and manufacturing tolerances for the separator, devise appropriate test procedures to verify that the critical dimensions and tolerances are maintained during the manufacturing process, and carry out those procedures on each separator manufactured to verify conformance of the manufactured products. The manufacturer shall also maintain records of these tests and their test results and submit evidence that this procedure is incorporated into the manufacturing procedure, that the test is or will be routinely implemented, and that an appropriate procedure is in place for the disposition of units that fail this tolerance tests.

* * * * *

**Subpart F [Amended]**

18.. In §53.61, revise the heading of paragraph (g);

revise paragraph (g)(1) and (g)(2)(i); and

add paragraph (g)(2)(iii) to read as follows:

**§53.61 Test conditions.**

* * * * *

(g) *Vibrating Orifice Aerosol Generator (VOAG) and Flow-Focusing Monodisperse Aerosol Generator (FMAG) conventions.* * * *

(1) *Particle aerodynamic diameter*. The VOAG and FMAG produce near-monodisperse droplets through the controlled breakup of a liquid jet. When the liquid solution consists of a non-volatile solute dissolved in a volatile solvent, the droplets dry to form particles of near-monodisperse size.

(i) The physical diameter of a generated spherical particle can be calculated from the operational parameters of the VOAG and FMAG as:

* * *

(2) * * *

(i) Solid particle tests performed in this subpart shall be conducted using particles composed of ammonium fluorescein. For use in the VOAG or FMAG, liquid solutions of known volumetric concentration can be prepared by diluting fluorescein powder ($C_2OH_{12}O_5$, FW = 332.31, CAS 2321-07-5) with aqueous ammonia. Guidelines for preparation of fluorescein solutions of the desired volume concentration ($C_{vol}$) are presented in Vanderpool and Rubow (1988) (Reference 2 in appendix A of this subpart). For purposes of converting particle physical

diameter to aerodynamic diameter, an ammonium fluorescein particle density of 1.35 g/cm$^3$ shall be used.

* * * * *

(iii) Calculation of the physical diameter of the particles produced by the VOAG and FMAG requires knowledge of the liquid solution's volume concentration ($C_{vol}$). Because uranine is essentially insoluble in oleic acid, the total particle volume is the sum of the oleic acid volume and the uranine volume. The volume concentration of the liquid solution shall be calculated as:

* * * * *

19. In §53.62, revise paragraph (e)(1) to read as follows:

**§53.62 Test procedure: Full wind tunnel test.**

* * * * *

(e) *Calculations*-

*(1) Graphical treatment of effectiveness data*. For each wind speed given in table F-2 of this subpart, plot the particle average sampling effectiveness of the candidate sampler as a function of aerodynamic diameter (Dae) on semi-logarithmic graph paper where the aerodynamic particle diameter is the particle size established by the parameters of the VOAG or FMAG in conjunction with the known particle density. Construct a best-fit, smooth curve through the data by extrapolating the sampling effectiveness curve through 100 percent at an aerodynamic diameter of 0.5 µm and 0 percent at an aerodynamic diameter of 10 µm. Correction for this presence of multiplets shall be performed using the techniques presented by

Marple, et al. (1987). This multiplet-corrected effectiveness curve shall be used for all remaining calculations in this paragraph (e).

20. Revise Table F-1 to Subpart F of Part 53 to read as follows:

**Table F-1 to Subpart F of Part 53 - Performance Specifications for $PM_{2.5}$ Class II Equivalent Samplers**

| Performance test | Specifications | Acceptance criteria |
|---|---|---|
| § 53.62 Full Wind Tunnel Evaluation | Solid VOAG or FMAG produced aerosol at 2 km/hr and 24 km/hr | $Dp_{50}$ = 2.5 µm ±0.2 µm Numerical Analysis Results: 95% ≤$R_c$ ≤105%. |
| § 53.63 Wind Tunnel Inlet Aspiration Test | Liquid VOAG or FMAG produced aerosol at 2 km/hr and 24 km/hr | Relative Aspiration: 95% ≤A ≤105%. |
| § 53.64 Static Fractionator Test | Evaluation of the fractionator under static conditions | $Dp_{50}$ = 2.5 µm ±0.2 µm Numerical Analysis Results: 95% ≤$R_c$ ≤105%. |
| § 53.65 Loading Test | Loading of the clean candidate under laboratory conditions | Acceptance criteria as specified in the post-loading evaluation test (§ 53.62, § 53.63, or § 53.64). |
| § 53.66 Volatility Test | Polydisperse liquid aerosol produced by air nebulization of A.C.S. reagent grade glycerol, 99.5% minimum purity | Regression Parameters Slope = 1 ±0.1, Intercept = 0 ±0.15 mg, r ≥0.97. |

**PART 58—AMBIENT AIR QUALITY SURVEILLANCE**

21. The authority citation for part 58 continues to read as follows:

**Authority:** 42 U.S.C. 7403, 7405, 7410, 7414, 7601, 7611, 7614, and 7619.

**Subpart A – General Provisions**

22. In § 58.1, remove the definition for "Approved Regional Method (ARM)" and revise the definition for "Traceable."

The revision reads as follows:

**§ 58.1 Definitions.**

* * * * *

*Traceable* means a measurement result from a local standard whereby the result can be related to the International System of Units (SI) through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty. Traceable measurement results must be compared and certified, either directly or via not more than one intermediate standard, to a National Institute of Standards and Technology (NIST)-certified reference standard. Examples include but are not limited to NIST Standard Reference Material (SRM), NIST-traceable Reference Material (NTRM), or a NIST-certified Research Gas Mixture (RGM). Traceability to the SI through other National Metrology Institutes (NMIs) in addition to NIST is allowed if a Declaration of Equivalence (DoE) exists between NIST and that NMI.

* * * * *

**Subpart B Monitoring Network**

23. In §58.10, revise paragraphs (a)(1), (b)(10), (b)(13), add paragraph (b)(14), and revise paragraph (d) to read as follows:

**§58.10 Annual monitoring network plan and periodic network assessment.**

(a)

(1) Beginning July 1, 2007, the state, or where applicable local, agency shall submit to the Regional Administrator an annual monitoring network plan which shall provide for the documentation of the establishment and maintenance of an air quality surveillance system that consists of a network of SLAMS monitoring stations that can include FRM and FEM monitors that are part of SLAMS, NCore, CSN, PAMS, and SPM stations. The plan shall include a statement of whether the operation of each monitor meets the requirements of appendices A, B, C, D, and E of this part, where applicable. The Regional Administrator may require additional information in support of this statement. The annual monitoring network plan must be made available for public inspection and comment for at least 30 days prior to submission to the EPA and the submitted plan shall include and address, as appropriate, any received comments.

* * * * *

(b) * * *

(10) Any monitors for which a waiver has been requested or granted by the EPA Regional Administrator as allowed for under Appendix D or Appendix E to 40 CFR part 58. For those monitors where a waiver has been approved, the annual monitoring network plan shall include the date the waiver was approved.

* * * * *

(13) The identification of any $PM_{2.5}$ FEMs used in the monitoring agency's network where the data are not of sufficient quality such that data are not to be compared to the NAAQS. For required SLAMS where the agency identifies that the $PM_{2.5}$ Class III FEM does not produce data of sufficient quality for comparison to the NAAQS, the monitoring agency must ensure that an operating FRM or filter-based FEM meeting the sample frequency requirements described in

§ 58.12 or other Class III $PM_{2.5}$ FEM with data of sufficient quality is operating and reporting data to meet the network design criteria described in appendix D to this part.

(14) The identification of any site(s) intended to address being "…sited in an at-risk community where there are anticipated effects from sources in the area" as required in appendix D section 4.7.1(b)(3) of this part. An initial approach to the question of whether any new or moved sites are needed and to identify the communities in which they intend to add monitoring for meeting this requirement, if applicable, shall be submitted in accordance with the requirements of appendix D paragraph 4.7.1(b)(3) of this part which includes submission to the EPA Regional Administrator no later than July 1, 2024. Specifics on the resulting proposed new or moved sites for $PM_{2.5}$ network design to address at-risk communities, if applicable, would need to be detailed in annual monitoring network plans due to each applicable EPA Regional office no later than July 1, 2025 (40 CFR 58.10). The plan shall provide for any required sites to be operational no later than 24 months from date of approval of a plan or January 1, 2027, whichever comes first.

* * * * *

(d) The state, or where applicable local, agency shall perform and submit to the EPA Regional Administrator an assessment of the air quality surveillance system every 5 years to determine, at a minimum, if the network meets the monitoring objectives defined in appendix D to this part, whether new sites are needed, whether existing sites are no longer needed and can be terminated, and whether new technologies are appropriate for incorporation into the ambient air monitoring network. The network assessment must consider the ability of existing and proposed sites to support air quality characterization for areas with relatively high populations of susceptible individuals (e.g., children with asthma) and other at-risk populations, and, for any sites that are

being proposed for discontinuance, the effect on data users other than the agency itself, such as nearby states and tribes or health effects studies. The state, or where applicable local, agency must submit a copy of this 5-year assessment, along with a revised annual network plan, to the Regional Administrator. The assessments are due every five years beginning July 1, 2010.

* * * * *

24. In §58.11, revise paragraphs (a)(2) and (e) to read as follows:

**§58.11 Network technical requirements.**

(a)* * *

(2) Beginning January 1, 2009, State and local governments shall follow the quality assurance criteria contained in appendix A to this part that apply to SPM sites when operating any SPM site which uses an FRM or an FEM and meets the requirements of appendix E to this part, unless the Regional Administrator approves an alternative to the requirements of appendix A with respect to such SPM sites because meeting those requirements would be physically and/or financially impractical due to physical conditions at the monitoring site and the requirements are not essential to achieving the intended data objectives of the SPM site. Alternatives to the requirements of appendix A may be approved for an SPM site as part of the approval of the annual monitoring plan, or separately.

* * * * *

(e) State and local governments must assess data from Class III $PM_{2.5}$ FEM monitors operated within their network using the performance criteria described in table C-4 to subpart C of part 53 of this chapter, for cases where the data are identified as not of sufficient comparability to a collocated FRM, and the monitoring agency requests that the FEM data should not be used in comparison to the NAAQS. These assessments are required in the monitoring agency's annual

monitoring network plan described in § 58.10(b) for cases where the FEM is identified as not of sufficient comparability to a collocated FRM. For these collocated $PM_{2.5}$ monitors, the performance criteria apply with the following additional provisions:

(1) The acceptable concentration range (Rj), $\mu g/m^3$ may include values down to 0 $\mu g/m^3$.

(2) The minimum number of test sites shall be at least one; however, the number of test sites will generally include all locations within an agency's network with collocated FRMs and FEMs.

(3) The minimum number of methods shall include at least one FRM and at least one FEM.

(4) Since multiple FRMs and FEMs may not be present at each site, the precision statistic requirement does not apply, even if precision data are available.

(5) All seasons must be covered with no more than 36 consecutive months of data in total aggregated together.

(6) The key statistical metric to include in an assessment is the bias (both additive and multiplicative) of the $PM_{2.5}$ continuous FEM(s) compared to a collocated FRM(s). Correlation is required to be reported in the assessment, but failure to meet the correlation criteria, by itself, is not cause to exclude data from a continuous FEM monitor.

* * * * *

25. In §58.12, revise paragraphs (d)(1) and (3) to read as follows:

**§58.12 Operating schedules.**

* * * * *

(d)* * *

(1)

(i) Manual $PM_{2.5}$ samplers at required SLAMS stations without a collocated continuously

operating $PM_{2.5}$ monitor must operate on at least a 1-in-3 day schedule unless a waiver for an alternative schedule has been approved per paragraph (d)(1)(ii) of this section.(ii) For SLAMS $PM_{2.5}$ sites with both manual and continuous $PM_{2.5}$ monitors operating, the monitoring agency may request approval for a reduction to 1-in-6 day $PM_{2.5}$ sampling or for seasonal sampling from the EPA Regional Administrator. Other requests for a reduction to 1-in-6 day $PM_{2.5}$ sampling or for seasonal sampling may be approved on a case-by-case basis. The EPA Regional Administrator may grant sampling frequency reductions after consideration of factors (including but not limited to the historical $PM_{2.5}$ data quality assessments, the location of current $PM_{2.5}$ design value sites, and their regulatory data needs) if the Regional Administrator determines that the reduction in sampling frequency will not compromise data needed for implementation of the NAAQS. Required SLAMS stations whose measurements determine the design value for their area and that are within plus or minus 10 percent of the annual NAAQS, and all required sites where one or more 24-hour values have exceeded the 24-hour NAAQS each year for a consecutive period of at least 3 years are required to maintain at least a 1-in-3 day sampling frequency until the design value no longer meets these criteria for 3 consecutive years. A continuously operating FEM $PM_{2.5}$ monitor satisfies this requirement unless it is identified in the monitoring agency's annual monitoring network plan as not appropriate for comparison to the NAAQS and the EPA Regional Administrator has approved that the data from that monitor may be excluded from comparison to the NAAQS.

* * * * *

(iii) Required SLAMS stations whose measurements determine the 24-hour design value for their area and whose data are within plus or minus 5 percent of the level of the 24-hour $PM_{2.5}$ NAAQS must have an FRM or FEM operate on a daily schedule if that area's design value for

the annual NAAQS is less than the level of the annual $PM_{2.5}$ standard. A continuously operating FEM or $PM_{2.5}$ monitor satisfies this requirement unless it is identified in the monitoring agency's annual monitoring network plan as not appropriate for comparison to the NAAQS and the EPA Regional Administrator has approved that the data from that monitor may be excluded from comparison to the NAAQS. The daily schedule must be maintained until the referenced design values no longer meets these criteria for 3 consecutive years.(iv) Changes in sampling frequency attributable to changes in design values shall be implemented no later than January 1 of the calendar year following the certification of such data as described in §58.15.

* * * * *

26. Revise §58.15 to read as follows:

**§58.15 Annual air monitoring data certification.**

(a) The state, or where appropriate local, agency shall submit to the EPA Regional Administrator an annual air monitoring data certification letter to certify data collected by FRM and FEM monitors at SLAMS and SPM sites that meet criteria in appendix A to this part from January 1 to December 31 of the previous year. The head official in each monitoring agency, or his or her designee, shall certify that the previous year of ambient concentration and quality assurance data are completely submitted to AQS and that the ambient concentration data are accurate to the best of her or his knowledge, taking into consideration the quality assurance findings. The annual data certification letter is due by May 1 of each year.

(b) Along with each certification letter, the state shall submit to the Regional Administrator an annual summary report of all the ambient air quality data collected by FRM and FEM monitors at SLAMS and SPM sites. The annual report(s) shall be submitted for data collected from January 1 to December 31 of the previous year. The annual summary serves as the record of the

specific data that is the object of the certification letter.

(c) Along with each certification letter, the state shall submit to the Regional Administrator a summary of the precision and accuracy data for all ambient air quality data collected by FRM and FEM monitors at SLAMS and SPM sites. The summary of precision and accuracy shall be submitted for data collected from January 1 to December 31 of the previous year.

* * * * *

**Subpart C- [Amended]**

27. In §58.20, revise paragraphs (b), (c), (d) and (e) to read as follows: **§ 58.20 Special purpose monitors (SPM).**

* * * * *

(b) Any SPM data collected by an air monitoring agency using a Federal reference method (FRM) or Federal equivalent method (FEM) must meet the requirements of § 58.11, § 58.12, and appendix A to this part or an approved alternative to appendix A to this part. Compliance with appendix E to this part is optional but encouraged except when the monitoring agency's data objectives are inconsistent with those requirements. Data collected at an SPM using a FRM or FEM meeting the requirements of appendix A must be submitted to AQS according to the requirements of § 58.16. Data collected by other SPMs may be submitted. The monitoring agency must also submit to AQS an indication of whether each SPM reporting data to AQS monitor meets the requirements of appendices A and E to this part.

(c) All data from an SPM using an FRM or FEM which has operated for more than 24 months are eligible for comparison to the relevant NAAQS, subject to the conditions of §§ 58.11(e) and 58.30, unless the air monitoring agency demonstrates that the data came from a

particular period during which the requirements of appendix A, appendix C, or appendix E to this part were not met, subject to review and EPA Regional Office approval as part of the annual monitoring network plan described in § 58.10.

(d) If an SPM using an FRM or FEM is discontinued within 24 months of start-up, the Administrator will not base a NAAQS violation determination for the $PM_{2.5}$ or ozone NAAQS solely on data from the SPM.

(e) If an SPM using an FRM or FEM is discontinued within 24 months of start-up, the Administrator will not designate an area as nonattainment for the CO, $SO_2$, $NO_2$, or 24-hour $PM_{10}$ NAAQS solely on the basis of data from the SPM. Such data are eligible for use in determinations of whether a nonattainment area has attained one of these NAAQS.

* * * * *

28. Amend Appendix A to Part 58 by:

a. Revising paragraph 2.6.1 and adding paragraphs 2.6.1.1 and 2.6.1.2;

b. Removing paragraph 3.1.2.2 and renumbering paragraphs 3.1.2.3, 3.1.2.4, 3.1.2.5 and 3.1.2.6 to 3.1.2.2, 3.1.2.3, 3.1.2.4 and 3.1.2.5 respectively;

c. Revising paragraphs 3.1.3.3, 3.2.4, 4.2.1, and 4.2.5; and

d. In Section 6 by revising References 1, 4, 6, 7, 9, 10 and 11, and Table A-.

The revisions and additions read as follows:

**Appendix A to Part 58 - Quality Assurance Requirements for Monitors used in Evaluations of National Ambient Air Quality Standards**

* * * * *

2.6.1. Gaseous pollutant concentration standards (permeation devices or cylinders of compressed gas) used to obtain test concentrations for CO, $SO_2$, NO, and $NO_2$ must be EPA Protocol Gases certified in accordance with one of the procedures given in Reference 4 of this appendix.

2.6.1.1 The concentrations of EPA Protocol Gas standards used for ambient air monitoring must be certified with a 95-percent confidence interval to have an analytical uncertainty of no more than ±2.0 percent (inclusive) of the certified concentration (tag value) of the gas mixture. The uncertainty must be calculated in accordance with the statistical procedures defined in Reference 4 of this appendix.

2.6.1.2 Specialty gas producers advertising certification with the procedures provided in Reference 4 of this appendix and distributing gases as "EPA Protocol Gas" for ambient air monitoring purposes must adhere to the regulatory requirements specified in 40 CFR Part 75.21(g) or not use "EPA" in any form of advertising. Monitoring organizations must provide information to the EPA on the specialty gas producers they use on an annual basis. PQAOs, when requested by the EPA, must participate in the EPA Ambient Air Protocol Gas Verification Program at least once every 5 years by sending a new unused standard to a designated verification laboratory.

* * * * *

3.1.3.3 Using audit gases that are verified against the NIST standard reference methods or special review procedures and validated per the certification periods specified in reference 4 of this Appendix (EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards) for CO, SO2, and NO2 and using O3 analyzers that are verified quarterly against a standard reference photometer.

* * * * *

3.2.4 PM2.5 *Performance Evaluation Program (PEP) Procedures*. The PEP is an independent assessment used to estimate total measurement system bias. These evaluations will be performed under the NPEP as described in section 2.4 of this appendix or a comparable program. A prescribed number of Performance evaluation sampling events will be performed annually within each PQAO. For PQAOs with less than or equal to five monitoring sites, five valid performance evaluation audits must be collected and reported each year. For PQAOs with greater than five monitoring sites, eight valid performance evaluation audits must be collected and reported each year. A valid performance evaluation audit means that both the primary monitor and PEP audit concentrations are valid and equal to or greater than 2 µg/m3. Siting of the PEP monitor must be consistent with section 3.2.3.4(c). However, any horizontal distance greater than 4 meters and any vertical distance greater than one meter must be reported to the EPA regional PEP coordinator. Additionally for every monitor designated as a primary monitor, a primary quality assurance organization must:

* * * * *

4.2.1 ***Collocated Quality Control Sampler Precision Estimate for $PM_{10}$, $PM_{2.5}$ and Pb*** .

Precision is estimated via duplicate measurements from collocated samplers. It is recommended that the precision be aggregated at the PQAO level quarterly, annually, and at the 3-year level. The data pair would only be considered valid if both concentrations are greater than or equal to the minimum values specified in section 4(c) of this appendix. For each collocated data pair, calculate $t_i$, using equation 6 of this appendix:

Equation 6

$$t_i = \frac{X_i - Y_i}{\sqrt{(X_i + Y_i)/2}} \times 100$$

where $X_i$ is the concentration from the primary sampler and $Y_i$ is the concentration value from the audit sampler. The coefficient of variation upper bound is calculated using Equation 7 of this appendix:

Equation 7

$$CV90_{NAAQS} = 100 * \sqrt{\frac{k \times \sum_{i=1}^{k} t_i^2 - \left(\sum_{i=1}^{k} t_i\right)^2}{2k(k-1)}} \times \sqrt{\frac{k-1}{NAAQS\ Concentration * X^2_{0.1,k-1}}}$$

where $k$ is the number of valid data pairs being aggregated, and $X^2_{0.1,k-1}$ is the 10th percentile of a chi-squared distribution with k-1 degrees of freedom. The factor of 2 in the denominator adjusts for the fact that each $t_i$ is calculated from two values with error.

* * * * *

4.2.5. *Performance Evaluation Programs Bias Estimate for $PM_{2.5}$.* The bias estimate is calculated using the PEP audits described in section 3.2.4. of this appendix. The bias estimator is based on, $s_i$, the absolute difference in concentrations divided by the square root of the PEP concentration.

Equation 8

$$100 * \frac{\sum_{i=1}^{n} s_i}{n\sqrt{NAAQS\ concentration}} \quad \text{where} \quad s_i = \frac{meas - audit}{\sqrt{audit}} \times 100$$

* * * * *

6. References

(1) American National Standard Institute - Quality Management Systems For Environmental Information And Technology Programs- - Requirements With Guidance For Use. ASQ/ANSI E4-2014. February 2014. Available from ANSI Webstore https://webstore.ansi.org/

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(4) EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards. EPA-600/R-12/531. May, 2012. Available from U.S. Environmental Protection Agency, National Risk Management Research Laboratory, Research Triangle Park NC 27711. https://www.epa.gov/nscep.

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(6) List of Designated Reference and Equivalent Methods. Available from U.S. Environmental Protection Agency, Center for Environmental Measurements and Modeling, Air Methods and Characterization Division, MD-D205-03, Research Triangle Park, NC 27711. https://www.epa.gov/amtic/air-monitoring-methods-criteria-pollutants.

(7) Transfer Standards for the Calibration of Ambient Air Monitoring Analyzers for Ozone. EPA-454/B-13-004 U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, October, 2013. https://www.epa.gov/sites/default/files/2020-09/documents/ozonetransferstandardguidance.pdf.

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(9) Quality Assurance Handbook for Air Pollution Measurement Systems, Volume 1 - A Field Guide to Environmental Quality Assurance. EPA-600/R-94/038a. April 1994. Available from U.S. Environmental Protection Agency, ORD Publications Office, Center for Environmental Research Information (CERI), 26 W. Martin Luther King Drive, Cincinnati, OH 45268. https://www.epa.gov/amtic/ambient-air-monitoring-quality-assurance#documents.

(10) Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II: Ambient Air Quality Monitoring Program Quality System Development. EPA-454/B-13-003. https://www.epa.gov/amtic/ambient-air-monitoring-quality-assurance#documents

(11) National Performance Evaluation Program Standard Operating Procedures.

https://www.epa.gov/amtic/ambient-air-monitoring-quality-assurance#npep

**Table A-1 of Appendix A to Part 58 - Minimum Data Assessment Requirements for NAAQS Related Criteria Pollutant Monitors**

| Method | Assessment method | Coverage | Minimum frequency | Parameters reported | AQS assessment type |
|---|---|---|---|---|---|
| **Gaseous Methods (CO, $NO_2$, $SO_2$, $O_3$)** | | | | | |
| One-Point QC for $SO_2$, $NO_2$, O3, CO | Response check at concentration 0.005-0.08 ppm $SO_2$, $NO_2$, O3, and 0.5 and 5 ppm CO | Each analyzer | Once per 2 weeks[5] | Audit concentration[1] and measured concentration.[2] | One-Point QC. |
| Annual performance evaluation for $SO_2$, $NO_2$, O3, CO | See section 3.1.2 of this appendix | Each analyzer | Once per year | Audit concentration[1] and measured concentration[2] for each level | Annual PE. |
| NPAP for $SO_2$, $NO_2$, O3, CO | Independent Audit | 20% of sites each year | Once per year | Audit concentration[1] and measured concentration[2] for each level | NPAP. |
| **Particulate Methods** | | | | | |
| Continuous[4] method - collocated quality control sampling $PM_{2.5}$ | Collocated samplers | 15% | 1-in-12 days | Primary sampler concentration and duplicate sampler concentration.[3] | No Transaction reported as raw data. |
| Manual method - collocated quality control sampling $PM_{10}$, $PM_{2.5}$, Pb-TSP, Pb-$PM_{10}$ | Collocated samplers | 15% | 1-in-12 days | Primary sampler concentration and duplicate sampler concentration.[3] | No Transaction reported as raw data. |
| Flow rate verification | Check of sampler flow rate | Each sampler | Once every month[5] | Audit flow rate and measured flow rate | Flow Rate Verification. |

| Method | Assessment method | Coverage | Minimum frequency | Parameters reported | AQS assessment type |
|---|---|---|---|---|---|
| $PM_{10}$ (low Vol) $PM_{2.5}$, Pb-$PM_{10}$ | | | | indicated by the sampler | |
| Flow rate verification $PM_{10}$ (High-Vol), Pb-TSP | Check of sampler flow rate | Each sampler | Once every quarter[5] | Audit flow rate and measured flow rate indicated by the sampler | Flow Rate Verification. |
| Semi-annual flow rate audit $PM_{10}$, TSP, $PM_{10}$-2.5, $PM_{2.5}$, Pb-TSP, Pb-$PM_{10}$ | Check of sampler flow rate using independent standard | Each sampler, | Once every 6 months[5] | Audit flow rate and measured flow rate indicated by the sampler | Semi Annual Flow Rate Audit. |
| Pb analysis audits Pb-TSP, Pb-$PM_{10}$ | Check of analytical system with Pb audit strips/filters | Analytical | Once each quarter[5] | Measured value and audit value (ug Pb/filter) using AQS unit code 077 | Pb Analysis Audits. |
| Performance Evaluation Program $PM_{2.5}$ | Collocated samplers | (1) 5 valid audits for primary QA orgs, with ≤5 sites.<br>(2) 8 valid audits for primary QA orgs, with >5 sites.<br>(3) All samplers in 6 years | Distributed over all 4 quarters[5] | Primary sampler concentration and performance evaluation sampler concentration | PEP. |
| Performance Evaluation Program Pb-TSP, Pb-$PM_{10}$ | Collocated samplers | (1) 1 valid audit and 4 collocated samples for primary QA orgs, with ≤5 sites.<br>(2) 2 valid audits and 6 collocated samples for | Distributed over all 4 quarters[5] | Primary sampler concentration and performance evaluation sampler concentration.<br>Primary sampler concentration and duplicate sampler concentration | PEP. |

| Method | Assessment method | Coverage | Minimum frequency | Parameters reported | AQS assessment type |
|---|---|---|---|---|---|
| | | primary QA orgs with >5 sites | | | |

[1] Effective concentration for open path analyzers.

[2] Corrected concentration, if applicable for open path analyzers.

[3] Both primary and collocated sampler values are reported as raw data.

[4] $PM_{2.5}$ is the only particulate criteria pollutant requiring collocation of continuous and manual primary monitors.

[5] EPA's recommended maximum number of days that should exist between checks to ensure that the checks are routinely conducted over time and to limit data impacts resulting from a failed check.

* * * * *

29. Amend Appendix B to Part 58 by:

a. Revising paragraph 2.6.1 and adding paragraphs 2.6.1.1 and 2.6.1.2;

b. Removing paragraph 3.1.2.2;

c. Revising paragraphs 3.1.3.3, 3.2.4, 4.2.1, and 4.2.5; and

d. In Section 6, revising References 1, 4, 6, 7, 9, 10 and 11, and Table B-1.

The revisions and additions read as follows:

**Appendix B to Part 58 - Quality Assurance Requirements for Prevention of Significant Deterioration (PSD) Air Monitoring**

* * * * *

2.6.1 Gaseous pollutant concentration standards (permeation devices or cylinders of compressed gas) used to obtain test concentrations for CO, $SO_2$, NO, and $NO_2$ must be EPA Protocol Gases certified in accordance with one of the procedures given in Reference 4 of this appendix.

2.6.1.1 The concentrations of EPA Protocol Gas standards used for ambient air monitoring must be certified with a 95-percent confidence interval to have an analytical uncertainty of no more than ±2.0 percent (inclusive) of the certified concentration (tag value) of the gas mixture. The uncertainty must be calculated in accordance with the statistical procedures defined in Reference 4 of this appendix.

2.6.1.2 Specialty gas producers advertising certification with the procedures provided in Reference 4 of this appendix and distributing gases as "EPA Protocol Gas" for ambient air monitoring purposes must adhere to the regulatory requirements specified in 40 CFR Part 75.21(g) or not use "EPA" in any form of advertising. The PSD PQAOs must provide information to the PSD reviewing authority on the specialty gas producers they use (or will use) for the duration of the PSD monitoring project. This information can be provided in the QAPP or monitoring plan, but must be updated if there is a change in the specialty gas producers used.

* * * * *

3.1.3.3 Using audit gases that are verified against the NIST standard reference methods or special review procedures and validated per the certification periods specified in reference 4 of this Appendix (EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards) for CO, $SO_2$, and $NO_2$ and using $O_3$ analyzers that are verified quarterly against a standard reference photometer.

* * * * *

3.2.4 *PM2.5 Performance Evaluation Program (PEP) Procedures*. The PEP is an independent assessment used to estimate total measurement system bias. These evaluations will be performed under the NPEP as described in section 2.4 of this appendix or a comparable program. Performance evaluations will be performed annually within each PQAO. For PQAOs with less

than or equal to five monitoring sites, five valid performance evaluation audits must be collected and reported each year. For PQAOs with greater than five monitoring sites, eight valid performance evaluation audits must be collected and reported each year. A valid performance evaluation audit means that both the primary monitor and PEP audit concentrations are valid and equal to or greater than 2 µg/m3. Siting of the PEP monitor must be consistent with section 3.2.3.4(c). However, any horizontal distance greater than 4 meters and any vertical distance greater than one meter must be reported to the EPA regional PEP coordinator. Additionally for every monitor designated as a primary monitor, a primary quality assurance organization must:

* * * * *

4.2.1 ***Collocated Quality Control Sampler Precision Estimate for $PM_{10}$, $PM_{2.5}$ and Pb*** .

Precision is estimated via duplicate measurements from collocated samplers. It is recommended that the precision be aggregated at the PQAO level quarterly, annually, and at the 3-year level. The data pair would only be considered valid if both concentrations are greater than or equal to the minimum values specified in section 4(c) of this appendix. For each collocated data pair, calculate $t_i$, using equation 6 of this appendix:

Equation 6

$$t_i = \frac{X_i - Y_i}{\sqrt{(X_i + Y_i)/2}} \times 100$$

where $X_i$ is the concentration from the primary sampler and $Y_i$ is the concentration value from the audit sampler. The coefficient of variation upper bound is calculated using Equation 7 of this appendix:

Equation 7

$$CV90_{NAAQS} = 100 * \sqrt{\frac{k \times \sum_{i=1}^{k} t_i^2 - \left(\sum_{i=1}^{k} t_i\right)^2}{2k(k-1)}} \times \sqrt{\frac{k-1}{NAAQS\ Concentration * X^2_{0.1,k-1}}}$$

where *k* is the number of valid data pairs being aggregated, and $X^2_{0.1,k-1}$ is the 10th percentile of a chi-squared distribution with k-1 degrees of freedom. The factor of 2 in the denominator adjusts for the fact that each $t_i$ is calculated from two values with error.

* * * * *

4.2.5 *Performance Evaluation Programs Bias Estimate for $PM_{2.5}$*. The bias estimate is calculated using the PEP audits described in section 3.2.4. of this appendix. The bias estimator is based on, $s_i$, the absolute difference in concentrations divided by the square root of the PEP concentration.

Equation 8

$$100 * \frac{\sum_{i=1}^{n} s_i}{n\sqrt{NAAQS\ concentration}} \quad \text{where} \quad s_i = \frac{meas - audit}{\sqrt{audit}} \times 100$$

* * * * *

6. **References**

(1) American National Standard Institute - Quality Management Systems For Environmental Information And Technology Programs- - Requirements With Guidance For Use. ASQ/ANSI E4-2014. February 2014. Available from ANSI Webstore https://webstore.ansi.org/

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(4) EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards. EPA-600/R-12/531. May, 2012. Available from U.S. Environmental Protection Agency, National Risk Management Research Laboratory, Research Triangle Park NC 27711. https://www.epa.gov/nscep.

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(6) List of Designated Reference and Equivalent Methods. Available from U.S. Environmental Protection Agency, Center for Environmental Measurements and Modeling, Air Methods and Characterization Division, MD-D205-03, Research Triangle Park, NC 27711. https://www.epa.gov/amtic/air-monitoring-methods-criteria-pollutants.

(7) Transfer Standards for the Calibration of Ambient Air Monitoring Analyzers for Ozone. EPA-454/B-13-004 U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, October, 2013. https://www.epa.gov/sites/default/files/2020-09/documents/ozonetransferstandardguidance.pdf.

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(9) Quality Assurance Handbook for Air Pollution Measurement Systems, Volume 1 - A Field Guide to Environmental Quality Assurance. EPA-600/R-94/038a. April 1994. Available from U.S. Environmental Protection Agency, ORD Publications Office, Center for Environmental Research Information (CERI), 26 W. Martin Luther King Drive, Cincinnati, OH 45268. https://www.epa.gov/amtic/ambient-air-monitoring-quality-assurance#documents.

(10) Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II: Ambient Air Quality Monitoring Program Quality System Development. EPA-454/B-13-003. https://www.epa.gov/amtic/ambient-air-monitoring-quality-assurance#documents

(11) National Performance Evaluation Program Standard Operating Procedures. https://www.epa.gov/amtic/ambient-air-monitoring-quality-assurance#npep

**Table B-1 - Minimum Data Assessment Requirements for NAAQS Related Criteria Pollutant PSD Monitors**

| Method | Assessment method | Coverage | Minimum frequency | Parameters reported | AQS Assessment type |
|---|---|---|---|---|---|
| **Gaseous Methods ($CO$ , $NO_2$ , $SO_2$ , $O_3$ )** | | | | | |
| One-Point QC for $SO_2$, $NO_2$, $O_3$, CO | Response check at concentration 0.005-0.08 ppm $SO_2$, $NO_2$, $O_3$, & 0.5 and 5 ppm CO | Each analyzer | Once per 2 weeks[5] | Audit concentration[1] and measured concentration[2] | One-Point QC. |
| Quarterly performance evaluation for $SO_2$, $NO_2$, $O_3$, CO | See section 3.1.2 of this appendix | Each analyzer | Once per quarter[5] | Audit concentration[1] and measured concentration[2] for each level | Annual PE. |
| NPAP for $SO_2$, $NO_2$, $O_3$, CO[3] | Independent Audit | Each primary monitor | Once per year | Audit concentration[1] and measured concentration[2] for each level | NPAP. |
| **Particulate Methods** | | | | | |
| Collocated sampling $PM_{10}$, $PM_{2.5}$, Pb | Collocated samplers | 1 per PSD Network per pollutant | Every 6 days or every 3 days if daily monitoring required | Primary sampler concentration and duplicate sampler concentration[4] | No Transaction reported as raw data. |
| Flow rate verification $PM_{10}$, $PM_{2.5}$, Pb | Check of sampler flow rate | Each sampler | Once every month[5] | Audit flow rate and measured flow rate indicated by the sampler | Flow Rate Verification. |
| Semi-annual flow rate audit $PM_{10}$, $PM_{2.5}$, Pb | Check of sampler flow rate using independent standard | Each sampler | Once every 6 months or beginning, middle and end of monitoring[5] | Audit flow rate and measured flow rate indicated by the sampler | Semi Annual Flow Rate Audit. |
| Pb analysis audits Pb-TSP, Pb-$PM_{10}$ | Check of analytical system with Pb audit strips/filters | Analytical | Each quarter[5] | Measured value and audit value (ug Pb/filter) using AQS unit code 077 for parameters: 14129 - Pb (TSP) LC FRM/FEM | Pb Analysis Audits. |

| Method | Assessment method | Coverage | Minimum frequency | Parameters reported | AQS Assessment type |
|---|---|---|---|---|---|
| | | | | 85129 - Pb (TSP) LC Non-FRM/FEM. | |
| Performance Evaluation Program $PM_{2.5}$[3] | Collocated samplers | (1) 5 valid audits for PQAOs with <= 5 sites. (2) 8 valid audits for PQAOs with > 5 sites. (3) All samplers in 6 years | Over all 4 quarters[5] | Primary sampler concentration and performance evaluation sampler concentration | PEP. |
| Performance Evaluation Program Pb[3] | Collocated samplers | (1) 1 valid audit and 4 collocated samples for PQAOs, with <=5 sites. (2) 2 valid audits and 6 collocated samples for PQAOs with >5 sites. | Over all 4 quarters[5] | Primary sampler concentration and performance evaluation sampler concentration. Primary sampler concentration and duplicate sampler concentration | PEP. |

[1] Effective concentration for open path analyzers.

[2] Corrected concentration, if applicable for open path analyzers.

[3] NPAP, $PM_{2.5}$ PEP and Pb-PEP must be implemented if data is used for NAAQS decisions otherwise implementation is at PSD reviewing authority discretion.

[4] Both primary and collocated sampler values are reported as raw data

[5] A maximum number of days should be between these checks to ensure the checks are routinely conducted over time and to limit data impacts resulting from a failed check.

* * * * * *

30. In Appendix C to Part 58, add paragraph 2.2 and remove and reserve paragraph 2.4.

The addition reads as follows:

**Appendix C to Part 58—Ambient Air Quality Monitoring Methodology**

* * * * *

2.2 $PM_{10}$, $PM_{2.5}$, or $PM_{10-2.5}$ continuous FEMs with existing valid designations may be calibrated using network data from collocated FRM and continuous FEM data under the following provisions:

2.2.1 Data to demonstrate a calibration may include valid data from State, local, or tribal air agencies or data collected by instrument manufacturers in accordance with § 53.35 or other data approved by the Administrator.

2.2.2 A request to update a designated methods calibration may be initiated by the instrument manufacturer of record or the EPA Administrator.

2.2.3 Requests for approval of an updated $PM_{10}$, $PM_{2.5}$, or $PM_{10-2.5}$ continuous FEM calibration must meet the general submittal requirements of section 2.7 of this appendix.

2.2.4 Data included in the request should represent a subset of representative locations where the method is operational. For cases with a small number of collocated FRMs and continuous FEMs sites, an updated candidate calibration may be limited to the sites where both methods are in use.

2.2.5 Data included in a candidate method updated calibration may include a subset of sites where there is a large grouping of sites in one part of the country such that the updated calibration would be representative of the country as a whole.

2.2.6 Improvements should be national in scope and ideally implemented through a firmware change.

2.2.7 The goal of a change to a methods calibration is to increase the number of sites meeting measurements quality objectives of the method as identified in section 2.3.1.1 of Appendix A to this part.

2.2.8 For meeting MQO's, the primary objective is to meet the bias goal as this statistic will likely have the most influence on improving the resultant data collected.

2.2.9 Precision data are to be included, but so long as precision data are at least as good as existing network data or meet the MQO referenced above, no further work is necessary with precision.

2.2.10 Data available to use may include routine primary and collocated data.

2.2.11 Audit data may be useful to confirm the performance of a candidate updated calibration but should not be used as the basis of the calibration to keep the independence of the audit data.

2.2.12 Data utilized as the basis of the updated calibration may be obtained by accessing EPA's AQS database.

2.2.13 Years of data to use in a candidate method calibration should include two recent years where we are past the certification period for the previous year's data, which is May 1$^{st}$ of each year.

2.2.14 Data from additional years is to be used to test an updated calibration such that the calibration is independent of the test years of interest. Data from these additional years need to minimally demonstrate that a larger number of sites are expected to meet bias MQO especially at sites near the level of the NAAQS for the PM indicator of interest

2.2.15 Outliers may be excluded using routine outlier tests.

2.2.16 The range of data used in a calibration may include all data available or alternatively use data in the range from the lowest measured data available up to 125% of the 24-hour NAAQS for the PM indicator of interest.

2.2.17 Other improvements to a PM continuous method may be included as part of a recommended update so long as appropriate testing is conducted with input from EPA ORD's Reference and Equivalent (R&E) Methods Designation program.

2.2.18 EPA encourages early communication by instrument manufacturers considering an update to a PM method. Instrument companies should initiate such dialogue by contacting EPA ORD's Reference and Equivalent (R&E) Methods Designation program. The contact information for this can be found at 40 CFR 53.4, “Applications for reference or equivalent method determinations.”

2.2.19 Manufacturers interested in improving instrument’s performance through an updated factory calibration must submit a written Modification Request to EPA with supporting rationale. Because the testing requirements and acceptance criteria of any. field and/or lab tests can depend upon the nature and extent of the intended modification, applicants should contact EPA’s R&E Methods Designation program for guidance prior to development of the Modification Request.

* * * * *

31. In Appendix D to Part 58,

a. Revise paragraphs 1 and 1.1(b);

b. Revise the introductory text before the table in paragraph 4.7.1(a);

c. Revise paragraph 4.7.1(b)(3) and 4.7.2.

The revisions read as follows:

**Appendix D to Part 58—Network Design Criteria for Ambient Air Quality Monitoring**

* * *

**1. Monitoring Objectives and Spatial Scales**

The purpose of this appendix is to describe monitoring objectives and general criteria to be applied in establishing the required SLAMS ambient air quality monitoring stations and for choosing general locations for additional monitoring sites. This appendix also describes specific requirements for the number and location of FRM and FEM sites for specific pollutants, NCore multipollutant sites, $PM_{10}$ mass sites, $PM_{2.5}$ mass sites, chemically-speciated $PM_{2.5}$ sites, and $O_3$ precursor measurements sites (PAMS). These criteria will be used by EPA in evaluating the adequacy of the air pollutant monitoring networks.

1.1 * * *

(b) Support compliance with ambient air quality standards and emissions strategy development. Data from FRM and FEM monitors for NAAQS pollutants will be used for comparing an area's air pollution levels against the NAAQS. Data from monitors of various types can be used in the development of attainment and maintenance plans. SLAMS, and especially NCore station data, will be used to evaluate the regional air quality models used in developing emission strategies, and to track trends in air pollution abatement control measures' impact on improving air quality. In monitoring locations near major air pollution sources, source-oriented monitoring data can provide insight into how well industrial sources are controlling their pollutant emissions.

* * * * *

4.7.1* * *

(a) State, and where applicable local, agencies must operate the minimum number of required $PM_{2.5}$ SLAMS sites listed in Table D-5 of this appendix. The NCore sites are expected to

complement the $PM_{2.5}$ data collection that takes place at non-NCore SLAMS sites, and both types of sites can be used to meet the minimum $PM_{2.5}$ network requirements. The total number of $PM_{2.5}$ sites needed to support the basic monitoring objectives of providing air pollution data to the general public in a timely manner, support compliance with ambient air quality standards and emission strategy development, and support for air pollution research studies will include more sites than the minimum numbers required in Table D-5 of this appendix. Deviations from these $PM_{2.5}$ monitoring requirements must be approved by the EPA Regional Administrator. * * *

(b)* * *

(3) For areas with additional required SLAMS, a monitoring station is to be sited in an at-risk community, particularly where there are anticipated effects from sources in the area (e.g., a major port, rail yard, airport, industrial area, or major transportation corridor).

* * * * *

4.7.2 Requirement for Continuous $PM_{2.5}$ Monitoring. The State, or where appropriate, local agencies must operate continuous $PM_{2.5}$ analyzers equal to at least one-half (round up) the minimum required sites listed in Table D-5 of this appendix. At least one required continuous analyzer in each MSA must be collocated with one of the required FRM/FEM monitors, unless at least one of the required FRM/FEM monitors is itself a continuous FEM monitor in which case no collocation requirement applies. State and local air monitoring agencies must use methodologies and quality assurance/quality control (QA/QC) procedures approved by the EPA Regional Administrator for these required continuous analyzers.

* * * * *

32. Appendix E to part 58 is revised to read as follows:

## Appendix E to Part 58—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring



### 1. Introduction1.1 Applicability.

(a) This appendix contains specific location criteria applicable to ambient air quality monitoring probes, inlets, and optical paths of SLAMS, NCore, PAMS, and other monitor types whose data are intended to be used to determine compliance with the NAAQS. These specific location criteria are relevant after the general location has been selected based on the monitoring objectives and spatial scale of representation discussed in appendix D to this part. Monitor probe material and sample residence time requirements are also included in this appendix. Adherence to these siting criteria is necessary to ensure the uniform collection of compatible and comparable air quality data.

(b) The probe and monitoring path siting criteria discussed in this appendix must be followed to the maximum extent possible. It is recognized that there may be situations where some deviation from the siting criteria may be necessary. In any such case, the reasons must be thoroughly documented in a written request for a waiver that describes how and why the proposed siting deviates from the criteria. This documentation should help to avoid later questions about the validity of the resulting monitoring data. Conditions under which the EPA

would consider an application for waiver from these siting criteria are discussed in section 4 of this appendix.

(c) The pollutant-specific probe and monitoring path siting criteria generally apply to all spatial scales except where noted otherwise. Specific siting criteria that are phrased with a "must" are defined as requirements and exceptions must be approved through the waiver provisions. However, siting criteria that are phrased with a "should" are defined as goals to meet for consistency but are not requirements.

**2. Monitors and Samplers with Probe Inlets2.1 Horizontal and Vertical Placement.**

The probe must be located greater than or equal to 2.0 and less than or equal to 15. meters above ground level for all $O_3$ and $SO_2$ monitoring, and for neighborhood or larger spatial scale Pb, $PM_{10}$, $PM_{10-2.5}$, $PM_{2.5}$, $NO_2$, and CO sites. Middle scale CO and $NO_2$ monitors must also have sampler inlets greater than or equal to 2.0 and less than or equal to 15. meters above ground level. Middle scale $PM_{10-2.5}$ sites are required to have sampler inlets greater than or equal to 2.0 and less than or equal to 7.0 meters above ground level. Microscale Pb, $PM_{10}$, $PM_{10-2.5}$, and $PM_{2.5}$ sites are required to have sampler inlets greater than or equal to 2.0 and less than or equal to 7.0 meters above ground level. Microscale near-road $NO_2$ monitoring sites are required to have sampler inlets greater than or equal to 2.0 and less than or equal to 7.0 meters above ground level. The probe inlets for microscale carbon monoxide monitors that are being used to measure concentrations near roadways must be greater than or equal to 2.0 and less than or equal to 7.0 meters above ground level. Those probe inlets for microscale carbon monoxide monitors measuring concentrations near roadways in downtown areas or urban street canyons must be greater than or equal to 2.5 and less than or equal to 3.5 meters above ground level. The probe must be at least 1.0 meter vertically or horizontally away from any supporting structure, walls,

parapets, penthouses, *etc.,* and away from dusty or dirty areas. If the probe is located near the side of a building or wall, then it should be located on the windward side of the building relative to the prevailing wind direction during the season of highest concentration potential for the pollutant being measured.

**2.2 Spacing from Minor Sources.**

(a) It is important to understand the monitoring objective for a particular location in order to interpret this particular requirement. Local minor sources of a primary pollutant, such as $SO_2$, lead, or particles, can cause high concentrations of that particular pollutant at a monitoring site. If the objective for that monitoring site is to investigate these local primary pollutant emissions, then the site is likely to be properly located nearby. This type of monitoring site would in all likelihood be a microscale type of monitoring site. If a monitoring site is to be used to determine air quality over a much larger area, such as a neighborhood or city, a monitoring agency should avoid placing a monitor probe inlet near local, minor sources. The plume from the local minor sources should not be allowed to inappropriately impact the air quality data collected at a site. Particulate matter sites should not be located in an unpaved area unless there is vegetative ground cover year-round, so that the impact of windblown dusts will be kept to a minimum.

(b) Similarly, local sources of nitric oxide (NO) and ozone-reactive hydrocarbons can have a scavenging effect causing unrepresentatively low concentrations of $O_3$ in the vicinity of probes for $O_3$. To minimize these potential interferences the probe inlet should be away from furnace or incineration flues or other minor sources of $SO_2$ or NO. The separation distance should take into account the heights of the flues, type of waste or fuel burned, and the sulfur content of the fuel.

**2.3 Spacing from Obstructions.**

(a) Buildings and other obstacles may possibly scavenge $SO_2$, $O_3$, or $NO_2$, and can act to restrict airflow for any pollutant. To avoid this interference, the probe inlet must have unrestricted airflow pursuant to paragraph (b) of this section and should be located away from obstacles. The horizontal distance from the obstacle to the probe inlet must be at least twice the height that the obstacle protrudes above the probe inlet. An obstacle that does not meet the minimum distance requirement is considered an obstruction that restricts airflow to the probe inlet.

(b) A probe inlet located near or along a vertical wall is undesirable because air moving along the wall may be subject to possible removal mechanisms. A probe inlet must have unrestricted airflow with no obstructions (as defined in paragraph (a) of this section) in a continuous arc of at least 270 degrees. An unobstructed continuous arc of 180 degrees is allowable when network design criteria regulations specified in Appendix D of this part require monitoring in street canyons and the probe is located on the side of a building. This arc must include the predominant wind direction for the season of greatest pollutant concentration potential. For particle sampling, a minimum of 2.0 meters of horizontal separation from walls, parapets, and structures is required for rooftop site placement.

(c) A sampling station having a probe inlet located closer to an obstacle than this criterion allows should be classified as middle scale or microscale rather than neighborhood or urban scale, since the measurements from such a station would more closely represent these smaller scales.

(d) For near-road monitoring stations, the monitor probe shall have an unobstructed air flow, where no obstacles exist at or above the height of the monitor probe, between the monitor probe and the outside nearest edge of the traffic lanes of the target road segment.

**2.4 Spacing from Trees.**

(a) Trees can provide surfaces for $SO_2$, $O_3$, or $NO_2$ adsorption or reactions, and surfaces for particle deposition. Trees can also act as obstructions in cases where they are located between the air pollutant sources or source areas and the monitoring site, and where the trees are of a sufficient height and leaf canopy density to interfere with the normal airflow around the probe inlet. To reduce this possible interference/obstruction, the probe inlet should be 20 meters or more from the drip line of trees and must be at least 10 meters from the drip line of trees. If a tree or trees is an obstacle, the probe inlet must meet the distance requirements of section 2.3.

(b) The scavenging effect of trees is greater for $O_3$ than for other criteria pollutants. Monitoring agencies must take steps to consider the impact of trees on ozone monitoring sites and take steps to avoid this problem.

(c) Beginning January 1, 2024, microscale sites of any air pollutant, shall have no trees or shrubs located at or above the line-of-sight fetch between the probe and the source under investigation, such as a roadway or a stationary source.

**2.5 Spacing from Roadways.**

**TABLE E-1 OF APPENDIX E TO PART 58—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND PROBES FOR MONITORING NEIGHBORHOOD AND URBAN SCALE OZONE ($O_3$) AND OXIDES OF NITROGEN (NO, $NO_2$, $NO_X$, $NO_Y$)**

| Roadway average daily traffic, vehicles per day | Minimum distance[1 3] (meters) | Minimum distance[1 2 3] (meters) |
|---|---|---|
| ≤1,000 | 10 | 10 |
| 10,000 | 10 | 20 |
| 15,000 | 20 | 30 |

| | | |
|---|---|---|
| 20,000 | 30 | 40 |
| 40,000 | 50 | 60 |
| 70,000 | 100 | 100 |
| ≥110,000 | 250 | 250 |

[1]Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

[2]Applicable for ozone monitors whose placement has not already been approved as of December 18, 2006.

[3]All distances listed are expressed as having 2 significant figures. When rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures.

**2.5.1 Spacing for Ozone Probes.**

In siting an $O_3$ monitor, it is important to minimize destructive interferences from sources of NO, since NO readily reacts with $O_3$. Table E-1 of this appendix provides the required minimum separation distances between a roadway and a probe inlet for various ranges of daily roadway traffic. A sampling site having a monitor probe located closer to a roadway than allowed by the Table E-1 requirements should be classified as middle scale or microscale, rather than neighborhood or urban scale, since the measurements from such a site would more closely represent these smaller scales.

**2.5.2 Spacing for Carbon Monoxide Probes.**

(a) Near-road microscale CO monitoring sites, including those located in downtown areas, urban street canyons, and other near-road locations such as those adjacent to highly trafficked roads, are intended to provide a measurement of the influence of the immediate source on the pollution exposure on the adjacent area.

(b) Microscale CO monitor probe inlets in downtown areas or urban street canyon locations shall be located a minimum distance of 2.0 meters and a maximum distance of 10 meters from the edge of the nearest traffic lane.

(c) Microscale CO monitor probe inlets in downtown areas or urban street canyon locations shall be located at least 10 meters from an intersection and preferably at a midblock location. Midblock locations are preferable to intersection locations because intersections represent a much smaller portion of downtown space than do the streets between them. Pedestrian exposure is probably also greater in street canyon/corridors than at intersections.

**TABLE E-2 OF APPENDIX E TO PART 58—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND PROBES FOR MONITORING NEIGHBORHOOD SCALE CARBON MONOXIDE**

| Roadway average daily traffic, vehicles per day | Minimum distance[1] [2] (meters) |
|---|---|
| ≤10,000 | 10 |
| 15,000 | 25 |
| 20,000 | 45 |
| 30,000 | 80 |
| 40,000 | 115 |
| 50,000 | 135 |
| ≥60,000 | 150 |

[1]Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

[2]All distances listed are expressed as having 2 significant figures. When rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures.

**2.5.3 Spacing for Particulate Matter ($PM_{2.5}$, $PM_{2.5-10}$, $PM_{10}$, Pb) Inlets**

(a) Since emissions associated with the operation of motor vehicles contribute to urban area particulate matter ambient levels, spacing from roadway criteria are necessary for ensuring national consistency in PM sampler siting.

(b) The intent is to locate localized hot-spot sites in areas of highest concentrations whether it be from mobile or multiple stationary sources. If the area is primarily affected by mobile sources and the maximum concentration area(s) is judged to be a traffic corridor or street canyon location, then the monitors should be located near roadways with the highest traffic volume and at separation distances most likely to produce the highest concentrations. For the microscale traffic corridor site, the location must be greater than or equal 5.0 and less than or equal to 15 meters from the major roadway. For the microscale street canyon site, the location must be greater than or equal 2.0 and less than or equal to 10 meters from the roadway. For the middle scale site, a range of acceptable distances from the roadway is shown in Figure E-1 of this appendix. This figure also includes separation distances between a roadway and neighborhood or larger scale sites by default. Any PM probe inlet at a site, 2.0 to 15 meters high, and further back than the middle scale requirements will generally be neighborhood, urban or regional scale. For example, according to Figure E-1 of this appendix, if a PM sampler is primarily influenced by roadway emissions and that sampler is set back 10 meters from a 30,000 ADT (average daily traffic) road, the site should be classified as microscale, if the sampler's inlet height is between 2.0 and 7.0 meters. If the sampler's inlet height is between 7.0 and 15 meters, the site should be classified as middle scale. If the sampler is 20 meters from the same road, it will be classified as middle scale; if 40 meters, neighborhood scale; and if 110 meters, an urban scale.

**2.5.4 Spacing for Nitrogen Dioxide ($NO_2$) Probes.**

(a) In siting near-road $NO_2$ monitors as required in paragraph 4.3.2 of appendix D of this part, the monitor probe shall be as near as practicable to the outside nearest edge of the traffic lanes of the target road segment; but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment. Where possible, the near-road $NO_2$ monitor probe should be within 20 meters of the target road segment.

(b) In siting $NO_2$ monitors for neighborhood and larger scale monitoring, it is important to minimize near-road influences. Table E-1 of this appendix provides the required minimum separation distances between a roadway and a probe inlet for various ranges of daily roadway traffic. A sampling site having a monitor probe located closer to a roadway than allowed by the Table E-1 requirements should be classified as microscale or middle scale rather than neighborhood or urban scale.

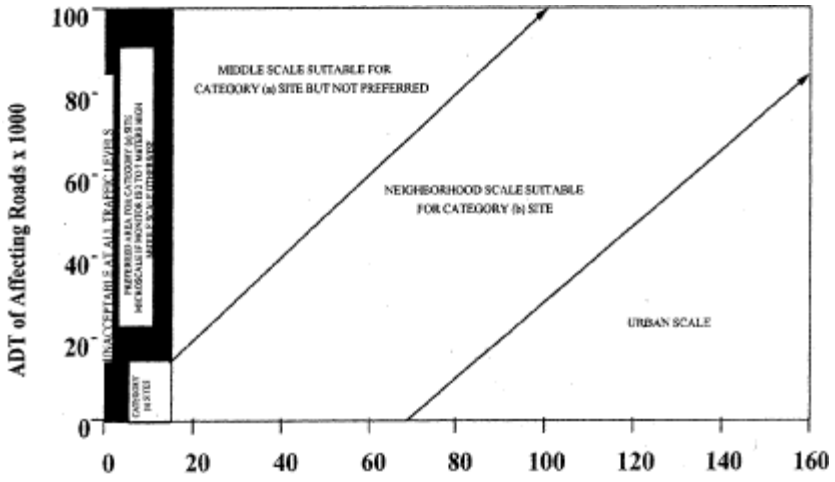


**Figure E-1. Distance of PM samplers to nearest traffic lane (meters)**

**2.6 Probe Material and Pollutant Sampler Residence Time.**

(a) For the reactive gases ($SO_2$, $NO_2$, and $O_3$), special probe material must be used for monitors. Studies have been conducted to determine the suitability of materials such as

polypropylene, polyethylene, polyvinyl chloride, Tygon®, aluminum, brass, stainless steel, copper, borosilicate glass, polyvinylidene fluoride (PVDF), polytetrafluoroethylene (PTFE), perfluoroalkoxy (PFA), and fluorinated ethylene propylene (FEP) for use as intake sampling lines. Of the above materials, only borosilicate glass, PVDF, PTFE, PFA, and FEP have been found to be acceptable for use as intake sampling lines for all the reactive gaseous pollutants. Furthermore, the EPA[25] has specified borosilicate glass or FEP Teflon® as the only acceptable probe materials for delivering test atmospheres in the determination of reference or equivalent methods. Therefore, borosilicate glass, PVDF, PTFE, PFA, FEP, or their equivalent must be the only material in the sampling train (from probe inlet to the back of the monitor) that can be in contact with the ambient air sample for reactive gas monitors. Nafion™ is composed primarily of PTFE and can be considered equivalent to PTFE. It has been shown in tests to exhibit virtually no loss of ozone at 20 second residence times.

(b) For volatile organic compound (VOC) monitoring at PAMS, FEP Teflon® is unacceptable as the probe material because of VOC adsorption and desorption reactions on the FEP Teflon®. Borosilicate glass, stainless steel, or its equivalent are the acceptable probe materials for VOC and carbonyl sampling. Care must be taken to ensure that the sample residence time is kept to 20 seconds or less.

(c) No matter how nonreactive the sampling probe material is initially, after a period of use reactive particulate matter is deposited on the probe walls. Therefore, the time it takes the gas to transfer from the probe inlet to the sampling device is also critical. Ozone in the presence of nitrogen oxide (NO) will show significant losses even in the most inert probe material when the residence time exceeds 20 seconds.[26] Other studies[27] [28] indicate that a 10 second or less residence

time is easily achievable. Therefore, sampling probes for reactive gas monitors (i.e., $SO_2$, $NO_2$, and $O_3$) must have a sample residence time less than 20 seconds.

**2.7 Summary.**

Table E-3 of this appendix presents a summary of the general requirements for probe siting criteria with respect to distances and heights. It is apparent from Table E-3 that different elevation distances above the ground are shown for the various pollutants. The discussion in this appendix for each of the pollutants describes reasons for elevating the monitor or probe inlet. The differences in the specified range of heights are based on the vertical concentration gradients. For source oriented and near-road monitors, the gradients in the vertical direction are very large for the microscale, so a small range of heights are used. The upper limit of 15 meters is specified for the consistency between pollutants and to allow the use of a single manifold for monitoring more than one pollutant.

**TABLE E-3 OF APPENDIX E TO PART 58—SUMMARY OF PROBE SITING CRITERIA**

| Pollutant | Scale | Height from ground to probe [8] (meters) | Horizontal or vertical distance from supporting structures[2] [8] to probe inlet (meters) | Distance from drip line of trees to probe [8] (meters) | Distance from roadways to probe [8] (meters) |
|---|---|---|---|---|---|
| $SO_2$[2] [3] [4] [5] | Middle (300 m) Neighborhood Urban, and Regional (1 km) | 2.0-15 | ≥1.0 | ≥10 | N/A. |
| CO[3] [4] [6] | Micro [downtown or street canyon sites], micro [near-road sites], middle (300 m) and Neighborhood (1 km) | 2.5-3.5; 2.0-7.0; 2.0-15 | ≥1.0 | ≥10 | 2.0-10 for downtown areas or street canyon microscale; ≤50 for near-road microscale; see Table E-2 of this appendix for middle |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | and neighborhood scales. |
| $O_3$[2 3 4] | Middle (300 m) Neighborhood, Urban, and Regional (1 km) | 2.0-15 | ≥1.0 | ≥10 | *See* Table E-1 of this appendix for all scales. |
| $NO_2$[2 3 4] | Micro (Near-road [50-300 m]) | 2.0-7.0 (micro); | ≥1.0 | ≥10 | ≤50 for near-road micro-scale. |
| | Middle (300 m) | 2.0-15 | ≥1.0 | ≥10 | |
| | Neighborhood, Urban, and Regional (1 km) | 2.0-15 (all other scales) | ≥1.0 | ≥10 | *See* Table E-1 of this appendix for all other scales. |
| Ozone precursors (for PAMS)[2 3 4] | Neighborhood and Urban (1 km) | 2.0-15 | ≥1.0 | ≥10 | *See* Table E-1 of this appendix for all scales. |
| PM, Pb[2 3 4 7] | Micro, Middle, Neighborhood, Urban and Regional | 2.0-7.0 (micro); 2.0-7.0 (middle $PM_{10-2.5}$); 2.0-7.0 for near-road; 2.0-15 (all other scales) | ≥2.0 (all scales, horizontal distance only) | ≥10 (all scales) | 2.0-10 (micro); *see* Figure E-1 of this appendix for all other scales. ≤50 for near-road. |

N/A—Not applicable.

[1]When probe is located on a rooftop, this separation distance is in reference to walls, parapets, or penthouses located on roof.

[2]Should be greater than 20 meters from the dripline of tree(s) and must be 10 meters from the dripline.

[3]Distance from sampler or probe inlet to obstacle, such as a building, must be at least twice the height the obstacle protrudes above the sampler or probe inlet. Sites not meeting this criterion may be classified as microscale or middle scale (*see* text).

[4]Must have unrestricted airflow in a continuous arc of at least 270 degrees around the probe or sampler; 180 degrees if the probe is on the side of a building or a wall for street canyon monitoring.

[5]The probe or sampler should be away from minor sources, such as furnace or incineration flues. The separation distance is dependent on the height of the minor source's emission point (such as a flue), the type of fuel or waste burned, and the quality of the fuel (sulfur, ash, or lead content). This criterion is designed to avoid undue influences from minor sources.

[6]For microscale CO monitoring sites, the probe must be ≥10 meters from a street intersection and preferably at a midblock location.

[7]Collocated monitor inlets must be within 4.0 meters of each other and at least 2.0 meters apart for flow rates greater than 200 liters/min or at least 1.0 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference, unless a waiver is in place as approved by the Regional Administrator pursuant to section 3 of Appendix A. For $PM_{2.5}$, collocated monitor inlet heights should be within 1 meter of each other vertically.

[8] All distances listed are expressed as having 2 significant figures. When rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures.

**3. Open Path Analyzers**

**3.1 Horizontal and Vertical Placement.**

At least 80 percent of the monitoring path, must be located greater than or equal 2.0 and less than or equal to 15 meters above ground level for all $O_3$ and $SO_2$ monitoring sites, and for neighborhood or larger spatial scale $NO_2$, and CO sites. Middle scale CO and $NO_2$ sites must also have monitoring paths greater than or equal 2.0 and less than or equal to 15 meters above ground level. Microscale near-road monitoring sites are required to have monitoring paths greater than or equal 2.0 and less than or equal to 7.0 meters above ground level. The monitoring path for microscale carbon monoxide monitors that are being used to measure concentrations near roadways must be greater than or equal 2.0 and less than or equal to 7.0 meters above ground level. Those monitoring paths for microscale carbon monoxide monitors measuring concentrations near roadways in downtown areas or urban street canyons must be greater than or equal 2.5 and less than or equal to 3.5 meters above ground level. At least 90 percent of the monitoring path must be at least 1.0 meter vertically or horizontally away from any supporting structure, walls, parapets, penthouses, *etc.,* and away from dusty or dirty areas. If a significant portion of the monitoring path is located near the side of a building or wall, then it should be

located on the windward side of the building relative to the prevailing wind direction during the season of highest concentration potential for the pollutant being measured.

**3.2 Spacing from Minor Sources.**

(a) It is important to understand the monitoring objective for a particular location in order to interpret this particular requirement. Local minor sources of a primary pollutant, such as $SO_2$ can cause high concentrations of that particular pollutant at a monitoring site. If the objective for that monitoring site is to investigate these local primary pollutant emissions, then the site is likely to be properly located nearby. This type of monitoring site would in all likelihood be a microscale type of monitoring site. If a monitoring site is to be used to determine air quality over a much larger area, such as a neighborhood or city, a monitoring agency should avoid placing a monitoring path near local, minor sources. The plume from the local minor sources should not be allowed to inappropriately impact the air quality data collected at a site.

(b) Similarly, local sources of nitric oxide (NO) and ozone-reactive hydrocarbons can have a scavenging effect causing unrepresentatively low concentrations of $O_3$ in the vicinity of monitoring paths for $O_3$. To minimize these potential interferences, at least 90 percent of the monitoring path must be away from furnace or incineration flues or other minor sources of $SO_2$ or NO. The separation distance should take into account the heights of the flues, type of waste or fuel burned, and the sulfur content of the fuel.

**3.3 Spacing from Obstructions.**

(a) Buildings and other obstacles may possibly scavenge $SO_2$, $O_3$, or $NO_2$, and can act to restrict airflow for any pollutant. To avoid this interference, at least 90 percent of the monitoring path must have unrestricted airflow and should be located away from obstacles. The horizontal distance from the obstacle to the monitoring path must be at least twice the height that the

obstacle protrudes above the monitoring path. An obstacle that does not meet the minimum distance requirement is considered an obstruction that restricts airflow to the monitoring path.

(b) A monitoring path located near or along a vertical wall is undesirable because air moving along the wall may be subject to possible removal mechanisms. At least 90 percent of the monitoring path for open path analyzers must have unrestricted airflow with no obstructions (as defined in paragraph (a) of this section) in a continuous arc of at least 270 degrees. An unobstructed continuous arc of 180 degrees is allowable when network design criteria regulations specified in Appendix D of this part require monitoring in street canyons and the monitoring path is located on the side of a building. This arc must include the predominant wind direction for the season of greatest pollutant concentration potential.

(c) Special consideration must be given to the use of open path analyzers due to their inherent potential sensitivity to certain types of interferences, or optical obstructions. A monitoring path must be clear of all trees, brush, buildings, plumes, dust, or other optical obstructions, including potential obstructions that may move due to wind, human activity, growth of vegetation, etc. Temporary optical obstructions, such as rain, particles, fog, or snow, should be considered when siting an open path analyzer. Any of these temporary obstructions that are of sufficient density to obscure the light beam will affect the ability of the open path analyzer to continuously measure pollutant concentrations. Transient, but significant obscuration of especially longer measurement paths could occur as a result of certain meteorological conditions (*e.g.*, heavy fog, rain, snow) and/or aerosol levels that are of a sufficient density to prevent the open path analyzer's light transmission. If certain compensating measures are not otherwise implemented at the onset of monitoring (*e.g.*, shorter path lengths, higher light source intensity), data recovery during periods of greatest primary pollutant potential could be

compromised. For instance, if heavy fog or high particulate levels are coincident with periods of projected NAAQS-threatening pollutant potential, the representativeness of the resulting data record in reflecting maximum pollutant concentrations may be substantially impaired despite the fact that the site may otherwise exhibit an acceptable, even exceedingly high overall valid data capture rate.

(d) A sampling station having a monitoring path located closer to an obstacle than this criterion allows should be classified as middle scale or microscale rather than neighborhood or urban scale, since the measurements from such a station would more closely represent these smaller scales.

(e) For near-road monitoring stations, the monitoring path shall have an unobstructed air flow, where no obstacles exist at or above the height of the monitoring path, between the monitoring path and the outside nearest edge of the traffic lanes of the target road segment.

**3.4 Spacing from Trees.**

(a) Trees can provide surfaces for $SO_2$, $O_3$, or $NO_2$ adsorption or reactions. Trees can also act as obstructions in cases where they are located between the air pollutant sources or source areas and the monitoring site, and where the trees are of a sufficient height and leaf canopy density to interfere with the normal airflow around the monitoring path. To reduce this possible interference/obstruction, at least 90 percent of the monitoring path should be 20 meters or more from the drip line of trees and must be at least 10 meters from the drip line of trees. If a tree or trees could be considered an obstacle, the monitoring path must meet the distance requirements of section 3.3.

(b) The scavenging effect of trees is greater for $O_3$ than for other criteria pollutants. Monitoring agencies must take steps to consider the impact of trees on ozone monitoring sites and take steps to avoid this problem.

(c) Beginning January 1, 2024, microscale sites of any air pollutant shall have no trees or shrubs located at or above the line-of-sight fetch between the monitoring path and the source under investigation, such as a roadway or a stationary source.

**3.5 Spacing from Roadways.**

**TABLE E-4 OF APPENDIX E TO PART 58—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND MONITORING PATHS FOR MONITORING NEIGHBORHOOD AND URBAN SCALE OZONE ($O_3$) AND OXIDES OF NITROGEN (NO, $NO_2$, $NO_X$, $NO_Y$)**

| Roadway average daily traffic, vehicles per day | Minimum distance[1 3] (meters) | Minimum distance[1 2 3] (meters) |
|---|---|---|
| ≤1,000 | 10 | 10 |
| 10,000 | 10 | 20 |
| 15,000 | 20 | 30 |
| 20,000 | 30 | 40 |
| 40,000 | 50 | 60 |
| 70,000 | 100 | 100 |
| ≥110,000 | 250 | 250 |

[1]Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

[2]Applicable for ozone open path monitors whose placement has not already been approved as of December 18, 2006.

[3] All distances listed are expressed as having 2 significant figures. When rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures.

**3.5.1 Spacing for Ozone Monitoring Paths.**

In siting an $O_3$ open path analyzer, it is important to minimize destructive interferences form sources of NO, since NO readily reacts with $O_3$. Table E-4 of this appendix provides the required minimum separation distances between a roadway and at least 90 percent of a monitoring path for various ranges of daily roadway traffic. A monitoring site having a monitoring path located closer to a roadway than allowed by the Table E-4 requirements should be classified as microscale or middle scale, rather than neighborhood or urban scale, since the measurements from such a site would more closely represent these smaller scales. The monitoring path(s) must not cross over a roadway with an average daily traffic count of 10,000 vehicles per day or more. For those situations where a monitoring path crosses a roadway with fewer than 10,000 vehicles per day, monitoring agencies must consider the entire segment of the monitoring path in the area of potential atmospheric interference from automobile emissions. Therefore, this calculation must include the length of the monitoring path over the roadway plus any segments of the monitoring path that lie in the area between the roadway and minimum separation distance, as determined from the Table E-4 of this appendix. The sum of these distances must not be greater than 10 percent of the total monitoring path length.

**3.5.2 Spacing for Carbon Monoxide Monitoring Paths.**

(a) Near-road microscale CO monitoring sites, including those located in downtown areas, urban street canyons, and other near-road locations such as those adjacent to highly trafficked roads, are intended to provide a measurement of the influence of the immediate source on the pollution exposure on the adjacent area.

(b) Microscale CO monitoring paths in downtown areas or urban street canyon locations shall be located a minimum distance of 2.0 meters and a maximum distance of 10 meters from the edge of the nearest traffic lane.

(c) Microscale CO monitoring paths in downtown areas or urban street canyon locations shall be located at least 10 meters from an intersection and preferably at a midblock location. Midblock locations are preferable to intersection locations because intersections represent a much smaller portion of downtown space than do the streets between them. Pedestrian exposure is probably also greater in street canyon/corridors than at intersections.

**TABLE E-5 OF APPENDIX E TO PART 58—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND MONITORING PATHS FOR MONITORING NEIGHBORHOOD SCALE CARBON MONOXIDE**

| Roadway average daily traffic, vehicles per day | Minimum distance[1] [2] (meters) |
|---|---|
| ≤10,000 | 10 |
| 15,000 | 25 |
| 20,000 | 45 |
| 30,000 | 80 |
| 40,000 | 115 |
| 50,000 | 135 |
| ≥60,000 | 150 |

[1]Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

[2] All distances listed are expressed as having 2 significant figures. When rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures.

**3.5.3 Spacing for Nitrogen Dioxide ($NO_2$) Monitoring Paths.**

(a) In siting near-road $NO_2$ monitors as required in paragraph 4.3.2 of appendix D of this part, the monitoring path shall be as near as practicable to the outside nearest edge of the traffic lanes of the target road segment; but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment.

(b) In siting $NO_2$ open path monitors for neighborhood and larger scale monitoring, it is important to minimize near-road influences. Table E-5 of this appendix provides the required minimum separation distances between a roadway and at least 90 percent of a monitoring path for various ranges of daily roadway traffic. An open path analyzer having a monitoring path located closer to a roadway than allowed by the Table E-4 requirements should be classified as microscale or middle scale rather than neighborhood or urban scale. The monitoring path(s) must not cross over a roadway with an average daily traffic count of 10,000 vehicles per day or more. For those situations where a monitoring path crosses a roadway with fewer than 10,000 vehicles per day, monitoring agencies must consider the entire segment of the monitoring path in the area of potential atmospheric interference form automobile emissions. Therefore, this calculation must include the length of the monitoring path over the roadway plus any segments of the monitoring path that lie in the area between the roadway and minimum separation distance, as determined form the Table E-5 of this appendix. The sum of these distances must not be greater than 10 percent of the total monitoring path length.

**3.6 Cumulative Interferences on a Monitoring Path.**

The cumulative length or portion of a monitoring path that is affected by minor sources, trees, or roadways must not exceed 10 percent of the total monitoring path length.

**3.7 Maximum Monitoring Path Length.**

The monitoring path length must not exceed 1 kilometer for open path analyzers in neighborhood, urban, or regional scale. For middle scale monitoring sites, the monitoring path length must not exceed 300 meters. In areas subject to frequent periods of dust, fog, rain, or snow, consideration should be given to a shortened monitoring path length to minimize loss of monitoring data due to these temporary optical obstructions. For certain ambient air monitoring

scenarios using open path analyzers, shorter path lengths may be needed in order to ensure that the monitoring site meets the objectives and spatial scales defined in appendix D to this part. The Regional Administrator may require shorter path lengths, as needed on an individual basis, to ensure that the SLAMS sites meet the appendix D requirements. Likewise, the Administrator may specify the maximum path length used at NCore monitoring sites.

**3.8. Summary.**

Table E-6 of this appendix presents a summary of the general requirements for monitoring path siting criteria with respect to distances and heights. It is apparent from Table E-6 that different elevation distances above the ground are shown for the various pollutants. The discussion in this appendix for each of the pollutants describes reasons for elevating the monitoring path. The differences in the specified range of heights are based on the vertical concentration gradients. For source oriented and near-road monitors, the gradients in the vertical direction are very large for the microscale, so a small range of heights are used. The upper limit of 15 meters is specified for the consistency between pollutants and to allow the use of a monitoring path for monitoring more than one pollutant.

**TABLE E-6 OF APPENDIX E TO PART 58—SUMMARY OF MONITORING PATH SITING CRITERIA**

| Pollutant | Maximum monitoring path length | Height from ground to 80% of monitoring path[1 8] (meters) | Horizontal or vertical distance from supporting structures[2] to 90% of monitoring path[1 8] (meters) | Distance from trees to 90% of monitoring path[1 8] (meters) | Distance from roadways to monitoring path[1 8] (meters) |
|---|---|---|---|---|---|
| $SO_2$[3 4 5 6] | Middle (300 m) Neighborhood | 2.0-15 | ≥1.0 | ≥10 | N/A |

| | | | | | |
|---|---|---|---|---|---|
| | Urban, and Regional (1 km) | | | | |
| CO[4 5 7] | Micro [downtown or street canyon sites], micro [near-road sites], middle (300. m) and Neighborhood (1.0 km) | 2.5-3.5; 2.0-7.0; 2.0-15 | ≥1.0 | ≥10 | 2.0-10 for downtown areas or street canyon microscale; ≤50. for near-road microscale; see Table E-5 of this appendix for middle and neighborhood scales. |
| $O_3$[3 4 5] | Middle (300. m) Neighborhood, Urban, and Regional (1.0 km) | 2.0-15 | ≥1.0 | ≥10 | *See* Table E-4 of this appendix for all scales. |
| $NO_2$[3 4 5] | Micro (Near-road [50-300 m]) | 2.0-7.0 (micro); | ≥1.0 | ≥10 | ≤50. for near-road micro-scale. |
| | Middle (300 m) | 2.0-15 | ≥1.0 | ≥10 | |
| | Neighborhood, Urban, and Regional (1 km) | 2.0-15 (all other scales) | ≥1.0 | ≥10 | *See* Table E-4 of this appendix for all other scales. |
| Ozone precursors (for PAMS)[3 4 5] | Neighborhood and Urban (1 km) | 2.0-15 | ≥1.0 | ≥10 | *See* Table E-4 of this appendix for all scales. |

N/A—Not applicable.

[1]Monitoring path for open path analyzers is applicable only to middle or neighborhood scale CO monitoring, middle, neighborhood, urban, and regional scale $NO_2$ monitoring, and all applicable scales for monitoring $SO_2$, $O_3$, and $O_3$ precursors.

[2]When the monitoring path is located on a rooftop, this separation distance is in reference to walls, parapets, or penthouses located on roof.

[3]At least 90 percent of the monitoring path should be greater than 20 meters from the dripline of tree(s) and must be 10 meters from the dripline when the tree(s).

[4]Distance from 90 percent of monitoring path to obstacle, such as a building, must be at least twice the height the obstacle protrudes above the monitoring path. Sites not meeting this criterion may be classified as microscale or middle scale (*see* text).

[5]Must have unrestricted airflow 270 degrees around at least 90 percent of the monitoring path; 180 degrees if the monitoring path is adjacent to the side of a building or a wall for street canyon monitoring.

[6]The monitoring path should be away from minor sources, such as furnace or incineration flues. The separation distance is dependent on the height of the minor source's emission point (such as a flue), the type of fuel or waste burned, and the quality of the fuel (sulfur, ash, or lead content). This criterion is designed to avoid undue influences from minor sources.

[7]For microscale CO monitoring sites, the monitoring path must be ≥10. meters from a street intersection and preferably at a midblock location.

[8] All distances listed are expressed as having 2 significant figures. When rounding is performed to assess compliance with these siting requirements, the distance measurements will be rounded such as to retain at least two significant figures.

**4. Waiver Provisions**

Most sampling probes or monitors can be located so that they meet the requirements of this appendix. New sites with rare exceptions, can be located within the limits of this appendix. However, some existing sites may not meet these requirements and still produce useful data for some purposes. The EPA will consider a written request from the State, or where applicable local, agency to waive one or more siting criteria for some monitoring sites providing that the State or their designee can adequately demonstrate the need (purpose) for monitoring or establishing a monitoring site at that location.

4.1 For establishing a new site, a waiver may be granted only if both of the following criteria are met:

4.1.1 The site can be demonstrated to be as representative of the monitoring area as it would be if the siting criteria were being met.

4.1.2 The monitor or probe cannot reasonably be located so as to meet the siting criteria because of physical constraints (e.g., inability to locate the required type of site the necessary distance from roadways or obstructions).

4.2 However, for an existing site, a waiver may be granted if either of the criteria in sections 4.1.1 and 4.1.2 of this appendix are met.

4.3 Cost benefits, historical trends, and other factors may be used to add support to the criteria in sections 4.1.1 and 4.1.2 of this appendix, however, they in themselves, will not be acceptable reasons for granting a waiver. Written requests for waivers must be submitted to the Regional Administrator. Approved waivers must be renewed minimally every 5 years and ideally as part of the annual monitoring network plan accompanying the network assessment as defined in §58.10(d). The approval date of the waiver must be documented in the annual monitoring network plan to support the requirements of §58.10(a)(1) and 58.10(b)(10).

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35. Appendix G of Part 58 is revised to read as follows:

**Appendix G to Part 58—Uniform Air Quality Index (AQI) and Daily Reporting**

1. General Information

2. Reporting Requirements

3. Data Handling

**1. General Information**

1.1 *AQI Overview*. The AQI is a tool that simplifies reporting air quality to the general public in a nationally uniform and easy to understand manner. The AQI converts concentrations of pollutants for which the EPA has established national ambient air quality standard (NAAQS), into a uniform scale from 0-500. These pollutants are ozone ($O_3$), particulate matter ($PM_{2.5}$,

$PM_{10}$), carbon monoxide (CO), sulfur dioxide ($SO_2$), and nitrogen dioxide ($NO_2$). The scale of the index is divided into general categories that are associated with health messages.

**2. Reporting Requirements**

2.1 *Applicability.* The AQI must be reported daily for a metropolitan statistical area (MSA) with a population over 350,000. When it is useful and possible, it is recommended, but not required for an area to report a sub-daily AQI as well.

2.2 *Contents of AQI Report*.

2.2.1 *Content of AQI Report Requirements*. An AQI report must contain the following:

a. The reporting area(s) (the MSA or subdivision of the MSA).

b. The reporting period (the day for which the AQI is reported).

c. The main pollutant (the pollutant with the highest index value).

d. The AQI (the highest index value).

e. The category descriptor and index value associated with the AQI and, if choosing to report in a color format, the associated color. Use only the following descriptors and colors for the six AQI categories:

| Table 1. AQI Categories | | |
|---|---|---|
| For this AQI | Use this descriptor | And this color[1] |
| 0 to 50 | “Good” | Green |
| 51 to 100 | “Moderate” | Yellow |
| 101 to 150 | “Unhealthy for Sensitive Groups” | Orange |
| 151 to 200 | “Unhealthy” | Red |
| 201 to 300 | “Very Unhealthy” | Purple |
| 301 and above | “Hazardous” | Maroon[1] |

[1]Specific color definitions can be found in the most recent reporting guidance (Technical Assistance Document for the Reporting of Daily Air Quality), which can be found at

*https://www.airnow.gov/publications/air-quality-index/technical-assistance-document-for-reporting-the-daily-aqi/).*

f. The pollutant specific sensitive groups for any reported index value greater than 100. The sensitive groups for each pollutant are identified as part of the periodic review of the air quality criteria and the NAAQS. For convenience, EPA lists the relevant groups for each pollutant in the most recent reporting guidance (Technical Assistance Document for the Reporting of Daily Air Quality), which can be found at *https://www.airnow.gov/publications/air-quality-index/technical-assistance-document-for-reporting-the-daily-aqi/*).

2.2.2 *Contents of AQI Report When Applicable.* When appropriate, the AQI report may also contain the following, but such information is not required:

a. Appropriate health and cautionary statements.

b. The name and index value for other pollutants, particularly those with an index value greater than 100.

c. The index values for sub-areas of your MSA.

d. Causes for unusually high AQI values.

e. Pollutant concentrations.

f. Generally, the AQI report applies to an area's MSA only. However, if a significant air quality problem exists (AQI greater than 100) in areas significantly impacted by the MSA but not in it (for example, $O_3$ concentrations are often highest downwind and outside an urban area), the report should identify these areas and report the AQI for these areas as well.

2.3. *Communication, Timing, and Frequency of AQI Report*. The daily AQI must be reported 7 days per week and made available via website or other means of public access. The daily AQI

report represents the air quality for the previous day. Exceptions to this requirement are in section 2.4 of this appendix.

Reporting the AQI sub-daily is recommended, but not required, to provide more timely air quality information to the public for making health-protective decisions.

Submitting hourly data in real-time to the EPA's AirNow (or future analogous) system is recommended, but not required, and assists the EPA in providing timely air quality information to the public for making health-protective decisions.

Submitting hourly data for appropriate monitors (referenced in Section 3.2) satisfies the daily AQI reporting requirement because the AirNow system makes daily and sub-daily AQI reports widely available through its website and other communication tools.

Forecasting the daily AQI provides timely air quality information to the public and is recommended but not required. Sub-daily forecasts are also recommended, especially when air quality is expected to vary substantially throughout the day, like during wildfires. Long-term (multi-day) forecasts can also be made available when useful.

2.4. *Exceptions to Reporting Requirements*.

i. If the index value for a particular pollutant remains below 50 for a season or year, then it may be excluded from the calculation of the AQI in section 3.

ii. If all index values remain below 50 for a year, then the AQI may be reported at the discretion of the reporting agency. In subsequent years, if pollutant levels rise to where the AQI would be above 50, then the AQI must be reported as required in section 2 of this appendix.

iii. As previously mentioned in Section 2.3, submitting hourly data in real-time from appropriate monitors (referenced in Section 3.2) to the EPA's AirNow (or future analogous) system satisfies the daily AQI reporting requirement.

**3. Data Handling.**

3.1 *Relationship of AQI and pollutant concentrations*. For each pollutant, the AQI transforms ambient concentrations to a scale from 0 to 500. As appropriate, the AQI is associated with the national ambient air quality standards (NAAQS) for each pollutant. In most cases, the index value of 100 is associated with the numerical level of the short-term standard (i.e., averaging time of 24-hours or less) for each pollutant. The index value of 50 is associated with the numerical level of the annual standard for a pollutant, if there is one, at one-half the level of the short-term standard for the pollutant, or at the level at which it is appropriate to begin to provide guidance on cautionary language. Higher categories of the index are based on the potential for increasingly serious health effects to occur following exposure and increasing proportions of the population that are likely to be affected. The reported AQI corresponds to the pollutant with the highest calculated AQI. For the purposes of reporting the AQI, the sub-indexes for $PM_{10}$ and $PM_{2.5}$ are to be considered separately. The pollutant responsible for the highest index value (the reported AQI) is called the "main" pollutant for that day.

3.2 *Monitors Used for AQI Reporting*. Concentration data from State/Local Air Monitoring Station (SLAMS) or parts of the SLAMS required by 40 CFR 58.10 must be used for each pollutant except PM. For PM, calculate and report the AQI on days for which air quality data has been measured (e.g., from continuous $PM_{2.5}$ monitors required in Appendix D to this part). PM measurements may be used from monitors that are not reference or equivalent methods (for example, continuous $PM_{10}$ or $PM_{2.5}$ monitors). Detailed guidance for relating non-approved measurements to approved methods by statistical linear regression is referenced here:

Reference for relating non-approved PM measurements to approved methods (Eberly, S., T. Fitz-Simons, T. Hanley, L. Weinstock., T. Tamanini, G. Denniston, B. Lambeth, E. Michel, S.

Bortnick. Data Quality Objectives (DQOs) For Relating Federal Reference Method (FRM) and Continuous $PM_{2.5}$ Measurements to Report an Air Quality Index (AQI). U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-454/B-02-002, November 2002)

3.3 *AQI Forecast*. The AQI can be forecasted at least 24-hours in advance using the most accurate and reasonable procedures considering meteorology, topography, availability of data, and forecasting expertise. The guidance document, "Guidelines for Developing an Air Quality (Ozone and $PM_{2.5}$) Forecasting Program," can be found at *https://www.airnow.gov/publications/weathercasters/guidelines-developing-air-quality-forecasting-program/.*

3.4. *Calculation and Equations*.

i. The AQI is the highest value calculated for each pollutant as follows:

a. Identify the highest concentration among all of the monitors within each reporting area and truncate as follows:

(1) Ozone - truncate to 3 decimal places

$PM_{2.5}$ - truncate to 1 decimal place

$PM_{10}$ - truncate to integer

CO - truncate to 1 decimal place

$SO_2$ - truncate to integer

$NO_2$ - truncate to integer

(2) [Reserved]

b. Using Table 2, find the two breakpoints that contain the concentration.

c. Using Equation 1, calculate the index.

d. Round the index to the nearest integer.

Table 2 - Breakpoints for the AQI

| These breakpoints | | | | | | | Equal these AQI's | |
|---|---|---|---|---|---|---|---|---|
| **$O_3$ (ppm) 8-hour** | **$O_3$ (ppm) 1-hour[1]** | **$PM_{2.5}$ ($\mu g/m^3$) 24-hour** | **$PM_{10}$ ($\mu g/m^3$) 24-hour** | **CO (ppm) 8-hour** | **$SO_2$ (ppb) 1-hour** | **$NO_2$ (ppb) 1-hour** | **AQI** | **Category** |
| 0.000-0.054 | - | 0.0 – (9.0-10.0) | 0-54 | 0.0-4.4 | 0-35 | 0-53 | 0-50 | Good. |
| 0.055-0.070 | - | (9.1-10.1) - 35.4 | 55-154 | 4.5-9.4 | 36-75 | 54-100 | 51-100 | Moderate. |
| 0.071-0.085 | 0.125-0.164 | 35.5 - 55.4 | 155-254 | 9.5-12.4 | 76-185 | 101-360 | 101-150 | Unhealthy for Sensitive Groups. |
| 0.086-0.105 | 0.165-0.204 | 55.5 - 125.4 | 255-354 | 12.5-15.4 | [3] 186-304 | 361-649 | 151-200 | Unhealthy. |
| 0.106-0.200 | 0.205-0.404 | 125.5 - 225.4 | 355-424 | 15.5-30.4 | [3] 305-604 | 650-1249 | 201-300 | Very Unhealthy. |
| 0.201-([2]) | 0.405+ | 225.5+ | 425+ | 30.5+ | [3] 605+ | 1250+ | 301+ | [4] Hazardous. |

[1] Areas are generally required to report the AQI based on 8-hour ozone values. However, there are a small number of areas where an AQI based on 1-hour ozone values would be more precautionary. In these cases, in addition to calculating the 8-hour ozone index value, the 1-hour ozone index value may be calculated, and the maximum of the two values reported.
[2] 8-hour $O_3$ concentrations do not define higher AQI values (>301). AQI values > 301 are calculated with 1-hour $O_3$ concentrations.
[3] 1-hr $SO_2$ concentrations do not define higher AQI values (≥200). AQI values of 200 or greater are calculated with 24-hour $SO_2$ concentration.
[4] AQI values between breakpoints are calculated using equation 1 in Appendix G. For AQI values in the hazardous category, AQI values greater than 500 should be calculated using equation 1 and the concentration specified for the AQI value of 500. The AQI value of 500 are as follows: $O_3$ 1-hour – 0.604 ppm; $PM_{2.5}$ 24-hour – 325.4 $\mu g/m^3$; $PM_{10}$ 24-hour – 604 $\mu g/m^3$; CO ppm – 50.4 ppm; $SO_2$ 1-hour – 1004 ppb; and $NO_2$ 1-hour – 2049 ppb.

ii. If the concentration is equal to a breakpoint, then the index is equal to the corresponding index value in Table 2. However, Equation 1 can still be used. The results will be equal. If the concentration is between two breakpoints, then calculate the index of that pollutant with Equation 1. It should also be noted that in some areas, the AQI based on 1-hour $O_3$ will be more

precautionary than using 8-hour values (see footnote 1 to Table 2). In these cases, the 1-hour values as well as 8-hour values may be used to calculate index values and then use the maximum index value as the AQI for $O_3$.

$$I_p = \frac{I_{Hi} - I_{Lo}}{BP_{Hi} - BP_{Lo}}\left(C_p - BP_{Lo}\right) + I_{Lo} \quad (Equation\ 1)$$

Where:

$I_p$ = the index value for pollutant$_p$

$C_p$ = the truncated concentration of pollutant$_p$

$BP_{Hi}$ = the breakpoint that is greater than or equal to $C_p$

$BP_{Lo}$ = the breakpoint that is less than or equal to $C_p$

$I_{Hi}$ = the AQI value corresponding to $BP_{Hi}$

$I_{lo}$ = the AQI value corresponding to $BP_{Lo}$.

iii. If the concentration is larger than the highest breakpoint in Table 2 then the last two breakpoints in Table 2 may be used when Equation 1 is applied.

Example

iv. Using Table 2 and Equation 1, calculate the index value for each of the pollutants measured and select the one that produces the highest index value for the AQI. For example, if a $PM_{10}$ value of 210 μg/m$^3$ is observed, a 1-hour $O_3$ value of 0.156 ppm, and an 8-hour $O_3$ value of 0.130 ppm, then do this:

a. Find the breakpoints for $PM_{10}$ at 210 μg/m$^3$ as 155 μg/m$^3$ and 254 μg/m$^3$, corresponding to index values 101 and 150;

b. Find the breakpoints for 1-hour $O_3$ at 0.156 ppm as 0.125 ppm and 0.164 ppm, corresponding to index values 101 and 150;

c. Find the breakpoints for 8-hour $O_3$ at 0.130 ppm as 0.116 ppm and 0.374 ppm, corresponding to index values 201 and 300;

d. Apply Equation 1 for 210 μg/$m^3$, $PM_{10}$:

$$\frac{150 - 101}{254 - 155}(210 - 155) + 101 = 128$$

e. Apply Equation 1 for 0.156 ppm, 1-hour $O_3$:

$$\frac{150 - 101}{0.164 - 0.125}(0.156 - 0.125) + 101 = 140$$

f. Apply Equation 1 for 0.130 ppm, 8-hour $O_3$:

$$\frac{300 - 201}{0.374 - 0.116}(0.130 - 0.116) + 201 = 206$$

g. Find the maximum, 206. This is the AQI. A minimal AQI report could read: “Today, the AQI for my city is 206, which is Very Unhealthy, due to ozone.” It would then reference the associated sensitive groups.