Policy Assessment for the Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides, External Review Draft

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Policy Assessment for the Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides, External Review Draft

U. S. Environmental Protection Agency
Office of Air Quality Planning and Standards
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LIST OF ACRONYMS AND ABBREVIATIONS

AHR	airway hyperresponsiveness
APEX	Air Pollutants Exposure model
AQCD	Air Quality Criteria Document
AQS	Air Quality System
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CHAD	Consolidated Human Activity Database
DV	design value
ED	emergency department
EGU	Electricity generating unit
EPA	Environmental Protection Agency
FEM	federal equivalent method
FEV_1	forced expiratory volume in one minute
FRM	federal reference method
IRP	Integrated Review Plan
ISA	Integrated Science Assessment
ME	microenvironment
NAAQS	National Ambient Air Quality Standard
NCEA	National Center for Environmental Assessment
NEI	National Emissions Inventory
NO_2	nitrogen dioxide
O_3	ozone
OAQPS	Office of Air Quality Planning and Standards
ppb	parts per billion
ppm	parts per million
PA	Policy Assessment
PM	particulate matter
REA	Risk and Exposure Assessment
SLAMS	State and Local Air Monitoring Stations
SO_2	sulfur dioxide
SO_3	sulfur trioxide
SO_X	oxides of sulfur
sRaw	specific airway resistance
USB	United States background
UVF	ultraviolet fluorescence

1 INTRODUCTION

1.1 PURPOSE

This document, *Policy Assessment for the Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides, External Review Draft* (hereafter referred to as *Draft PA*), presents the draft policy assessment for the U.S. Environmental Protection Agency's (EPA's) current review of the primary (health-based)[1] national ambient air quality standard (NAAQS) for sulfur oxides (SO_X).[2] The overall plan and schedule for this review were presented in the *Integrated Review Plan for the Primary National Ambient Air Quality Standard for Sulfur Dioxide* (IRP; U.S. EPA, 2014). The IRP also identified key policy-relevant issues to be addressed in this review and discussed the key documents that generally inform NAAQS reviews, including an Integrated Science Assessment (ISA), a Risk and Exposure Assessment (REA), and a Policy Assessment (PA).

The PA presents a staff evaluation of the policy implications of the key scientific and technical information in the ISA and REA for consideration by the Administrator.[3] Ultimately, a final decision on the primary standard for SO_X will reflect the judgments of the Administrator. The role of the PA is to help "bridge the gap" between the Agency's scientific assessments presented in the ISA and REA, and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS.

In evaluating the adequacy of the current standard and whether it is appropriate to consider alternative standards, the PA focuses on information that is most pertinent to evaluating the basic elements of the NAAQS: indicator, averaging time, form, and level.[4] These elements,

[1] The EPA is separately reviewing the welfare effects associated with sulfur oxides and the public welfare protection provided by the secondary SO_2 standard, in conjunction with a review of the secondary standards for nitrogen oxides and particulate matter with respect to their protection of the public welfare from adverse effects related to ecological effects (U.S. EPA, 2017a).

[2] This review focuses on the presence in ambient air of sulfur oxides, a group of closely related gaseous compounds that include sulfur dioxide and sulfur trioxide and of which sulfur dioxide is the most prevalent. Particulate atmospheric transformation products of SO_X, such as sulfates, are addressed in the review of the NAAQS for particulate matter.

[3] The terms "staff," "we," and "our" throughout this document refer to the staff in the EPA's Office of Air Quality Planning and Standards (OAQPS).

[4] The basic elements of a standard include the indicator, averaging time, form, and level. The indicator defines the chemical species or mixture to be measured in the ambient air for the purpose of determining whether an area attains the standard. The averaging time defines the period over which air quality measurements are to be obtained and averaged or cumulated. The form of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard. The level of the standard defines the air quality concentration used for that purpose (i.e., an ambient air concentration of the indicator).

which together serve to define each standard, must be considered collectively in evaluating the health protection afforded by the primary standard for SO_X.

The development of the PA is also intended to facilitate advice to the Agency and recommendations to the Administrator from an independent scientific review committee, the Clean Air Scientific Advisory Committee (CASAC), as provided for in the Clean Air Act (CAA). As discussed below in section 1.2.1, the CASAC is to advise not only on the Agency's assessment of the relevant scientific information, but also on the adequacy of the current standards, and to make recommendations as to any revisions of the standards that may be appropriate. The EPA makes available to the CASAC and the public one or more drafts of the PA for CASAC review and public comment.

The decision whether to prepare one or more drafts of the PA is influenced by preliminary staff conclusions and associated CASAC advice and public comments, among other factors. Typically, a second draft PA has been prepared in cases where the available information calls into question the adequacy of the current standard and analyses of potential alternative standards are developed taking into consideration CASAC advice and public comment. In such cases, a second draft PA includes preliminary staff conclusions regarding potential alternative standards and undergoes CASAC review and public comment prior to preparation of the final PA. When such analyses are not undertaken, a second draft PA may not be warranted.

In this draft PA, we take into account the available scientific and technical information, as assessed in the second draft *Integrated Science Assessment for Sulfur Oxides – Health Criteria* (second draft ISA [U.S. EPA, 2016]) and the draft *Risk and Exposure Assessment for the Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides, External Review Draft* (draft REA [U.S. EPA, 2017b]). The evaluation and preliminary staff conclusions presented in this draft PA for the primary NAAQS for SO_X have been informed by comments and advice received from the CASAC in their reviews of the other draft Agency documents prepared thus far in this NAAQS review. Review and comments from the CASAC, and public comment, on this draft of the PA will inform the final evaluation and staff conclusions in the final PA. The final PA will inform the Administrator's decision in this review of the primary SO_2 NAAQS.

Beyond informing the EPA Administrator and facilitating the advice and recommendations of the CASAC, the PA is also intended to be a useful reference to all parties interested in the review of the primary NAAQS for SO_X. In these roles, it is intended to serve as a source of policy-relevant information that is informing the Agency's review of the primary NAAQS for SO_X, and it is written to be understandable to a broad audience.

1.2 BACKGROUND

1.2.1 Legislative Requirements

Two sections of the 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 that 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…." 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]

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 Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980), cert. denied. 449 U.S. 1042 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981), cert. denied, 455 U.S. 1034 (1982); *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

[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, man-made 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."

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 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 Association v. EPA*, 647 F.2d at 1161-62; *Mississippi v. EPA*, 744 F. 3d at 1353.

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 at 1185.

Section 109(d)(1) requires that "[n]ot later than December 31, 1980, and at five-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section [108] and the national ambient air quality standards…and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate…." Section 109(d)(2) requires that an 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 CASAC of the EPA's Science Advisory Board.[7]

[7] Lists of the CASAC members and of members of the CASAC Sulfur Oxides Panel are available at: https://yosemite.epa.gov/sab/sabpeople.nsf/WebCommitteesSubcommittees/CASAC%20Sulfur%20Oxides%20Panel

1.2.2 History of the Reviews of the Primary NAAQS for SO_X

The initial air quality criteria for SO_X were issued in 1969 (34 FR 1988, February 11, 1969). Based on these criteria, the EPA, in initially promulgating NAAQS for SO_X in 1971, established the indicator as SO_2. The two primary standards set in 1971 were 0.14 parts per million (ppm) averaged over a 24-hour period, not to be exceeded more than once per year, and 0.03 ppm, as an annual arithmetic mean.

The first review of the air quality criteria and standards for SO_X was completed in several stages. In the first stage, the EPA released the Air Quality Criteria Document (AQCD) for PM and SO_X in December 1981, and an addendum presenting information from subsequently available controlled human exposure studies in 1982 (U.S. EPA, 1982a, 1982b). The policy aspects of the air quality criteria, and preliminary exposure analyses were evaluated by OAQPS staff in the 1982 Staff Paper (U.S. EPA, 1982c).

In 1986, the EPA published a second addendum to the 1982 AQCD, presenting newly available evidence from epidemiologic and controlled human exposure studies (U.S. EPA, 1986a). Policy-relevant aspects of the new evidence and staff findings from a companion population exposure assessment were evaluated in a 1986 Addendum to the 1982 Staff Paper (U.S. EPA, 1986b, 1986c). The CASAC reviewed all of these documents and provided advice and recommendations with regard to decisions for the review of the standards. Based on the evidence in the 1982 and 1986 documents, staff evaluations and CASAC recommendations, in 1988, the EPA proposed to retain the existing standards and solicited comment on the alternative of retaining the existing standards while additionally establishing a 1-hour standard of 0.4 ppm to protect against short-term exposures (53 FR 14926, April 26, 1988). In 1992, the American Lung association brought a lawsuit to compel the EPA to review and, if appropriate, revise the primary standards for SO_X, and the remainder of the review was then completed under court order (59 FR 58962, November 15, 1994; 61 FR 25566, May 22, 1996).

In response to publication of additional relevant controlled human studies on health effects of short-term SO_2 concentrations, the EPA prepared a supplement to the second addendum to the 1982 AQCD (1994 AQCD supplement [U.S. EPA, 1994a]). Policy-relevant aspects of the full body of evidence, including that newly available, along with the 1986 exposure analysis were evaluated in the 1994 Supplement to the 1982 Staff Paper (U.S. EPA, 1994b). In 1994, based on the available evidence, staff evaluations, CASAC advice, and public comment on the 1988 proposal, the EPA re-proposed to retain the existing standards and also solicited comment on retaining the existing standards in combination with one of three policy options to further reduce the health risk posed by exposure to high 5-minute peaks of SO_2 if additional protection were judged to be necessary (59 FR 58958, November 15, 1994). The three alternatives were: (1) Revising the existing primary SO_2 NAAQS by adding a new 5-minute

standard of 0.60 ppm SO_2, not to be exceeded more than once per calendar year; (2) establishing a new regulatory program under section 303 of the CAA to supplement protection provided by the existing NAAQS, with a trigger level of 0.60 ppm SO_2, not to be exceeded more than once per calendar year; and (3) augmenting implementation of existing standards by focusing on those sources or source types likely to produce high 5-minute peak concentrations of SO_2.

This review was completed in 1996 with the EPA's decision to retain without revision the existing standards (61 FR 25566, May 22, 1996). In reaching this decision, the Administrator concluded, based on the staff exposure analysis, that exposure of individuals with asthma to SO_2 levels that can reliably elicit adverse health effects was likely a rare event when viewed in the context of the entire population of people with asthma. As a result, the Administrator judged that 5-minute peaks of SO_2 did not pose a broad public health problem when viewed from a national perspective, and a 5-minute standard was not promulgated (61 FR 25566, May 22, 1996).

In 1996, the American Lung Association and the Environmental Defense Fund challenged the EPA's decision not to establish a 5-minute standard. On January 30, 1998, the Court of Appeals for the District of Columbia ("D.C. Circuit") found that the EPA had failed to adequately explain its determination that no revision to the SO_2 NAAQS was appropriate and remanded the decision back to EPA for further explanation. Specifically, the court determined that the EPA had not provided adequate rationale to support the judgment that 5-minute peaks of SO_2 do not pose a public health problem from a national perspective even though these peaks will likely cause adverse health impacts in a subset of individuals with asthma. *American Lung Ass'n v. EPA*, 134 F. 3d 388, 392-393 (D.C. Cir. 1998). Following the remand, the EPA requested that states voluntarily submit 5-minute SO_2 monitoring data for the EPA to use to gain a better understanding of the magnitude and frequency of high, 5-minute peak SO_2 concentrations.

The next and most recent review of the air quality criteria and primary standards for SO_X was completed in 2010 (75 FR 35520, June 22, 2010). As a result of this review, the EPA promulgated a new 1-hour standard to provide the requisite protection for at-risk populations such as people with asthma against an array of adverse respiratory health effects related to short-term SO_2 exposures. The 1-hour standard was set with SO_2 as the indicator based on its common occurrence in the atmosphere and the predominance of SO_2 studies in the health effects information for SO_X. The standard was set at a level of 75 parts per billion (ppb), based on the 3-year average of the annual 99th percentile of 1-hour daily maximum SO_2 concentrations. The EPA also revoked the then-existing 24-hour and annual primary standards based largely on the conclusion that the 1-hour standard would also control longer-term average concentrations, maintaining 24-hour and annual concentrations generally well below the levels of those standards, and on the lack of evidence indicating the need for such longer-term standards. The

2010 action also addressed the remand by the D.C. Circuit in 1998. The 2010 and prior standards are summarized in Table 1-1.

Table 1-1. History of the primary national ambient air quality standard(s) for sulfur oxides since 1971.

Final Rule/Decision	Indicator	Averaging Time	Level	Form
April 30, 1971 (36 FR 8186)	SO_2	24 hours	140 ppb[a]	one allowable exceedance
		1 year	30 ppb[a]	arithmetic average
May 22, 1996 (61 FR 25566)	Both the 24-hour and annual average standards retained without revision			
June 22, 2010 (75 FR 35520)	SO_2	1 hour	75 ppb	99th percentile of yearly distribution of 1-hour daily maximums, averaged over 3 years
		24-hour and annual standards revoked		

[a] Although the levels were set in terms of ppm (0.14 ppm for the 24-hour standard and 0.03 ppm for the annual standard), they are shown here in ppb for consistency with units of current standard.

In conjunction with the 2010 revisions to the standards, the EPA revised the SO_2 ambient air monitoring regulations to require that monitoring agencies using continuous SO_2 methods report the highest 5-minute concentration for each hour of the day; many agencies additionally report all twelve 5-minute concentrations for each hour of the day (75 FR 35554, June 22, 2010; 40 CFR 58.16). The rationale for this requirement was to provide additional monitoring data for use in subsequent reviews of the primary standard, particularly in considering the extent of protection provided by the 1-hour standard against 5-minute peak SO_2 concentrations of concern (75 FR 35554, June 22, 2010).

After publication of the final rule, a number of industry groups and states filed petitions for review arguing (1) that the EPA failed to follow notice-and-comment rulemaking procedures because the proposal did not indicate that EPA was considering changing its method of determining attainment from an air-monitoring approach to a hybrid approach using computer modeling in combination with air monitoring, and (2) that the decision to establish a 1-hour SO_2 NAAQS at 75 ppb was arbitrary and capricious because it was lower than statutorily authorized. The D.C. Circuit rejected these challenges, dismissing the first argument for lack of jurisdiction and denying the petitions with respect to the second argument, explaining that the EPA did not act arbitrarily in setting the 2010 standard. *National Environmental Developmental Association's Clean Air Project v. EPA,* 686 F. 3d 803 (D.C. Cir. 2012). Accordingly, the 2010 standard was upheld. *Id*.

1.2.3 Current SO_2 NAAQS Review

In May 2013, the EPA announced the initiation of the current periodic review of the air quality criteria for sulfur oxides and the primary NAAQS for sulfur oxides and issued a call for information in the *Federal Register* (78 FR 27387, May 10, 2013). A wide range of external experts as well as EPA staff representing a variety of areas of expertise (e.g., epidemiology, human and animal toxicology, statistics, risk/exposure analysis, atmospheric science) participated in a workshop, held by the EPA on June 12-13, 2013 in Research Triangle Park, NC. The workshop provided for a public discussion of the key policy-relevant issues around which the EPA has structured the review and of the most meaningful new scientific information that would be available in this review to inform our understanding of these issues.

Building from the workshop discussions, the EPA developed the draft *Integrated Review Plan for the Primary National Ambient Air Quality Standards for Sulfur Dioxide* (IRP, U.S. EPA, 2014) outlining the schedule, process, and key policy-relevant questions that would guide the evaluation of the air quality criteria for SO_2 and the review of the primary NAAQS for SO_X. The draft IRP was released in March 2014 (79 FR 14035, March 12, 2014) and was the subject of a consultation with the CASAC on April 22, 2014 (79 FR 16325, March 25, 2014). Comments received from the CASAC and the public were considered in the preparation of the final IRP, which was released in October 2014 (U.S. EPA, 2014).

The process for development of the first draft ISA included review of preliminary drafts of key ISA chapters by subject matter experts at a public workshop hosted by the EPA's National Center for Environmental Assessment (NCEA) on June 23-24, 2014 (79 FR 33750, June 12, 2014). Comments received from this review as well as comments from the public and the CASAC on the draft IRP were considered in preparation of the *Integrated Science Assessment for Sulfur Oxides – Health Criteria (External Review Draft – November 2015),* released in November 2015 (80 FR 73183, November 24, 2015). The first draft ISA was reviewed by the CASAC at a public meeting in January 2016 and a public teleconference in April 2016 (80 FR 79330, December 21, 2015; 80 FR 79330, December 21, 2015; Diez Roux, 2016).

The EPA released the *Integrated Assessment for Sulfur Oxides – Health Criteria (Second External Review Draft – December 2016)* in December 2016 (81 FR 89097), which was reviewed by the CASAC at a public meeting in March 2017 and a public teleconference in June 2017 (82 FR 11449, February 23, 2017; 82 FR 23563, May 23, 2017). Completion of the final ISA is expected in December 2017.

As part of the planning process for development of the REA, the EPA completed the *Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides: Risk and Exposure Assessment Planning Document* (REA Planning Document, U.S. EPA, 2017c) in February 2017 (82 FR 11356), and held a consultation with the CASAC at a public meeting in

March 2017 (82 FR 11449). In consideration of CASAC comments at that consultation and public comments, the EPA developed the draft REA (U.S. EPA, 2017b). The draft REA and this draft PA are being provided to the CASAC for their review and released to the public for comment. The CASAC advice and public comments will be considered in completing these documents.

The schedule for completion of this review is governed by a consent decree entered by the court, which, in relevant part, specifies that the appropriate EPA official issue a final Integrated Science Assessment addressing human health effects of SO_X no later than December 14, 2017; sign a notice setting forth its proposed decision concerning its review of the primary NAAQS for SO_X no later than May 25, 2018; and sign a notice setting forth its final decision concerning its review of the primary NAAQS for SO_X no later than January 28, 2019 (Consent Decree at 4, *Center for Biological Diversity et al. v. Pruitt*, Case No. 3:16-cv-03796-VC (N.D. Cal. April 28, 2017), Document No. 37).

1.3 GENERAL APPROACH AND ORGANIZATION OF THIS DOCUMENT

This draft PA draws on the policy-relevant aspects of the scientific evidence and quantitative air quality, exposure and risk analyses. With regard to the health effects evidence, we consider the nature of the key effects associated with SO_2 in ambient air, the types and magnitudes of exposures associated with effects, and populations at greatest risk, as well as the uncertainties. Based on this information, we summarize associated potential public health impacts of SO_2 in ambient air. We additionally consider the magnitude of exposures and risks estimated in the REA, along with the associated uncertainties. This evaluation supports preliminary staff conclusions with regard to the key policy-relevant questions for the review, including whether the currently available information appears to call into question the adequacy of public health protection afforded by the current standard.

Following this introductory chapter, chapter 2 focuses on current air quality, including sources of SO_2 to ambient air, the ambient monitoring network for SO_2, and trends and current conditions. Chapter 3 focuses on the review of the primary NAAQS for SO_X presenting background information on the rationale for previous reviews and the approach followed in the current review. Chapter 3 further discusses the adequacy of the current standards, taking into account evidence- and exposure-/risk-based considerations, and includes preliminary staff conclusions. Chapter 3 also identifies key uncertainties and areas for future research.

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2 CURRENT AIR QUALITY

This chapter presents a summary of our current understanding of SO_X in ambient air largely drawn from the more detailed discussion provided in the second draft ISA (second draft ISA, chapter 2). Section 2.1 summarizes the current information on sources and emissions and section 2.2 summarizes current ambient air monitoring methods and networks. Recent concentrations of SO_2 in ambient air are summarized in section 2.3.

2.1 SOURCES TO AMBIENT AIR

In this section, we describe the most recently available information on sources and emissions of SO_X into the ambient air. The section does not provide a comprehensive list of all sources, nor does it provide estimates of emission rates or emission factors for all source categories. Rather, the discussion here is intended to identify the larger source categories, either on a national or local scale, and generally describe their emissions and distribution within the U.S. based on the U.S. EPA 2014 National Emissions Inventory (NEI).

Sulfur oxides are emitted into air from specific sources (e.g., fuel combustion processes) and also formed in the atmosphere from other atmospheric compounds (e.g., as an oxidation product of reduced sulfur compounds, such as sulfides). Sulfur oxides are also transformed in the atmosphere to particulate sulfur compounds, such as sulfates. Sulfur oxides known to occur in the troposphere include SO_2 and sulfur trioxide (SO_3) (second draft ISA, section 2.3). As a result of rapid atmospheric chemical reactions involving SO_3, the most prevalent sulfur oxide in the atmosphere is SO_2 (second draft ISA, section 2.3).

Fossil fuel combustion is the main anthropogenic source of SO_2 emissions, while volcanos and landscape fires (wildfires as well as controlled burns) are the main natural sources (second draft ISA, section 2.1).[1] Industrial chemical production, pulp and paper production, natural biological activity (plants, fungi, and prokaryotes), and volcanoes are among many sources of reduced sulfur compounds that contribute, through various oxidation reactions in the atmosphere, to the formation of SO_2 in the atmosphere (second draft ISA, section 2.1). Anthropogenic SO_2 emissions originate primarily from point sources, including coal-fired electricity generating units (EGUs) and other industrial facilities (second draft ISA, section

[1] The 2008 ISA (U.S. EPA, 2008) described a modeling analysis that estimated SO_2 concentrations for 2001 in the absence of any U.S. anthropogenic emissions of SO_2 (2008 ISA, section 2.5.3). Such concentrations are referred to as United States background or USB. The 2008 ISA analysis estimated USB concentrations of SO_2 to be below 0.01 ppb over much of the U.S., ranging up to a maximum of 0.03 ppb. In the U.S. Northwest, geothermal sources (e.g., volcanoes) were estimated to be responsible for up to 80% of the ambient air concentrations resulting solely from natural sources and sources outside of the U.S. (second draft ISA, section 2.5.5).

2.2.1). The largest SO_2-emitting sector within the U.S. is electricity generation, of which 97% of SO_2 from electricity generation is from coal combustion, as shown in Figure 2-1. Other anthropogenic sources of SO_2 emissions include industrial fuel combustion and process emissions, industrial processing, commercial marine activity, and fire used in landscape management and agriculture (second draft ISA, section 2.2.1).

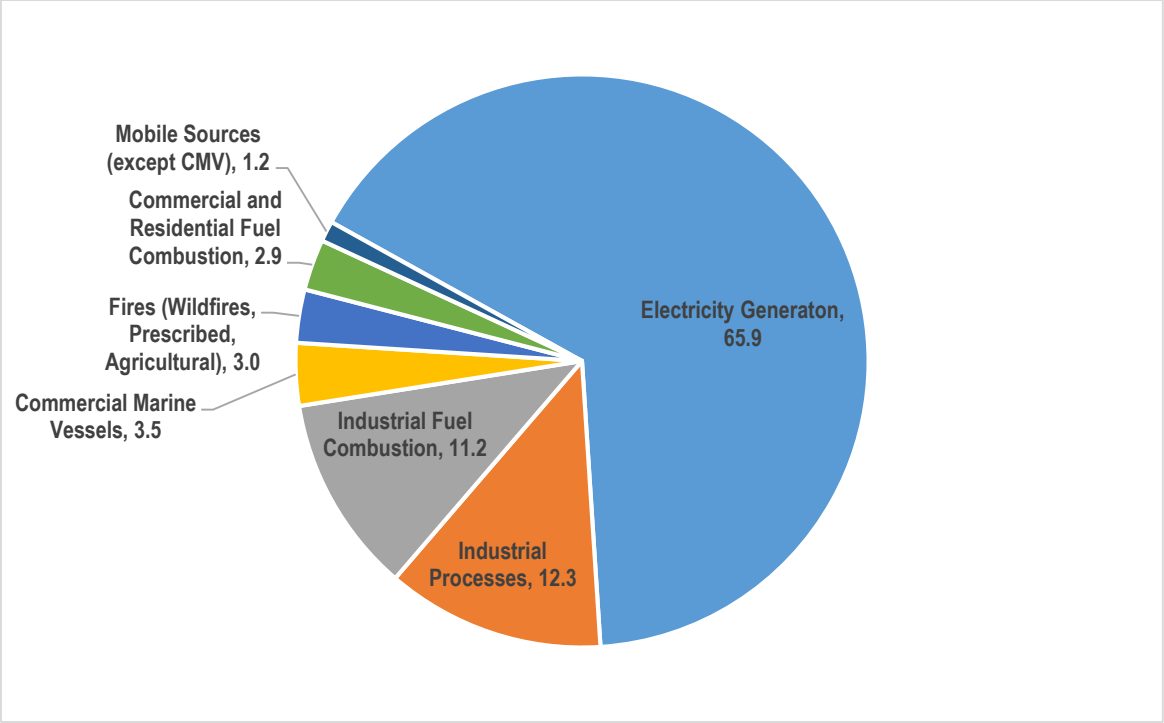

Figure 2-1. Percent contribution of SO_2 emissions by sector (Source: 2014 NEI).[2]

Figure 2-2 illustrates the emissions trends from 1990 to 2015. Declines in SO_2 emissions are likely related to the implementation of Clean Air Act national control programs including Phase I and II of the Acid Rain Program, the Clean Air Interstate Rule, and the Cross-State Air Pollution Rule. An additional factor is changes in market conditions, e.g., reduction in energy generation by coal (U.S. EIA, 2017).[3]

[2] Total SO_2 emissions from the 2014 NEI were 4,942,063 tons.

[3] The reduction in energy generation by coal resulted in the use of fuels that emit less SO_2 in energy generation (U.S. EIA, 2016).

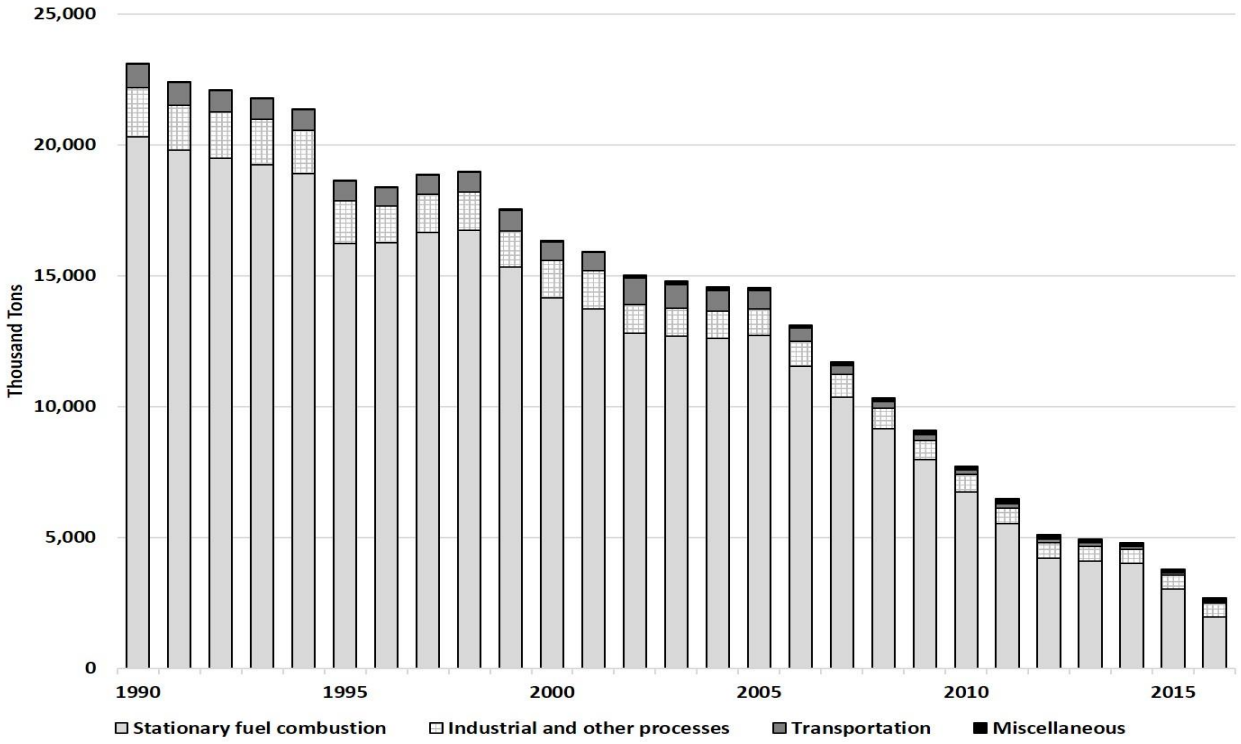

Figure 2-2. National SO_2 emission trends by sector.

2.2 AMBIENT AIR MONITORING METHODS AND NETWORK

To promote uniform enforcement of the air quality standards set forth under the CAA, the EPA has established federal reference methods (FRMs) and federal equivalent methods (FEMs) for ambient air sample collection and analysis. Measurements for determinations of NAAQS compliance must be made with FRMs or FEMs. The current SO_2 monitoring network relies on the automated pulsed ultraviolet fluorescence (UVF) FRM (40 CFR Appendix A-1 to Part 50; 40 CFR Appendix A-2 to Part 50). The UVF method is a continuous automated method that quantifies SO_2 concentrations, providing averages across desired time periods, such as 5-minute and 1-hour averages.

Measurements of SO_2 concentrations in ambient air are collected by networks of FRM monitors, primarily operated by state and local monitoring agencies in the U.S. The main network providing ambient data for NAAQS surveillance monitoring purposes is the State and Local Air Monitoring Stations (SLAMS) network. In 2016, there were 363 SLAMS sites reporting SO_2 concentrations to the Air Quality System (AQS), the EPA's repository for detailed air pollution data. For each SO_2 monitoring site, the SLAMS monitoring agencies report hourly concentrations and either the maximum 5-minute concentration in the hour (one of twelve 5-

minute periods within an hour) or all twelve 5-minute average SO_2 concentrations within the hour.

Five minute SO_2 data have become much more widely available due to regulatory requirements promulgated in 2010 (Figure 2-3).[4] Although 5-minute data were available for fewer than 10% of monitoring sites at the time of the last review, such data (either all 12 values in each hour or just the maximum 5-minute concentrations) are currently available for nearly all of the operating SO_2 sites nationwide, providing a more robust foundation for characterization of 5-minute ambient air concentrations in this review. Further, the newly available monitoring data also include more monitors reporting the 12 consecutive 5-minute concentrations for each hour than were available in the last review (Figure 2-3). Of the monitors reporting 5-minute data in 2016, almost 40% are reporting all twelve 5-minute SO_2 measurements in each hour while about 60% are reporting the maximum 5-minute SO_2 concentration in each hour.[5]

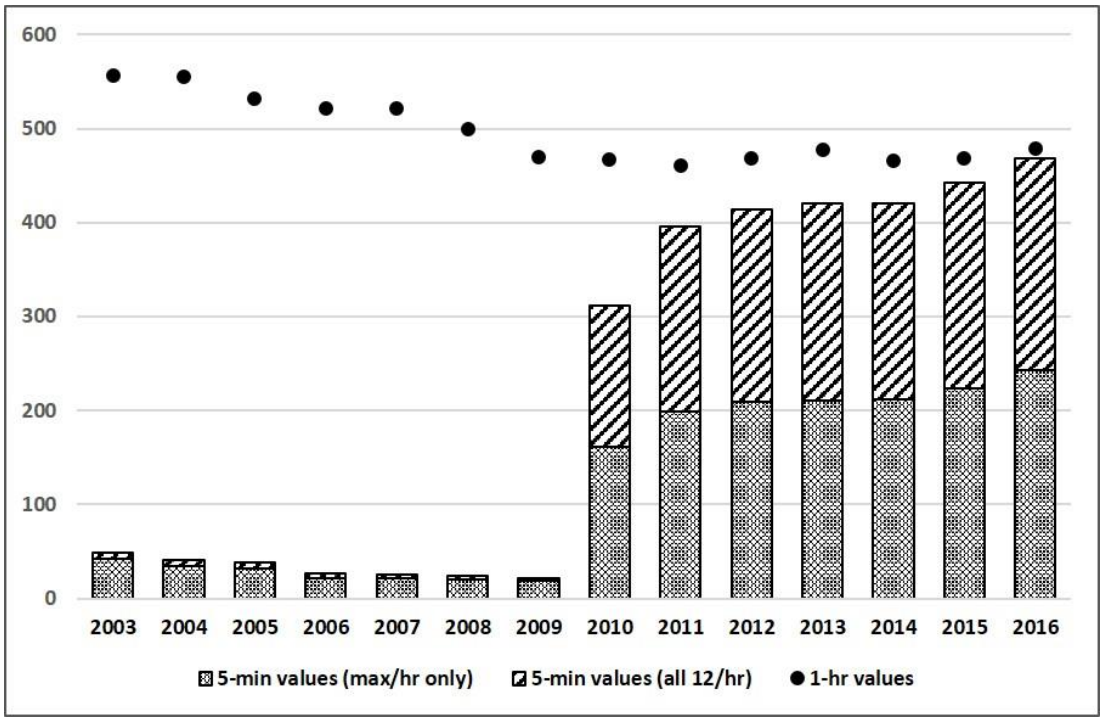

Figure 2-3. Temporal trend in number of monitors with 5-minute data.

[4] At SO_2 NAAQS compliance monitoring sites, air monitoring agencies are now required to report, for every hour of the day, the hourly average and either the maximum 5-minute value (one of twelve 5-minute periods) in the hour or all twelve 5-minute averages within the hour (75 FR 35554, June 22, 2010).

[5] In 2016, three of the sites reported both the continuous 5-minute data and the maximum 5-minute data separately. Therefore, these monitors are included in the count for each of the types of 5-minute monitors.

2.3 AMBIENT AIR MONITORING CONCENTRATIONS

This section briefly summarizes trends and current conditions based on recent ambient air monitoring data.

2.3.1 Trends

Ambient air concentrations of SO_2 in the U.S. have declined substantially from 1980 to 2015. Figure 2-4 illustrates this decline in terms of the distribution of 3-year average of annual 99th percentile daily maximum 1-hour concentrations[6] at 45 monitoring sites that have been operating across this period. The average of this dataset has declined by more than 83% over the 35-year period. Over the past 15 years, a larger dataset of 227 sites operating from 2000-2015 also indicates a decline, which is on the order of 67% for the average of that dataset (Figure 2-5).[7] Daily maximum 5-minute SO_2 concentrations have also consistently declined over time from 2011 to 2015 (Figure 2-6).[8]

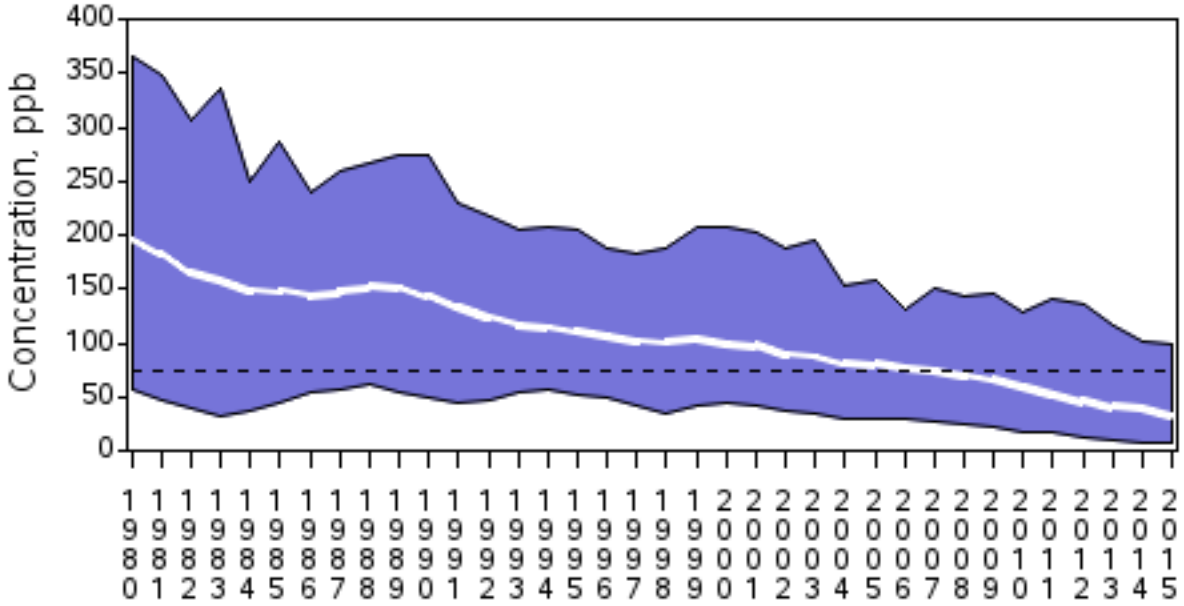

Figure 2-4. National temporal trend in SO_2 concentrations: 1980-2015 (45 sites). Three-year average of annual 99th percentile of daily maximum 1-hour concentrations. *(Note: Dashed line indicates the current standard [75 ppb].)*

[6] The form of the current 1-hour SO_2 NAAQS is the 99th percentile of yearly distribution of 1-hour daily maximums, averaged over 3 years.

[7] In Figures 2-4 and 2-5, the year on the x-axis represents the last year of the 3 year average (e.g., 2015 represents the average of 2013-2015).

[8] In Figure 2-6, the number of sites with monitors for 2011, 2012, 2013, 2014, and 2015 were 301, 321, 366, 359, and 352, respectively.

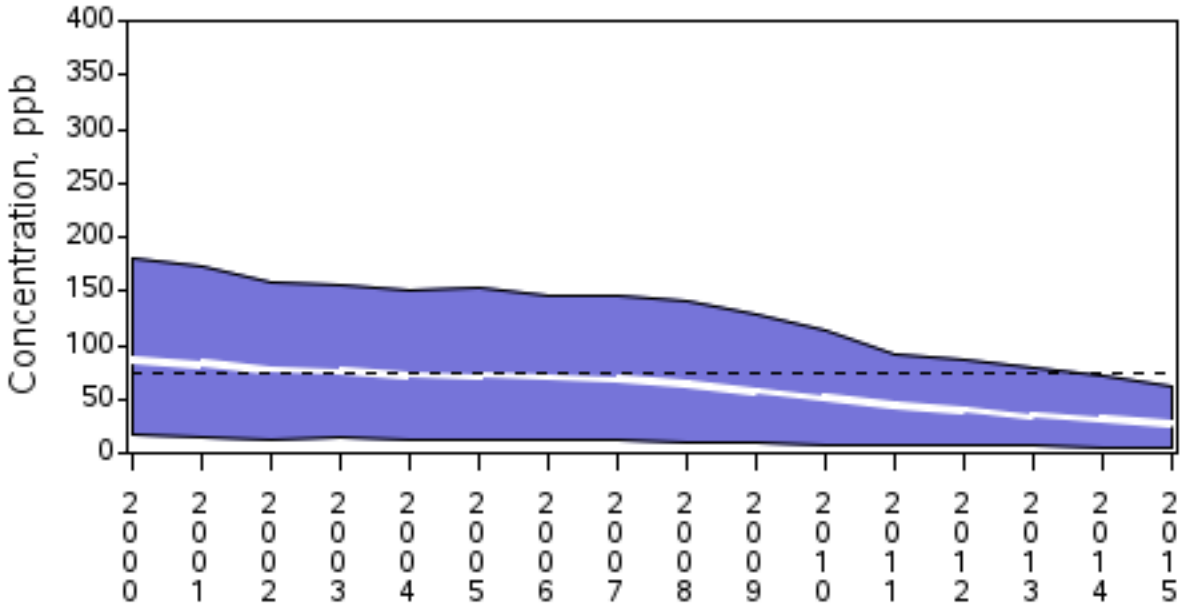

Figure 2-5. Temporal trend in SO_2 concentrations: 2000-2015 (227 sites). Three-year average of annual 99th percentile of daily maximum 1-hour concentrations. *(Note: Dashed line indicates the current standard [75 ppb]).*

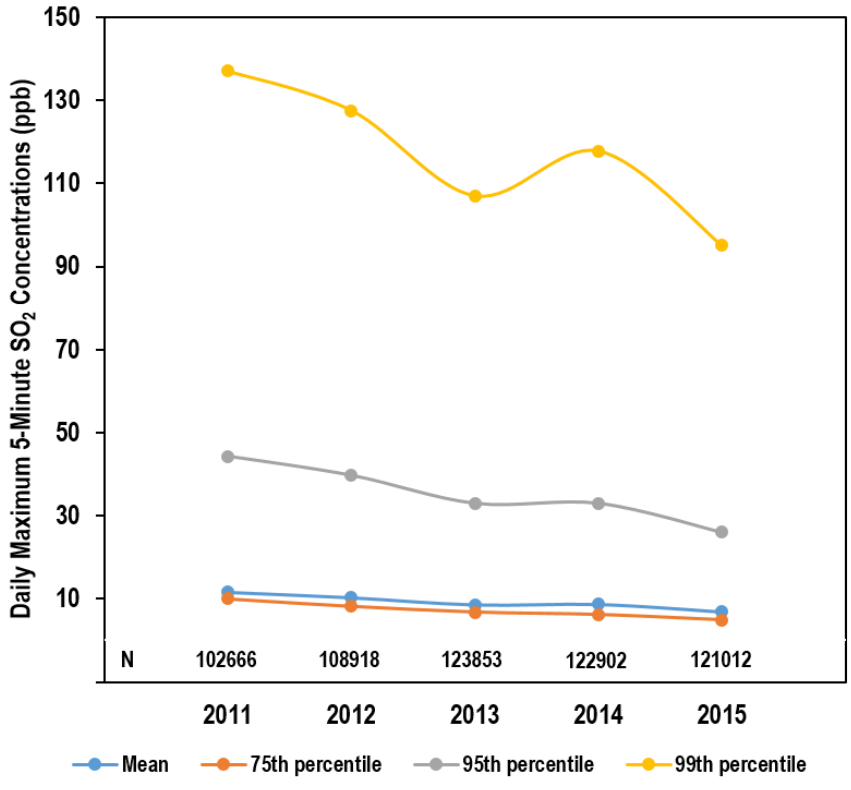

Figure 2-6. Temporal trend in daily maximum 5-minute SO_2 concentrations: 2011-2015. (N = number of measurements)

2.3.2 Current Concentrations

2.3.2.1 Geographic Variation in Concentrations

Concentrations of SO_2 vary across the U.S. and tend to be higher in areas with sources having relatively higher SO_2 emissions (e.g., EGUs). Consistent with the locations of larger SO_2 sources, higher concentrations are primarily located in the eastern half of the continental U.S., especially in the Ohio River valley, upper Midwest, and along the Atlantic coast (Figure 2-7). The point source nature of SO_2 emissions contribute to the relatively high spatial variability of SO_2 concentrations compared with pollutants such as ozone (O_3) (second draft ISA, section 3.2.3). Another contributing factor to the spatial variability is the dispersion and oxidation of SO_2 in the atmosphere, resulting in decreasing SO_2 concentrations with increasing distance from the source. Sulfur oxides emitted from point sources tends to travel away from the emissions source as a plume, which may or may not impact large portions of surrounding populated areas depending on meteorological conditions and terrain.

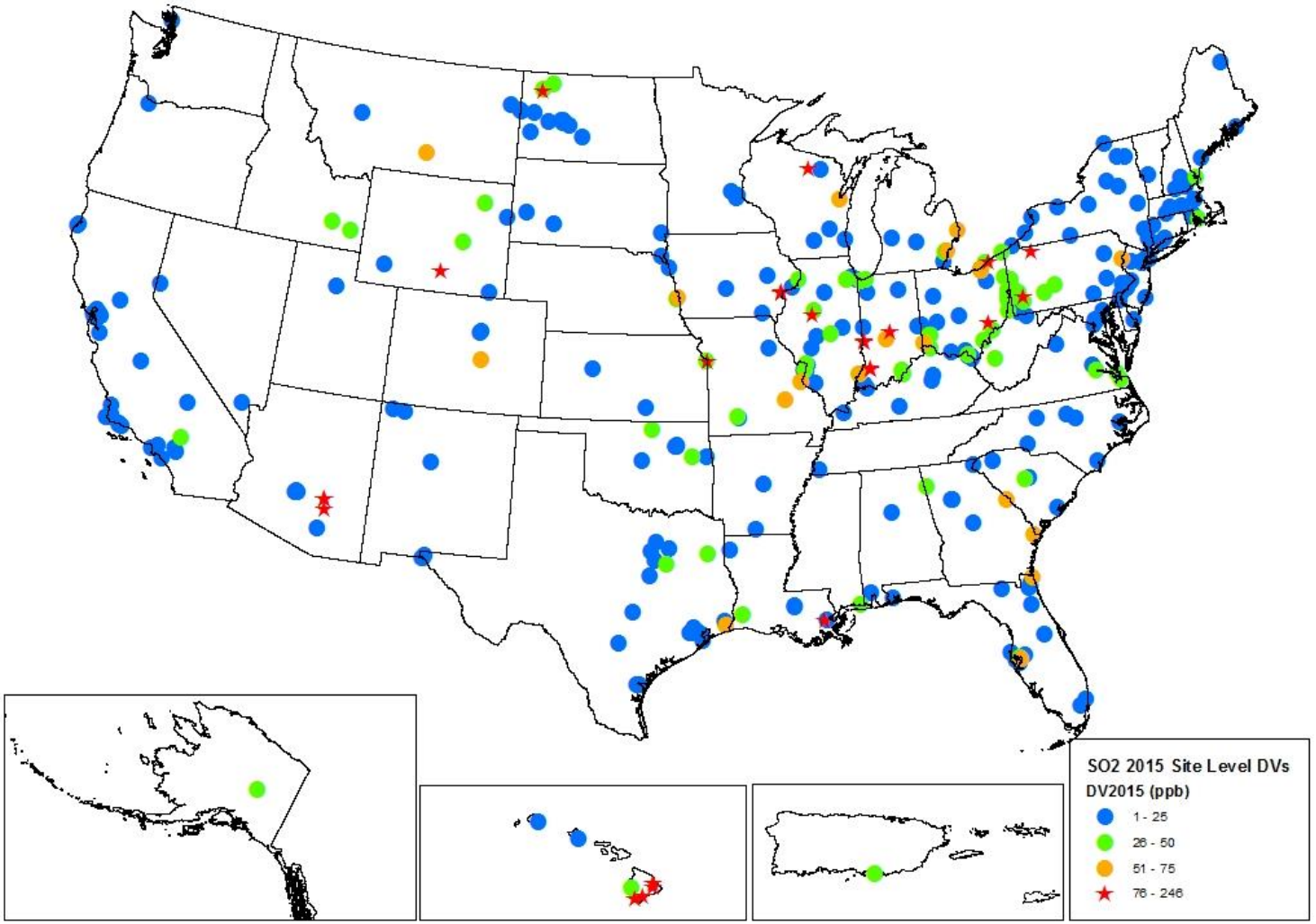

Figure 2-7. Concentrations of SO_2 in terms of the current standard (3-year average of annual 99th percentile daily maximum 1-hour concentrations) at sites with datasets meeting completeness requirements for 2013-2015.

2.3.2.2 Seasonal and Diel Variability in Concentrations

Recent (2013-2015) data indicate that 1-hour daily maximum SO_2 concentrations vary across seasons, with the greatest variations seen in the upper percentile concentrations (versus average or lower percentiles) for each season (second draft ISA, section 2.5.3.2). This is seen in the data presented for six urban areas in the draft ISA[9] (second draft ISA, section 2.5.3.2). This variation, along with month-to-month variations in 1-hour daily maximum SO_2 concentrations also presented in the ISA, were generally consistent with month-to-month emissions patterns and the expected atmospheric chemistry of SO_2 for a given season. For example, "summertime minima, observed in the New York City, NY and Houston, TX, sites may correspond to enhanced oxidation of SO_2 to SO_4^{2-} by photochemically derived atmospheric oxidants that are more prevalent during the humid summer (Khoder, 2002)" (second draft ISA, p. 2-55). The differences in seasonal pattern (as well as magnitude) of concentrations among areas studied indicate the variability of SO_2 concentrations across local and regional scales (second draft ISA, section 2.5.3.2).

Consistent with the nationwide diel patterns reported in the last review, 1-hour average and 5-minute hourly maximum SO_2 concentrations for 2013-2015 in all six urban areas evaluated were generally low during nighttime and approached maxima values during daytime hours (second draft ISA, section 2.5.3.3, Figures 2-23 and 2-24). The timing and duration of daytime maxima in the six sites evaluated were likely related to a combination of source emissions and meteorological parameters (second draft ISA, section 2.5.3.3; U.S. EPA 2008, section 2.5.1). For example, SO_2 emitted from elevated point sources (e.g., power plants and industrial sources) may be entrained into the mixed boundary layer, which expands during the day with rising surface temperatures (U.S. EPA 2008, section 2.5.1, Figures 2-23 and 2-24).

2.3.2.3 Relationship Between 1-hour and 5-minute Concentrations

Peak concentrations within a plume of SO_2 downwind from, but relatively nearby to, a source can greatly exceed mean concentrations across the plume (second draft ISA, section 2.5.4). Further, measured 5-minute concentrations at a particular location can be much higher than the average concentration at the same location for the associated hour. However, as emissions travel further downwind and experience ever increasing dispersion, these differences lessen both spatially and temporally. This can contribute to greater spatial and temporal

[9] The six locations evaluated are: Cleveland, OH, Pittsburgh, PA, New York City, NY, St. Louis, MO-IL, Houston, TX, and Gila County, AZ (second draft ISA, section 2.5.2.2). These six locations were based on (1) their relevance to current health studies (i.e., areas with peer-reviewed, epidemiologic analysis), (2) the existence of four or more monitoring sites located within the area boundaries, and (3) the presence of several diverse SO2 sources within a given focus area boundary.

variability in 5-minute than in 1-hour concentrations, as is seen in the six urban locations evaluated in the ISA (second draft ISA, p. 2-52).

Using monitoring data from 2013-2015, Figure 2-8 illustrates the general pattern of lower 5-minute concentrations with lower 1-hour concentrations. The left panel of Figure 2-8 shows that across the monitors meeting data completeness criteria, on days when the maximum 1-hour concentrations are relatively low, the maximum 5-minute concentrations are also relatively low. Similarly, as shown in the right panel of Figure 2-8, at sites with relatively lower design values,[10] the distribution of maximum 5-minute concentrations is also lower. This is documented by the distinct reduction in 99th percentile daily maximum 5-minute concentrations at lower design values. For example, in areas with design values at or below the current standard (75 ppb), 99.9 percent of daily maximum 5-minute concentrations are at or below approximately 150 ppb.[11] This contrasts with the much higher distribution of daily maximum 5-minute concentrations at sites with design values exceeding the current standard. The 99th percentile of these daily maximum 5-minute concentrations is 365 ppb, meaning that one percent of the days at these sites has a maximum 5-minute concentration above 365 ppb (i.e., 210 occurrences).

[10] The design value (DV) for the standard is the metric used to determine whether areas meet or exceed the NAAQS. A design value is a statistic that describes the air quality status of a given area relative to the NAAQS. Design values are considered to be valid if the monitoring data used to calculate them meet the regulatory completeness criteria which for SO_2 require four quarters of all three years of the period to have data for at least 75 percent of the sampling days (40 CFR 50.17 and appendix T to Part 50).

[11] Additional information related to data in Figure 2-8 is presented in Appendix B.

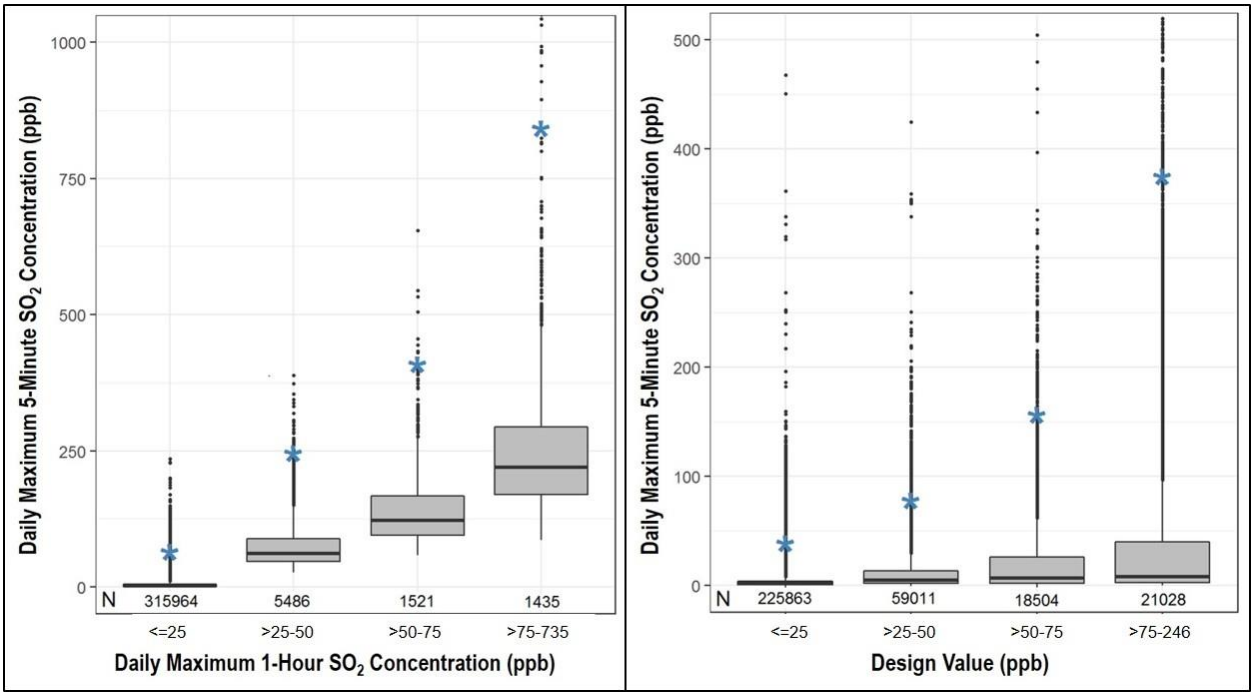

Figure 2-8. Distributions of daily maximum 5-minute concentrations during 2013-2015. Left panel presents varying distributions with varying daily maximum 1-hour concentrations. Right panel presents varying distributions with varying design values; the last bin (>75 ppb) presents data for sites not meeting the current standard. *(Note: The values represented in the boxplots are the 25th percentile, the median, and the 75th percentile. The asterisk represents the 99th percentile.)*

Analyses of the current monitoring dataset, expanded since the last review, provide information on the occurrence of daily maximum 5-minute concentrations of interest at monitors having differing design values. For example, analysis of these data for the years 2013 to 2015 indicates that among monitors with design values meeting the current standard (i.e., at or below 75 ppb), the vast majority have zero days with a daily maximum 5-minute concentration above 100 ppb or even 400 ppb. Among the few monitors with any days recording a 5-minute concentrations above 400 ppb, the maximum number of such days in a year was five; for monitors with any days recording 5-minute concentrations above 200 ppb, the maximum number of such days/year was 22 (Appendix C, Figures C-2 and C-4, lower panel).

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3 REVIEW OF THE PRIMARY STANDARD FOR SULFUR OXIDES

This chapter evaluates the policy implications of the key scientific and technical information in the second draft ISA and draft REA. This evaluation is based on consideration of the available body of evidence assessed in the second draft ISA and of quantitative analyses of SO_2 air quality, exposures and risks presented in the draft REA and in this document. Based on this information, the staff offer preliminary conclusions regarding each of the critical elements of the standard, including indicator, averaging time, form, and level. The final PA will also be informed by the advice and recommendations received from the CASAC during its review of the draft PA, and by public comments received on the draft document. The final PA is designed to help the Administrator in considering the currently available scientific and risk information and formulating judgments regarding the adequacy of the current primary standard.[1]

3.1 APPROACH

Staff's approach in this review of the primary standard for SO_X takes into consideration the approaches used in the previous review. The past and current approaches described below are both based, most fundamentally, on using the EPA's assessment of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding a primary standard for SO_X that is requisite to protect public health with an adequate margin of safety. In reaching conclusions on options for the Administrator's consideration, we note that the final decision to retain or revise the current SO_2 primary standard is a public health policy judgment to be made by the Administrator.

The final decision by the Administrator will draw upon the available scientific evidence for SO_2-attributable health effects, and on quantitative analyses of population exposures and health risks, including judgments about the appropriate weight to assign the range of uncertainties inherent in the evidence and analyses. Therefore, in developing conclusions in this draft PA, we are mindful that the Administrator's judgments on the standard will reflect an interpretation of the available scientific evidence and exposure/risk information in consideration of the strengths and limitations of that evidence and information. Our general approach to

[1] The basic elements of a standard include the indicator, averaging time, form, and level. The indicator defines the chemical species or mixture to be measured in the ambient air for the purpose of determining whether an area attains the standard. The averaging time defines the period over which air quality measurements are to be obtained and averaged or cumulated. The form of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard. The level of the standard defines the air quality concentration used for that purpose (i.e., an ambient air concentration of the indicator).

informing these judgments, discussed more fully below, recognizes that the available health effects evidence reflects a continuum from relatively higher SO_2 concentrations, at which scientists generally agree that health effects are likely to occur, through lower concentrations at which the likelihood and magnitude of a response become increasingly uncertain. This approach is consistent with the requirements of sections 108 and 109 of the CAA, as well as with how the EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish primary standards that in the Administrator's judgment 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 reduces risk sufficiently so as to protect public health with an adequate margin of safety.[2]

Section 3.1.1 below summarizes the approach used in the last review of the primary NAAQS for SO_X and section 3.1.2 summarizes the general approach for the current review.

3.1.1 Approach in the Previous Review

The last review of the primary NAAQS for SO_X was completed in 2010 and resulted in substantial revisions to the standards (75 FR 35520, June 22, 2010). In consideration of the evidence of respiratory effects in people with asthma in response to exposures as short as five minutes, the EPA established a new short-term standard to provide increased protection for this at-risk group and other potentially at-risk populations[3] against an array of adverse respiratory effects that have been linked to short-term SO_2 exposures in both controlled human exposure and epidemiologic studies (75 FR 35525, June 22, 2010; 2008 ISA, section 5.5). Specifically, the EPA replaced the then-existing 24-hour standard with a short-term standard defined by the 3-year average of the 99th percentile of the yearly distribution of 1-hour daily maximum SO_2 concentrations, with a level of 75 ppb. In addition to replacing the 24-hour standard with a new 1-hour standard, the EPA revoked the then-existing annual standard, based largely on the lack of sufficient health evidence to support a long-term standard and a recognition that a 1-hour standard set at 75 ppb would have the effect of generally maintaining annual SO_2 concentrations well below the level of the revoked annual standard (75 FR 35550, June 22, 2010).

[2] The four basic elements of the NAAQS (indicator, averaging time, level and form) are considered collectively in evaluating the health protection afforded by the current standard.

[3] As used here and similarly throughout the document, the term *population* refers to persons having a quality or characteristic in common, such as a specific pre-existing illness or a specific age or lifestage. A lifestage refers to a distinguishable time frame in an individual's life characterized by unique and relatively stable behavioral and/or physiological characteristics that are associated with development and growth. Identifying at-risk populations includes consideration of intrinsic (e.g., genetic or developmental aspects) or acquired (e.g., disease or smoking status) factors that increase the risk of health effects occurring with exposure to sulfur oxides as well as extrinsic, nonbiological factors, such as those related to socioeconomic status, reduced access to health care, or exposure.

The emphasis in the 2010 review on short-term exposures of people with asthma reflected the health effects evidence that has expanded in this area over the four decades since the then-existing 24-hour and annual standards were set in 1971. A key element of the expanded evidence base was a series of controlled human exposure studies which documented effects on lung function in people with asthma exposed, while at moderate or greater levels of exertion, for periods as short as five minutes. In the 2010 review, the EPA also conducted quantitative analyses of air quality data, including 5-minute ambient air measurements, and of potential exposures for people with asthma. Consideration of these key aspects of the evidence and quantitative analyses informed the decision in the 2010 review, which additionally addressed the court remand[4] to the EPA of the EPA's 1996 decision to retain the 1971 standards without revision.

The evidence-based and quantitative assessments performed for the 2010 review focused particularly on the issue of exposures to SO_2 in ambient air of a duration as short as five minutes (2008 ISA; 2009 REA). The quantitative analyses documented in the REA included characterizations of the likelihood of people with asthma being exposed (while they were at elevated exertion[5]) to concentrations of SO_2 from ambient air of a magnitude documented to elicit decrements in lung function (2009 REA). These analyses were performed both for air quality conditions associated with just meeting the then-existing standards and for conditions associated with just meeting potential alternative standards. The REA additionally included air quality analyses that explored the extent to which potential alternative standards with 1-hour, 24-hour, and annual averaging times might be expected to control 5-minute ambient air concentrations (2009 REA, section 7.3). Together the evidence-based and quantitative assessments informed the policy options considered by the Administrator in that review. Considerations, conclusions and judgments by the Administrator that provided the basis for her decisions in the 2010 review are summarized below.

3.1.1.1 Considering the Need for Revision

The conclusions reached by the Administrator in the last review were based on the extensive body of scientific evidence on SO_2-related health effects and quantitative analyses of air quality, exposure and risk. In her conclusion on the adequacy of the then-existing standards,

[4] See *Am. Lung Ass'n v. EPA*, 134 F.3d 388 (D.C. Cir. 1998) (remanding the 1996 decision to EPA).

[5] The phrase "elevated ventilation" (or "moderate or greater exertion") was used in the 2009 REA and Federal Register notices in the last review to refer to activity levels that in adults would be associated with ventilation rates at or above 40 liters per minute; an equivalent ventilation rate was derived in order to identify corresponding rate for the range of ages and sizes of the simulated populations (2009 REA, section 4.1.4.4). Accordingly, this phrase is used in this draft PA when referring to the REA from the last review. Otherwise, however, the draft REA and draft PA for this review generally uses the phrase "elevated ventilation" to refer to the same occurrence.

which were set in 1971, the Administrator emphasized the evidence and quantitative analyses concerning 5-minute exposures. The Administrator gave particular attention to the robust evidence base, comprised of findings from controlled human exposure, epidemiologic, and animal toxicological studies that collectively were judged "sufficient to infer a causal relationship" between short-term SO_2 exposures ranging from 5 minutes to 24 hours and respiratory morbidity (75 FR 35535, June 22, 2010). The "definitive evidence" for this conclusion came from studies of 5- to 10-minute controlled exposures that reported respiratory symptoms and decreased lung function in exercising individuals with asthma (2008 ISA, section 5.2). Supporting evidence was provided by epidemiologic studies of a broader range of respiratory outcomes, with uncertainty noted about the magnitude of the study effect estimates, quantification of the exposure concentration-response relationship, potential confounding by co-pollutants, and other areas (75 FR 35535-35536, June 22, 2010; 2008 ISA, section 5.3).

In the controlled human exposure studies of exercising individuals with asthma, a dose-response relationship was documented, with both the percentage of individuals affected and the severity of the response increasing with increasing SO_2 concentrations (75 FR 35525, June 22, 2010). The evidence from these studies documents the occurrence of SO_2-related decrements in lung function based on reductions in forced expiratory volume (FEV_1) and increases in specific resistance of the airways (sRaw). Moderate[6] or greater decrements in lung function were reported in response to short (5- to 10-minute) exposures to concentrations as low as 200 to 300 ppb in approximately 5-30% of exercising individuals with asthma. In response to exposures at or above 400 ppb, approximately 20-60% experienced such decrements, frequently accompanied by respiratory symptoms; in many studies, responses at these concentrations were often statistically significant at the group mean level[7] (75 FR 35525-35526, June 22, 2010).

In reaching conclusions regarding the significance of the reported responses to the 5- to 10-minute controlled exposures, the Administrator considered guidelines from the American Thoracic Society (ATS), the CASAC's written advice and recommendations, and judgments made by the EPA in considering similar effects in previous NAAQS reviews (75 FR 35526 and

[6] In assessments for NAAQS reviews, the lung function responses described as indicative of a moderate functional response include increases in sRaw of at least 100% (e.g., 2008 ISA; U.S. EPA, 1994, Table 8; U.S. EPA, 1996, Table 8-3). The moderate category has also generally included reductions in FEV_1 of 10 to 20% (e.g., U.S. EPA, 1996, Table 8). For the 2008 ISA, the midpoint of that range (15%) was used to indicate a moderate response. A focus on 15% reduction in FEV_1 is also consistent with the relationship observed between sRaw and FEV_1 responses in the Linn et al. studies for which "a 100% increase in sRaw roughly corresponds to a 12 to 15% decrease in FEV_1" (U.S. EPA, 1994, p. 20). Thus, in the 2008 review, moderate or greater SO_2-related bronchoconstriction or decrements in lung function referred to the occurrence of at least a doubling in sRaw or at least a 15% reduction in FEV_1 (2008 ISA, p. 3-5).

[7] At concentrations of 400 to 500 ppb, the 2008 ISA notes that the evidence shows "stronger evidence with some statistically significant increases in respiratory symptoms," and at 600 ppb to 1 ppm, the 2008 ISA notes the evidence to show "clear and consistent increases in SO_2 induced respiratory symptoms" (2008 ISA, Table 3-1).

35536, June 22, 2010). Based on these considerations, the Administrator judged that the effects reported in exercising people with asthma following 5- to 10-minute SO_2 exposures at or above 200 ppb, especially at or above 400 ppb, can result in adverse health effects (75 FR 35536, June 22, 2010). In so doing, she recognized that effects reported for exposures below 400 ppb are appreciably less severe than those at and above 400 ppb (75 FR 35547, June 22, 2010).

In applying the health effects evidence to her consideration of the adequacy of the then-existing standards, the Administrator gave particular attention to the quantitative analyses that evaluated the potential for exercising individuals with asthma to experience exposures of a magnitude associated with adverse effects under air quality conditions that just met the then-existing standards. In addition to comparison of 5-minute air concentrations in 40 U.S. counties to 5-minute concentrations of potential concern (benchmark concentrations ranging from 100-400 ppb), the analyses included a population exposure-based assessment in two study areas, St. Louis, MO and Greene County, MO. Five-minute exposure concentrations were estimated for people with asthma while at elevated exertion levels. The 5-minute exposure concentrations were compared to benchmark concentrations, and also used to estimate the risk of lung function decrements in simulated at-risk populations. Among these analyses, the Administrator emphasized those that utilized the 5-minute benchmark concentrations that were derived from the controlled human exposure evidence and ranged from 100 ppb to 400 ppb. Based on her judgments regarding the significance of effects associated with 5-minute concentrations at or above 200 ppb and 400 ppb, the Administrator considered results of comparisons of exposure estimates to those benchmark concentrations to be particularly important, giving greater emphasis to those at or above 400 ppb (75 FR 35547, June 22, 2010).

The exposure-based assessment estimated the portion of the population with asthma in these two areas that would be expected to experience 5-minute exposures at or above 400 ppb and 200 ppb while engaged in activities causing them to be at elevated exertion levels. The Administrator particularly noted the exposure analysis results for the St. Louis case study. This analysis estimated that for air quality simulated to just meet the then-existing standards, substantial percentages of children with asthma at moderate or greater exertion[8] would be exposed, at least once annually, to air quality exceeding the 200 ppb and 400 ppb 5-minute benchmarks (75 FR 35536, June 22, 2010). The Administrator judged these 5-minute exposures to be significant from a public health perspective due to their estimated frequency: approximately 24% of children with asthma in St. Louis were estimated to be exposed while at moderate or greater exertion at least once per year to air quality exceeding the 5-minute 400 ppb

[8] In the 2009 REA, an equivalent ventilation rate of 22 L/min-m^2 was identified as the minimum value to reflect "moderate" or greater exertion that would correspond to the elevated ventilation rate for the exercising subjects in the controlled human exposure studies, which was 40-50 L/min (2009 REA, p. 236).

benchmark. Additionally, approximately 73% of children with asthma in St. Louis at moderate or greater exertion were estimated to be exposed at least once per year to air quality exceeding the 5-minute 200 ppb benchmark (75 FR 35536, June 22, 2010).

The Administrator also took note of the CASAC conclusion that the then-existing standards did not adequately protect public health. Specifically, the CASAC advised that: "the current 24-hour and annual standards are not adequate to protect public health, especially in relation to short-term exposures to SO_2 (5-10 minutes) by exercising asthmatics" (Samet, 2009, p. 15). Based on all of the considerations summarized above, the Administrator concluded that the then-existing 24-hour and annual primary standards were not providing the requisite protection of public health with an adequate margin of safety. In considering approaches to revising the standards, the Administrator concluded it to be appropriate to set a new standard that would provide requisite protection with an adequate margin of safety to people with asthma at elevated ventilation and that would afford protection from the adverse health effects of 5-minute to 24-hour SO_2 exposures (75 FR 35536, June 22, 2010).

3.1.1.2 Approach for Considering Revisions to the Standards

With regard to revisions to provide requisite public health protection, the Administrator concluded it was appropriate to set a 1-hour SO_2 standard at a level of 75 ppb based on the 3-year average of the 99th percentile of the yearly distribution of 1-hour daily maximum concentrations. The rationale and approach for selecting the 1-hour standard is presented below in terms of the individual elements of a NAAQS: indicator, averaging time, form, and level.

3.1.1.2.1 Indicator

In reaching her decision on the indicator for the new standard, the Administrator considered the conclusions of the ISA and REA, as well as advice from the CASAC and public comments (75 FR 35536, June 22, 2010). The EPA continued to focus on SO_2 as the most appropriate indicator for gaseous sulfur oxides because the available scientific information regarding health effects was overwhelmingly indexed by SO_2. Although the presence of gaseous SO_X species other than SO_2 in ambient air had been recognized, no alternative to SO_2 had been advanced as a more appropriate surrogate for ambient gaseous SO_X (75 FR 35536, June 22, 2010). Controlled human exposure studies and animal toxicological studies provided specific evidence for health effects following exposures to SO_2, and epidemiologic studies typically reported effects associated with SO_2 concentrations. Based on the information available in the last review and consistent with the views of the CASAC that "for indicator, SO_2 is clearly the preferred choice" (Samet, 2009, p. 14), the Administrator concluded it was appropriate to continue to use SO_2 as the indicator for a standard that was intended to address effects associated with exposure to SO_2, alone or in combination with other gaseous sulfur oxides (75 FR 35536,

June 22, 2010). In so doing, the EPA recognized that measures leading to reductions in population exposures to SO_2 will also likely reduce exposures to other sulfur oxides (75 FR 35536, June 22, 2010).

3.1.1.2.2 Averaging Time

With regard to the setting of the new standard, the Administrator agreed with the staff conclusion, based on conclusions in the ISA, advice from the CASAC, and air quality analyses, that the standard should be set to provide protection from short-term exposures of 5 minutes to 24 hours (75 FR 35539, June 22, 2010). Based on air quality analyses presented in the REA, the Administrator judged that the requisite protection from 5- to 10-minute exposure events could be provided without having a standard with a 5-minute averaging time (75 FR 35539, June 22, 2010). She judged that a standard with a 5-minute averaging time would result in significant and unnecessary instability in public health protection (75 FR 35539, June 22, 2010).[9] Accordingly, she considered other averaging times.

Results of air quality analyses in the REA suggested that a standard based on 24-hour average SO_2 concentrations would not likely be an effective or efficient approach for addressing 5-minute peak SO_2 concentrations, likely over-controlling in some areas, while under-controlling in others (2009 REA, section 10.5.2.2). In contrast, these analyses suggested that a 1-hour averaging time would be more efficient and effective at limiting 5-minute peaks of SO_2 (2009 REA, section 10.5.2.2.). Drawing on this information, the Administrator concluded that a 1-hour standard, with the appropriate form and level, would be likely to substantially reduce 5- to 10-minute peaks of SO_2 that had been shown in controlled human exposure studies to result in increased prevalence of respiratory symptoms and/or decrements in lung function in exercising people with asthma (75 FR 35539, June 22, 2010). Further she found that a 1-hour standard could substantially reduce the upper end of the distribution of SO_2 concentrations in ambient air that were more likely to be associated with respiratory outcomes (75 FR 35539, June 22, 2010).

The Administrator additionally took note of advice from the CASAC. The CASAC stated that the REA had presented a "convincing rationale" for a 1-hour standard, and that "a one-hour standard is the preferred averaging time" (Samet, 2009, pp. 15, 16). The CASAC further stated that it was "in agreement with having a short-term standard and finds that the REA supports a one-hour standard as protective of public health" (Samet, 2009, p. 1). Thus, in consideration of the available information summarized here and the CASAC's advice, the Administrator concluded that a 1-hour standard (given the appropriate level and form) was an appropriate

[9] Such instability could reduce public health protection by disrupting an area's ongoing implementation plans and associated control programs (75 FR 35537, June 22, 2010).

means of controlling short-term exposures to SO_2 ranging from 5 minutes to 24 hours (75 FR 35539, June 22, 2010).

3.1.1.2.3 Form

In considering the statistical form for the new short-term standard, the Administrator judged that the form of the standard should reflect the health effects evidence presented in the ISA that indicated that the percentage of people with asthma affected and the severity of the response increased with increasing SO_2 concentrations (75 FR 35541, June 22, 2010). She additionally found it reasonable to consider stability (e.g., to avoid disruption of programs implementing the standard and the related public health protections from those programs) as part of her consideration of the form for the standard (75 FR 35541, June 22, 2010). In so doing, she noted that a concentration-based form averaged over three years would likely be appreciably more stable than a no-exceedance based form, which had been the form of the then-existing 24-hour standard (75 FR 35541, June 22, 2010). The CASAC additionally stated that "[t]here is adequate information to justify the use of a concentration-based form averaged over 3 years" (Samet, 2009, p. 16). In consideration of this information, the Administrator judged a concentration-based form averaged over three years to be most appropriate (75 FR 35541, June 22, 2010).

In selecting a specific concentration-based form, the Administrator considered health evidence from the ISA as well as air quality and exposure information from the REA. In so doing, the Administrator concluded that the form of a new 1-hour standard should be especially focused on limiting the upper end of the distribution of ambient SO_2 concentrations (i.e., above 90^{th} percentile SO_2 concentrations) in order to provide protection with an adequate margin of safety against effects reported in epidemiologic and controlled human exposure studies (75 FR 35541, June 22, 2010). The Administrator further noted, based on results of air quality and exposure analyses in the REA, that a 99^{th} percentile form was likely to be appreciably more effective at limiting 5-minute peak exposures of concern than a 98^{th} percentile form (75 FR 35541, June 22, 2010). Thus, the Administrator selected a 99^{th} percentile form averaged over three years (75 FR 35541, June 22, 2010).

3.1.1.2.4 Level

In selecting the level of a new 1-hour standard, the Administrator gave primary emphasis to the body of health effects evidence assessed in the ISA. In so doing, she noted that the controlled human exposure studies provided the most direct evidence of respiratory effects from exposure to SO_2. The Administrator drew on evidence from these studies in reaching judgments on the magnitude of adverse respiratory effects and associated potential public health

significance for the air quality exposure and risk analysis results of air quality scenarios representing just meeting alternative levels for a new 1-hour standard.

In particular, the Administrator considered effects in exercising people with asthma after 5- to 10-minute exposures as low as 200 ppb to be adverse in light of the CASAC advice on relevance of these effects, conclusions on similar effects in prior NAAQS reviews, and ATS guidelines (ATS, 1985, 2000). This judgment was based on several findings from the controlled human exposures studies. Five-to 10-minute exposures to 400 ppb or greater resulted in moderate or greater decrements in lung function in 20-60% of exercising individuals with asthma. These decrements are often statistically significant at the group mean level and frequently accompanied by respiratory symptoms. Thus, exposures to SO_2 concentrations at or above 400 ppb were concluded to clearly result in adverse respiratory effects based on the ATS guidelines (ATS, 1985). Further, 5- to 10-minute exposures to 200 to 300 ppb resulted in moderate or greater decrements in lung function in 5-30% of exercising individuals with asthma (75 FR 35546, June 22, 2010). Although such effects have not been shown to be statistically significant at the full study group mean level,[10] or to be frequently accompanied by respiratory symptoms, the Administrator considered effects associated with exposures as low as 200 ppb to be adverse in light of the CASAC's advice[11] and similar conclusions in prior reviews as well as the ATS guidelines (ATS, 1985, 2000).

The Administrator then considered what the findings of the REA exposure analyses indicated with regard to varying degrees of protection that different 1-hour standard levels might be expected to provide against 5-minute benchmark concentrations of 200 ppb and 400 ppb.[12] For example, the exposure assessment for St. Louis[13] estimated that a 1-hour standard at 100 ppb would likely protect more than 99% of children with asthma in that city from experiencing any days in a year with at least one 5-minute exposure at or above 400 ppb while at moderate or greater exertion, and approximately 97% of those children with asthma from experiencing any days in a year with at least one exposure at or above 200 ppb while at moderate or greater exertion (75 FR 35547, June 22, 2010). Results for the air quality scenario for a 1-hour standard

[10] As summarized in section 3.2.1.1 below and described more fully in the second draft ISA for this review, study subjects have since been characterized as falling into two subpopulations that differ in susceptibility to SO_2.

[11] The CASAC letter on the first draft SO_2 REA to the Administrator stated: "CASAC believes strongly that the weight of clinical and epidemiology evidence indicates there are detectable clinically relevant health effects in sensitive subpopulations down to a level at least as low as 0.2 ppm SO_2" (Henderson, 2008).

[12] The Administrator additionally noted the results of the 40-county analysis of limited available 5-minute concentration data that indicated for a 1-hour standard level of 100 ppb a maximum annual average of two days per year with 5-minute concentrations above 400 ppb and 13 days with 5-minute concentrations above 200 ppb (76 FR 35546, June 22, 2010).

[13] St. Louis was one of two study areas assessed in the REA (2009 REA).

level of 50 ppb suggested that such a standard would somewhat further limit exposures, such that more than 99% of children at moderate or greater exertion would likely be protected from experiencing any days in a year with a 5-minute exposure at or above the 200 ppb benchmark concentration (75 FR 35542-47, June 22, 2010).

In considering the implications of the exposure assessment results the Administrator noted that although she considered the health effects resulting from 5-minute SO_2 exposures as low as 200 ppb to be adverse, she also recognized that such effects are appreciably less severe than those at SO_2 concentrations at or above 400 ppb and found little difference between the results for standard levels of 50 and 100 ppb with regard to 5-minute exposures at or above 400 ppb. She recognized that a standard level below 100 ppb may somewhat further limit 5-minute SO_2 ambient air concentrations and exposures above 200 ppb, although she did not judge that a standard level of 50 ppb was warranted.

Before reaching her conclusion with regard to level for the 1-hour standard, the Administrator additionally considered the epidemiological evidence among the U.S. epidemiologic studies (some conducted in multiple locations) reporting mostly positive and sometimes statistically significant associations between ambient SO_2 concentrations and emergency department visits and hospital admissions. She noted there was a cluster of three studies for which 99th percentile 1-hour daily maximum concentrations were estimated to be between 78-150 ppb and for which the SO_2 effect estimate remained positive and statistically significant in copollutant models with particulate matter (PM) (75 FR 35547, June 22, 2010).[14]

Given the above considerations and the comments received on the proposal, the Administrator determined that the appropriate judgment, based on the entire body of evidence and information available in this review, and the related uncertainties,[15] was a standard level of 75 ppb. She concluded that such a standard, with a 1-hour averaging time and 99th percentile form, would provide a significant increase in public health protection compared to the current standards and would be expected to provide protection, with an adequate margin of safety, against the respiratory effects that have been linked with SO_2 exposures in both controlled human exposure and epidemiologic studies. Specifically, she concluded that such a standard would limit 1-hour exposures at and above 75 ppb. (75 FR 35548, June 22, 2010). Such a standard was also considered likely "to maintain SO2 concentrations below those in locations

[14] Regarding the monitor concentrations in these studies, the EPA noted that although they may be a reasonable approximation of concentrations occurring in the areas, the monitored concentrations were likely somewhat lower than the absolute highest 99th percentile 1-hour daily maximum SO_2 concentrations occurring across these areas (75 FR 35547, June 22, 2010).

[15] Such uncertainties included both those with regard to the epidemiologic evidence and also those with regard to the information from controlled human exposure studies for at-risk groups, including representation of individuals with more severe asthma than that in study subjects (75 FR 35546, June 22, 2010).

where key U.S. epidemiologic studies have reported that ambient SO2 is associated with clearly adverse respiratory health effects, as indicated by increased hospital admissions and emergency department visits." The Administrator also found that "a 1-hour standard at a level of 75 ppb is expected to substantially limit asthmatics' exposure to 5–10 minute SO2 concentrations ≥ 200 ppb, thereby substantially limiting the adverse health effects associated with such exposures." Lastly, the Administrator noted "that a standard level of 75 ppb is consistent with the consensus recommendation of CASAC". The Administrator also considered the likelihood of public health benefits at lower standard levels, and judged a 1-hour standard at 75 ppb to be sufficient to protect public health with an adequate margin of safety (75 FR 35547-35548, June 22, 2010).

This judgment included consideration of the appropriate degree of protection with an adequate margin of safety for populations at increased risk for adverse respiratory effects from short-term exposures to SO_2 for which the evidence supports a causal relationship with SO_2 exposures. In reaching these conclusions, the Administrator considered the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognized that the CAA does not require that primary NAAQS be set at a zero-risk level or to protect the most susceptible individual, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety (75 FR 35548, June 22, 2010).

3.1.1.2.5 Revoking the Then-Existing 24-Hour and Annual Standards

In addition to setting a new 1-hour standard at 75 ppb, the then-current 24-hour and annual standards were revoked in the last review based largely on the recognition that a 1-hour standard set at 75 ppb would have the effect of generally maintaining 24-hour and annual SO_2 concentrations well below the levels of those standards (75 FR 35550, June 22, 2010). In addition, the annual standard was also revoked because of the lack of evidence supporting a relationship between long-term SO_2 exposures and adverse health effects. That is, the 2008 ISA judged the health evidence linking long-term SO_2 exposure to adverse health effects to be "inadequate" to infer the presence or absence of a causal relationship (75 FR 35550, June 22, 2010; 2008 ISA, section 5.5).

3.1.2 Approach for the Current Review

To evaluate whether it is appropriate to consider retaining the current SO_2 primary standard, or whether consideration of revision is appropriate, we have adopted an approach in this review that builds on the general approach used in the last review and reflects the body of evidence and information now available. As summarized above, the Administrator's decisions in the prior review were based on an integration of information on health effects associated with exposure to SO_2, expert judgments on the adversity and public health significance of key health effects, air quality and related analyses and quantitative exposure and risk assessments, and

policy judgments as to when the standard is requisite to protect public health with an adequate margin of safety.

In conducting this assessment, we draw on the current evidence and quantitative assessments of exposure pertaining to the public health risk of SO_2 in ambient air. In considering the scientific and technical information, we consider both the information available at the time of the last review and information newly available since the last review, including the second draft ISA and draft REA for this review. Figure 3-1 below illustrates the basic construct of our two-part approach in developing preliminary conclusions regarding options to consider with regard to the adequacy of the current primary standard and, as appropriate, potential alternative standards. In the boxes of Figure 3-1, the range of questions that we consider in sections 3.2.1 and 3.2.2 below are represented by a summary of policy-relevant questions that frame our consideration of the scientific evidence and quantitative analyses.

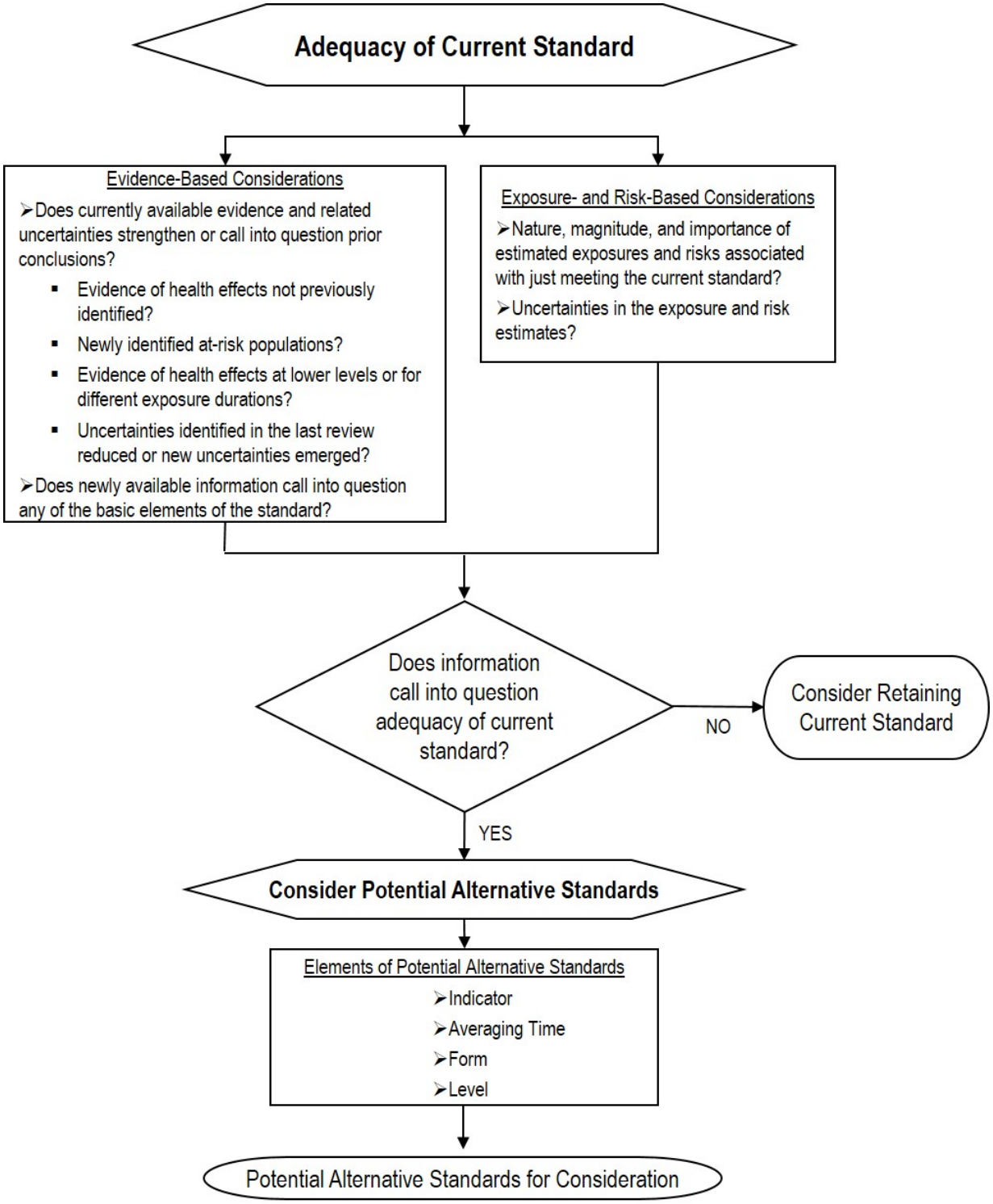

Figure 3-1. Overview of the approach for review of the current primary standard.

3.2 ADEQUACY OF THE CURRENT STANDARD

In considering the adequacy of the current SO_2 primary standard, the overarching question we consider is:

- **Does the currently available scientific evidence- and exposure/risk-based information, as reflected in the ISA and REA, support or call into question the adequacy of the protection afforded by the current SO_2 primary standard?**

To assist us in interpreting the currently available scientific evidence and the results of recent quantitative exposure/risk analyses to address this question, we have focused on a series of more specific questions, as detailed in sections 3.2.1 and 3.2.2 below. In considering the scientific and technical information, we consider both the information available at the time of the last review and information newly available since the last review which have been critically analyzed and characterized in the 2008 ISA for the last review and the second draft ISA for the current review.

3.2.1 Evidence-based Considerations

In considering the evidence with regard to the overarching question posed above regarding the adequacy of the current standard, we address a series of more specific questions that focus on policy-relevant aspects of the evidence. These questions begin with consideration of the available evidence regarding the health effects associated with exposure to SO_X, and particularly SO_2 (section 3.2.1.1). The subsequent questions consider identification of populations at-risk of SO_2-related health effects (section 3.2.1.2), and the exposure durations and levels of SO_2 associated with health effects (section 3.2.1.3). Important uncertainties associated with the evidence are considered in section 3.2.1.4.

3.2.1.1 Health Effects Associated with Exposure to SO_X

Among the species of SO_X (a group of closely related gaseous compounds including SO_2 and SO_3), SO_2 is the most commonly occurring in the atmosphere. Accordingly, the large body of scientific evidence has over the past reviews been predominantly focused on exposures to SO_2.

- **Is there newly available evidence that indicates the importance of SO_X other than SO_2 with regard to abundance in ambient air, and potential for human exposures and health effects?**

As in the last review, the health effects evidence evaluated in the second draft ISA for SO_X is focused on SO_2 (second draft ISA, p. 5-1). This is consistent with the conclusion that "[o]f the sulfur oxides, SO_2 is the most abundant in the atmosphere, the most important in atmospheric chemistry, and the one most clearly linked to human health effects" (second draft ISA, p. 2-1). While "SO_3 can be emitted by some sources, it reacts within seconds with water in

the stacks or immediately after release into the atmosphere to form H_2SO_4 and gas-phase sulfuric acid quickly condenses or contributes to particle formation" (second draft ISA, section 2.3). Thus, the second draft ISA states that "only SO_2 is present at concentrations relevant for chemistry in the troposphere, boundary layer, and for human exposures" (second draft ISA, p. 2-17), and also that the available health evidence for SO_X is focused on SO_2 (second draft ISA, p. 5-1). Thus, we conclude that the current evidence, including that newly available in this review, continues to support a focus on SO_2 in considering the adequacy of public health protection provided by the primary NAAQS for SO_X.

- **Does the current evidence alter our conclusions from the previous review regarding the health effects associated with exposure to SO_2?**

Rather than altering our conclusions from the last review, the current evidence continues to support our prior conclusions regarding the key health effects associated with SO_2 exposure. Specifically, the full body of evidence continues to support the conclusion that short-term SO_2 exposures of durations as short as a few minutes are causally related to respiratory effects in at-risk individuals (second draft ISA, section 5.2.1.9). With regard to respiratory effects and long-term exposures, as well as total mortality and short-term exposures, the evidence available in this review is "suggestive of, but not sufficient to infer," a causal relationship (second draft ISA, sections 5.2.2.7 and 5.5.1.6). The evidence is inadequate for reaching conclusions regarding causality for other categories of effects (second draft ISA, section 1.6.2).[16]

Respiratory Effects

As in the last review, the currently available evidence in this review supports the conclusion that there is a causal relationship between short-term SO_2 exposure and respiratory effects, particularly in individuals with asthma (second draft ISA, p. l-16).[17] The clearest evidence for this conclusion comes from controlled human exposure studies available at the time of the previous review and included in the 2008 ISA. These studies demonstrate lung function

[16] Based on the currently available evidence, the ISA concluded that the evidence was inadequate to infer the presence or absence of a causal relationship between SO_2 exposures and reproductive and developmental effects; between long-term SO_2 exposures and mortality or cancer; and, between short- or long-term SO_2 exposures and cardiovascular effects (second draft ISA, section1.6.2).

[17] While effects have been documented for short (5 to 10 minutes) exposures lower than 1.0 ppm in controlled exposure studies of individuals with asthma, the exposure concentrations consistently eliciting effects in study subjects without asthma are higher. Such exposures are generally above 1.0 or 5.0 ppm, with most studies reporting no respiratory symptoms at concentrations up to 2.0 ppm (second draft ISA, section 5.2.1.7).

decrements[18] and respiratory symptoms in people with asthma exposed to SO_2 for 5 to 10 minutes at elevated breathing rates (second draft ISA, section 5.2.1). The epidemiologic evidence, including recent evidence not available at the time of the previous review, includes studies reporting positive associations for asthma-related hospital admissions and emergency department visits with short-term SO_2 exposures (second draft ISA, section 5.2.1). These findings are generally supportive of the causal relationship conclusion for which the controlled exposure studies are the primary basis (second draft ISA, section 5.2.1.9).

Sulfur dioxide is a highly reactive and water-soluble gas that once inhaled is absorbed almost entirely in the upper respiratory tract[19] (second draft ISA, sections 4.2 and 4.3). Under conditions of elevated ventilation (e.g., while exercising), SO_2 penetrates into the tracheobronchial region,[20] where it may contribute to responses linked to asthma exacerbation in individuals with asthma (second draft ISA, sections 4.2, 4.3 and 5.2). More specifically, bronchoconstriction, which is characteristic of an asthma attack, is the most sensitive indicator of SO_2-induced lung function effects. Associated with this bronchoconstriction response is an increase in airway resistance which is an index of airway hyperresponsiveness (AHR),[21] Exercising individuals without asthma have also been found to exhibit such responses, but at much higher SO_2 exposure concentrations, above 1000 ppb (second draft ISA, section 1.5.2).

Bronchoconstriction, evidenced by decrements in lung function, is observed in controlled human exposure studies after approximately 5- to 10-minute exposures and can occur at SO_2 concentrations as low as 200 ppb in some people with asthma exposed while breathing at elevated ventilation, such as during exercise (second draft ISA, section 5.2.1.2).[22] More consistent decrements in lung function are seen in such individuals with asthma following exposures to 400 ppb and greater (second draft ISA, section 5.2.1.2). In contrast, respiratory effects are not observed in other people with asthma (nonresponders) and healthy adults exposed

[18] The specific responses reported in the evidence base that are described in the ISA as lung function decrements are increased specific airway resistance (sRaw) and reduced forced expiratory volume in 1 second (FEV_1) (second draft ISA, section 5.2.1.2).

[19] The term "upper respiratory tract" refers to the portion of the respiratory tract, including the nose, mouth and larynx, that precedes the tracheobronchial region (second draft ISA, sections 4.2 and 4.3).

[20] The term "tracheobronchial region" refers to the region of the respiratory tract subsequent to the larynx and preceding the deep lung (or alveoli). This region includes the trachea and bronchii.

[21] Airway hyperresponsiveness, which is an increased propensity of the airways to narrow in response to bronchoconstrictive stimuli, is a characteristic feature of people with asthma (second draft ISA, section 5.2.1.2).

[22] The data from controlled human exposure studies of people with asthma indicate there to be two subpopulations that differ in their airway responsiveness to SO_2, with the second subpopulation being insensitive to SO_2 bronchoconstrictive effects at concentrations as high as 1.0 ppm (second draft ISA, pp. 5-14 to 5-20; Johns et al., 2010).

while exercising to SO_2 concentrations below 1000 ppb (second draft ISA, sections 5.2.1.2 and 5.2.1.7). Across studies, bronchoconstriction in response to SO_2 exposure is mainly seen during conditions of increased ventilation rates, such as exercise or laboratory-facilitated rapid, deep breathing.[23] These conditions lead to a shift from nasal breathing to oral/nasal breathing, which increases the concentration of SO_2 reaching the tracheobronchial region of lower airways, where depending on dose and the exposed individual's susceptibility, it may cause bronchoconstriction (second draft ISA, sections 4.1.2.2, 4.2.2 and 5.2.1.2).

The evidence base of controlled human exposure studies for people with asthma is the same in this review as in the last review. Such studies reporting asthma exacerbation-related effects for individuals with asthma are summarized in Tables 5-1 and 5-2, and section 5.2.1.2 of the second draft ISA. The main responses observed include increases in specific airway resistance (sRaw) and reductions in forced expiratory volume in one second (FEV_1) after 5- to 10-minute exposures. As in the last review, the second draft ISA in this review quantifies the percentage of exposed study subjects with at least 100%, 200% or 300% increases in sRaw (i.e., a doubling, tripling or greater increase) and also those with at least 15%, 20% or 30% reduction in FEV_1. As recognized in the last review, the results of these studies indicate that among individuals with similar disease status, some individuals have a greater response to SO_2 than others (second draft ISA, p. 5-14). The SO_2-induced bronchoconstriction in these studies occurs rapidly, in as little as two minutes from exposure start, and is transient, with recovery following cessation of exposure (second draft ISA, p. 5-41).

The studies of subjects with asthma breathing at elevated ventilation have found effects to become more pronounced with increased exposure concentrations. Among individuals with asthma, both the percentage of individuals affected and the severity of the response increases with increasing SO_2 concentrations. For example, at concentrations ranging from 200 to 300 ppb, as many as 5 to 30% of exercising study subjects with asthma experienced moderate[24] or greater decrements in lung function (second draft ISA, Table 5-2). At concentrations at or above 400 ppb, moderate or greater decrements in lung function occurred in 20 to 60% of exercising study subjects with asthma, and compared to exposures at 200 to 300 ppb, a larger percentage of subjects experienced severe decrements in lung function (i.e., an increase in sRaw of at least 200%, and/or a reduction in FEV_1 of at least 20%) (second draft ISA, Table 5-2). Moreover, at

[23] In the laboratory, study subjects perform this rapid, deep breathing through a mouthpiece that provides a mixture of oxygen with enough carbon dioxide to prevent the imbalance of gases in the blood usually resulting from hyperventilation. Breathing in the laboratory with this technique is referred to as eucapnic hyperpnea.

[24] As in the last review (described in section 3.1.1.1 above), the second draft ISA describes moderate or greater lung function decrements as the occurrence of at least a doubling in sRaw or at least a 15% reduction in FEV_1 (second draft ISA, section 1.6.1.1).

the higher SO_2 concentrations, moderate or greater decrements in lung function were frequently accompanied by respiratory symptoms, such as cough, wheeze, chest tightness, or shortness of breath (second draft ISA, Table 5-2).

With regard to newly available epidemiological studies, there are a limited number of such studies that have investigated SO_2 effects related to asthma exacerbation, with the most cohesive evidence coming from studies on asthma-related emergency department (ED) visits (second draft ISA, section 5.2.1.2). As in the last review, areas of uncertainty in the epidemiologic evidence relate to the characterization of exposure through the use of fixed site monitor concentrations as surrogates for population exposure (often over a substantially sized area and for durations greater than an hour) and the potential for confounding by PM or other copollutants (second draft ISA, section 5.2.1). In general, the pattern of associations across the newly available studies is consistent with the studies available in the last review (second draft ISA, p. 5-70).

As in the last review, the evidence base for short-term SO_2 exposures and respiratory effects other than asthma exacerbation is limited and inconsistent. The second draft ISA finds the evidence for an effect of SO_2 exposure on allergy exacerbation, COPD exacerbation, respiratory infection, respiratory effects in healthy populations, and respiratory mortality to be inconsistent within and across disciplines and outcomes, and finds there to be uncertainty associated with the epidemiological evidence for these endpoints that is related to potential confounding by copollutants (second draft ISA, section 5.2.1.9).

The evidence base for long-term SO_2 exposure and respiratory effects is somewhat augmented since the last review such that the second draft ISA in the current review concludes it to be suggestive of, but not sufficient to infer, a causal relationship (second draft ISA, section 5.2.2). The support for this conclusion comes mainly from the limited epidemiological study findings of associations between long-term SO_2 concentrations and increases in asthma incidence combined with findings of laboratory animal studies involving newborn rodents that indicate a potential for SO_2 exposure to contribute to the development of asthma, especially allergic asthma, in children (second draft ISA, section 1.6.1.2). The evidence showing increases in asthma incidence is coherent with results of animal toxicological studies that provide a pathophysiologic basis for the development of asthma. The overall body of evidence, however, lacks consistency (second draft ISA, section 1.6.1.2). Further there are uncertainties, discussed in section 3.2.1.4 below, that apply to the epidemiologic evidence, including that newly available, across the respiratory effects examined for long-term SO_2 exposure (second draft ISA, section 5.2.2.7).

Other Health Effects

For effects other than respiratory effects, the current evidence is generally similar to the evidence available in the last review, and is supportive of similar conclusions. With regard to a relationship between short-term SO_2 exposure and total mortality, the second draft ISA reaches the same conclusion as in the previous review that the evidence is suggestive of, but not sufficient to infer, a causal relationship (second draft ISA, section 5.5.1). This conclusion is based on previous and recent multicity epidemiologic studies providing consistent evidence of positive associations, although there is uncertainty regarding the potential for SO_2 to have an independent effect on mortality. While recent studies have analyzed some key uncertainties and data gaps from the previous review, uncertainties still exist, given the limited number of studies that examined copollutant confounding, the evidence for a decrease in the size of SO_2-mortality associations in copollutant models with NO_2 and PM_{10}, and the lack of a potential biological mechanism for mortality following short-term SO_2 exposures (second draft ISA, section 1.6.2.4).

For other categories of health effects,[25] the evidence is inadequate to infer the presence or absence of a causal relationship, mainly due to inconsistent evidence across specific outcomes and uncertainties regarding exposure measurement error, copollutant confounding, and potential modes of action (second draft ISA, sections 5.3.1, 5.3.2, 5.4, 5.5.1, 5.5.2, 5.6). These conclusions are consistent with those made in the previous review.

In summary, rather than altering our conclusions from the previous review, the current evidence provides continued support for our previous conclusions regarding the health effects associated with exposure to SO_2 and most particularly respiratory effects following short-term SO_2 exposure, particularly in individuals with asthma. Accordingly, as in prior reviews, this review gives primary focus to those effects most pertinent to exposures related to current concentrations in ambient air, in particular, asthma exacerbation in individuals with asthma.

3.2.1.2 Populations At-Risk of SO_2-Related Health Effects

Populations or lifestages can be at increased risk of an air pollutant-related health effect due to one or more of a number of factors. These factors can be intrinsic, such as physiological factors that may influence the internal dose or toxicity of a pollutant, or extrinsic, such as sociodemographic, or behavioral factors. The questions considered in this section address what the currently available evidence indicates regarding which populations are particularly at risk of health effects related to exposure to SO_2 in ambient air.

[25] The other categories evaluated in the ISA include cardiovascular effects with short or long term exposures; reproductive and developmental effects; and cancer and total mortality with long-term exposure (second draft ISA, Table 1-1).

- **Does the current evidence alter our understanding of populations that are particularly at-risk from SO_2 exposures? Is there new evidence that suggests additional at-risk populations that should be given increased focus in this review?**

The currently available evidence continues to support our primary conclusions from the previous review that people with asthma are at increased risk for SO_2-related health effects, specifically for respiratory effects, and specifically asthma exacerbation, associated with short-term exposures while at elevated ventilation (second draft ISA, sections 5.2.1.2 and 6.3.1). This conclusion of the at-risk status of people with asthma is based on the well-established, and well-characterized, evidence from controlled human exposure studies, supported by the evidence on mode of action for SO_2 and with limited additional support from epidemiologic studies (second draft ISA, sections 5.2.1.2 and 6.3.1). Somewhat similar to the conclusion in the last review that children and older adults are potentially susceptible populations, the second draft ISA (relying on a more systematic approach for evaluating the evidence than in the last review) indicates the evidence to be suggestive of increased risk for these groups, with some limitations and inconsistencies (second draft ISA, sections 6.5.1.1 and 6.5.1.2).[26]

Further, the second draft ISA finds that children with asthma may be particularly at risk compared to adults with asthma (second draft ISA, section 6.3.1). This conclusion reflects several characteristics of children as compared to adults, which include their greater responsiveness to methacholine,[27] a chemical that can elicit bronchoconstriction in people with asthma, as well as their greater use of oral breathing, particularly by boys (second draft ISA, sections 5.2.1.2 and 4.1.2). Oral breathing (vs nasal breathing) and increased ventilation are factors that allow for greater SO_2 penetration into the tracheobronchial region of the lower airways, and reflect conditions of individuals with asthma in which bronchoconstriction-related responses have been observed in the controlled exposure studies (second draft ISA, sections 4.2.2, 5.2.1.2 and 6.3.1).

[26] The current evidence for risk to older adults relative to other lifestages comes from epidemiological studies, for which the findings are somewhat inconsistent, and studies with which there are uncertainties in the association with the health outcome (second draft ISA, section 6.5.1.2).

[27] The second draft ISA concluded that potential differences in airway responsiveness of children to SO_2 relative to adolescents and adults may be inferred by the responses to methacholine (second draft ISA, section 5.2.1.2). Methacholine is a chemical that can elicit bronchoconstriction through its action on airway smooth muscle receptors. It is commonly used to identify people with asthma and accordingly has been used to screen subjects for studies of SO_2 effects. An analysis of the extent to which airway responsiveness to methacholine, a history of respiratory symptoms, and atopy were significant predictors of airway responsiveness to SO_2, found that about 20 to 25% of subjects ranging in age from 20 to 44 years were hyperresponsive to methacholine (second draft ISA, section 5.2.1.2; Nowak et al., 1997). Another study focused on individuals with airway responsiveness to methacholine found only a weak correlation between airway responsiveness to SO_2 and methacholine (second draft ISA, section 5.2.1.2; Horstman et al., 1986).

We additionally recognize the well-documented finding that some individuals with asthma have a greater response to SO_2 than others with similar disease status (second draft ISA, section 5.2.1.2; Horstman et al., 1986; Johns et al., 2010). This occurrence is quantitatively analyzed in a study newly available in this review. This study uses the available individual subject data from five studies involving exposure of individuals with asthma to multiple concentrations of SO_2 for 5 to 10 minutes while at elevated ventilation to examine the differences in lung function response (Johns et al., 2010). As noted in the second draft ISA, "these data demonstrate a bimodal distribution of airway responsiveness to SO_2 in individuals with asthma, with one subpopulation that is insensitive to the bronchoconstrictive effects of SO_2 even at concentrations as high as 1.0 ppm, and another subpopulation that has an increased risk for bronchoconstriction at low concentrations of SO_2" (second draft ISA, p. 5-17). To date, the characteristics that may define the subpopulation of responders have not been identified. The current evidence for factors other than those discussed above (asthma status and lifestage) is inadequate to determine whether they might contribute to an increased risk of SO_2-related effects (second draft ISA, section 6.6).

3.2.1.3 Exposure Concentrations Associated with Health Effects

At the time of the last review, the EPA's conclusions regarding concentrations of SO_2 associated with respiratory effects were based primarily on the strong evidence base of controlled human exposure studies of individuals with asthma. These studies have documented bronchoconstriction-related moderate or greater decrements in lung function following 5- to 10-minute exposures during exercise. The severity of observed responses, the percentage of individuals responding, statistical significance at the study group level and the accompanying occurrence of respiratory symptoms have been found to increase with increasing exposure concentration (75 FR 35526, June 22, 2010). This information was critical in the REA analyses in the last review, the results of which were a primary consideration in reaching a conclusion on the level for the 2010 standard.

- **Does the current evidence alter our conclusions from the previous review regarding the exposure duration and concentrations associated with health effects?**

The current evidence, including that newly available in this review, supports conclusions from the last review on exposure duration and concentrations associated with SO_2–related health effects. These conclusions were largely based on the longstanding evidence base of controlled human exposure studies that demonstrates a relationship between 5- and 10-minute SO_2 exposure concentrations and decrements in lung function (e.g., increased sRaw and reduced FEV_1) in individuals with asthma exposed while at elevated ventilation rate (second draft ISA, section

1.6.1.1). At the higher concentrations, there are clear and consistent increases in SO_2-induced respiratory symptoms (second draft ISA, Table 5-2).

The available and well characterized evidence documents an effect of short-term exposures on the respiratory system. As summarized in section 3.2.1.1, SO_2-induced bronchonstriction occurs rapidly in responding study subjects with asthma exposed for just a few minutes while breathing at elevated ventilation rates (second draft ISA, section 5.2.1.2). Additionally, exposures as short as 5 minutes have been found to elicit a similar bronchoconstrictive response as somewhat longer exposures. For example, during exposure to SO_2 over a 30-minute period with continuous exercise, the response to SO_2 has been found to develop rapidly and is maintained throughout the 30-minute exposure (second draft ISA, p. 5-14). In a study involving short exercise periods within a 6-hour exposure period, the effects observed following exercise were documented to return to baseline levels within one hour after the cessation of exercise, even with continued exposure (Linn et al., 1984). In considering the epidemiological evidence with regard to the question of exposure duration, while we note the associations of asthma-related emergency room visits and hospital admissions with 1-hour to 24-hour ambient air concentration metrics, we recognize that current methods are not able to address whether these associations are due to exposure on the order of hours or much shorter-term exposure to peaks in SO_2 concentration. As noted in the second draft ISA, the air quality metrics in the epidemiological studies are for time periods longer than the 5- to 10-minute exposures eliciting effects in the controlled human exposure studies and may not adequately capture the spatial and temporal variation in SO_2 concentrations (second draft ISA, pp. 5-47, 5-55).

With regard to the evidence for exposure concentrations eliciting effects, we focus primarily on the controlled human exposure study findings for which data are available to the EPA for individual subjects with asthma that were exposed during elevated ventilation, summarized in Table 3-1 (second draft ISA, Table 5-2).[28] These data demonstrate that SO_2 concentrations as low as 200 to 300 ppb for 5 to 10 minutes elicited moderate or greater bronchoconstriction, measured as a decrease in FEV_1 of at least 15% or an increase in sRaw of at least 100% in a subset of the subjects (second draft ISA, section 5.2.1). Both the percent of individuals affected and the severity of response increased with increasing SO_2 concentrations. At concentrations ranging from 200 to 300 ppb, the lowest levels tested in free breathing chamber studies, 5 to 30% of exercising individuals with asthma experienced moderate or greater decrements in lung function (second draft ISA, section 5.2.1). At concentrations at or above 400 ppb, moderate or greater decrements in lung function occurred in 20 to 60% of exercising

[28] The findings summarized in Table 5-2 of the second draft ISA and in Table 3-1 of this draft PA are based on results that have been adjusted for effects at exercise in clean air so that they have separated out any effect of exercise in causing bronchoconstriction and reflect the SO_2-specific effect.

individuals with asthma and a larger percentage of individuals with asthma experienced more severe decrements in lung function (i.e., an increase in sRaw of at least 200%, and/or a 20% or more decrease in FEV_1), compared to exposures at 200 to 300 ppb (second draft ISA, section 5.2.1). Additionally, at concentrations at or above 400 ppb, moderate or greater decrements in lung function were frequently accompanied by respiratory symptoms, with some of these findings reaching statistical significance (second draft ISA, section 5.2.1).

Table 3-1. Percentage of adults with asthma in controlled human exposure studies experiencing sulfur dioxide-induced decrements in lung function and respiratory symptoms (adapted from Table 5-2 in the second draft ISA).

SO_2 Conc (ppm)	Exposure Duration (min)	N	Ventil-ation (L/min)	Cumulative Percentage of Responders (Number of Subjects)[a]				Study	Respiratory Symptoms: Supporting Studies
				sRaw	≥100% ↑	≥200% ↑	≥300% ↑		
				FEV_1	≥15% ↓	≥20% ↓	≥30% ↓		
0.2	5	23	~48	sRaw	9% (2)[b]	0	0	Linn et al. (1983b)	Limited evidence of SO_2-induced increases in respiratory symptoms in some people with asthma: Bethel et al., 1985; Horstman et al., 1986; Linn et al., 1983b; Linn et al., 1987; Linn et al., 1988; Linn et al. 1990; Schachter et al., 1984
	10	40	~40	sRaw	7.5% (3)[c]	2.5% (1)[c]	0[c]	Linn et al. (1987)[c]	
	10	40	~40	FEV_1	9% (3.5)[c]	2.5% (1)[c]	1% (0.5)[c]	Linn et al. (1987)[c]	
0.25	5	19	~50−60	sRaw	32% (6)	16% (3)	0	Bethel et al. (1985)	
	5	9	~80−90	sRaw	22% (2)	0	0	Bethel et al. (1985)	
	10	27	~42	sRaw	0	0	0	Horstman et al. (1986)	
	10	28	~40	sRaw	4% (1)	0	0	Roger et al. (1985)	
0.3	10	20	~50	sRaw	10% (2)	5% (1)	5% (1)	Linn et al. (1988)[d]	
	10	21	~50	sRaw	33% (7)	10% (2)	0	Linn et al. (1990)[d]	
	10	20	~50	FEV_1	15% (3)	0	0	Linn et al. (1988)	
	10	21	~50	FEV_1	24% (5)	14% (3)	10% (2)	Linn et al. (1990)	
0.4	5	23	~48	sRaw	13% (3)	4% (1)	0	Linn et al. (1983b)	Stronger evidence with some statistically significant increases in respiratory symptoms: Balmes et al., 1987;[f] Gong et al., 1995 ; Linn et al., 1983b; Linn et al., 1987 ; Roger et al., 1985
	10	40	~40	sRaw	24% (9.5)[c]	9% (3.5)[c]	4% (1.5)[c]	Linn et al. (1987)[c]	
	10	40	~40	FEV_1	27.5% (11)[c]	17.5% (7)[c]	10% (4)[c]	Linn et al. (1987)[c]	
0.5	5	10	~50−60	sRaw	60% (6)	40% (4)	20% (2)	Bethel et al. (1983)	
	10	27	~42	sRaw	22.2% (6)	7.4% (1)	3.7% (1)	Horstman et al. (1986)	
	10	28	~40	sRaw	18% (5)	4% (1)	4% (1)	Roger et al. (1985)	

SO_2 Conc (ppm)	Exposure Duration (min)	N	Ventil-ation (L/min)	Cumulative Percentage of Responders (Number of Subjects)[a]				Study	Respiratory Symptoms: Supporting Studies
				sRaw	≥100% ↑	≥200% ↑	≥300% ↑		
				FEV_1	≥15% ↓	≥20% ↓	≥30% ↓		
	10	45	~30	sRaw	36% (16)	16% (7)	13% (6)	Magnussen et al. (1990)[f]	
0.6	5	23	~48	sRaw	39% (9)	26% (6)	17% (4)	Linn et al. (1983b)	Clear and consistent increases in SO_2-induced respiratory symptoms: Gong et al., 1995; Horstman et al., 1988; Linn et al., 1983b; Linn et al., 1987; Linn et al., 1990
	10	40	~40	sRaw	34% (13.5)[c]	24% (9.5)[c]	19% (7.5)[c]	Linn et al. (1987)[c]	
	10	20	~50	sRaw	60% (12)	35% (7)	10% (2)	Linn et al. (1988)	
	10	21	~50	sRaw	62% (13)	29% (6)	14% (3)	Linn et al. (1990)	
	10	40	~40	FEV_1	47.5% (19)[c]	39% (15.5)[c]	17.5% (7)[c]	Linn et al. (1987)[c]	
	10	20	~50	FEV_1	55% (11)	55% (11)	5% (1)	Linn et al. (1988)	
	10	21	~50	FEV_1	43% (9)	38% (8)	14% (3)	Linn et al. (1990)	
1.0	10	28	~40	sRaw	50% (14)	25% (7)	14% (4)	Roger et al. (1985)[e]	
	10	10	~40	sRaw	60% (6)	20% (2)	0	Kehrl et al. (1987)	
	10	27	~42	sRaw	55.6% (15)	25.9% (7)	11% (1)	Horstman et al. (1986)	

Conc = concentration; FEV_1 = forced expiratory volume in 1 sec; sRaw = specific airway resistance; SO_2 = sulfur dioxide.

[a]Data presented from all references from which individual data were available in the published paper or were provided to EPA (Johns, 2009; Johns and Simmons, 2009; Smith, 1993). Percentage of individuals who experienced greater than or equal to a 100, 200, or 300% increase in specific airway resistance, or a 15, 20, or 30% decrease in FEV_1. Lung function decrements are adjusted for the effects of exercise in clean air (calculated as the difference between the percent change relative to baseline with exercise/SO_2 and the percent change relative to baseline with exercise/clean air).

[b]Numbers in parenthesis represent the number of subjects experiencing the indicated effect.

[c]Responses of people with mild and moderate asthma reported in Linn et al. (1987) have been combined. Data are the average of the first and second round exposure responses following the first 10 min period of exercise.

[d]Analysis includes data from only people with mild Linn et al. (1988) and moderate Linn et al. (1990) asthma who were not receiving supplemental medication.

[e]One subject was not exposed to 1 ppm due to excessive wheezing and chest tightness experienced at 0.5 ppm. For this subject, the values used for 0.5 ppm were also used for 1.0 ppm under the assumption that the response at 1.0 ppm would be equal to or greater than the response at 0.5 ppm.

[f]Indicates studies in which exposures were conducted using a mouthpiece rather than a chamber.

The lowest exposure concentration in Table 3-1 is 200 ppb. This is the lowest exposure concentration tested by studies in which study subjects breathed freely (e.g., without using a mouthpiece).[29] In such studies that tested 200 ppb, a portion of the exercising study subjects with asthma (approximately 8 to 9%) responded with at least a doubling in sRaw or an increase in FEV1 of at least 15% (Table 3-1; Linn et al., 1983b; Linn et al., 1987).

With regard to exposure concentrations below 200 ppb, the available evidence is very limited. This information is derived from studies in which the subjects were exposed by mouthpiece rather than freely breathing in an exposure chamber (Sheppard et al., 1981; Sheppard et al., 1984; Koenig et al., 1989; Koenig et al., 1990; Trenga et al., 2001).[30] Additionally, some of these studies did not include an exposure to clean air while exercising that would have allowed for determining the effect of SO_2 *versus* that of exercise in causing bronchoconstriction. In those cases, the lung function measurements (e.g., sRaw, FEV_1) following SO_2 exposure are assessed relative to measurements taken prior to exposure (baseline), rather than being assessed relative to measurements for a control exposure to clean air while exercising. The studies cited here, of a limited number of adults and adolescents, reported small changes in FEV_1 or sRaw in the individual study subjects, with magnitudes of change appearing to be smaller than responses reported from studies at exposure concentrations of 200 ppb or more. For example, the increase in sRaw reported for two young adult subjects exposed to 100 ppb in the study by Sheppard et al. (1981) was approximately half the response of these subjects at 250 ppb. In the two studies of adolescents (aged 12 to 18 years), among the individual study subjects for which respiratory resistance increased with SO_2 exposure, the magnitude of increase was less than 100% in each subject (Koenig et al., 1990; Koenig et al., 1989).

In considering what can be gleaned from these mouthpiece studies of 100 ppb, we note that the results of studies that utilize a mouthpiece exposure system cannot be directly compared to results from studies involving freely breathing subjects because when a mouthpiece is used, the inhaled breath completely bypasses the nasal passages where SO_2 is efficiently removed, thus allowing more of the inhaled SO_2 to penetrate into the tracheobronchial airways (2008 ISA, p. 3-4; second draft ISA, section 4.1.2.2). This occurrence as well as limited evidence comparing

[29] Studies of free-breathing subjects generally make use of small rooms in which the atmosphere is experimentally controlled such that study subjects are exposed by freely breathing the surrounding air (e.g., Linn et al., 1987).

[30] A subset of these studies are cited in the second draft ISA; additionally, three of them (Sheppard et al., 1981; Koenig et al., 1990; Trenga et al., 2001) are cited in the 2008 ISA and a fourth (Sheppard et al., 1984) is cited in the 1986 Addendum and 1994 Supplement to the 1982 AQCD. The fifth study (Koenig et al., 1989) is not cited in the prior AQCDs, the 2008 ISA, or the second draft ISA. This study is an investigation involving nine adolescent subjects with allergic asthma (positive response to a methacholine challenge test at or below 20 mg/mL) exposed by mouthpiece to 0.1 ppm during exercise. Measurements of FEV_1 and R_T were taken at baseline and subsequent to SO_2 and air only exposures during exercise (Koenig et al., 1989).

responses by mouthpiece and chamber exposures leads to the expectation that SO_2-responsive people with asthma breathing SO_2 using a mouthpiece, particularly while at elevated ventilation, would experience greater lung function responses than if exposed to the same test concentration while freely breathing in an exposure chamber (second draft ISA, p. 5-22; Linn et al., 1983a).

We have also considered what can be gleaned from the epidemiological studies regarding exposure concentrations associated with health effects. Although exposure concentrations eliciting respiratory responses are not available from such studies, the ambient air concentrations occurring in studies that find associations with outcomes such as asthma-related ED visits and hospitalizations have the potential to indicate ambient air concentrations that may contribute to exposures that may be eliciting effects. For example, in recognizing the general coherence of epidemiological study findings for 24-hour ambient air concentrations with the findings of the controlled human exposure studies for exercising study subjects with asthma exposed for 5 to 10 minutes, the 2008 ISA recognized that "it is possible that these epidemiologic associations are determined in large part by peak exposures within a 24-h period" (2008 ISA, p. 5-5). In considering the epidemiological studies in this light, however, we note that given the important role of SO_2 as a precursor to PM in ambient air, a key uncertainty in the epidemiological evidence available in the last review was potential confounding by PM (second draft ISA, p. 5-5). Among the U.S. epidemiologic studies (some conducted in multiple locations) reporting mostly positive and sometimes statistically significant associations between ambient SO_2 concentrations and emergency department visits and hospital admissions, few studies have attempted to address this uncertainty, e.g., through the use of copollutant models. For example, as in the last review, there are three U.S. studies for which the SO_2 effect estimate remained positive and statistically significant in copollutant models with PM (Appendix D).[31] No additional such studies have been newly identified in this review. Further, the second draft ISA states that uncertainty with regard to potential confounding by PM remains in the currently available epidemiologic evidence base (second draft ISA, p. 5-144).

3.2.1.4 Uncertainties in the Health Effects Evidence

A number of key uncertainties and limitations were identified in the previous review with respect to the health effects evidence, as described in the 2009 REA. This section considers the currently available information, including that newly available in this review, with regard to such areas of uncertainty.

[31] Based on data available for specific time periods at some monitors in the areas of these studies, the 99th percentile 1-hour daily maximum concentrations were estimated in the last review to be between 78-150 ppb (Thompson and Stewart, 2009).

- **To what extent have important uncertainties identified in the last review been reduced and/or have new uncertainties emerged?**

We have not identified any new uncertainties since the last review. However, we continue to recognize important uncertainties that also existed in the last review. This array of important areas of uncertainty related to the current health evidence, including that newly available in this review, is summarized below.

Although the evidence clearly demonstrates that short-term SO_2 exposures cause respiratory effects, particularly asthma exacerbation in exercising individuals with asthma, as in the previous review, we continue to recognize uncertainties that remain in several aspects of our understanding of these effects. Such uncertainties include those associated with severity and prevalence of responses to very short (5- to 10-minute) SO_2 exposures below 200 ppb and responses of some population groups not included in the controlled exposure studies (e.g., those with more severe asthma and children). There are also uncertainties concerning the potential influence of exposure history and co-exposure to other pollutants on the relationship between short-term SO_2 exposures and respiratory effects. With regard to the evidence base, we also recognize a complication associated with interpreting the epidemiologic evidence related to uncertainty in the exposure estimates. The following discussion touches on each of these types of uncertainty.

With regard to the potential for and magnitude of these effects in at-risk populations exposed to 5- to 10-minute concentrations below 200 ppb, there is very limited evidence from small mouthpiece studies of exposure concentrations as low as 100 ppb, as discussed in section 3.2.1.3 above. These studies indicate the likelihood of an appreciable reduction in SO_2-induced response in exercising people with asthma from that observed from exposures at 200 ppb. Given the limited size of these studies and their differences from free breathing chamber studies, however, uncertainties remain with regard to a complete characterization of the extent of response in exercising individuals with asthma exposed through natural or free breathing to exposure concentrations below 200 ppb. The extent to which the epidemiological evidence, including that newly available, can inform this area of uncertainty also may be limited.[32] Accordingly, this remains an area of uncertainty in this review.

Some uncertainty also remains with regard to the extent to which the controlled human exposure study evidence describes the responses of the populations most at risk of SO_2-related

[32] As associations reported in the epidemiologic analyses are associated with air quality concentration metrics as surrogates for the actual pattern of exposures experienced by study population individuals over the period of a particular study, the studies are limited in what they can convey regarding the specific patterns of exposure circumstances (e.g., magnitude of concentrations over specific durations and frequency) that might be eliciting reported health outcomes.

respiratory effects (e.g., those with the most severe responses, or greatest likelihood of response). For example, the available studies have generally involved subjects with mild or moderate asthma, such that the response of individuals with more severe asthma is unknown.[33] Further, while it is well documented that some individuals have a greater response to SO_2 than others with the same disease status, the factors contributing to this greater susceptibility are not yet known (second draft ISA, pp. 5-14 to 5-20).

Uncertainty also remains related to the responses for children with asthma. Although the epidemiological evidence includes a number of studies focused on health outcomes in children that are supportive of the qualitative conclusions of causality (second draft ISA, section 5.2.1.2), there are few controlled human exposure studies to inform our understanding of concentrations associated with effects. Those studies have not included subjects younger than 12 years (second draft ISA, p. 5-21). Some characteristics particular to school age children younger than 12 years, such as increased propensity for mouth breathing (second draft ISA, section 4.1.2.2), however, suggest that this age group of children with asthma might be expected to experience larger lung function decrements than adults with asthma (second draft ISA, p. 5-24).

Other areas of uncertainty concerning the potential influence of SO_2 exposure history and co-exposure to other pollutants on the relationship between short-term SO_2 exposures and respiratory effects also remain from the last review. There is some limited evidence regarding the potential for an increased response to SO_2 exposures occurring in the presence of other common pollutants (e.g., PM, nitrogen dioxide and ozone), although the studies are limited (e.g., with regard to their relevance to ambient exposures) and/or provide inconsistent results (second draft ISA, p. 5-24; 2008 ISA, section 3.1.4.7). There is also some evidence suggestive of a potential for SO_2 exposure to contribute to an increased sensitivity to allergens, however the studies are very few and are limited to experimental animal models (second draft ISA, section 5.2.1.9).

There are additional complications associated with interpretation of epidemiologic studies of SO_2 in ambient air that pertain to exposure measurement error and copollutant confounding (second draft ISA, sections 3.4, 5.2.1.1 and 5.2.1.2). With regard to the former, a key uncertainty in the epidemiologic evidence is whether study findings reflect an independent association for SO_2 given that the studies assigned exposure from fixed site monitors while SO_2 concentrations in ambient air tend to show high spatiotemporal variability within a city, and

[33] The second draft ISA identifies two studies that have investigated the influence of asthma severity on responsiveness to SO_2, with one finding that a larger change in lung function observed in the moderate/severe asthma group was attributable to the exercise component of the study protocol while the other did not assess the role of exercise in differences across individuals with asthma of differing severity (Linn et al., 1987; Trenga et al., 1999). Based on the criteria used in the study by Linn et al (1987) for placing individuals in the "moderate/severe" group, the ISA concluded that the asthma of these individuals "would likely be classified as moderate by today's classification standards" (second draft ISA, p. 5-20; Johns et al., 2010; Reddel, 2009).

correlations with personal exposure are poorly characterized. Accordingly, there is uncertainty regarding the extent to which measurements at the study monitors, and the associated air quality concentration metric for the study, adequately represent the spatiotemporal variability in ambient SO_2 concentrations in the study area (second draft ISA, sections 5.2.1.2 and 3.4.1.3).

Further, not only is SO_2 but one component of a complex mixture of pollutants present in the ambient air, an issue not unique to SO_2 epidemiological studies, but SO_2 is also a precursor to sulfate, which can be a principal component of PM, an air pollutant commonly occurring across the U.S. This uncertainty affects the extent to which effect estimates from epidemiologic studies reflect the independent contribution of SO_2 to the adverse respiratory outcomes assessed in these studies. This area of uncertainty was recognized in the last review and remains in the current review. In first summarizing the epidemiological evidence from the last review, the second draft ISA indicated that it was strongest for increased respiratory symptoms and respiratory-related hospital admissions and ED visits, especially in children, while noting that "a key uncertainty was potential confounding by copollutants, particularly PM" (second draft ISA, p. 5-5). With regard to the newly available evidence, the second draft ISA states that "[t]he caution expressed in the 2008 SO_X ISA (U.S. EPA, 2008d) related to the limitation of attributing an independent effect to SO_2 (due to the relationship of SO_2 levels to PM levels) is still a concern" (second draft ISA, p. 5-144).[34]

There remains uncertainty in the evidence with regard to the potential role of long-term exposure to SO_2 in eliciting SO_2-related respiratory effects. As noted in section 3.2.1.1 above, the ISA has determined the evidence to be suggestive of this being a causal relationship. The strongest evidence supporting this conclusion is provided by epidemiological study findings of associations between long-term SO_2 concentrations and increases in asthma incidence combined with findings of laboratory animal studies involving newborn rodents that indicate a potential for SO_2 exposure to contribute to the development of asthma, especially allergic asthma, in children. However, uncertainties that relate to the limitations of the animal toxicological evidence, particularly for long-term exposure, and the potential for confounding by other pollutants is unexamined, and largely unavailable, for epidemiologic studies of asthma among children (second draft ISA, section 5.2.2.7).

Another area of uncertainty recognized by the ISA, is that contributing to conclusions regarding the potential for SO_2 in ambient air to contribute to health effects other than respiratory

[34] A few recent epidemiologic studies add evidence for SO_2 in copollutant models with PM, NO_2, or O_3, although the pollutants are measured at central site monitors (second draft ISA, p. 5-8). Across the full epidemiologic evidence base, some associations were relatively unchanged in magnitude after adjustment for a copollutant, while others did not persist. However, the second draft concludes that "inference from copollutant models is limited given potential differences in exposure measurement error for SO_2 compared to NO_2, CO, PM, and O_3 and in many cases, high copollutant correlations" (second draft ISA, p. 5-139).

effects. As noted in section 3.2.1.1 above, the ISA has determined the evidence to be suggestive of, but insufficient to infer, a causal relationship between short-term SO_2 exposure and mortality and to be inadequate to infer the presence or absence of a causal relationship for other types of exposures and health effects for which there are studies available.

In summary, a variety of uncertainties from the last review remain, including those related to the extent of effects at concentrations below those evaluated in controlled human exposure studies of exercising individuals with asthma, and the potential for greater impacts in individuals with more severe asthma and in children with asthma (second draft ISA, section 5.2.1.9).

3.2.1.5 Public Health Implications

Implications and the magnitude of potential impacts on public health are dependent upon the type and severity of the effect, as well as the size of population affected. With regard to SO_2 concentrations in ambient air, the public health implications and potential public health impacts relate to the effects causally related to SO_2 exposures of interest in this review. These are respiratory effects of short-term exposures, and particularly those effects associated with asthma exacerbation in people with asthma. As summarized in section 3.2.1.1, the most strongly demonstrated effects are bronchoconstriction-related effects resulting in decrements in lung function elicited by short term exposures during periods of elevated ventilation, while asthma-related health outcomes such as ED visits and hospital admissions have also been statistically associated with ambient air SO_2 concentration metrics in epidemiological studies (second draft ISA, section 5.2.1.9).

In considering public health implications, in addition to the difference in severity of different effects, it is important to consider aspects of the same effect with regard to its impact on population groups of differing susceptibility. For example, with regard to bronchoconstriction-related effects, the same percentage increase in sRaw or reduction in FEV_1 for two groups of individuals that differ in their baseline sRaw or FEV_1 may result in the two groups being affected differently with regard to increased susceptibility to other physiological threats or challenges. Accordingly, consideration of such baseline differences and also the relative transience or persistence of such sRaw or FEV_1 changes, as well as other factors, is important to characterizing implications for public health, as recognized by the American Thoracic Society in their statements on evaluating adverse health effects of air pollution (ATS, 2000; Thurston et al., 2017).

The most recent policy statement by the ATS on what constitutes an adverse health effect of air pollution provides 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).

The earlier ATS statement, in addition to emphasizing clinically relevant effects, also emphasized both the need to consider changes in "the risk profile of the exposed population," and effects on the portion of the population that may have a diminished reserve that puts its members at potentially increased risk if affected by another agent (ATS, 2000). These concepts, including the consideration of the magnitude of effects occurring in just a subset of study subjects, continue to be recognized as important in the more recent ATS statement (Thurston et al., 2017) and continue to be relevant to the evidence base for SO_2.[35]

As summarized in section 3.2.1.3 above, people with asthma are the key population at risk for SO_2-related effects and children with asthma are considered to be at relatively greater risk than other age groups within this at-risk population (second draft ISA, section 6.3.1). In recognizing that asthma as a disease can vary in its severity, we take note of the lack of evidence for individuals with the most severe asthma. The evidence base of controlled exposure studies of exercising people with asthma provides limited information that indicates there to be similar relative responses of individuals with differences in severity of their asthma,[36] although the evidence indicates that the absolute changes in lung function are larger for individuals with more severe asthma compared to those characterized as having mild asthma. It is uncertain whether a greater response to the exercise itself (vs the SO_2 exposure) played a role in such findings, however the available studies "suggest that adults with moderate/severe asthma may have more limited reserve to deal with an insult compared with individuals with mild asthma" (second draft ISA, p. 5-20; Linn et al., 1987; Trenga et al., 1999).

The information below characterizes the size and other features of the populations in the U.S. concluded to be at risk of SO_2-related effects, when under elevated ventilation conditions. As a whole, the discussion in this section indicates the potential for exposures to SO_2 in ambient air to be of appreciable public health importance. Such considerations contributed to the basis for the 2010 decision to appreciably strengthen the primary SO_2 NAAQS and to establish a 1-hour standard to protect the at-risk populations from short term exposures of concern. Such considerations remain relevant in the current review.

[35] In the Administrator's judgments on the then-existing standard in the last review, as well as on the appropriate level for the new 1-hour standard, the Administrator considered the 2000 ATS policy statement, as well as advice from CASAC and recommendations and judgments made by EPA in previous NAAQS reviews (section 3.1.1 above).

[36] These studies categorized with regard to asthma severity based mainly on the individual's use of medication to control asthma, such that individuals not regularly using medication were classified as minimal/mild, and those regularly using medication as moderate/severe (Linn et al., 1987). The second draft ISA indicates that the moderate/severe grouping would likely be classified as moderate by today's asthma classification standards due to the level to which their asthma was controlled and ability to engage in moderate to heavy levels of exercise (second draft ISA, p. 5-20 to 5-21; Johns et al., 2010; Reddel, 2009).

- **What does the information available in this review indicate with regard to the size of at-risk populations and their distribution in the U.S.?**

The magnitude and characterization of a public health impact is dependent upon the size and characterization of the populations affected, as well as the type or severity of the effect. As summarized above, the population group most at risk of health effects associated with exposure to SO_2 in ambient air is people with asthma. The National Center for Health Statistics data for 2015 indicate that approximately 8.0% of the U.S. population has asthma (Table 3-2; CDC, 2017). These data indicate the size of the key at-risk population for SO_2 in ambient air. It is this population that the primary NAAQS for SO_2 is intended to protect. Table 3-2 below considers the currently available information that helps to characterize key features of this population.

The age group for which the prevalence documented by these data is greatest is children aged five to 19, with 10.2% of children aged 15 to 19 years having asthma. In 2012 (the most recent year for which such an evaluation is available), it was the leading chronic illness affecting children (Bloom et al., 2013). The prevalence is greater for boys than girls. Among populations of different races or ethnicities, black non-Hispanic children have the highest prevalence, at 13.4%. Asthma prevalence is also increased among populations in poverty (e.g., 11.1% among people living in households below the poverty level compared to 7.2% of those living above it). Population groups with relatively greater asthma prevalence might be expected to have a relatively greater potential for SO_2 impacts.

Table 3-2. 2015 National Asthma Prevalence.

Characteristic [1]	Number with Current Asthma (in thousands) [2]	Percent with Current Asthma
Total	24,633	7.8
Child (Age <18)	6,188	8.4
Adult (Age 18+)	18,445	7.6
All Age Groups		
0-4 years	935	4.7
5-14 years	4,033	9.8
15-19 years	2,107	10.2
20-24 years	1,655	7.6
25-34 years	2,916	6.8
35-64 years	9,907	8.0
65+ years	3,079	6.6
Child Age Group		
0-4 years	935	4.7
5-11 years	2,761	9.6
12-17 years	2,492	10.3
Sex		
Males	9,998	6.5
Boys (Age <18)	3,705	9.9
Men (Age 18+)	6,293	5.4
Females	14,634	9.1
Girls (Age <18)	2,483	6.9
Women (Age 18+)	12,151	9.7
Race/Ethnicity		
White NH [3]	15,244	7.8
Child (Age <18)	2,810	7.4
Adult (Age 18+)	12,435	7.9
Black NH	3,931	10.3
Child (Age <18)	1,336	13.4
Adult (Age 18+)	2,595	9.1
Other NH	1,793	6.9
Child (Age <18)	605	8.4
Adult (Age 18+)	1,188	6.3
Hispanic	3,665	6.6
Child (Age <18)	1,438	8.0
Adult (Age 18+)	2,227	5.9
Federal Poverty Threshold		
Below 100% of poverty level	5,086	11.1
100% to less than 250% of poverty level	7,664	8.4
250% to less than 450% of poverty level	4,989	6.3
450% of poverty level or higher	6,894	6.9

[1] Numbers within selected characteristics may not sum to total due to rounding

[2] Includes persons who answered "yes" to the questions "Have you EVER been told by a doctor or other health professional that you had asthma" and "Do you still have asthma?"

[3] NH = non-Hispanic

Adapted from https://www.cdc.gov/asthma/most_recent_data.htm

3.2.2 Exposure/Risk-based Considerations

Our consideration of the scientific evidence available in the current review, as at the time of the last review (summarized in section 3.1 above), is informed by results from a quantitative analysis of estimated population exposure and associated risk. The overarching consideration is whether the current exposure/risk information alters our overall conclusions from the previous review regarding health risk associated with exposure to SO_2 in ambient air. As in our consideration of the evidence in section 3.2.1 above, we have organized the discussion regarding the exposure/risk information around a set of key questions to assist us in considering the exposure/risk analyses of at-risk populations living in three urban areas under air quality conditions simulated to just meet the existing SO_2 primary standard.

Prior to addressing the individual exposure/risk questions, we provide a summary of key aspects of the assessment, including the study areas, populations simulated, modeling tools and exposure and risk metrics derived (section 3.2.2.1). We then consider aspects of the questions beginning with the magnitude of exposure and risk estimated for the simulated at-risk populations (section 3.2.2.2), followed by the key uncertainties associated with the quantitative analyses with regard to drawing conclusions as to the adequacy of protection afforded by the current SO_2 standard (section 3.2.2.3). Lastly, we consider the exposure and risk estimates from the quantitative assessment with regard to the extent to which such estimates may be judged to be important from a public health perspective (section 3.2.2.4).

3.2.2.1 Exposure/risk analyses

In the assessment conducted for this review, described in detail in the draft REA, we have estimated SO_2 exposure and risk associated with air quality conditions that just meet the current standard. These analyses inform our understanding of the protection provided by the current SO_2 standard from effects that the health effects evidence indicates to be elicited in some portion of exercising people with asthma by short (e.g., 5to 10 minutes) elevations in SO_2 exposure concentrations. The analyses estimate exposure and risk for at-risk populations in three urban study areas in: (1) Fall River, MA; (2) Indianapolis, IN; and, (3) Tulsa, OK.

The three study areas present a variety of circumstances with regard to population exposure to short-term peak concentrations of SO_2 in ambient air. This set of study areas and the associated exposed populations are intended to be informative to the EPA's consideration of potential exposures and risks that may be associated with the air quality conditions that meet the current SO_2 standard. As discussed further in sections 3.2.2.2 and 3.2.2.4 below, the Fall River study area is found to present particularly informative exposure circumstances given that it provides an example of an area in the U.S. in which there is substantial overlap between locations that are relatively more populated and where SO_2 concentrations are relatively higher

(draft REA, section 5.4). As such, this area represents places in the U.S. with the potential for exposures of greatest concern, making it important in considering the protection provided by the current standard.

The three study areas range in total population size from approximately 180,000 to 540,000 and reflect different mixtures of SO_2 emissions sources, including utilities using fossil fuel and non-utility sources, such as petroleum refineries and secondary lead smelting (draft REA, section 3.1). They include locations in New England, Ohio River Valley and the Midwest, the latter two regions comprising the part of the U.S. with generally the greatest prevalence of elevated SO_2 concentrations and large emissions sources (Figure 2-7, Appendix F). Additionally, continuous 5-minute ambient air monitoring data (i.e., all 12 5-minute values for each hour) are available in two of the three study areas, with hourly maximum 5-minute concentration data available in the third (draft REA, section 3.2).

Asthma prevalence estimates for the populations simulated in the three study areas ranges from 8.0 to 8.7% (draft REA, section 5.1). For children, the study area prevalence rates range from 9.7 to 11.2% (draft REA, section 5.1). Variation within each studyrelated to age, sex and whether family income is above or below the poverty level was also accounted for (section 4.1.2 and Appendix E of draft REA,).[37] This variation is greatest in the Fall River study area, with census block level, age-specific prevalence estimates ranging from 7.9 to 18.6% for girls and from 10.7 to 21.5% for boys (draft REA, Table 4-1).

In the draft REA, 1-hour SO_2 concentrations were estimated across a 3-year period (consistent with the period represented by the form of the standard) using air quality modeling of SO_2 emissions sources in each area, and were adjusted, as described in the draft REA, such that the air quality modeling receptor location with the highest concentrations just met the current standard.[38] In addition, sensitivity analyses were performed using an alternative adjustment approach and are summarized in section 3.2.2.2. Relationships between 1-hour and 5-minute concentrations at local monitors were then used to estimate 5-minute concentrations associated with the adjusted 1-hour concentrations across the 3-year period at all receptor locations in each area (draft REA, section 3.5).

The exposure modeling, presented in detail in the draft REA, relied on the EPA's Air Pollutant Exposure model (APEX), which estimates human exposure using a stochastic, event-based microenvironmental approach. This model has a history of application, evaluation, and

[37] As described in section 4.1.2 and Appendix E of the draft REA, asthma prevalence in the exposure modeling domain is estimated based on national prevalence information and study area demographic information related to age, sex and poverty status.

[38] As described in more detail in section 3.4 of the draft REA, the adjustments were implemented with a focus on reducing emissions from the source contributing to the standard exceedances until the areas just met the standard.

progressive model development in estimating human exposure and dose for reviews of NAAQS for gaseous pollutants (U.S. EPA, 2008; 2010; 2014). This general exposure modeling approach was also used in the 2009 REA for the last review of the primary standard for SO_X, although a number of updates have been made to the model and various datasets used with it (2009 REA; U.S. EPA, 2017b, section 3.4). For example, exposure modeling for the draft REA includes reliance on updates to several key inputs to the model including (1) a significantly expanded Consolidated Human Activity Database (CHAD), that now has over 55,000 diaries, with over 25,000 for school-aged children; (2) the updated NHANES data (2009-2014), which are the basis for the age- and sex-specific body mass distributions from which APEX samples to specify the individuals in the modeled population; (3) the algorithms used to estimate age- and sex-specific resting metabolic rate, a key input to estimating a simulated individual's activity-specific ventilation rate; and (4) the ventilation rate algorithm itself. Further, the current model uses updated population demographic data based on the most recent Census.

The APEX model probabilistically generates a sample of hypothetical individuals from an actual population database and simulates each individual's movements through time and space (e.g., indoors at home, inside vehicles) to estimate his or her exposure to a pollutant. Population characteristics are taken into account to represent the demographic profile of the population in each study area. Age and gender demographics for the simulated at-risk population (adults and children with asthma) were drawn from the prevalence estimates provided by the 2011-2015 National Health Interview Survey.[39] The APEX model generates each simulated person or profile by probabilistically selecting values for a set of profile variables, including demographic variables, status and physical attributes (e.g., residence with air conditioning, height, weight, body surface area) and ventilation rate.

Based on minute-by-minute activity levels, and physiological characteristics of the simulated person (see draft REA, section 4.1), APEX estimates an equivalent ventilation rate (EVR), based on normalizing the simulated individuals' activity-specific ventilation rate to their body surface area; the EVR is used to identify exposure periods during which an individual is at or above a specified ventilation level (draft REA, section 4.1.4.4). The level specified is based on the ventilation rates of subjects in the controlled human exposure studies of exercising people with asthma (Table 3-1). The APEX simulations performed for this review have focused on

[39] Information about the National Health Interview Survey is available at http://www.cdc.gov/nchs/nhis.htm.

exposures to SO_2 emitted into ambient air that occurs in microenvironments,[40] without additional contribution from indoor SO_2 emissions sources.[41]

As in the last review, the draft REA for this review uses the APEX model estimates of 5-minute exposure concentrations for simulated individuals with asthma at elevated ventilation to characterize health risk in two ways based on information from the controlled human exposure studies on the occurrence of bronchoconstriction-related effects in some study subjects with asthma who are exposed during exercise (draft REA, section 4.5). In drawing on this evidence base for this purpose, the draft REA has given primary focus to the well-documented studies summarized in Table 5-2 and Figure 5-1 of the second draft ISA for 5- to 10-minute exposure concentrations ranging from 200 ppb to 600 ppb (Table 3-1 of this document). The first risk metric is based on comparison of the estimated 5-minute exposure concentrations individuals at elevated ventilation to 5-minute concentrations of potential concern (benchmark concentrations), and the second utilizes exposure-response information for study subjects experiencing bronchoconstriction-related effects on lung function (specifically a doubling or more in sRaw) to estimate the portion of the simulated at-risk population likely to experience one or more days with an SO_2-related increase in sRaw of at least 100%. Both of these metrics are used in the draft REA to characterize health risk associated with 5-minute peak SO_2 exposures among the simulated at-risk population during periods of elevated ventilation. These risk metrics were also derived in the REA for the last review and the associated estimates informed the Administrator's 2010 decision on the new standard (75 FR 35546-35547, June 22, 2010).

For the benchmarks metric, the draft REA for this review, like the 2009 REA in the last review, uses benchmark concentrations that range from 400 ppb down to 100 ppb (draft REA, section 4.5.1). At the upper end of this range, 400 ppb represents the lowest concentration in free-breathing controlled human exposure studies of exercising people with asthma where moderate or greater lung function decrements occurred that were often statistically significant at the group mean level and were frequently accompanied by respiratory symptoms. The 200 ppb benchmark concentration represents the lowest level tested in studies where subjects were freely breathing in exposure chambers (moderate or greater lung function decrements in some of these

[40] Five microenvironments (MEs) are modeled in the draft REA as representative of a larger number of microenvironments. The 2009 REA results indicated that the majority of peak SO_2 exposures occurred while individuals were within outdoor microenvironments (2009 REA, Figure 8-21). Based on that finding and the objective (i.e., understanding how often and where short-term peak SO_2 exposures occur), the approach implemented in the draft REA recognizes the added efficiency of minimizing the number of MEs, particularly indoor MEs, that are parameterized and included in the modeling. Accordingly, the number of MEs was aggregated to address exposures of ambient origin that occur within a core group of indoor, outdoor, and vehicle MEs (draft REA, section 4.2).

[41] Indoor sources are generally minor in comparison to SO_2 from ambient air (draft REA, sections 2.1.1 and 2.1.2).

subjects) (75 FR 35527, June 22, 2010). The lowest benchmark concentration (100 ppb), which is one half the lowest exposure concentration tested in free breathing exposure studies, has been included in consideration of the nonzero percentage of subjects with asthma experiencing moderate transient decrements in lung function at the 200 ppb exposure concentration (approximately 8 to 9%) and the lack of specific study data for some groups of individuals with asthma, such as primary-school-age children and those with more severe asthma.[42]

The exposure-response (E-R) function for the risk of lung function decrements was developed from the individual subject results for sRaw from the controlled exposure studies of exercising freely breathing people with asthma exposed to SO_2 concentrations from 1000 ppb down as low as 200 ppb (draft REA, Table 4-9). Beyond the assessment of these studies and their results in past reviews, there has been extensive evaluation of the individual subject results, including a data quality review in the last SO_2 NAAQS review (Johns and Simmons, 2009), and detailed analysis in two subsequent publications (Johns et al., 2010; Johns and Linn, 2011). The sRaw responses reported in these studies have been summarized in the second draft ISA, as in the last review, in terms of percent of study subjects experiencing responses of a magnitude equal to a doubling or tripling or more. Across the exposure range from 200 to 1000 ppb, the percentage of exercising study subjects with asthma having at least a doubling of sRaw increases from about 8-9% (at exposures of 200 ppb) up to approximately 50-60% (at exposures of 1000 ppb) (draft REA, Table 4-9). The E-R function used in the main analysis of the draft REA was derived from these data using a probit function (draft REA, section 4.5.2).

In summary, while the general approach and methodology for the exposure-based assessment in this review is similar to that in the last review, there are a number of ways in which these analyses differ (see 2009 REA and draft REA for this review). In addition to the expansion in the number and type of study areas assessed, we note the number of improvements to input data and modeling approaches, including the availability of continuous 5-minute air

[42] Recognizing that even the study subjects described as "moderate/severe" group (had well-controlled asthma, were generally able to withhold medication, were not dependent on corticosteroids, and were able to engage in moderate to heavy levels of exercise) would likely be classified as moderate by today's classification standards (second draft ISA, pp. 5-20 to 5-21; Johns et al., 2010; Reddel, 2009), we have considered the evidence with regard to the response of individuals with severe asthma that are not generally represented in the full set of controlled human exposure studies. There is no evidence to indicate such individuals would experience moderate or greater lung function decrements at lower SO_2 exposure concentrations than individuals with moderate asthma. With regard to the severity of the response, the limited data that are available indicate a similar magnitude SO_2-specific response (in sRaw) as that for individuals with less severe asthma, although the individuals with more severe asthma are indicated to have a greater response to exercise prior to SO_2 exposure, indicating that those individuals "may have more limited reserve to deal with an insult compared with individuals with mild asthma" (second draft ISA, p. 5-21). As noted in sections 3.2.1.3 and 3.2.1.4 above, evidence from controlled human exposure studies are not available for children younger than 12 years old, and the second draft ISA indicates that the information regarding behavior and methacholine responsiveness for the subset of this age group that is of school age (e.g., 5-12 years) indicates a potential for greater response (second draft ISA, pp. 5-21 to 5-24).

monitoring data at monitors within two of the three study areas. The current draft REA extends the time period of simulation to a 3-year simulation period, consistent with the form established for the now-current standard. Further, the years simulated reflect more recent emissions and circumstances subsequent to the 2010 decision.

3.2.2.2 At-risk population exposures and risk

In this section, we summarize the exposure and risk estimates from the draft REA and consider the following question.

- **What is the magnitude of population exposure and risk in at-risk populations in areas simulated to just meet the current SO_2 standard? What portion of the at-risk populations are estimated to experience exposures of concern or lung function decrements at levels of potential health concern?**

In addressing these questions, we consider the population estimates provided by the draft REA simulations of exposure to SO_2 emitted into ambient air (draft REA, Chapters 5 and 6). In considering these REA estimates for air quality conditions just meeting the current standard, we particularly focus on the extent of protection provided by the standard from SO_2 exposures of potential concern. As described in the prior section, the draft REA presents two sets of risk estimates for the 3-year simulation in each study area: (1) the number (and percent) of simulated persons experiencing exposures at or above the particular benchmark concentrations of interest, while at elevated ventilation; and (2) the number and percent of people estimated to experience at least one SO_2-related lung function decrement in a year and the number and percent of people experiencing multiple lung function decrements associated with SO_2 exposures.

In presenting the exposure and risk estimates, the draft REA recognizes that the approach applied to adjust air quality to conditions just meeting the current standard can have important impacts on the risk and exposures estimates (draft REA, section 6.2.2). Because of this, the draft REA presents results for two different approaches to adjusting air quality. The first approach uses the highest design value across all modeled air quality receptors to adjust the air quality concentrations in each area to just meet the standard (draft REA, section 3.4). This is done by estimating the amount of SO_2 concentration reduction needed for this highest receptor to be adjusted to the current SO_2 standard, and based on this amount, all other receptors impacted by the highest source(s) are adjusted accordingly. The second approach is included as a sensitivity analysis that recognizes the potential uncertainty associated with the modeled concentrations, particularly the very highest modeled concentrations. Accordingly, the second approach uses the air quality receptor having the 99^{th} percentile of the distribution of design values (instead of the receptor having the maximum design value) to estimate the SO_2 concentration reductions needed to adjust the air quality to just meet the standard (draft REA, section 6.2.2.1). In study areas in which modeled concentrations at a very small number of receptors are substantially higher than

those at all other air quality receptors, these two different approaches can result in very different SO_2 concentrations across an area. In such study areas, in particular, the first approach generally results in much more significant reductions being applied to reduce SO_2 concentrations at the small group of highest modeled receptors such that concentrations at those receptors are just at or just below the standard and concentrations at the other receptors across the area are appreciably lower. Given that these two approaches to adjusting air quality can result in important differences in the magnitude of risk to at-risk populations in areas simulated to just meet the current standard, the tables below present estimates based on both approaches.[43]

Of the two types of risk metrics derived in the draft REA, we turn first to the results for the benchmark-based risk metric with regard to the percent of the study area populations with asthma estimated to experience at least one daily maximum 5-minute exposure per year at or above the different benchmark concentrations while at elevated ventilation (Table 3-3). Under air quality conditions just meeting the current standard across the three study areas, approximately 20 to 25% of children with asthma, on average across the 3-year period, are estimated to experience one or more days per year with a 5-minute exposure at or above 100 ppb while breathing at elevated ventilation rates (Table 3-3). With regard to the 200 ppb benchmark, as many as 0.7 percent of the simulated population of children with asthma, on average across the 3-year period, was estimated to experience a single day with a 5-minute exposure at or above 200 ppb while breathing at elevated ventilation rates (Table 3-3). The percentage in a single year ranged up to 2.2% for a single day, while less than 0.1% of children with asthma were estimated to experience more than a single day with an exposure at or above 200 ppb while at elevated ventilation (draft REA, Tables 6-5 and 6-6). No simulated children with asthma were estimated to experience a day with a 5-minute exposure at or above 300 or 400 ppb. The estimates for adults are lower, generally due to the lesser amount and frequency of time spent outdoors (draft REA, section 5.2).

[43] Details regarding these sensitivity analyses focused on the impact of the adjustment approach are presented in the draft REA, section 6.2.2.1.

Table 3-3. Air quality conditions adjusted to just meet the current standard: Percent of simulated populations of children with asthma estimated to experience at least one daily maximum 5-minute exposure per year at or above indicated concentrations while at elevated ventilation.

5-minute Exposure Concentration (ppb)	Percent (%) of Population of Children (5-18 years) with Asthma Average per year [A]		
	Fall River, MA	Indianapolis, IN	Tulsa, OK
≥ 100	19.4 – 26.7	<0.1[B] – 0.1	0.1 – 0.4
≥ 200	<0.1 – 0.7	0 – <0.1	0
≥ 300	0	0	0

[A] The values presented in each cell are the average of the results for the three years simulated based on the two approaches to air quality adjustment (drawn from Table 6-5 of the draft REA).

[B] <0.1 is used to represent nonzero estimates below 0.1%. A value of zero (0) indicates there were no individuals having the selected exposure in any year.

We next consider the estimates for risk of lung function decrements in terms of a doubling or more in sRaw (Table 3-4). Under conditions just meeting the current standard in the three study areas, as many as 1.1% of children with asthma, on average across the 3-year period, were estimated to experience at least one day per year with a SO_2-related increase in sRaw of 100% or more in the study area with the highest estimates (Table 3-4, Fall River). The corresponding percent estimated to experience two or more such days ranged as high as 0.6%, on average across the 3-year simulation period (draft REA, Table 6-8). Additionally, in the same study area, as much as 0.2% of the simulated populations of children with asthma, on average across the 3-year period, was estimated to experience a single day with a SO_2-related increase in sRaw of 200% or more. The estimates for adults are very slightly lower, again, generally due to the lesser time spent outdoors (draft REA, section 5.3).

Table 3-4. Air quality conditions adjusted to just meet the current standard: Percent of simulated population of children with asthma estimated to experience at least one day per year with a SO_2-related increase in sRaw of 100% or more.

Lung function decrement (increase in sRaw)	Percent (%) of Population of Children (5-18 years) with Asthma[A] Average per year		
	Fall River, MA	Indianapolis, IN	Tulsa, OK
≥ 100%	0.9 – 1.1	0	<0.1[B] - <0.1
≥ 200%	0.1 – 0.2	0	0

[A] The values presented in each cell are the average of the results for the three years simulated based on two approaches to air quality adjustment (drawn from Table 6-7 of the draft REA).
[B] <0.1 is used to represent nonzero estimates below 0.1%. A value of zero (0) indicates there were no individuals estimated to have the selected decrement in any year.

In understanding these results, we note that the three study areas selected provide a variety of circumstances with regard to population exposure to short-term peak concentrations of SO_2 in ambient air. These three study areas reflect different combinations of different types of SO_2 emissions sources, including utilities using fossil fuels and non-utility sources, and provide three different patterns of exposure to SO_2 concentrations in a populated area in the U.S. In this way, the three areas provide a variety of examples of exposure patterns that can be informative to the EPA's consideration of potential exposures and risks that may be associated with air quality conditions occurring under the current SO_2 standard. As indicated by the discussion above and also recognized in section 3.2.2.3 below, there is variability in the estimated magnitude of exposure and associated risk across study areas and uncertainties associated with these estimates.

In developing the air quality scenarios for the current standard in the three study areas, the draft REA recognizes that these scenarios of adjusted air quality provide representations of the pattern of air quality that might occur in each study area under conditions that just meet the current standard. Where such conditions include relatively large spatial extents of higher concentrations – i.e., areas with design values in proximity to the level of the standard – that overlap with the more populated parts of the study area, exposure and risk results are relatively higher (draft REA, section 5.4). Among the three study areas, this best describes the Fall River study area, which is an area where source characteristics contribute to a sizeable spread of source-influenced relatively higher concentrations that coincide or overlap with locations where people reside and/or frequent. This association between concentrations and population in Fall River is illustrated in Figure 5-4 of the draft REA. Inclusion of an area with these characteristics in the REA provides some insight into the potential exposure and risk associated with other areas across the U.S. with similar characteristics and is therefore particularly informative to evaluation of the level of protection provided by the standard.

The other two study areas (Indianapolis and Tulsa) provide examples of areas where the higher SO_2 concentrations that result from the sizeable SO_2 sources in the study area do not strongly coincide with parts of the area in which people reside and/or frequent (draft REA, section 5.4). This relationship between SO_2 concentrations and population is these two areas is illustrated in Figures 5-5 and 5-6 of the draft REA. Accordingly, the corresponding exposure and risk estimates for these area are lower than those estimated for the Fall River study area, even though the populations are larger (draft REA, sections 5.1 and 5.4).

As discussed above, among the three study areas, the Fall River study area presents the exposure circumstances associated with highest SO_2-related exposures and risk for the current standard air quality scenario. Because of this, we recognize that the Fall River study area is of particular importance in considering the adequacy of the protection afforded by the current standard. Recognizing this, we note that the draft REA indicates that the percent of children with asthma that might be expected to experience 5-minute SO_2 concentrations at or above the 200 ppb benchmark concentration, in an urban area that just meets the current standard, may be as high as 0.7%, on average across the three years, and 2.2% in a single-year period. With regard to the lung function risk, the draft REA indicates the percent of children that might be expected to experience at least a doubling of specific airway resistance, under conditions just meeting the current standard, may be as high as 1.1%, on average across the three-year period, and 1.9% in a single year. Thus, these results indicate that, in the single year with the highest concentrations across the 3-year period, nearly 98% of the population of children with asthma in the Fall River study area, would not be expected to experience a day with a 5-minute exposure at or above the 200 ppb and 400 ppb benchmarks and would not be expected to experience as much as a doubling in sRaw, a magnitude roughly consistent with the level of protection that was described in establishing the now-current standard in 2010 (as summarized in section 3.1.1.2.4 above).[44] On average across the 3-year period, the corresponding percentage is nearly 99% (Tables 3-3 and 3-4, above).

[44] Although the 2009 REA did not include an air quality scenario representing the now-current standard, among the scenarios it did include were single-year air quality scenarios representing standard levels of 100 and 50 ppb. For the single-year scenario representing a standard level of 100 ppb in the study area with the highest population exposure and risk, the 2009 REA estimated 2.7% of children with asthma to experience at least one day with exposure at or above 200 ppb, while at elevated ventilation (2.1-2.9% to experience one or more SO_2-attributable increases in sRaw of at least 100%); this estimate was 0.09% for the scenario representing a standard level of 50 ppb (0.4-0.9% to experience one or more SO_2-attributable increases in sRaw of at least 100%) (2009 REA, Table 9-8 and Appendix B). While we recognize a number of differences between the 2009 REA and the quantitative modeling and analyses performed in the current draft REA, we note that the single year estimates for the Fall River study area in the current draft REA fall between the estimates for the two most similar air quality scenarios assessed in the last review.

3.2.2.3 Uncertainties

In this section, we consider the uncertainties associated with the quantitative estimates of exposure and risk, including those recognized by the characterization of uncertainty in the draft REA (draft REA, section 6.2). The characterization in the draft REA is based on an approach intended to identify and compare the relative impact that important sources of uncertainty may have on the exposure and risk estimates. The approach used has been applied in REAs for past NAAQS reviews for ozone, nitrogen oxides, carbon monoxide (U.S. EPA, 2008; 2010; 2014) and SO_X (U.S. EPA, 2009). In the characterization of uncertainty for the current analysis, the draft REA utilized a qualitative uncertainty characterization approach adapted from the WHO approach for characterizing uncertainty in exposure assessment (WHO, 2008) accompanied by quantitative sensitivity analyses of key aspects of the assessment approach. This characterization and analyses are described in detail in chapter 6 of the draft REA. The approach used in the draft REA varies from that of WHO (2008) in that the draft REA approach placed a greater focus on evaluating the direction and the magnitude of the uncertainty (i.e., qualitatively rating how the source of uncertainty, in the presence of alternative information, may affect the estimated exposures and health risk results).

The characterization and analyses in the draft REA involve consideration of the various types of inputs and approaches that together result in the exposure and risk estimates for the three study areas. In so doing, the draft REA considers the limitations and uncertainties underlying these inputs and approaches and the extent of their influence on the resultant exposure/risk estimates. Consistent with the WHO (2008) guidance, the overall impact of the uncertainty is scaled by considering the extent or magnitude of the impact of the uncertainty as implied by the relationship between the source of the uncertainty and the exposure/risk output. The draft REA also evaluated the direction of influence, indicating how the source of uncertainty was judged to affect the exposure/risk estimates (e.g., likely to over- or under-estimation).

- **What are the key uncertainties associated with the exposure and risk estimates, including those of particular significance with regard to drawing conclusions as to the adequacy of the protection afforded by the current SO_2 standard?**

Based on the uncertainty characterization and associated analyses in the draft REA and consideration of associated policy implications, we recognize several areas of uncertainty as particular important in our consideration of the exposure and risk estimates, as was also the case in the last review. Generally, these areas include estimation of the spatial distribution of SO_2 concentrations across each study area under air quality conditions just meeting the existing standard, including the fine-scale temporal pattern of 5-minute concentrations. We additionally recognize the uncertainty with regard to population groups and exposure concentrations for which the health effects evidence base is limited or lacking.

With regard to the spatial distribution of SO_2 concentrations, the draft REA recognizes some uncertainty associated with the approach used to adjust the air quality surface to concentrations just meeting the current standard. Accordingly, the draft REA has investigated the potential quantitative impact of this uncertainty on the exposure and risk estimates by deriving estimates based on an alternative adjustment approach (described in section 6.2.2.1 of the draft REA). Given the results of this sensitivity analysis, we have considered estimates from both approaches in summarizing the draft REA estimates in section 3.2.2.2 above. Additionally, we recognize uncertainty in the estimates of 5-minute concentrations in ambient air across the modeling receptors in each study area. While the ambient air monitoring dataset available to inform these estimates is much expanded in this review over the dataset available in the last review, we are still drawing on relationships occurring at one location and over one range of concentrations to estimate the fine-scale temporal pattern in concentrations at other locations. This is an important area of uncertainty in the draft REA results because the ambient air 5-minute concentrations are integral to the 5-minute estimates of exposure. While we recognize this as an important area of uncertainty, the approach used has taken into account the currently available information and is considered to provide a reasonable representation of fine-scale temporal variability in the three study areas.

An additional area of uncertainty affecting our interpretation of the exposure and risk results for the set of study areas assessed concerns our understanding of, and the prevalence across the U.S. of, the different exposure circumstances they represent. As noted in section 3.2.2.2, the circumstances particularly pertinent to consideration of the adequacy of protection of the current standard include those in which areas where populations reside and/or exercise overlap with concentrations of SO_2 that are near, albeit just under, the level of the standard. Such circumstances are influenced by source characteristics and meteorological conditions, as well as housing and recreational area patterns in urban areas. While there is some uncertainty in our understanding of the prevalence of the exposure circumstances represented by the three study areas, including those for the Fall River study area, the available information indicates there to be many densely-populated areas in the U.S. in which there are facilities with sizeable SO_2 emissions (e.g., Appendix F).[45]

We also recognize an important area of uncertainty that is particular to our interpretation of the lung function risk estimates. This area concerns estimates of lung function risk derived for exposure concentrations below those represented in the evidence base. The exposure-response

[45] Although source characteristics and meteorological conditions - in addition to magnitude of emissions - influence the distribution of concentrations in ambient air, Appendix F focuses on the distribution of large sources, rather than ambient concentrations, due to limitations in the available information with regard to spatial (and temporal) patterns of SO_2 concentrations in the proximity of such sources in urban areas (second draft ISA, section 2.5.2.2).

function on which the primary risk estimates are based generates non-zero predictions of a percent of the at-risk population exposure expected to experience a day with at least a doubling of sRaw for all exposures experienced while at elevated ventilation. In considering these estimates, we recognize that the uncertainty in the response estimates increases substantially with decreasing exposure concentration below those supported by study data. In so doing, we note the contribution to the risk estimates of exposure concentrations below 200 ppb. Additionally, we note that the assessment focuses on the daily maximum 5-minute exposure during elevated ventilation, summarizing results in terms of the days on which the magnitude of such exposure exceeds a benchmark or contributes to increased sRaw. While the health effects evidence indicates the lack of a cumulative effect of multiple exposures over several hours or a day (second draft ISA, section 5.2.1.2), and a reduced response to repeated exercising exposure events over an hour (second draft ISA, section 5.2.1.2; Kehrl et al., 1987), information is somewhat limited with regard to the length of time after recovery from one exposure by which a repeat exposure would elicit a similar effect as that of the initial event.

Another area of uncertainty, which remains from the last review and is important to our consideration of the draft REA results, concerns the extent to which the quantitative results represent the populations at greatest risk of effects associated with exposures to SO_2 in ambient air. As recognized in sections 3.2.1.1 and 3.2.1.4, the controlled human exposure study evidence base does not include studies of children younger than 12 years old or studies of people with more severe asthma.[46] The limited evidence that informs our understanding of potential risk to these groups indicates the potential for them to experience greater effects than other population groups with asthma under similar exposure circumstances, as summarized in section 3.2.1.4 above. Further we note the lack of information on the factors contributing to increased susceptibility to SO_2-induced bronchoconstriction among some people with asthma. Thus, there is uncertainty associated with our interpretation of the exposure/risk estimates with regard to the extent to which they represent the populations at greatest risk of SO_2-related respiratory effects that is important to consideration of the exposure and risk results with regard to the adequacy of protection provided by the current standard.

In summary, among the multiple uncertainties and limitations in data and tools that affect the quantitative estimates of exposure and risk and their interpretation in the context of considering the current standard, we recognize several here as particularly important. These include uncertainties related to estimation of 5-minute concentrations in ambient air; the lack of information from controlled human exposure studies for the lower, more prevalent,

[46] We additionally recognize that limitations in the activity pattern information for children younger than five years old precluded their inclusion in the populations of children simulated in the draft REA.

concentrations of SO_2 and limited information regarding multiple exposure episodes within a day; the prevalence of different exposure circumstances represented by the three study areas; and, characterization of particular subgroups of people with asthma that may be at greater risk.

3.2.2.4 Potential public health implications

In considering public health implications of the quantitative exposure and risk estimates that may inform the Administrator's judgments in this area, this section discusses the information pertaining to the following question.

- **To what extent are the estimates of exposures and risks to at-risk populations that remain under conditions just meeting the current SO_2 standard important from a public health perspective?**

Several factors are important to consideration of public health implications. These include the magnitude or severity of the effects associated with the exposures estimated in the draft REA, as well as their adversity at the individual and population scale. Other important considerations include the size of the population estimated to experience such effects or to experience exposures associated with such effects. These considerations are discussed below.

Based on the currently available evidence which is largely consistent with that available in the last review (as summarized in section 3.2.1 above), the quantitative exposure and risk analyses focus on the potential for lung function decrements in people with asthma exposed to SO_2 while at elevated ventilation. Additionally, we have again focused on estimates for two types of risk metrics, one involving comparison to benchmark concentrations and the second involving estimates of lung function risk with regard to moderate or greater increases in sRaw. In considering these estimates, we recognize that although the lung function decrements, which are related to bronchoconstriction, are expected to be transient, we additionally recognize that such decrements, while occurring, may contribute to a diminished reserve in lung function (second draft ISA, p. 1-17, section 5.2.1.2). For population groups already at diminished reserve, such as those with more severe asthma, this may be particularly important. Thus, the discussion here reflects consideration of the health evidence, and exposure and risk estimates, as well as the consideration of potential public health implications in previous NAAQS decisions and ATS policy statements (as also discussed in section 3.2.1.5).

In light of the conclusion that among all people with asthma, children may be particularly at risk (summarized in section 3.2.1.2 above) and the draft REA findings of higher exposures and risks for children (in terms of percent of that population), we have focused the discussion here on children. We recognize that the draft REA results for air quality conditions just meeting the current standards indicate that, on average across the 3-year period simulated (consistent with the form of the current standard), less than 1% of the simulated population of children with asthma

might be expected to experience a single day with a 5-minute exposure at or above 200 ppb while breathing at elevated ventilation rates. The draft REA simulations also estimated no children with asthma to experience any days in a 3-year simulation period with a 5-minute exposure at or above 300 or 400 ppb. With regard to the lowest benchmark considered (100 ppb), the draft REA also indicates that in some areas of the U.S., approximately 25% of children with asthma, on average across the 3-year period, might be expected to experience one or more days per year with a 5-minute exposure at or above 100 ppb while breathing at elevated ventilation rates, with higher percentages in some years. With regard to estimates of lung function decrements, the draft REA indicates that in some areas, approximately 1% of children with asthma, on average across a 3-year period, might be expected to experience at least one day per year with a SO_2-related increase in sRaw of 100% or more; the estimate for two or more days is appreciably lower, at 0.4% (draft REA, Table 6-8). Additionally, under such conditions (just meeting the current standard), the estimated percent of children with asthma that might be expected to experience a single day per year with a SO_2-related increase in sRaw of 200% or more, on average across the 3-year period, is 0.2% (Table 3-4).

In considering the severity of responses associated with the REA estimates, we take note of the health effects evidence for the different benchmark concentrations and judgments made with regard to the severity of these effects in the last review. As in the last review, we recognize that the responses documented for exposures of 400 ppb are frequently accompanied by respiratory symptoms and thus are appropriately considered to be adverse respiratory effects consistent with past and recent ATS position statements. With regard to the lower benchmark concentration of 200 ppb, we recognize that, while the responses documented in studies of exercising subjects with asthma are not consistently accompanied by respiratory symptoms, conclusions in past NAAQS reviews recognized that moderate decrements in lung function can be clinically significant in some individuals with asthma (75 FR 35526, June 22, 2010). Accordingly, the Administrator in the last review considered effects associated with exposures as low as 200 ppb to be adverse in light of CASAC advice,[47] ATS statements and conclusions in past NAAQS reviews. While noting the lack of information for some populations groups with asthma, including primary-school-age children and people with more severe asthma, we additionally recognize the uncertainty with regard to effects that might be associated with exposures as low as 100 ppb (as discussed in section 3.2.1.3 and 3.2.1.4 above).

As indicated in section 3.1 above, the at-risk population in this review is people with asthma, as was the case in the last review. Further, children with asthma are identified as

[47] The CASAC letter on the first draft SO_2 REA to the Administrator stated: "CASAC believes strongly that the weight of clinical and epidemiology evidence indicates there are detectable clinically relevant health effects in sensitive subpopulations down to a level at least as low as 0.2 ppm SO_2" (Henderson, 2008).

particularly at risk. The size of the at-risk population in the U.S. is substantial. As summarized in section 3.2.1.5, nearly eight percent of the U.S. population (more than 24 million people) and 8.4% of U.S. children have asthma. The prevalence in U.S. child populations of different races or ethnicities ranges from 7.4% to 13.4% (Table 3-2 above). This is well reflected in the draft REA study areas in which the asthma prevalence ranged from 8% to 8.7% of the total populations and 9.7% to 11.2% of the children, with the highest prevalence represented in the Fall River study area. In Fall River, the prevalence varies among census tracts, with the highest tract having a prevalence in boys of 21.5% (draft REA, Table 4-1).

In considering the three study areas and the variation in exposure/risk estimates among them, we recognize the Fall River study area to be particularly informative to consideration of public health risk associated with and public health protection provided by the current standard. This is because, as summarized in section 2.2.2.2 above, the source characteristics and population distribution in the area cause the locations of relatively higher SO_2 concentrations in ambient air across the area (i.e., those closest to just meeting the standard) to overlap with locations of higher population density. These exposure circumstances contribute to higher exposure and risk estimates than in the other study areas (draft REA, section 5.4), making estimates for Fall River important in considering the adequacy of protection provided by the current standard. Thus, we have given particular attention to estimates for this study area.

Although exposure and risk estimates were not available in the last review for air quality conditions just meeting the now-current standard, the findings and considerations summarized here are generally similar to those considered in the last review, and indicate a level of protection consistent with that described in the 2010 decision. The exposure and risk estimates for the three study areas assessed in the draft REA for this review reflect differences in exposure circumstances among those areas and illustrate the exposures and risk that might be expected to occur in other areas with such circumstances under air quality conditions that just meet the current standard. Thus, the draft REA estimates indicate the magnitude of exposure and risk that might be expected in some areas and illustrate the importance to consideration of the public health protection afforded by the current standard of those areas where locations of relatively higher SO_2 concentrations in ambient air across the area coincide with the locations of higher population density. These considerations, and others raised above, are important to conclusions regarding the public health significance of the draft REA results. We recognize that such conclusions also depend in part on public health policy judgments that will weigh in the Administrator's decision in this review with regard to the adequacy of protection afforded by the current standard. Such judgments include those concerning the public health significance of effects at exposures for which evidence is limited or lacking, such as effects at the lower

benchmark concentrations considered and lung function risk estimates associated with exposure concentrations lower than those tested in the controlled exposure studies.

3.2.3 Preliminary Staff Conclusions on the Current Standard

This section describes preliminary staff conclusions regarding the adequacy of the current primary SO_2 standard. These preliminary conclusions are based on considerations described above, and in the discussion below regarding the currently available scientific evidence (as summarized in the second draft ISA, and the ISA and AQCDs from prior reviews), and the risk and exposure information drawn from the draft REA. Conclusions in the final PA will draw upon the final ISA, developed in consideration of CASAC review and public comment on the second draft ISA, and on the final REA, developed in consideration of CASAC review and public comment on the draft REA. Further, staff conclusions presented in the final PA will take into account advice from the CASAC and public comment on the draft PA and on these preliminary conclusions.

Taking into consideration the discussions responding to specific questions above in this and the prior chapter, this section addresses the following overarching policy question.

- **Does the currently available scientific evidence- and exposure/risk-based information, as reflected in the ISA and REA, support or call into question the adequacy of the protection afforded by the current SO_2 standard?**

In considering this question, we recognize as an initial matter that, as is the case in NAAQS reviews in general, the extent to which the current primary SO_2 standard is judged to be adequate will depend on a variety of factors inclusive of science policy judgments and public health policy judgments. These factors include public health policy judgments concerning the appropriate benchmark concentrations on which to place weight, as well as judgments on the public health significance of the effects that have been observed at the exposures evaluated in the health effects 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 exposure assessment for the three areas studied and the associated uncertainties. Thus, we recognize that the Administrator's conclusions regarding the adequacy of the current standard will depend in part on public health policy judgments, science policy judgments regarding aspects of the evidence and exposure/risk estimates, as well as, judgments about the level of public health protection with an adequate margin of safety that is requisite under the Clean Air Act.

Our response to this question takes into consideration the discussions that address the specific policy-relevant questions in prior sections of this document (see sections 3.2.1-3.2.2) and the approach described in section 3.1 that builds on the approach from the last review. We

focus first on consideration of the evidence, including that newly available in this review, and the extent to which it alters key conclusions supporting the current standard. We then turn to consideration of the quantitative exposure and risk estimates drawn from the draft REA, including associated limitations and uncertainties, 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 standard. We additionally consider the key aspects of the evidence and exposure/risk estimates emphasized in establishing the now-current standard, and the associated public health policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that are integral to decisions on the adequacy of the current primary SO_2 standard.

In considering the currently available evidence, staff gives great weight to the long-standing body of health effects evidence for SO_2, augmented in some aspects since the last review, that provides the foundation of our understanding of the health effects of SO_2 in ambient air. In so doing, we give particular attention to the evidence from controlled human exposure studies that demonstrates that very short exposures to less than 1000 ppb SO_2, while breathing at elevated ventilation rates, induces bronchoconstriction in some people with asthma; and, supports the identification of people with asthma as the population at risk from short-term peak concentrations in ambient air (second draft ISA; 2008 ISA; 1994 AQCD supplement).

Further, while the evidence base has been augmented since the time of the last review, we note that the newly available evidence does not lead to different conclusions regarding the primary health effects of SO_2 in ambient air or regarding exposure concentrations associated with those effects; nor does it identify different populations at risk of SO_2 -related effects. In this way, the health effects evidence available in this review is consistent with evidence available in the last review when the current standard was established. This strong evidence base continues to demonstrate a causal relationship between short-term SO_2 exposures and respiratory effects, particularly in people with asthma. This conclusion is primarily based on evidence from controlled human exposure studies available at the time of the last review that reported lung function decrements and respiratory symptoms in people with asthma exposed to SO_2 for 5 to 10 minutes while breathing at elevated ventilation. Support is provided by the epidemiological evidence that is coherent with the controlled exposure studies. The epidemiological evidence, including that recently available, includes studies reporting positive associations for asthma-related hospital admissions and emergency department visits (of individuals of all ages,

including adults and children) with short-term SO_2 exposures (second draft ISA, section 5.2.1.2).[48]

The health effects evidence newly available in this review also does not extend our understanding of the range of 5-minute exposure concentrations eliciting effects in people with asthma exposed while breathing at elevated ventilation rates beyond what was understood in the last review. As in the last review, 200 ppb remains the lowest concentration tested in exposure studies where study subjects are freely breathing in exposure chambers. At that exposure concentration, approximately eight to nine percent of study subjects with asthma, breathing at elevated ventilation rates, experienced moderate or greater lung function decrements following 5- to 10-minute controlled exposures. The limited information available for lower exposure concentrations, while not amenable to direct quantitative comparisons, generally indicates somewhat lesser response. In considering what may be gleaned from the epidemiological evidence with regard to exposure concentrations eliciting effects, we recognize complications associated with interpretation of epidemiologic studies of SO_2 in ambient air that relate to whether measurements at the study monitors adequately represent the spatiotemporal variability in ambient SO_2 concentrations in the study areas and associated population exposures (second draft ISA, section 5.2.1.9).

In this review, as in the last review, we recognize some uncertainty with regard to exposure levels eliciting effects in some population groups not studied, such as individuals with severe asthma, as well as uncertainty in the extent of effects at exposure levels below those studied. Collectively, these aspects of the evidence and associated uncertainties contribute to a recognition that for SO_2, as for other pollutants, the available evidence base in a NAAQS review generally reflects a continuum, consisting of ambient 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.

As at the time of the last review, the exposure and risk estimates developed from modeling exposures to SO_2 emitted into ambient air are critically important to consideration of the potential for exposures and risks of concern under air quality conditions of interest, and consequently are critically important to judgments on the adequacy of public health protection provided by the current standard. In considering the public health implications of estimated occurrences of exposures of different magnitudes, we take note of guidance from the ATS, the CASAC's written advice and recommendations in past reviews, and judgments made by the EPA in considering similar effects in previous NAAQS reviews (75 FR 35526 and 35536, June 22,

[48] While uncertainties remain related to the potential for confounding by PM or other co-pollutants and the representation of fine-scale temporal variation in personal exposures, the findings of the epidemiological evidence continue to provide support for the conclusion on the causal relationship (second draft ISA, section 5.2.1.2).

2010). As recognized in section 3.2.1.5, an additional publication by the ATS that further addresses judgments on what constitutes an adverse health effect of air pollution is newly available in this review (Thurston et al., 2017). The more recent statement expands upon the 2000 statement, that was considered in the last SO_2 NAAQS review, and recognizes additional considerations with regard to such judgments that remain consistent with the EPA's judgments in the 2010 review. In that review, the Administrator judged that the effects reported in exercising people with asthma following 5- to 10-minute SO_2 exposures at or above 200 ppb, and especially at or above 400 ppb (often accompanied by respiratory symptoms and for which the evidence is stronger), can result in adverse health effects (75 FR 35536, June 22, 2010). In so doing, she also recognized that effects reported for exposures below 400 ppb are less severe than those at and above 400 ppb (75 FR 35547, June 22, 2010).

In considering the draft REA analyses available in this review, we are aware of a number of ways in which these analyses differ from those available in the last review. In addition to the expansion in the number and type of study areas assessed, we note the number of improvements to input data and modeling approaches, including the availability of continuous 5-minute air monitoring data at monitors within two of the three study areas. The current draft REA extends the time period of simulation by including a 3-year simulation period consistent with the form established for the now-current standard. Further, the years simulated reflect more recent emissions and circumstances subsequent to the 2010 decision. In considering the draft REA results, we also take note of the array of emissions and exposure circumstances represented by the three study areas. As summarized in section 3.2.2 above, the areas fall into three different geographic regions of the U.S. They range in total population size from approximately 180,000 to approximately one half million, and vary in population demographic characteristics. Additionally, the types of large sources of SO_2 emissions represented in the three study areas vary with regard to emissions characteristics and include EGUs, petroleum refineries, glass-making facilities, secondary lead smelters (from battery recycling), and chemical manufacturing.

As at the time of the last review, people with asthma are the population at risk of SO2-related respiratory effects. Children with asthma may be particularly at risk (section 3.2.1.2 above). While there are more adults in the U.S. with asthma than children with asthma, the draft REA results in terms of percent of the simulated at-risk populations, indicates higher exposures and risks for children with asthma as compared to adults. This finding relates to children's greater frequency and duration of occasions outdoors (section 3.2.2.2 above). In light of these conclusions and findings, we have focused our consideration of the draft REA results here on children.

As can be seen by the variation in exposure estimates, the three study areas in the draft REA represent an array of exposure circumstances, including those contributing to relatively

higher and relatively lower exposures and associated risk. As recognized in the draft REA, the analyses there are not intended to provide a comprehensive national assessment. Rather, the analyses for this array of study areas are intended to indicate the magnitude of exposures and risks that may be expected in areas of the U.S. that just meet the current standard but that may differ in ways affecting population exposures of interest. In that way, the draft REA is intended to be informative to the EPA's consideration of potential exposures and risks associated with the current standard and the Administrator's decision on the adequacy of protection provided by the current standard. As discussed in sections 3.2.2.2 and 3.2.2.4 above, consideration of exposures occurring in those areas where locations of relatively higher SO_2 concentrations in ambient air across an area that just meets the current standard coincide with the locations of higher population density are particularly important to consideration of the public health protection afforded by the current standard.

With regard to the draft REA representation of air quality conditions associated with just meeting the current standard, while we note reduced uncertainty in a few aspects of the approach for developing this air quality scenario, we recognize the uncertainty associated with the application of adjustments to the highest model receptor in the study area. As summarized in sections 3.2.2.2 and 3.2.2.3 above, sensitivity analyses described in section 6.2.2 of the draft REA indicate the quantitative impact potentially associated with area of uncertainty. Given the importance of this aspect of the REA to consideration of the level of protection provided by the current standard, we have considered the results for each study area in terms of a range bounded on the low end by the results for the main analysis and on the upper end by those based on the alternative adjustment approach used in the sensitivity analysis. In this context, we note that across all three study areas, which provide an array of SO_2 emissions and exposure situations, the percent of children with asthma estimated to experience at least one day with as much as a doubling in sRaw (attributable to SO_2), on average across the 3-year period, ranges from 0.9 to 1.1%; the highest estimate is just under 2% for the highest single year. Less than 1% of children with asthma are estimated to experience, while at elevated ventilation, a daily maximum 5-minute exposure per year at or above 200 ppb, on average across the 3-year period, with a maximum of approximately 2% in the highest single year. Further, no child (or adult) with asthma is estimated to experience, while at elevated ventilation, a daily maximum 5-minute exposure per year at or above 400 ppb (in any of the three years simulated across the three study areas). Thus, in light of current ATS guidance, as well as conclusions and CASAC advice in prior NAAQS reviews, the draft REA exposure and risk estimates for the current review indicate that the current standard is likely to provide effective protection from SO_2-related health effects to at-risk populations of children and adults with asthma.

In summarizing the information discussed thus far, we reflect on the key aspects of the 2010 decision that established the current standard. As an initial matter, effects associated with 5- to 10-minute exposures as low as 200 ppb of people with asthma while breathing at elevated ventilation were considered to be adverse; this judgment was based on consideration of CASAC advice and EPA decisions in prior NAAQS reviews, as well as ATS guidance. We note that the newly available information in this review includes an additional statement from ATS on adversity which is generally consistent with the earlier statement (available at the time of the 2010 decision). While recognizing the differences between the current and past analyses, including the lack of an air quality scenario specific to the now-current standard in the last review, as well as uncertainties associated with such analyses, we note a rough consistency of the associated estimates when considering the array of study areas in both reviews. Overall, the newly available quantitative analyses appear to comport with the conclusions reached in the last review regarding control expected to be exerted by the now-current 1-hour standard on 5-minute exposures of concern. With regard to the results for the REA in the last review (which were for a single-year simulation), the 2010 decision recognized those results to indicate that a one-hour standard of 75 ppb might be expected to protect more than 97% of children with asthma (and somewhat less than 100%) from experiencing exposures at or above a 200 ppb benchmark concentration, and more than 99% of that population group from experiencing exposures at or above a 400 ppb benchmark. Single-year results for study areas assessed in the current draft REA indicate protection of approximately 98 to more than 99% of the populations of children with asthma from experiencing exposures at or above a 200 ppb benchmark concentration and of all of the study area at-risk populations from exposures at or above 400 ppb. Additionally, the 2010 decision also took note of the magnitude of the ambient air SO_2 concentrations in U.S. epidemiological studies of associations between ambient air concentrations and emergency department visits and hospital admissions, for which the effect estimate remained positive and statistically significant in copollutant models with PM. In considering these studies, the Administrator judged that the level chosen for the new 1-hour standard provided an adequate margin of safety. No additional such studies are available in the current review. Thus, in considering the key aspects of the decision in the last review, we find the currently available information to be consistent with that on which the decision establishing the current standard was based.

Based on all of the above, and taking into consideration related information, limitations and uncertainties, such as those recognized above, we draw preliminary conclusions regarding the extent to which the newly available information in this review supports or calls into question the adequacy of protection afforded by the current standard. In considering the conclusions that may be supported by the exposure and risk estimates, we take note of the more than 24 million

people with asthma in the U.S., including more than 6 million children. We additionally note the uncertainties or limitations of the current evidence base with regard to the exposure levels at which effects may be elicited in some population groups (e.g., children with asthma and individuals with severe asthma), as well as the severity of the effects. In so doing, we recognize that the controlled human exposure studies, on which the depth of our understanding of SO_2-related health effects is based, do not provide information with regard to responses in people with more severe asthma or in children younger than 12 years. Additionally, some aspects of our understanding continue to be limited; among these aspects are the potential for effects in some people with asthma exposed to concentrations below 200 ppb, as well as the potential for other air pollutants to affect responses to SO_2. In light of this we note the draft REA results for the lowest benchmark that indicate that in some areas of the U.S. with air quality conditions that just meet the current standard, appproximately 20 to 25% of children with asthma may experience one or more exposures, on average across a 3-year period, to concentrations at or above 100 ppb while at elevated ventilation. Thus, the evidence and exposure/risk information related to the lowest exposures studied lead us to conclude that the combined consideration of the body of evidence and the quantitative exposure estimates continue to provide support for a standard as protective as the current one.

Further, we recognize that conclusions regarding the adequacy of the current standard depend in part on public health policy judgments identified above and judgments about the level of public health protection with an adequate margin of safety. In so doing, we take note of the long-standing health effects evidence that documents the effects of SO_2 exposures as short as a few minutes on people with asthma that are exposed while breathing at elevated ventilation rates and recognize that such effects have been documented in the lowest concentration studied in exposure chambers with appropriate clean-air controls (200 ppb). In so doing, we recognize the limitations, and associated uncertainty, in the evidence available for lower exposure concentrations (e.g., 100 ppb), as was the case in the last review, and we note the lower responses reported. Thus, in focusing on the potential for 5-minute exposures at and above 200 ppb, that have been previously recognized as adverse (June 22, 2010; 75 FR 35547), we take note of the draft REA results that indicate the current standard may be expected to protect approximately 98% to nearly 99% of at-risk populations with asthma from experiencing any days with such exposures, in a single- and 3-year period, respectively. We additionally note the draft REA finding of no children (or adults) estimated to experience any days with a 5-minute exposure of 300 ppb or higher. In light of ATS guidance, CASAC advice and EPA conclusions in past NAAQS reviews, these results indicate effective protection of at-risk populations from SO_2-related health effects that we note is consistent with the level of protection specified when the standard was set. Thus, we reach the preliminary conclusion that the currently available

evidence and quantitative information, including the associated uncertainties, do not call into question the adequacy of protection provided by the current standard, and thus support consideration of retaining the current standard, without revision.

In summary, the newly available health effects evidence, critically assessed in the ISA as part of the full body of evidence, reaffirms conclusions on the respiratory effects recognized for SO_2 in the last review. Further, we observe the general consistency of the current evidence with the evidence that was available in the last review with regard to key aspects on which the current standard is based. We additionally note the quantitative exposure and risk estimates for conditions just meeting the current standard that indicate a similar level of protection, for at-risk populations from respiratory effects considered to be adverse, as that described in the last review for the now-current standard. We also recognize, as in the last review, the limitations and uncertainties associated with the available information. Collectively, these considerations (including those discussed above) provide the basis for the preliminary staff conclusion that consideration should be given to retaining the current standard, without revision. Accordingly, and in light of this preliminary staff conclusion that it is appropriate to consider the current standard to be adequate, we have not identified any potential alternative standards for consideration in this review.

3.3 KEY UNCERTAINTIES AND AREAS FOR FUTURE RESEARCH AND DATA COLLECTION

In this section, we highlight key uncertainties associated with reviewing and establishing the primary NAAQS for sulfur oxides. Such key uncertainties and areas for future research, model development, and data gathering are outlined below. In some cases, research in these areas can go beyond aiding standard setting to aiding in the development of more efficient and effective control strategies. We note, however, that a full set of research recommendations to meet standards implementation and strategy development needs is beyond the scope of this discussion. Rather, listed below are key uncertainties, research questions and data gaps that have been thus far highlighted in this review of the primary standard.

- A critical aspect of our consideration of the evidence and the quantitative dose estimates is our understanding of SO_2 effects below the lowest concentrations studied in controlled human exposure studies. Additional information related in several areas would reduce uncertainty in our interpretation of the available information for purposes of risk characterization. These areas include the following.
  - Our understanding of whether and to what extent some population groups, including children or people with severe asthma, are more responsive to peak SO_2 exposures (or responsive to lower concentrations), while breathing at elevated ventilation rates, than the groups that have been studied.

  - A better understanding of the effects and the shape of the exposure-response relationship at lower 5-minute exposure concentrations (i.e., below 200 ppb) would help to reduced uncertainty in our estimates of lung function effects and, accordingly, in characterizing SO2-related health effects.
  - Little information is available on the factors contributing to the susceptibility to lower concentrations of SO_2 of a subgroup of people with asthma, termed "responders" in the second draft ISA (second draft ISA, section 5.2.1.2; Johns and Linn, 2011).
  - There is also only very limited evidence regarding the potential influence of history of exposure and co-occurring exposure to other air pollutants, including particulate matter. Further research is needed in this area to better inform our characterization of health risk related to SO_2.

- An understanding of the fine-scale spatial and temporal gradients of ambient air SO_2 concentrations in residential areas, as well as near sources of SO_2 emissions, is a key element in our assessment of exposure and risk. Additional information in this area is needed. Current limitations in this area additionally contribute to uncertainty in characterization of ambient air SO_2 levels in the risk assessment and the resulting exposure and risk estimates. Further characterization of the fine-scale spatial and temporal variation in ambient air SO_2 concentrations in different environments and related to different sources, as well as different air quality conditions that just meet the existing standard, would help to reduce this uncertainty.

- Uncertainties with regard to other aspects of the health effects evidence include that regarding what can be gleaned from the epidemiologic studies showing an association between short-term SO_2 exposures and asthma-related hospital admission and emergency department visits. Uncertainty remains regarding the extent of copollutant confounding in these studies, particularly by PM. Additionally, there is uncertainty related to the representation of exposure through fixed site monitors and capturing peak SO_2 concentrations that limits the informativeness of the ambient air concentrations analyzed in the studies to standards reviews.

- While the CHAD is much expanded over the last review, limited information and associated uncertainty remain in several aspects of the available data. Additional information would reduce uncertainty in these aspects of our exposure and risk estimates.
  - Collection and analysis of multiday activity patterns that consider the attributes most influential to determining long-term activity patterns. Further research would assist in better evaluating and improving existing approaches used to generate longitudinal activity profiles (as discussed in the draft REA, section 4.1.5.1).
  - Activity data for some population subgroups, such as people with severe asthma and very young children.

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APPENDIX A

PREPARATION OF DATA FILES FOR GENERATION OF FIGURES IN CHAPTER 2

The raw data came from pre-generated AQS extract files. Files are located at http://www.epa.gov/airquality/airdata/ad_data.html. Documentation of files is located at http://aqsdr1.epa.gov/aqsweb/aqstmp/airdata/FileFormats.html. Hourly Data Files were used. A separate Hourly Data File for each parameter and year combination was run. The type of SO_2 data is determined by the parameter code and duration code and is coded as follows:

- 1-hour values data - parameter code = 42401 and duration code = 1
- 5-minute data (12 observations per hour) - parameter code = 42401 and duration code = H
- 5-minute data (hourly max) – parameter code = 42406 and duration code = 1

For the 1-hour data at a Site/POC to be used, it must have met the following completeness criteria:

- 75% or more of the hourly observations in a day (18 or more) must be present.
- 75% or more of the days in a quarter must be present and complete:
- 1st Quarter – 68 observations or 69 observations in leap year
  - 2nd Quarter – 69 observations
  - 3rd Quarter – 69 observations
  - 4th Quarter – 69 observations
- 4 quarters for each of at least 3 of the 5 years (2011-2015) must be present and complete. For this analytical purpose, the three years do not have to be consecutive. This dataset was prepared in June 2016.

After completeness criteria were applied, the following data screens were also performed to account for some outliers in the 5-minute data:

- Only 5 minute data with a corresponding hourly value in AQS (parameter 42401 and duration code 1) were kept.
- Only 5 minute values with an hourly mean value under 120% of the hourly value in AQS (parameter 42401 and duration code 1) were kept.
- Only hours where a 5-minute max hourly value (AQS parameter 42406 and duration code 1) was reported and fell between 1 and 12 times the AQS hourly value (parameter 42401 and duration code 1) were kept.

APPENDIX B

ADDITIONAL INFORMATION ON DATASETS PRESENTED IN FIGURE 2-8

Table B-1. Summary statistics (in ppb) for distributions of daily maximum 5-minute SO_2 concentrations on days with differing daily maximum 1-hour SO2 concentrations.

Bin	Daily Maximum 1-hour Concentration (ppb)			
	<=25	>25-50	>50-75	>75
N	315964	5486	1521	1435
25th percentile	1	46.6	95	170.1
Median	2.0	62	122.6	220
Mean	5	74	140	259
75th percentile	5.2	88	167.2	294.25
95th percentile	22.0	152.5	259	502.9
99th percentile	44	225.6	389	822.5

When the three data sets for sites with DVs at or below 75 ppb are combined, the 99th percentile is 58.3 ppb and the 99.9th percentile is 150 ppb.

Table B-2. Summary statistics (in ppb) for distributions of daily maximum 5-minute SO_2 concentrations at sites with differing design values.

Bin	Design Value (ppb)			
	<=25	>25-50	>50-75	>75
N	225863	59011	18504	21028
25th percentile	0.8	2	2	2.3
Median	1.7	5	7	8
Mean	3	10	20	41
75th percentile	3.8	13	26	40
95th percentile	12.2	37	82.6	199.6
99th percentile	28.3	68	146.1	365

Figure B-1. Monitoring data for sites meeting the current standard: Frequency of daily maximum 5-minute values on days with differing daily maximum 1-hour concentrations (2013-2015).

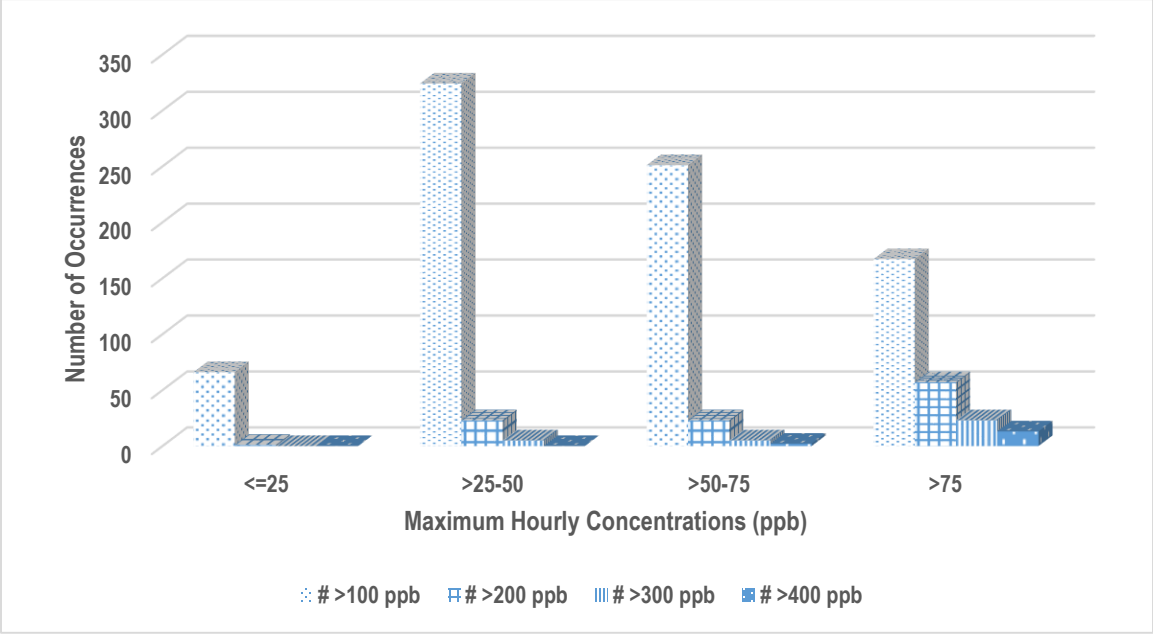
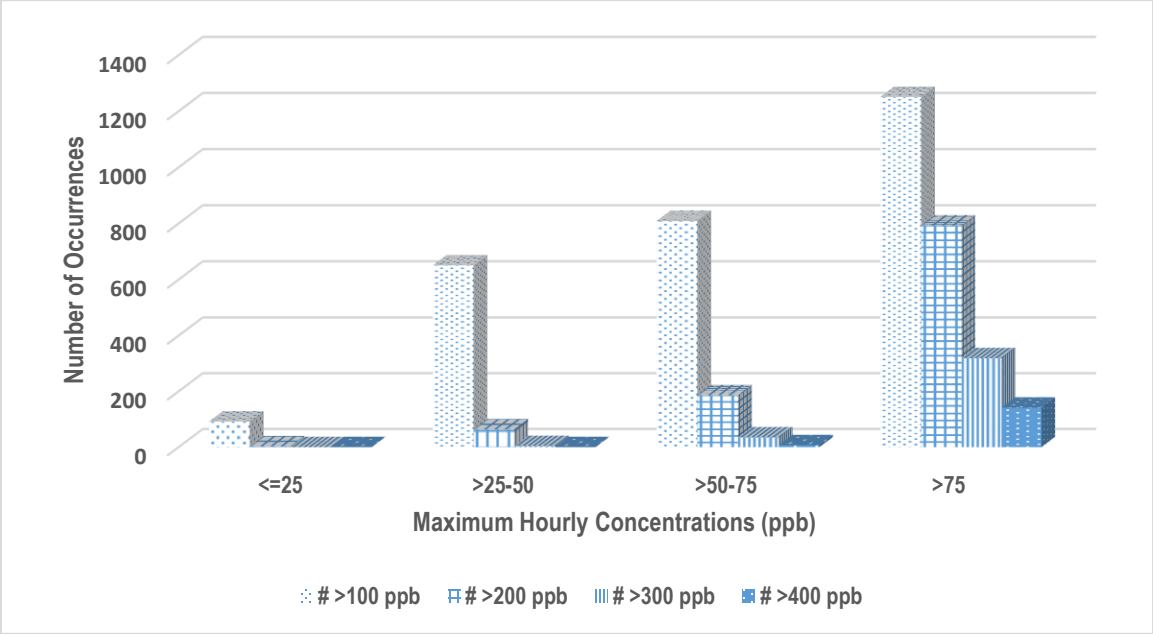


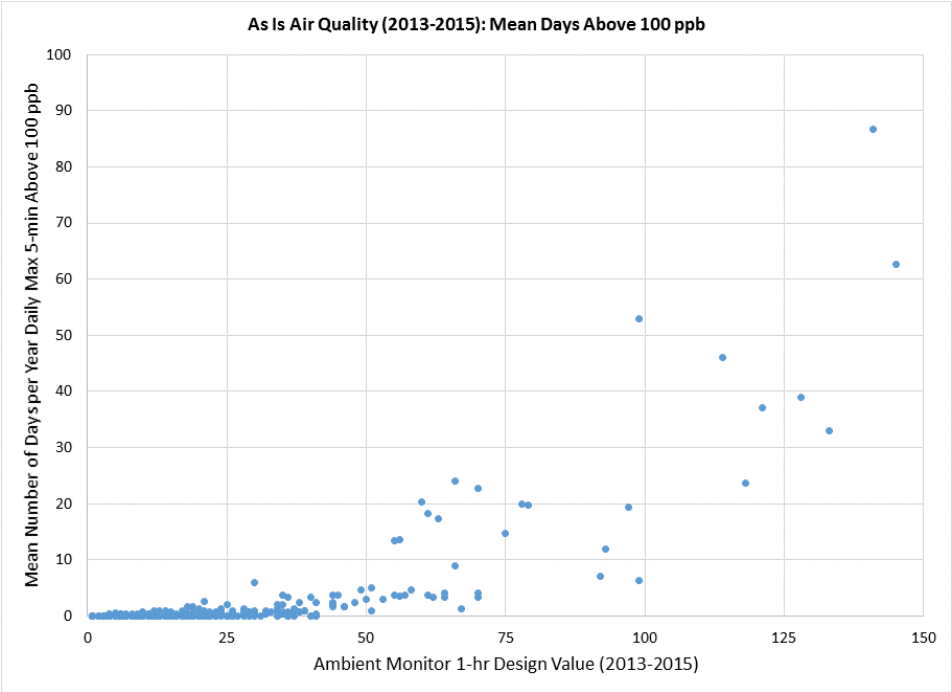
Figure B-2. Monitoring data for sites <u>not</u> <u>meeting</u> the current standard: Frequency of daily maximum 5-minute values on days with differing daily maximum 1-hour concentrations (2013-2015).



APPENDIX C

OCCURRENCES OF 5-MINUTE SO_2 CONCENTRATIONS OF INTEREST IN THE RECENT AMBIENT AIR MONITORING DATA (2013-2015)

Figure C-1. As is (unadjusted) SO_2 monitoring data (2013-2015). Mean number of days/year (top panel) and maximum number of days/year (bottom panel) with daily maximum 5-minute concentrations of SO_2 above 100 ppb.



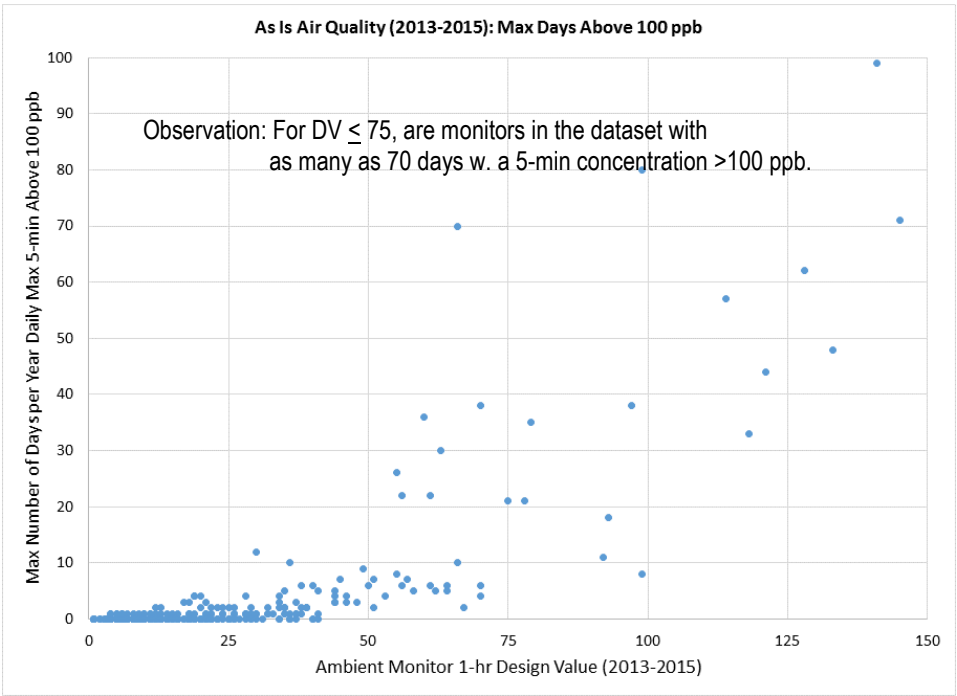
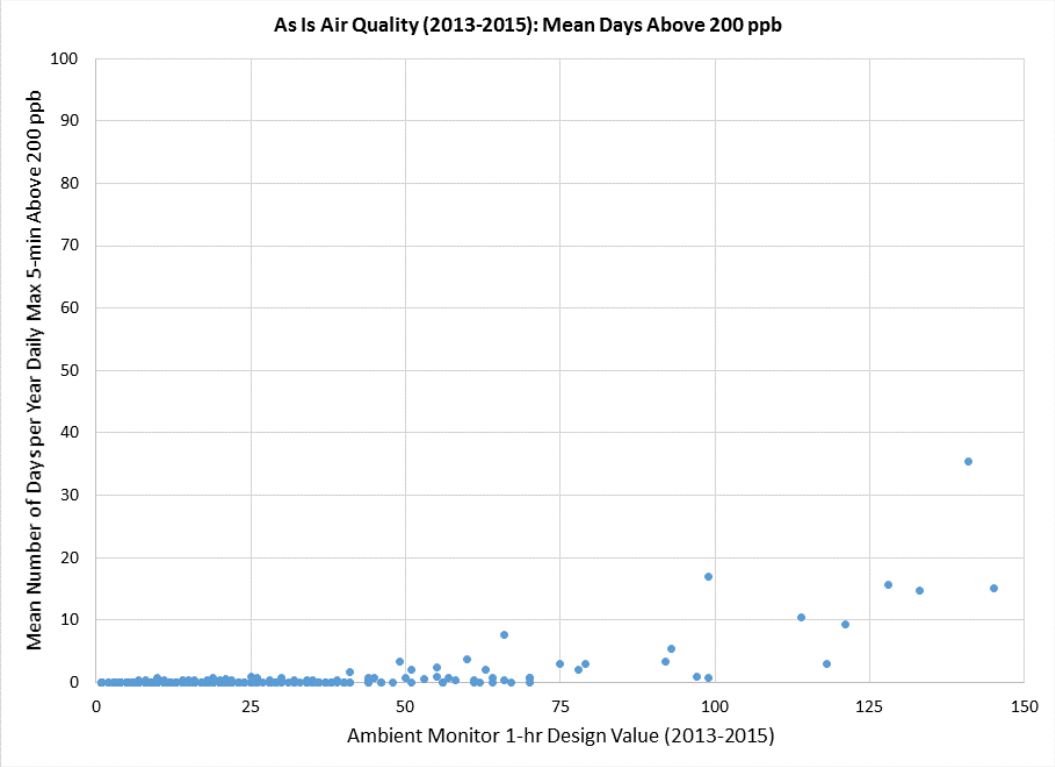


Figure C-2. As is (unadjusted) SO_2 monitoring data (2013-2015). Mean number of days/year (top panel) and maximum number of days/year (bottom panel) with daily maximum 5-minute concentrations of SO_2 above 200 ppb.



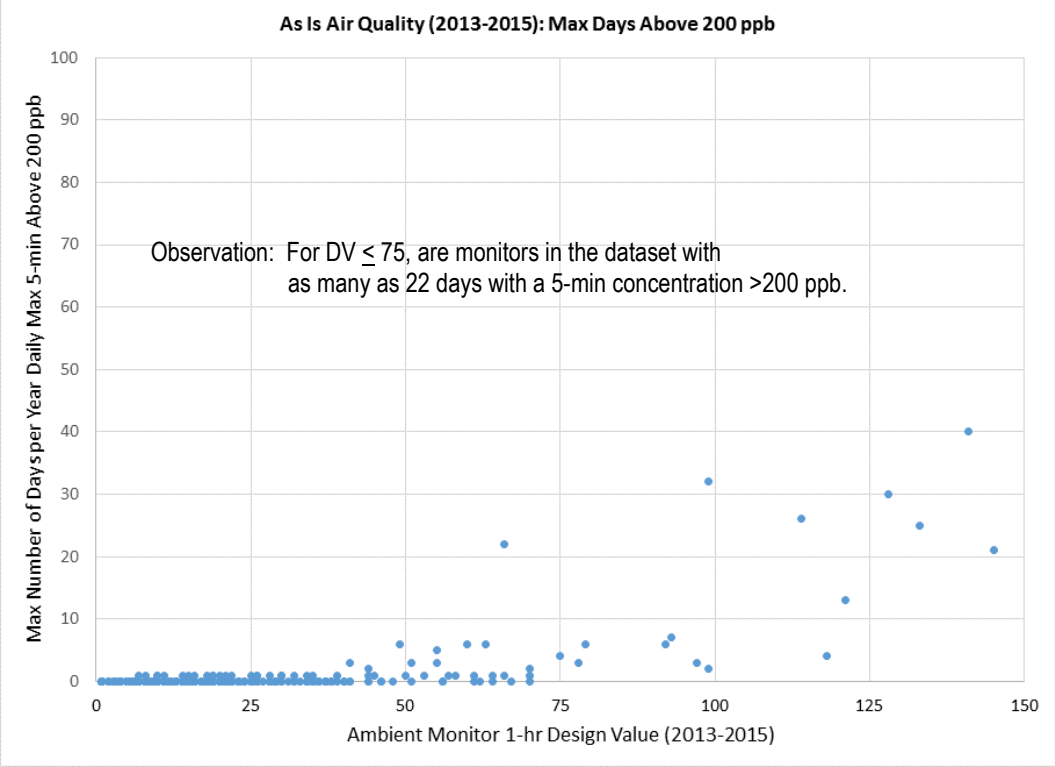
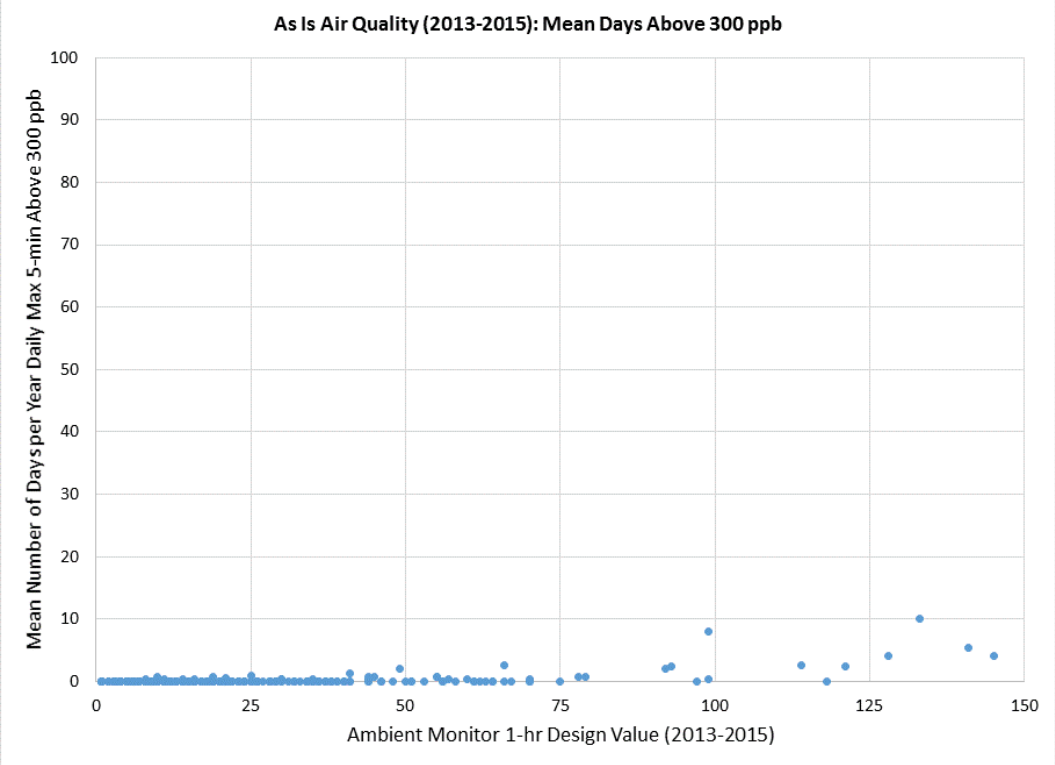


Figure C-3. As is (unadjusted) SO_2 monitoring data (2013-2015). Mean number of days/year (top panel) and maximum number of days/year (bottom panel) with daily maximum 5-minute concentrations of SO_2 above 300 ppb.



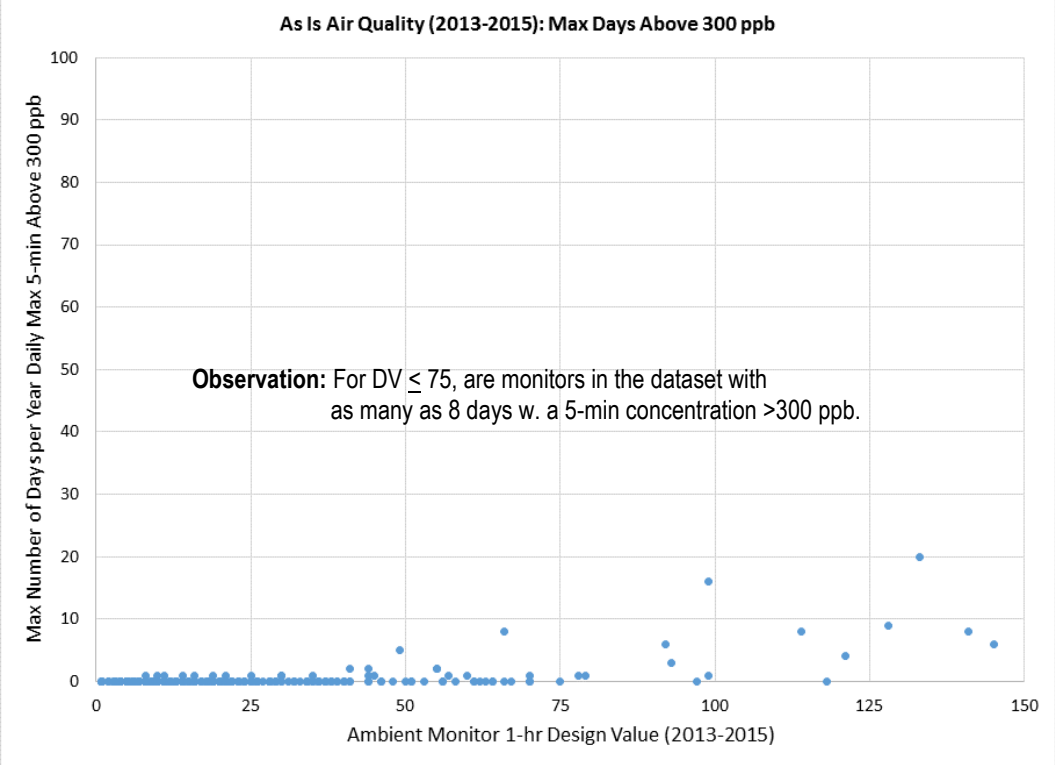
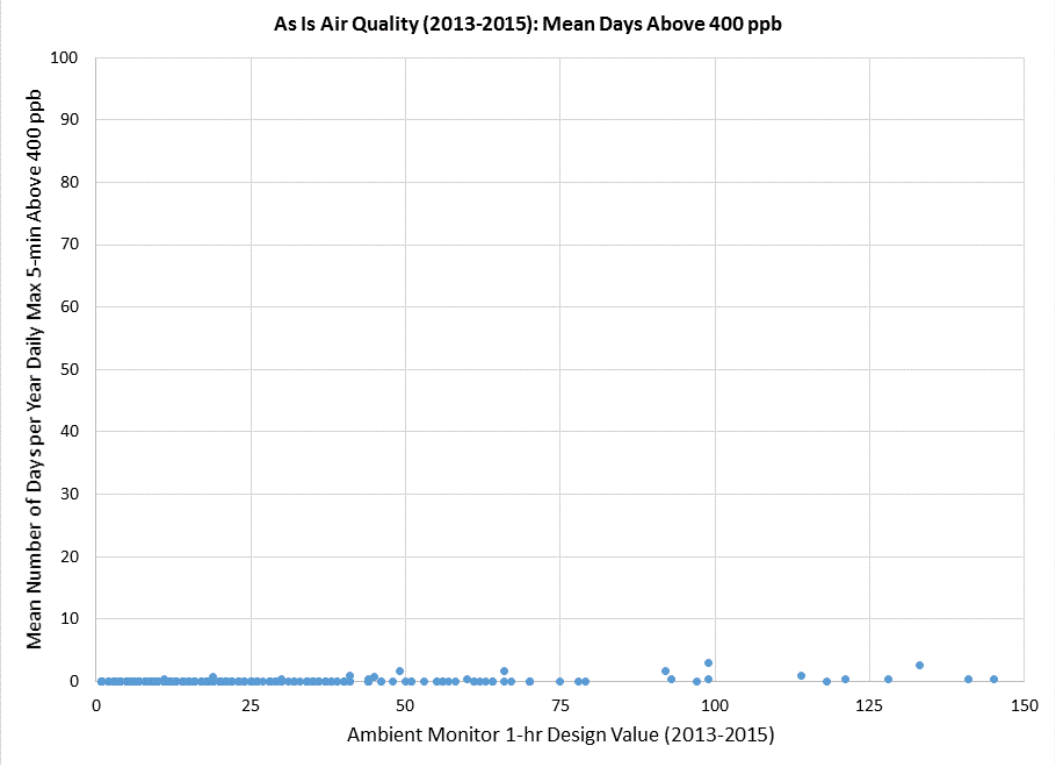


Figure C-4. As is (unadjusted) SO_2 monitoring data (2013-2015). Mean number of days/year (top panel) and maximum number of days/year (bottom panel) with daily maximum 5-minute concentrations of SO_2 above 400 ppb.



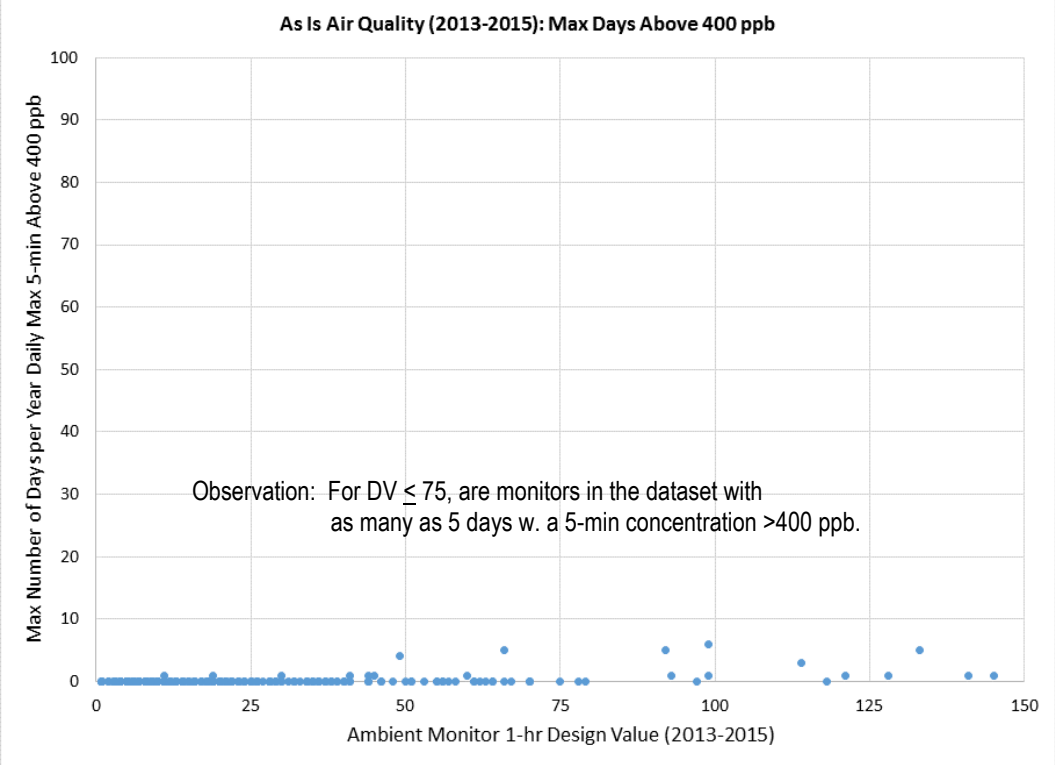


Figure C-5. Monitoring data (2013-2015), unadjusted. Total number of days across 3-year period with daily maximum 5-minute concentrations of SO_2 above 100, 200, 300 and 400 ppb across monitors grouped by design value.

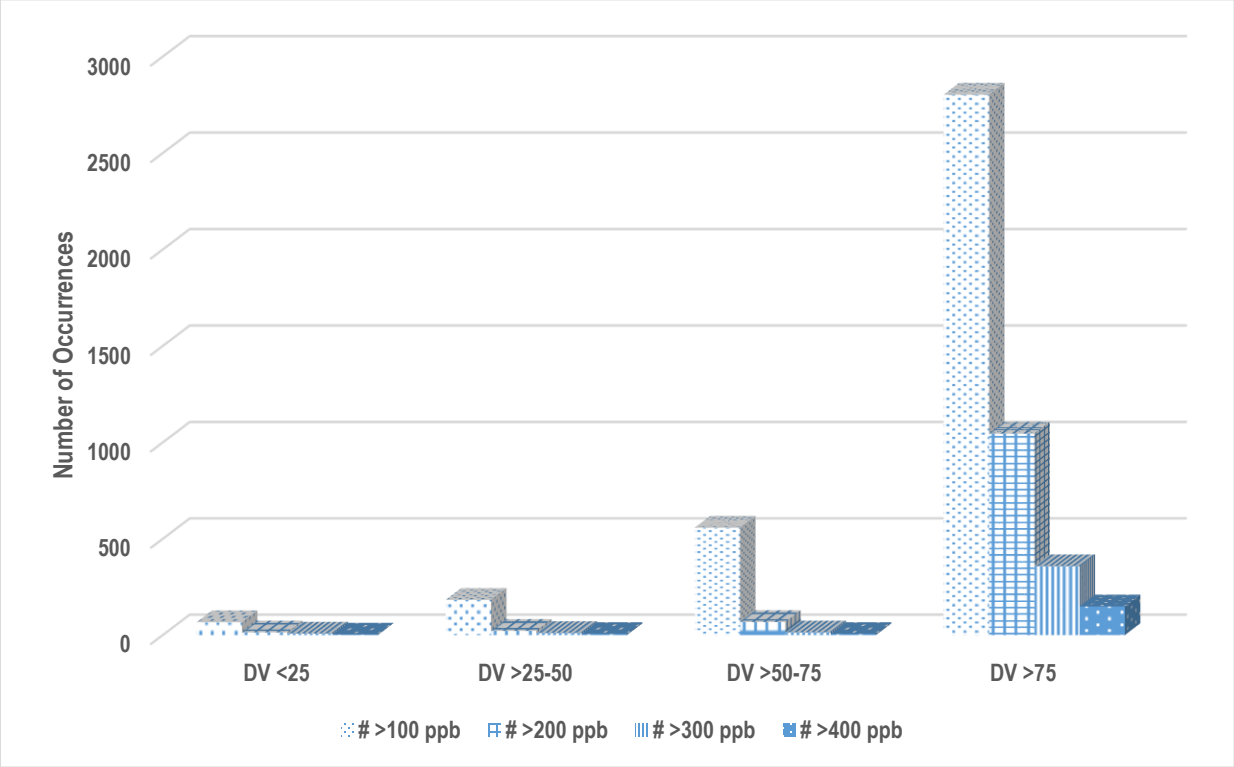
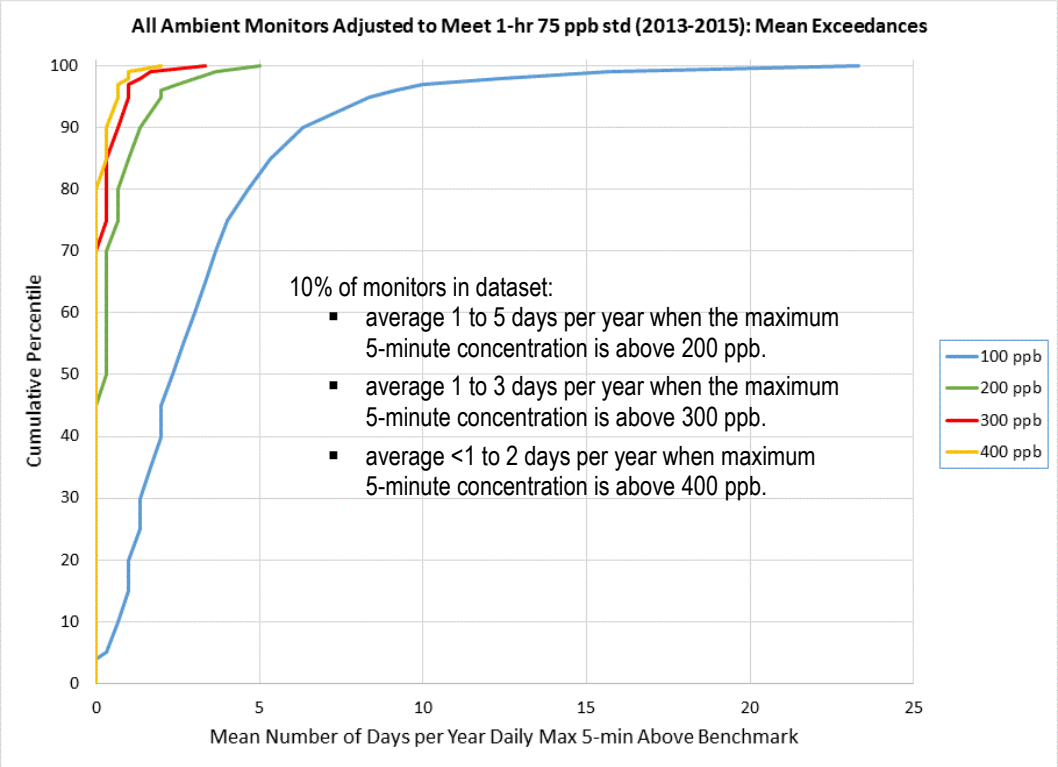
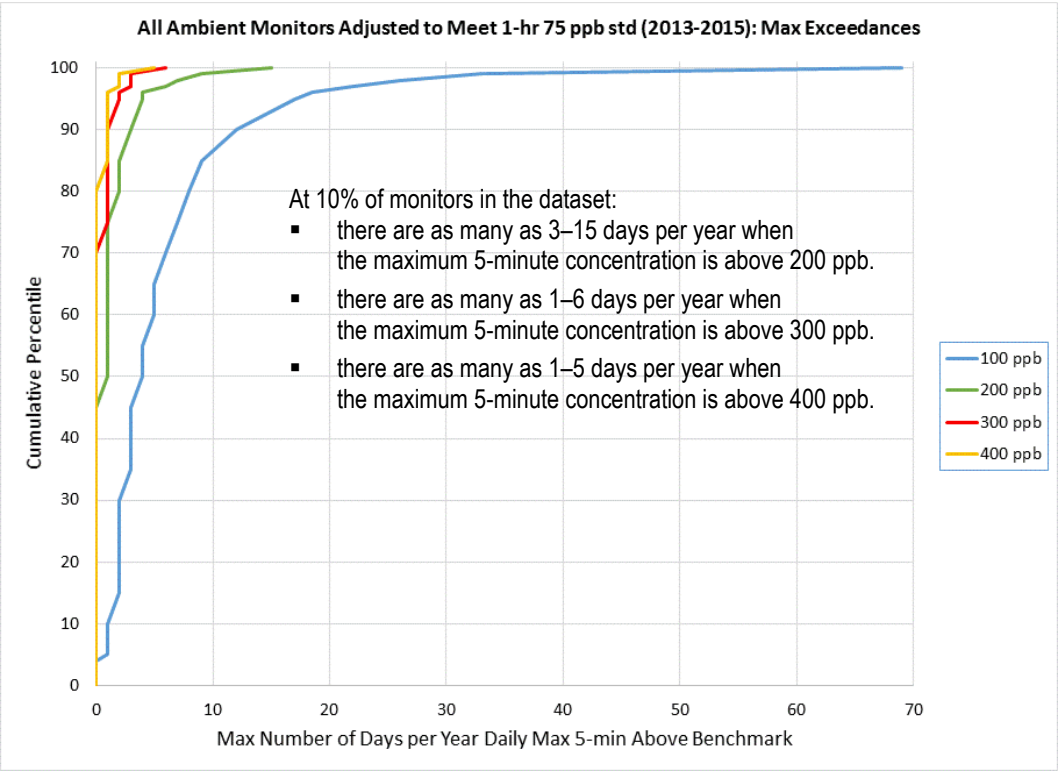


Figure C-6. Monitoring data (2013-2015) adjusted to just meet the current standard (75 ppb as a 3-year average of annual 99th percentile 1-hour daily maximum concentrations). Mean number of days/year (top panel) and maximum number of days/year (bottom panel) with daily maximum 5-minute concentrations of SO_2 above 100, 200, 300 and 400 ppb.





APPENDIX D

AIR QUALITY INFORMATION FOR GEOGRAPHICAL AREAS
OF THREE SELECTED U.S. EPIDEMIOLOGICAL STUDIES

Table D-1. Air quality information for geographical areas of the three U.S. epidemiological studies for which the SO_2 effect estimates for hospital admissions or emergency department visits (for asthma or other respiratory disease) and areawide 24-hour average SO_2 concentrations remained positive and statistically significant in copollutant models with particulate matter.

Study Information								Ambient Air Quality [A]			
Study Area	**Study Time Period**	**Study Reference**	**SO_2 Concentration Metric Associated with Health Outcome**	**Assignment of Monitors to Study Subjects for Study Analyses**	**Study-reported SO_2 Concentrations,** [B] 24-hour average (ppm)		**99th percentile of daily maximum 1-hour concentrations across study period at highest monitor in study dataset** (ppb)	**Annual 99th percentile of daily maximum 1-hour concentrations at monitor yielding highest design value** (ppb)		**Design Value for Current NAAQS** (3-year average of annual 99th percentile daily maximum 1-hour concentrations), ppm (monitor ID)	
					Mean	**Upper Percentiles**					
Bronx County, NY	Jan 1999-Dec 2000	ATSDR 2006 [C]	24-hr ave	2 monitors collecting data in series	12	-	78 [D]	1999 2000	-	[E]	
New York City, NY	Jan 1999-Dec 2002	Ito et al 2007	24-hr ave	Average across all (19) monitors	7.8	75th=10 95th=17	82 [F]	1999 2000 2001 2002	78 71 71 65	1999-2001 2000-2002	73 (36-061-0056) 69 (36-061-0056)
New Haven, CT	Jan 1988-Dec 1990	Schwartz, 1995	24-hr ave	Average across all (6) monitors	29.8	75th =38.2 90th=60.7	150 [G]	1988 1989 1990	159 167 116	1988-1990	147 (09-009-1123)

A Air quality information provided here is drawn from monitors reporting to AQS, as documented in Appendix E). Design values are SO_2 concentrations for the study area in the statistical form of the standard, derived in accordance with 40 CFR, Part 50, Appendix T. Presented is the highest valid design value at a monitor reporting to AQS for specified 3-year period.

B Ambient SO_2 concentrations in terms of study metric that are reported in the second draft ISA Table 5-9 (for ATSDR, 2006 and Ito et al., 2007) and Table 5-14 (for Schwartz, 1995). Where multiple monitors contribute data, these are the arithmetic mean and percentiles of the dataset of daily multi-monitor average concentrations for the full study period.

C This study was cited as NY DOH, 2006 in the 2008 ISA.

D This statistic is for combined dataset of 2 monitoring sites due to construction at the initial site (Thompson and Stewart, 2009). Data are from the first monitor (36-005-0073) for the period Jan 1 to July 14, 1999. Data are from the second monitor (36-005-0110), approximately ½ mile northeast of first, for the period Sept 2, 1999 to Nov 22, 2000.

E Due to incomplete quarters or years, there is not a valid design value for a monitor in the Bronx any of the 3-year periods that include the study period.

F This statistic is based on monitor 36-061-0080 (Thompson and Stewart, 2009), for which five quarters of data are available during the study period (from 1999 through first quarter of 2000).

G This statistic is based on monitor 09-009-1123 (Thompson and Stewart, 2009), for which 12 quarters of data are available during the study period (1988 through 1990).

REFERENCES

ATSDR (Agency for Toxic Substances and Disease Registry). (2006). A study of ambient air contaminants and asthma in New York City: Part A and B. Atlanta, GA: U.S. Department of Health and Human Services. http://permanent.access.gpo.gov/lps88357/ASTHMA_BRONX_FINAL_REPORT.pdf

Ito, K; Thurston, GD; Silverman, RA. (2007). Characterization of PM2.5, gaseous pollutants, and meteorological interactions in the context of time-series health effects models. J Expo Sci Environ Epidemiol 17: S45-S60. http://dx.doi.org/10.1038/sj.jes.7500627

Schwartz, J; Morris, R. (1995). Air pollution and hospital admissions for cardiovascular disease in Detroit, Michigan. Am J Epidemiol 142: 23-35.

Thompson, R; Stewart, M. (2009). *Air Quality Statistics for Cities Referenced in Key U.S. and Canadian Epidemiological Studies of Hospital Admissions and Emergency Department Visits for All Respiratory Causes and Asthma.* OAQPS Staff Memorandum to Ozone NAAQS Review, March 25. Washington, DC: Office of Air Radiation. (EPA docket number EPA-HQ-OAR-2007-0352). Available at: https://www3.epa.gov/ttn/naaqs/standards/so2/data/2009_03_Thompson_AirQuality.pdf

APPENDIX E

DERIVAITON OF DESIGN VALUES PRESENTED IN APPENDIX D

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

User ID: DST

DESIGN VALUE REPORT

Report Request ID: 1565153 Report Code: AMP480 Jun. 20, 2017

GEOGRAPHIC SELECTIONS

Tribal Code	State	County	Site	Parameter	POC	City	AQCR	UAR	CBSA	CSA	EPA Region
	09	009									

PROTOCOL SELECTIONS

Parameter Classification	Parameter	Method	Duration
DESIGN VALUE	42401		

SELECTED OPTIONS

Option Type	Option Value
SINGLE EVENT PROCESSING	EXCLUDE REGIONALLY CONCURRED EVENTS
WORKFILE DELIMITER	,
USER SITE METADATA	STREET ADDRESS
MERGE PDF FILES	YES
QUARTERLY DATA IN WORKFILE	NO
AGENCY ROLE	PQAO

DATE CRITERIA

Start Date	End Date
1990	1990

APPLICABLE STANDARDS

Standard Description
SO2 1-hour 2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
AIR QUALITY SYSTEM
PRELIMINARY DESIGN VALUE REPORT

Report Date: Jun. 20, 2017

Notes:
1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

Pollutant: Sulfur dioxide(42401)
Standard Units: Parts per billion(008)
NAAQS Standard: SO2 1-hour 2010
Statistic: Annual 99th Percentile **Level:** 75

Design Value Year: 1990
REPORT EXCLUDES MEASUREMENTS WITH REGIONALLY CONCURRED EVENT FLAGS.
State Name: Connecticut

		1990			1989			1988			3-Year	
Site ID	STREET ADDRESS	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Design Value	Valid Ind.
09-009-0010	EGAN CENTER, MATHEW ST	3	114 *	Y	4	113		3	118 *		115	N
09-009-0017	LOMBARD STREET				3	112 *		4	113		113	N
09-009-1003	ANIMAL SHELTER, COMMERCE ST	4	68	Y	4	99		4	95		87	Y
09-009-1123	715 STATE STREET	4	116	Y	4	167		4	159		147	Y
09-009-2123	Bank St at Meadow St (see c	4	83	Y	4	97		4	85		88	Y
09-009-3008	LYDIA STREET EXTENTION	3	93 *	Y	4	110		4	100		101	Y

Notes: 1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

CERTIFICATION EVALUATION AND CONCURRENCE FLAG MEANINGS

FLAG	MEANING
M	The monitoring organization has revised data from this monitor since the most recent certification letter received from the state.
N	The certifying agency has submitted the certification letter and required summary reports, but the certifying agency and/or EPA has determined that issues regarding the quality of the ambient concentration data cannot be resolved due to data completeness, the lack of performed quality assurance checks or the results of uncertainty statistics shown in the AMP255 report or the certification and quality assurance report.
S	The certifying agency has submitted the certification letter and required summary reports. A value of "S" conveys no Regional assessment regarding data quality per se. This flag will remain until the Region provides an "N" or "Y" concurrence flag.
U	Uncertified. The certifying agency did not submit a required certification letter and summary reports for this monitor even though the due date has passed, or the state's certification letter specifically did not apply the certification to this monitor.
X	Certification is not required by 40 CFR 58.15 and no conditions apply to be the basis for assigning another flag value
Y	The certifying agency has submitted a certification letter, and EPA has no unresolved reservations about data quality (after reviewing the letter, the attached summary reports, the amount of quality assurance data submitted to AQS, the quality statistics, and the highest reported concentrations).

Notes:
1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

User ID: DST

DESIGN VALUE REPORT

Report Request ID: 1565370 Report Code: AMP480 Jun. 21, 2017

GEOGRAPHIC SELECTIONS

Tribal Code	State	County	Site	Parameter	POC	City	AQCR	UAR	CBSA	CSA	EPA Region
	36	005									
	36	047									
	36	061									
	36	081									
	36	085									

PROTOCOL SELECTIONS

Parameter Classification	Parameter	Method	Duration
DESIGN VALUE	42401		

SELECTED OPTIONS

Option Type	Option Value
SINGLE EVENT PROCESSING	EXCLUDE REGIONALLY CONCURRED EVENTS
WORKFILE DELIMITER	,
USER SITE METADATA	STREET ADDRESS
MERGE PDF FILES	YES
QUARTERLY DATA IN WORKFILE	NO
AGENCY ROLE	PQAO

DATE CRITERIA

Start Date	End Date
2000	2002

APPLICABLE STANDARDS

Standard Description
SO2 1-hour 2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
AIR QUALITY SYSTEM
PRELIMINARY DESIGN VALUE REPORT

Report Date: Jun. 21, 2017

Notes: 1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

Pollutant: Sulfur dioxide(42401)
Standard Units: Parts per billion(008)
NAAQS Standard: SO2 1-hour 2010
Statistic: Annual 99th Percentile **Level:** 75

Design Value Year: 2000
REPORT EXCLUDES MEASUREMENTS WITH REGIONALLY CONCURRED EVENT FLAGS.
State Name: New York

		2000			1999			1998			3-Year	
Site ID	STREET ADDRESS	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Design Value	Valid Ind.
36-005-0073	IS 155, 470 JACKSON AV.				2	68 *	Y	4	70	Y	69	N
36-005-0080	MORRISANIA CENTER, 1225-57	1	94 *		4	77	Y	4	69	Y	80	N
36-005-0083	200TH STREET AND SOUTHERN B	2	62 *								62	N
36-005-0110	IS 52 681 KELLY ST	4	86		1	98 *	Y				92	N
36-047-0011	301 GREENPOINT AVENUE				3	51 *	Y	4	42	Y	47	N
36-047-0076	PS 321 180 7TH AV,	0	36 *		4	54	Y	3	59 *	Y	50	N
36-061-0010	MABEL DEAN HIGH SCH.ANNEX,	3	72 *		4	79	Y	3	64 *	Y	72	N
36-061-0056	PS 59, 228 E. 57TH STREET,	4	71		4	78	Y	4	69	Y	73	Y
36-081-0097	56TH AVE AT SPRINGFIELD BLV	4	50		4	53	Y	2	52 *	Y	52	N
36-085-0067	SUSAN WAGNER HS, 1200 MAN	1	54 *		4	46	Y	4	46	Y	49	N

Notes: 1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

Pollutant: Sulfur dioxide(42401)
Standard Units: Parts per billion(008)
NAAQS Standard: SO2 1-hour 2010
Statistic: Annual 99th Percentile **Level:** 75

Design Value Year: 2001
REPORT EXCLUDES MEASUREMENTS WITH REGIONALLY CONCURRED EVENT FLAGS.
State Name: New York

		2001			2000			1999			3-Year	
Site ID	STREET ADDRESS	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Design Value	Valid Ind.
36-005-0073	IS 155, 470 JACKSON AV.							2	68 *	Y	68	N
36-005-0080	MORRISANIA CENTER, 1225-57				1	94 *		4	77	Y	86	N
36-005-0083	200TH STREET AND SOUTHERN B	4	71	Y	2	62 *					67	N
36-005-0110	IS 52 681 KELLY ST	3	81 *	Y	4	86		1	98 *	Y	88	N
36-047-0011	301 GREENPOINT AVENUE							3	51 *	Y	51	N
36-047-0076	PS 321 180 7TH AV,				0	36 *		4	54	Y	45	N
36-061-0010	MABEL DEAN HIGH SCH.ANNEX,	2	69 *	Y	3	72 *		4	79	Y	73	N
36-061-0056	PS 59, 228 E. 57TH STREET,	4	71	Y	4	71		4	78	Y	73	Y
36-081-0097	56TH AVE AT SPRINGFIELD BLV	4	50	Y	4	50		4	53	Y	51	Y
36-081-0124	Queens College 65-30 Kiss	1	57 *	Y							57	N
36-085-0067	SUSAN WAGNER HS, 1200 MAN				1	54 *		4	46	Y	50	N

Notes: 1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

Pollutant: Sulfur dioxide(42401)
Standard Units: Parts per billion(008)
NAAQS Standard: SO2 1-hour 2010
Statistic: Annual 99th Percentile **Level:** 75

Design Value Year: 2002
REPORT EXCLUDES MEASUREMENTS WITH REGIONALLY CONCURRED EVENT FLAGS.
State Name: New York

		2002			2001			2000			3-Year	
Site ID	STREET ADDRESS	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Design Value	Valid Ind.
36-005-0080	MORRISANIA CENTER, 1225-57							1	94 *		94	N
36-005-0083	200TH STREET AND SOUTHERN B	4	62	Y	4	71	Y	2	62 *		65	N
36-005-0110	IS 52 681 KELLY ST	4	67	Y	3	81 *	Y	4	86		78	N
36-047-0076	PS 321 180 7TH AV,							0	36 *		36	N
36-061-0010	MABEL DEAN HIGH SCH.ANNEX,				2	69 *	Y	3	72 *		71	N
36-061-0056	PS 59, 228 E. 57TH STREET,	4	65	Y	4	71	Y	4	71		69	Y
36-081-0097	56TH AVE AT SPRINGFIELD BLV				4	50	Y	4	50		50	N
36-081-0124	Queens College 65-30 Kiss	4	57	Y	1	57 *	Y				57	N
36-085-0067	SUSAN WAGNER HS, 1200 MAN							1	54 *		54	N

Notes: 1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

CERTIFICATION EVALUATION AND CONCURRENCE FLAG MEANINGS

FLAG	MEANING
M	The monitoring organization has revised data from this monitor since the most recent certification letter received from the state.
N	The certifying agency has submitted the certification letter and required summary reports, but the certifying agency and/or EPA has determined that issues regarding the quality of the ambient concentration data cannot be resolved due to data completeness, the lack of performed quality assurance checks or the results of uncertainty statistics shown in the AMP255 report or the certification and quality assurance report.
S	The certifying agency has submitted the certification letter and required summary reports. A value of "S" conveys no Regional assessment regarding data quality per se. This flag will remain until the Region provides an "N" or "Y" concurrence flag.
U	Uncertified. The certifying agency did not submit a required certification letter and summary reports for this monitor even though the due date has passed, or the state's certification letter specifically did not apply the certification to this monitor.
X	Certification is not required by 40 CFR 58.15 and no conditions apply to be the basis for assigning another flag value
Y	The certifying agency has submitted a certification letter, and EPA has no unresolved reservations about data quality (after reviewing the letter, the attached summary reports, the amount of quality assurance data submitted to AQS, the quality statistics, and the highest reported concentrations).

Notes:
1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

APPENDIX F

GEOGRAPHIC DISTRIBUTION OF CONTINENTAL
U.S. FACILITIES EMITTING MORE THAN 1,000 TPY SO_2
AND POPULATION DENSITY BASED ON U.S. CENSUS TRACTS

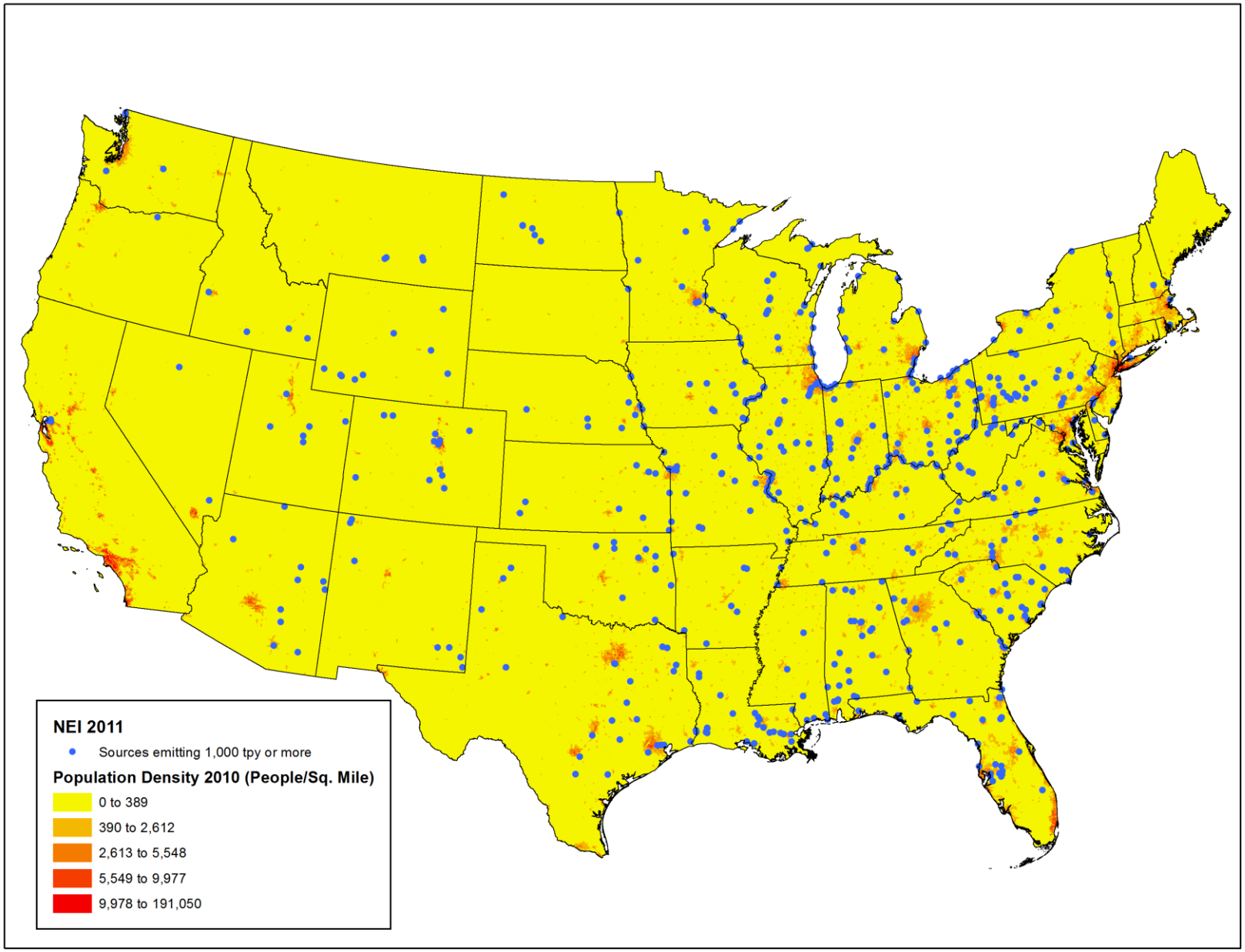


Figure F-1. Continental U.S.: Facilities emitting more than 1,000 tpy SO_2 (n=619 in 2011 NEI) and population density.

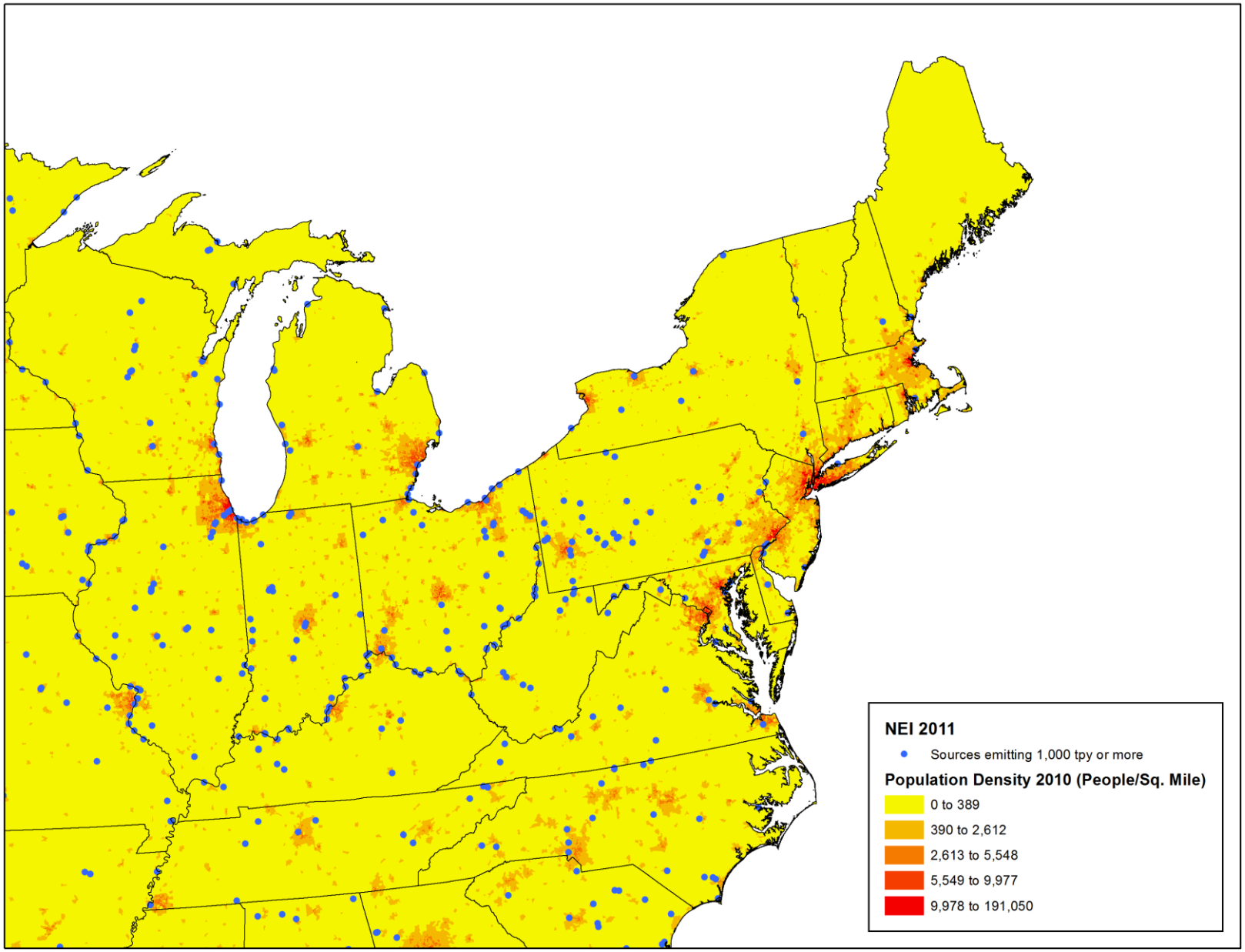


Figure F-2. Northeast U.S.: Facilities emitting more than 1,000 tpy SO_2 and population density.

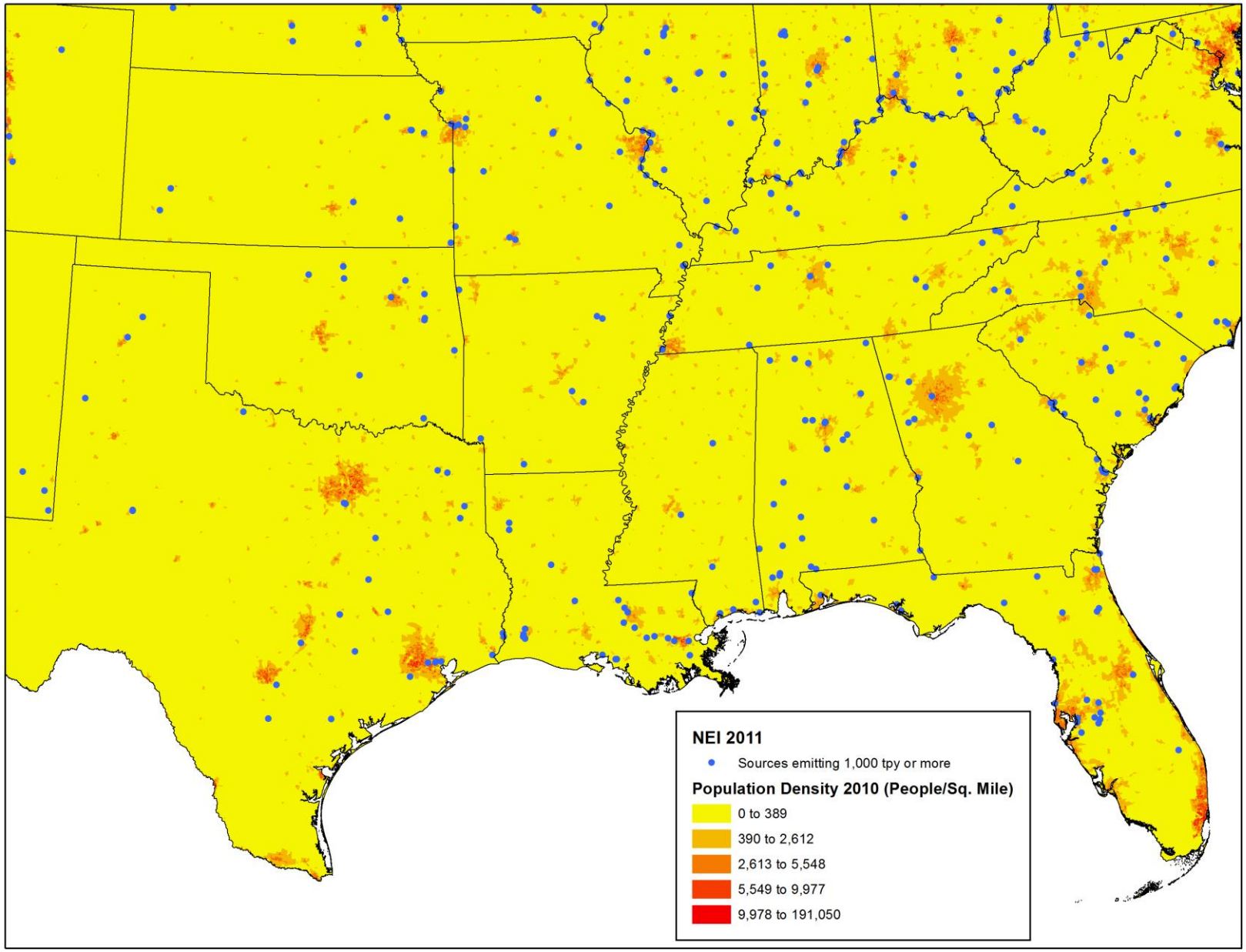


Figure F-3. Southeast U.S.: Facilities emitting more than 1,000 tpy SO_2 and population density.

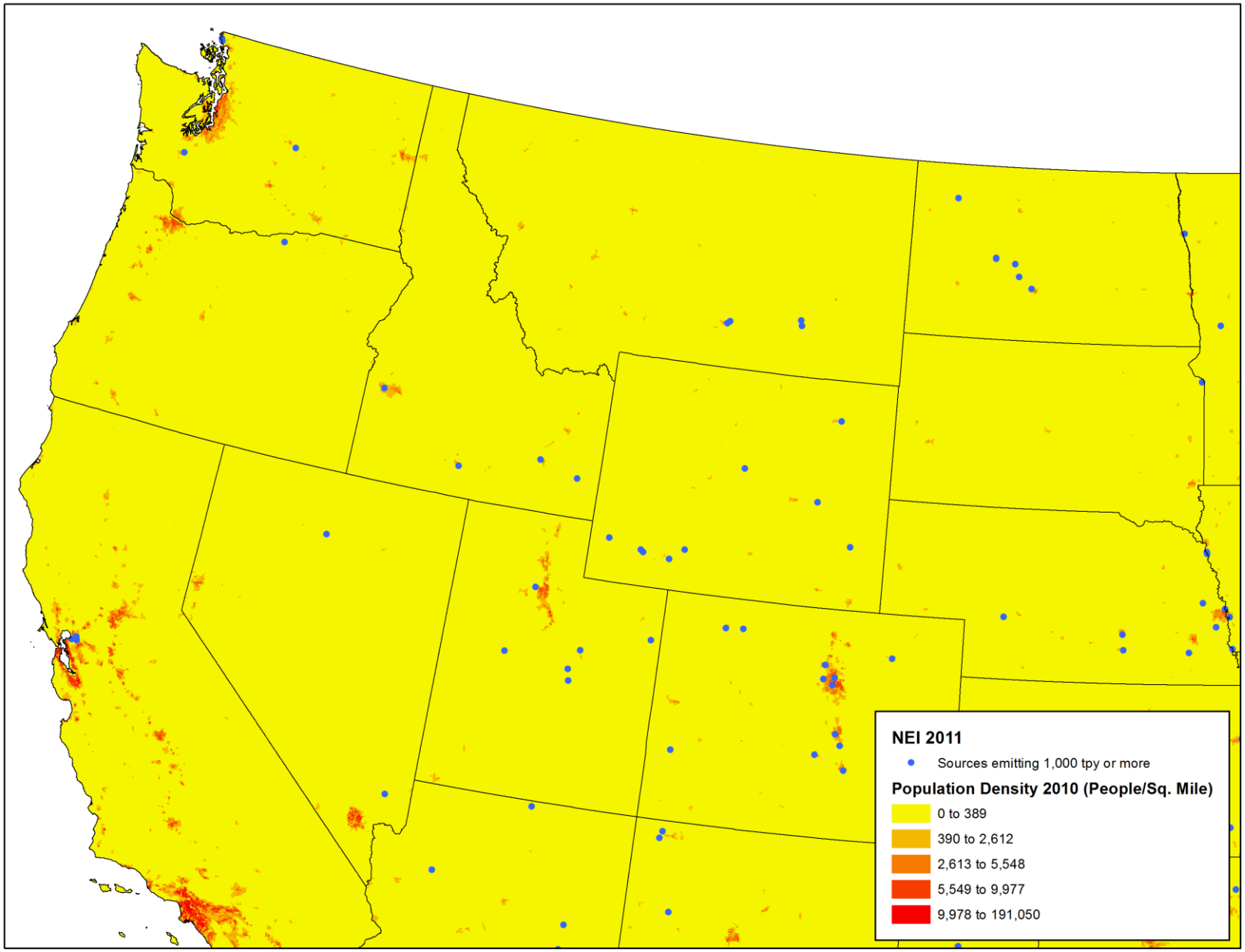


Figure F-4. Northwest U.S.: Facilities emitting more than 1,000 tpy SO_2 and population density.

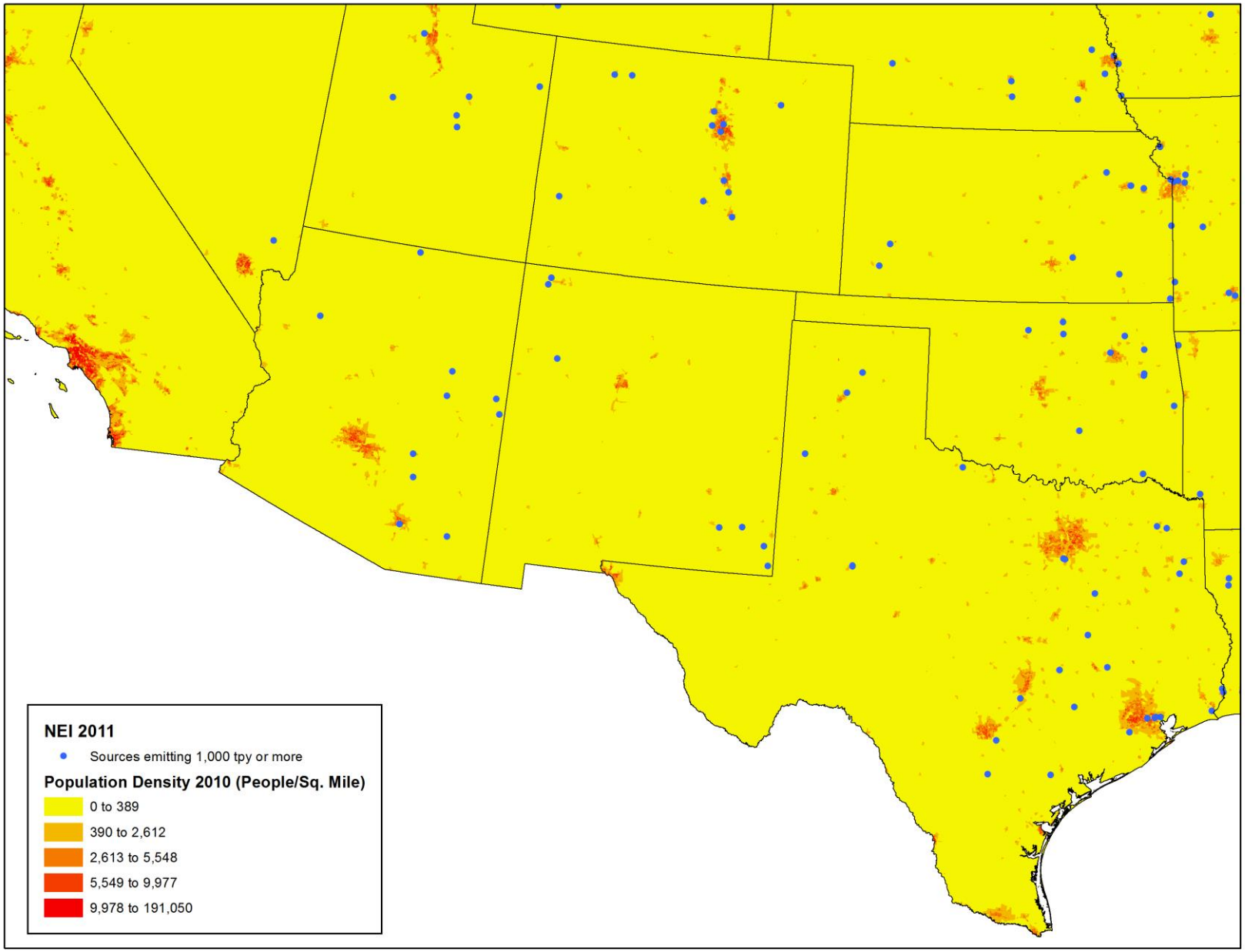


Figure F-5. Southwest U.S.: Facilities emitting more than 1,000 tpy SO_2 and population density.

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