Abt

memorandum

Environmental Research Area

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Date April 8, 2003 (Draft)

To Harvey Richmond, U.S. EPA/OAQPS

From Ellen Post, Abt Associates Inc.

Subject **Preliminary Recommended Methodology for PM_{10} and $PM_{10-2.5}$ Risk Analyses in Light of Reanalyzed Study Results**

The basic methodology for the proposed PM_{10} and $PM_{10-2.5}$ health risk analyses is very similar to the methodology used for the $PM_{2.5}$ risk analyses, described in detail in the Abt Associates draft technical support document (TSD), "Proposed Methodology for Particulate Matter Risk Analyses for Selected Urban Areas," dated January, 2002. The discussion of methodology in that draft TSD included

- an overview of the methods that we propose to use and the assumptions upon which the analyses are based, covering (1) the basic structure of the risk analyses, (2) air quality inputs, (3) simulating just meeting PM standards, (4) baseline incidence data, (5) calculation of health effects incidence, (6) characterization of uncertainties, and (7) proposed sensitivity analyses;

- a discussion of the health endpoints included, and the rationale for including them, as well as a discussion of the locations selected for the risk analyses and the rationale for choosing these locations;

- a discussion of how we selected one (or more) concentration-response (C-R) function for those health endpoints for which more than one C-R function is available;

- a discussion of baseline health effect incidence rates; and

- a discussion of sources of uncertainty.

There are a few aspects of the methodology for the proposed PM_{10} and $PM_{10-2.5}$ health risk analyses, however, that require further elaboration. First, the health endpoints, locations and studies included, and the rationale for including them, are specific to the PM_{10} and $PM_{10-2.5}$ health risk analyses. Second, the required air quality inputs will also be specific to the proposed PM_{10} and $PM_{10-2.5}$ health risk analyses. Each of these is discussed in turn below.

In addition, in response to comments made by the CASAC in February 2002 on the proposed methodology described in the January 2002 draft TSD, we propose to add two sensitivity analyses to those proposed for the $PM_{2.5}$ health risk analyses in that draft TSD. (We will also add these two sensitivity analyses to the revised $PM_{2.5}$ health risk analyses, to be described in a revised draft TSD.) These sensitivity analyses will address variability in background concentrations and seasonal concentration-response (C-R) relationships. They are described more fully below.

1. Selection of Health Endpoints, Urban Areas, and Studies

OAQPS staff carefully reviewed the evidence evaluated in the Third External Review Draft of Air Quality Criteria for Particulate Matter (April, 2002) (hereafter, 2002 draft PM CD). Tables 8A-1 and 8A-2 in the 2002 draft PM CD summarize the available U.S. and Canadian short-term exposure studies that provide effect estimates for all PM indicators for mortality and morbidity, respectively. Table 9-15 in the 2002 draft PM CD summarizes the available U.S. and Canadian short-term exposure studies specifically on $PM_{10-2.5}$. We are not proposing to conduct any PM_{10} or $PM_{10-2.5}$ risk analyses based on long-term exposure studies. The weight of the evidence presented in the draft PM CD suggests that the component of PM_{10} that is most likely associated with long-term exposure mortality is the fine fraction, $PM_{2.5}$. (We are including both short-term and long-term exposure studies in the $PM_{2.5}$ risk analyses.)

Health effect categories

We propose to include in the quantitative PM_{10} and $PM_{10-2.5}$ risk analyses only the more severe and better understood (in terms of health consequences) health endpoint categories for which the weight of the evidence supports the existence of a likely causal relationship between various PM indicators and the effect category. For these health effect categories, the risk analyses will be predicated on the assumption that the relationships are causal. In addition, only those categories which include studies that satisfy the study selection criteria (see below) will be included.

Urban areas

An urban area can be included in the proposed PM_{10} or $PM_{10-2.5}$ risk analyses only if it satisfies the following criteria:

- It has sufficient air quality data for a recent year (1999 or later) A city will be considered to have sufficient PM_{10} air quality data if it had at least one PM_{10} monitor at which there were at least 11 observations per quarter for a one year period. Sufficient air quality data for $PM_{10-2.5}$ is defined as a one year period with at least 11 daily values per quarter based on data from co-located PM_{10} and $PM_{2.5}$ monitors.[1]

- It is in the United States.

- It is the same as or close to the location where at least one C-R function for one of the recommended health endpoints (see below) has been estimated by a study that satisfies the study selection criteria (see below).[2]

- For the hospital admission effects category, the availability of relatively recent baseline incidence data, specific to International Classification of Disease (ICD) codes is necessary.[3]

Studies

Many studies, especially those carried out in recent years, fitted generalized additive models (GAM) to their time-series data. In late May 2002, EPA was informed by the Health Effects Institute (HEI) of a generally unappreciated aspect in the use of S-Plus statistical software often employed to fit these models. Using appropriate modifications of the default convergence criteria code in the S-Plus

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[1]To be consistent with the epidemiological studies which generally focus on using only population-oriented monitors, we will exclude from consideration any monitors where the monitoring objective was listed as "highest concentration monitor." The few monitors that would thus be excluded are sited in industrial or commercial areas and are intended to characterize local conditions near major point sources.

[2] Urban locations for which C-R functions were estimated often include several counties. (For example, in Klemm et al., 2000, the urban area labeled "Boston" consists of three counties: Middlesex, Norfolk, and Suffolk counties.) To the extent possible, in the PM risk analyses we will try to include the specific counties used in the urban location in the original epidemiological studies.

[3] The absence of hospital admissions baseline incidence data does not necessarily mean that we cannot use an urban area in the risk analysis, only that we cannot use it for the hospital admissions endpoint. Because comparisons across health effect categories is an additional consideration in the selection of urban areas for the PM_{10} risk analyses, however, an urban area could be excluded because of the lack of baseline incidence data.

software and a correct approach to estimating the variance of estimators will change the estimated C-R functions and could change the results of tests of significance of estimates, although it is not possible to predict *a priori* how estimates and significance tests will change. Many but not all of the C-R functions that were originally estimated using the S-Plus software for fitting GAMs have since been re-estimated using revised methods.

A study that has estimated one or more C-R functions for a recommended health endpoint in an urban location proposed to be used for the PM_{10} and/or $PM_{10-2.5}$ risk analyses must satisfy the following criteria:

- It is an acceptable, published, peer-reviewed study that has been evaluated by the 2002 draft PM CD.

- It directly measured PM using PM_{10} or $PM_{10-2.5}$ as the indicator.

- It either did not rely on GAMs using the S-Plus software to estimate C-R functions or has appropriately re-estimated them using revised methods.

In addition to the criteria discussed above, some additional considerations, specific to either the PM_{10} or the $PM_{10-2.5}$ risk analyses, were taken into account in the selection of urban areas. These, along with the resulting selection of health effects categories, urban areas, and studies, are detailed below, separately for the PM_{10} and $PM_{10-2.5}$ risk analyses in sections 1.1 and 1.2, respectively.

1.1 Health endpoints, urban areas, and studies proposed for the PM_{10} risk analyses

Based on OAQPS's review of the evidence evaluated in the 2002 draft PM CD, we propose to include the following broad categories of health endpoints associated with short-term exposures in the PM_{10} risk analyses:

- mortality (total and cause-specific)
- hospital admissions (and possibly emergency room visits) for cardiovascular and respiratory causes
- respiratory symptoms not requiring hospitalization.

Other effects reported to be associated with PM_{10} identified in the draft 2002 PM CD, such as decreased lung function, will be addressed qualitatively in the OAQPS PM Staff Paper.

In addition to the criteria listed above, the selection of urban areas that we propose to include in the PM_{10} risk analysis is further guided by the following considerations:

- Among its comments on the $PM_{2.5}$ risk analyses, the CASAC recommended that EPA expand its PM risk analyses for the current review to include PM_{10} risk analyses and to select cities across various parts of the United States.

- In addition, we would also like to include urban areas that would further inform comparisons both across the PM indicators (i.e.., $PM_{2.5}$, PM_{10}) and across health effects (e.g., mortality, hospital admissions).

- In light of these recommendations, we propose to include, at a minimum, those urban areas already selected for the $PM_{2.5}$ risk analyses (i.e., Boston, Detroit, Los Angeles, Philadelphia, Phoenix, San Jose, Seattle, and St. Louis), for which city-specific C-R functions for short-term exposure mortality are available from the NMMAPS study and/or other studies.

- Further, in selecting any additional urban areas, areas for which there are C-R functions with greater statistical power are preferred

Among studies that estimated C-R functions in locations for which there is sufficient air quality data, the statistical power of a study is an important consideration. In general, the power of a study increases as the number of its observations increases. The number of observations depends not only on the number of days on which health effect counts were obtained, but also on the size of the counts. The 2002 draft PM CD uses the natural logarithm of the mortality-days (i.e., the natural log of the product of the number of study days and the average number of deaths per day) as a surrogate or indicator reflecting the power of short-term exposure mortality epidemiological studies. In considering additional urban areas, we will consider only those urban areas in which studies with relatively greater statistical power were conducted. Specifically, for C-R functions for mortality from short-term exposure, we propose to consider only those studies that have a natural log of mortality-days greater than or equal to 9.0. This is the same statistical power criterion that we used in the $PM_{2.5}$ risk analyses.[4]

Based on the above criteria and considerations, we currently propose to include the following urban areas in the PM_{10} risk analyses:

- Boston, MA
- Chicago, IL
- Detroit, MI

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[4]Most of the epidemiological studies reporting total non-accidental mortality, also report on one or more cause specific mortality categories; in such studies the natural log of mortality days is often less than 9.0 because there are fewer deaths from a specific cause. Following the method used in the $PM_{2.5}$ risk analyses, we propose to include the cause-specific mortality C-R relationships reported in such studies as long as the natural log of total mortality days was greater than or equal to 9.0.

- Los Angeles, CA
- Minneapolis-St. Paul, MN
- Philadelphia, PA
- Phoenix, AZ
- Provo, UT
- San Jose, CA
- Seattle, WA
- St. Louis, MO

Most of these urban areas allow comparison both across PM indicators ($PM_{2.5}$ and PM_{10}) and across different health endpoints. While Chicago, Minneapolis-St. Paul, and Provo do not provide comparisons between $PM_{2.5}$ and PM_{10}, they do provide comparisons across health endpoints.

Exhibits 1 and 2 show the studies that are potentially available to be used in the PM_{10} health risk analyses for each of these urban areas for mortality and morbidity endpoints, respectively. Some of these studies will become available, however, only after they have been reanalyzed to address the S-Plus issue. Studies are classified into three groups:

- Studies that did not use GAM/S-Plus are shown in regular type; these studies can be included in the risk analyses.
- Studies that used GAM/S-Plus but were reanalyzed using revised methods are shown in bold; these studies are also currently available to be included.
- Studies that used GAM/S-Plus but have not yet been reanalyzed are shown in italics. These studies are *potentially* available – they will become available if they are reanalyzed.

We are not currently proposing to include Atlanta (shown in Exhibit 1) or Pittsburgh (shown in Exhibits 1 and 2), since PM_{10} studies that would provide the basis for comparisons across health endpoints have not been reanalyzed and, thus are not currently available for use in the PM_{10} risk analyses.

Many studies shown in Exhibits 1 and 2 estimated more than one C-R function (e.g., one single pollutant model and one or more multi-pollutant models). Several researchers reanalyzed some but not all of the C-R functions that they had originally estimated using the S-Plus software. It was typical, for instance, to reanalyze single pollutant models but not yet multi-pollutant models. A study that reanalyzed at least one C-R function for a health endpoint is shown in bold, even if other C-R functions for that health endpoint have not yet been reanalyzed.

Where both single and multi-pollutant models are available for a health endpoint in a given location, we propose to use both, as we similarly proposed for the $PM_{2.5}$ risk analyses. In some cases, however, this will not be possible. For those studies that used GAM/S-Plus and have reanalyzed only some of the C-R functions originally estimated (e.g., only the single pollutant functions), only those

models that have been reanalyzed will be included, as noted above. Where a C-R function has been estimated in a single city and a multi-city C-R function has been estimated which includes that city, both the single-city and the multi-city C-R functions will be included.[5]

[5] Regional results for mortality have been reanalyzed in the NMMAPS study, along with city-specific results. In addition, Schwartz (2003) has reanalyzed mortality results in 10 cities jointly. These multi-city functions can be applied in those cities included in the functions.

Exhibit 1. Mortality Endpoints, Urban Locations, and Studies Potentially Available for Use in the PM_{10} Risk Analyses

Urban Location	Short-Term Exposure Mortality Endpoint				
	Total (non-accidental)	**Cardiorespiratory**	**Cardiovascular**	**Circulatory**	**Respiratory/COPD**
Atlanta, GA	**Samet et al. (2000)***	*Samet et al. (2000)*			
Boston, MA	**Klemm et al. (2000)**				
Chicago, IL	Ito and Thurston (1996) **Moolgavkar (2000a)** **Samet et al. (2000)*** *Schwartz (2001)* Schwartz (2003)** Styer et al. (1995)	*Samet et al. (2000)*	**Moolgavkar (2000a)**	Ito and Thurston (1996)	Ito and Thurston (1996) **Moolgavkar (2000a)**
Detroit, MI	**Lippmann et al. (2000)** **Samet et al. (2000)*** Schwartz (2003)**	*Samet et al. (2000)*		**Lippmann et al. (2000)**	**Lippmann et al. (2000)**
Los Angeles, CA	Kinney et al. (1995) **Moolgavkar (2000a)** **Samet et al. (2000)***	*Samet et al. (2000)*	**Moolgavkar (2000a)**		**Moolgavkar (2000a)**
Minneapolis-St. Paul, MN	**Samet et al. (2000)*** Schwartz (2003)**	*Samet et al. (2000)*			
Philadelphia, PA	Lipfert et al. (2000)*** **Samet et al. (2000)***	*Samet et al. (2000)*			
Phoenix, AZ	*Mar et al. (2000)* **Samet et al. (2000)***	*Samet et al. (2000)*	**Mar et al. (2000)** *Moolgavkar (2000a)*		*Moolgavkar (2000a)*
Pittsburgh, PA	**Samet et al. (2000)***	*Samet et al. (2000)*			
Provo, UT	Pope et al. (1999)		Pope et al. (1999)		Pope et al. (1999)

Urban Location	Short-Term Exposure Mortality Endpoint				
	Total (non-accidental)	**Cardiorespiratory**	**Cardiovascular**	**Circulatory**	**Respiratory/COPD**
San Jose, CA	**Fairley (1999)** **Samet et al. (2000)***	*Samet et al. (2000)*	**Fairley (1999)**		**Fairley (1999)**
Seattle, WA	**Samet et al. (2000)*** Schwartz (2003)**	*Samet et al. (2000)*			
St. Louis, MO	**Klemm et al. (2000)**				

Note: Regular type indicates that the study did not use GAM/S-Plus; bold indicates that it used GAM/S-Plus but has been reanalyzed using revised methods; and italics indicates that the study used GAM/S-Plus and has not yet been reanalyzed.

*Reanalysis results were obtained from the HEI website at http://www.biostat.jhsph.edu/biostat/research/web.est.xls on March 13, 2003.

**Schwartz (2003) is a reanalysis of results in three earlier studies, to address the GAM/S-Plus issue. As part of this reanalysis, Schwartz estimated a single multi-city C-R function for short-term exposure mortality and daily deaths in 10 U.S. cities (see Table 2 in the paper), including four of the cities (Chicago, Detroit, Minneapolis, and Seattle) that we propose to include in our PM_{10} risk analyses.

***We currently do not have upper and lower bounds on the coefficient in the Lipfert study. We requested these from the authors and are currently uncertain as to whether this information will be provided in time for the PM risk analyses. We cannot use this study unless we obtain these upper and lower bounds.

Exhibit 2. Morbidity Endpoints, Urban Locations, and Studies Potentially Available for Use in the PM_{10} Risk Analyses

Urban Location	Hospital Admissions (total respiratory)	Hospital Admissions (COPD)	Hospital Admissions (Pneumonia)	Hospital Admissions (Asthma)	Hospital Admissions (Cardiovascular)	Emergency Room Visits (Asthma)	Respiratory Symptoms
Boston, MA							Schwartz et al. (1994)
Chicago, IL		**Moolgavkar (2000c)** *Samet et al. (2000)*	*Samet et al. (2000)*		**Moolgavkar (2000b)** Morris and Naumova (1998) *Samet et al. (2000)* *Schwartz (1999)*		
Detroit, MI		**Lippmann et al. (2000)** *Samet et al. (2000)* Schwartz (1994a)	**Lippmann et al. (2000)** *Samet et al. (2000)* Schwartz (1994a)		**Lippmann et al. (2000)*** *Samet et al. (2000)* Schwartz and Morris (1995)*		
Los Angeles, CA	Linn et al. (2000)	Linn et al. (2000) **Moolgavkar (2000c)**		Linn et al. (2000) Nauenberg and Basu (1999)**	Linn et al. (2000) **Moolgavkar (2000b)**		
Minneapolis-St. Paul		*Moolgavkar et al. (1997)* *Samet et al. (2000)* Schwartz (1994c)	*Moolgavkar et al. (1997)* *Samet et al. (2000)* Schwartz (1994c)		*Samet et al. (2000)* *Schwartz (1999)*		
Phoenix, AZ		*Moolgavkar (2000c)*			*Moolgavkar (2000b)*		
Pittsburgh, PA		*Samet et al. (2000)*	*Samet et al. (2000)*		*Samet et al. (2000)*		
Provo, UT		*Samet et al. (2000)*	*Samet et al. (2000)*		*Samet et al. (2000)*		Pope et al. (1991)

Urban Location	Hospital Admissions (total respiratory)	Hospital Admissions (COPD)	Hospital Admissions (Pneumonia)	Hospital Admissions (Asthma)	Hospital Admissions (Cardiovascular)	Emergency Room Visits (Asthma)	Respiratory Symptoms
San Jose, CA						Lipsett et al. (1997)***	
Seattle, WA		*Moolgavkar et al. (2000)* *Samet et al. (2000)*	*Samet et al. (2000)*	**Sheppard et al. (1999)**	*Samet et al. (2000)* *Schwartz (1999)*		
St. Louis, MO							Schwartz et al. (1994)

Note: Regular type indicates that the study did not use GAM/S-Plus; bold indicates that it used GAM/S-Plus but has been reanalyzed using revised methods; and italics indicates that the study used GAM/S-Plus and has not yet been reanalyzed.

*Lippmann et al. (2000) estimated separate C-R functions for hospital admissions for the following illnesses within the broad category of cardiovascular illnesses: Ischemic heart disease (ICD codes 410-414), dysrhythmias (ICD code 427), and congestive heart failure (ICD code 428). Schwartz and Morris (1995) estimated separate C-R functions for hospital admissions for ischemic heart disease (ICD codes 410-414) and congestive heart failure (ICD code 428).

**This study includes only emergency-related hospital admissions for asthma, excluding all scheduled admissions and transfers from other facilities. The model estimated is only for the wet season, from November 15 - March 1 (based on four years: 1991 - 1994).

***This study estimated a C-R function for ER visits for asthma. It presents results from a model including not only PM but also the interaction between PM and minimum temperature. We can use this study only if we obtain (1) daily minimum temperatures and (2) baseline incidence data for asthma ER visits.

1.2 Health endpoints, urban areas, and studies proposed for the $PM_{10-2.5}$ risk analyses

A number of studies have estimated C-R relationships between $PM_{10-2.5}$ and both non-accidental total mortality and cause-specific mortality (due to short-term exposure), and some of the more recent studies have reported positive and statistically significant results. However, based on the evaluation provided in the 2002 draft PM CD, OAQPS has judged that the weight of the evidence to date is not sufficient to support including short-term exposure mortality among the health endpoints in the $PM_{10-2.5}$ risk analyses. We therefore propose to include in the $PM_{10-2.5}$ risk analyses only the morbidity-related categories of health endpoints associated with short-term exposure proposed to be used in the PM_{10} risk analyses. This includes

- hospital admissions for cardiovascular and respiratory causes, and
- respiratory symptoms not requiring hospitalization.

Other morbidity effects reported to be associated with $PM_{10-2.5}$, identified in the draft 2002 PM CD, such as decreased lung function, will be addressed qualitatively in the OAQPS PM Staff Paper.

We would prefer to include urban areas in the $PM_{10-2.5}$ risk analyses for which we also plan to conduct $PM_{2.5}$ risk analyses, if there are epidemiological studies reporting associations for $PM_{10-2.5}$ in these locations. Because the $PM_{10-2.5}$ risk analyses require air quality data for PM_{10} and $PM_{2.5}$ at co-located monitors, the criterion of sufficient air quality data is significantly more limiting in the selection of urban areas for the $PM_{10-2.5}$ risk analyses than for either the PM_{10} or the $PM_{2.5}$ risk analyses.[6]

Based on these considerations, we currently propose to conduct $PM_{10-2.5}$ risk analyses for Detroit and St. Louis. While sufficient air quality data also are available for Los Angeles, the relevant epidemiological study has not been reanalyzed.

Exhibit 3 shows the studies potentially available to be used in the $PM_{10-2.5}$ health risk analyses for all three of these urban areas for morbidity endpoints. Studies are classified into the same three groups as before: (1) those that did not use GAM/S-Plus (shown in regular type); (2) those that used GAM/S-Plus but were reanalyzed using revised methods (shown in bold); and (3) those that used GAM/S-Plus but have not yet been reanalyzed (shown in italics).

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[6] We recently received year 2001 air quality data. The assessment of which locations have met the completeness criterion "for a recent year" is therefore based on air quality data in years 1999 through 2001. Although Boston was considered as a possible urban location for the $PM_{10-2.5}$ risk analyses, there were no co-located PM_{10} and $PM_{2.5}$ monitors in Boston that met the selection criterion in any of those years.

Exhibit 3. Health Endpoints, Urban Locations, and Studies Potentially Available for Use in the $PM_{10-2.5}$ Risk Analyses

Urban Location	Health Endpoint		
	Respiratory Hospital Admissions	**Ischemic Heart Disease Hospital Admissions**	**Respiratory Symptoms**
Detroit, MI	**Lippmann et al. (2000)**	**Lippmann et al. (2000)**	
Los Angeles, CA	*Moolgavkar (2000c)*		
St. Louis, MO			Schwartz and Neas (2000)*

Note: Regular type indicates that the study did not use GAM/S-Plus; bold indicates that it used GAM/S-Plus but has been reanalyzed using revised methods; and italics indicates that the study used GAM/S-Plus and has not yet been reanalyzed.
*A single C-R function was estimated in Schwartz and Neas (2000) based on combined data from six urban locations.

2. Air Quality Inputs

2.1. Estimating PM background levels

Since health risks will be calculated only for concentrations exceeding estimated background levels, estimates of background PM concentrations in the assessment locations are needed to calculate risk at "as is" concentrations in excess of background and for just meeting specified standards (for $PM_{10-2.5}$) attributable to concentrations exceeding background levels.

Consistent with the prior PM CD, the 2002 draft PM CD estimates background annual average PM_{10} concentrations to be in the range of 4 to 8 $\mu g/m^3$ in the Western United States and 5 to 11 $\mu g/m^3$ in the Eastern United States. We propose to use the midpoints of these ranges for the base case PM_{10} analysis. Thus background PM_{10} concentrations in the base case analysis will be estimated to be 8 $\mu g/m^3$ in the urban areas in the East (i.e., Boston, Philadelphia, Detroit, St. Louis, Atlanta, Chicago, and Minneapolis-St. Paul); and 6.0 $\mu g/m^3$ in those urban areas in the West (i.e., Los Angeles, San Jose, Phoenix, Seattle, and Provo).

The 2002 draft PM CD estimates background $PM_{2.5}$ concentrations to be in the range of 1 to 4 $\mu g/m^3$ in the Western United States and 2 to 5 $\mu g/m^3$ in the Eastern United States. Background $PM_{10-2.5}$ will be taken to be in the range of 3 (=4-1) to 4 (=8-4) $\mu g/m^3$ in the Western United States and 3 (=5-2) to 6 (=11-5) $\mu g/m^3$ in the Eastern United States.[7] We will use the midpoints of these ranges

[7] These ranges assume that the lowest background levels of PM_{10} and $PM_{2.5}$ occur in the same places, and similarly, the highest background levels of PM_{10} and $PM_{2.5}$ occur in the same places. While this assumption may not be true, we have no additional information on which to base ranges of background $PM_{10-2.5}$.

(3.5 :g/m^3 in the Western United States and 4.5 :g/m^3 in the Eastern United States) for the $PM_{10-2.5}$ base case analysis. Currently, however, we have only an Eastern city, Detroit, in the $PM_{10-2.5}$ risk analysis. Background $PM_{10-2.5}$ concentration in the base case analysis will be estimated to be 4.5 :g/m^3 in Detroit.

3. Sensitivity Analyses

In response to comments from the CASAC in February 2002, we propose to conduct two sensitivity analyses that were not included among those originally proposed for the $PM_{2.5}$ risk analyses. First, we propose to explore the impact of the assumption of a constant daily background level via sensitivity analyses. To assess the impact of using different daily background PM_{10} concentrations on the estimates of risk associated with "as is" PM_{10} concentrations in excess of background, two distributions of background levels, one for the East, and one for the West, will be developed. Each distribution will be lognormal with a mean equal to the midpoint of the range for that region of the country (see above) and a standard deviation based on the standard deviations of daily PM_{10} measurements from the Interagency Monitoring of Protected Visual Environments (IMPROVE) program. IMPROVE is a cooperative visibility monitoring effort between the EPA, federal land management agencies, and state air agencies. One of the functions of this program is to monitor visibility and aerosol conditions in Class I areas, and for the most part the IMPROVE monitors are located in rural areas. IMPROVE data from 1988 to 1999 will used in this analysis. An analogous procedure will be used for $PM_{10-2.5}$.

Second, we propose to explore the impact of estimating risk reductions on a seasonal rather than an annual basis, using seasonal PM_{10} C-R functions for mortality in San Jose estimated by Fairley (1999).[8] This will be carried out only for San Jose because that is the only location for which seasonal C-R functions were available that met the critiera for selection of health studies, endpoints, and urban locations. There were no studies providing C-R relationships on a seasonal basis for $PM_{10-2.5}$.

[8] Fairley (1999) used the S-Plus software to fit generalized additive models to time series data in San Jose. However, he reanalyzed not only the annual models but the seasonal models as well.

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