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Sulfur Dioxide Health Assessment Plan: Scope and Methods for Exposure and Risk Assessment

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DISCLAIMER

This draft scope and methods plan has been prepared by staff from the Ambient Standards Group, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency. Any opinions, findings, conclusions, or recommendations are those of the authors and do not necessarily reflect the views of the EPA. This document is being circulated to obtain review and comment from the Clean Air Scientific Advisory Committee (CASAC) and the general public. Comments on this document should be addressed to Dr. Stephen E. Graham, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, C504-06, Research Triangle Park, North Carolina 27711 (email: graham.stephen@epa.gov).

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List of Acronyms/Abbreviations

AERMOD	American Meteorological Society (AMS)/EPA Regulatory Model
ALA	American Lung Association
APEX	EPA's Air Pollutants Exposure model, version 4
AQS	EPA's Air Quality System
CASAC	Clean Air Scientific Advisory Committee
CEM	Continuous Emission Monitoring (CEM) data
CHAD	EPA's Consolidated Human Activity Database
CDF	Cumulative Density Function
COV	Coefficient of Variation
C-R	Concentration-Response relationship
CRSTER	Single Source Dispersion Model
EPA	United States Environmental Protection Agency
EOC	Exposure of Concern
FEV_1	decreased Forced Expiratory Volume in one second
HEM	EPA's Human Exposure Model
hr	Hour
ISA	Integrated Science Assessment
ISCST	EPA's Industrial Source Complex Short-Term model
km	Kilometer
ME	Microenvironment
min	Minute(s)
MW	Megawatt
NAAQS	National Ambient Air Quality Standards
NCEA	National Center for Environmental Assessment
NEI	National Emissions Inventory
NEM	NAAQS Exposure Model
NCDC	National Climatic Data Center
NWS	National Weather Service
O_3	Ozone
OAQPS	Office of Air Quality Planning and Standards
ORD	Office of Research and Development
PM	Particulate Matter
PMR	Peak-to-Mean Ratio
ppb	parts per billion
ppm	parts per million
PRB	Policy-Relevant Background
SD	Standard Deviation
SO_2	Sulfur Dioxide
SO_x	Sulfur Oxides
SR_{aw}	Specific Airway Resistance
TRIM	EPA's Total Risk Integrated Methodology
UARG	Utility Air Regulatory Group

1. INTRODUCTION

The U.S. Environmental Protection Agency (EPA) is presently conducting a review of the sulfur dioxide (SO_2) national ambient air quality standards (NAAQS). Sections 108 and 109 of the Clean Air Act (Act) govern the establishment and periodic review of the NAAQS. These standards are established for pollutants that may reasonably be anticipated to endanger public health and welfare, and whose presence in the ambient air results from numerous or diverse mobile or stationary sources. The NAAQS are to be based on air quality criteria, which are meant to accurately reflect the latest scientific knowledge useful in characterizing and assessing identifiable effects on public health or welfare that may be expected from the presence of the pollutant in ambient air. The EPA Administrator is to promulgate and periodically review, at five-year intervals, *primary* (health-based) and *secondary* (welfare-based) NAAQS for such pollutants.[1] Based on periodic reviews of the air quality criteria and standards, the Administrator is to make revisions in the criteria and standards, and promulgate any new standards, as appropriate. The Act also requires that an independent scientific review committee advise the Administrator as part of this NAAQS review process, a function now performed by the Clean Air Scientific Advisory Committee (CASAC).

EPA's plan and schedule for this SO_2 NAAQS review is presented in the *Plan for Review of the Primary National Ambient Air Quality Standard for Sulfur Dioxide* (US EPA, 2007a). That plan discusses the preparation of two key components in the NAAQS review process: an Integrated Science Assessment (ISA) and risk/exposure assessments. The ISA (US EPA, 2007b) critically evaluates and integrates scientific information on the health effects associated with exposure to oxides of sulfur (SO_x) in the ambient air. The risk/exposure assessments will develop, as appropriate, quantitative estimates of human exposure and health risk and related variability and uncertainties, drawing upon the information summarized in the ISA. This draft document describes the scope and methods planned to conduct these assessments.

1.1 OVERVIEW OF SCOPE AND METHODS PLAN

This plan is designed to outline the scope and approaches and highlight key issues in the estimation of population exposures and health risks posed by SO_2 under existing air quality levels, upon just meeting the current SO_2 primary NAAQS, and upon just meeting potential alternative standards that may be under consideration. The risk/exposure assessments will draw upon the information presented in the Integrated Science Assessment (ISA) and related Annexes. This includes information on atmospheric chemistry, air quality, human exposure, the impact of local source emissions, and health effects of concern.

SO_2 is one of a group of compounds known as sulfur oxides (SO_x), which include multiple chemicals (e.g., SO_2, SO, SO_3). However only SO_2 is present at concentrations

[1] Section 109(b)(1) [42 U.S.C. 7409] of the Act defines a primary standard as one "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."

significant for human exposures and the ISA indicates there is limited adverse health effect data for the other gaseous compounds. Therefore, as in past NAAQS reviews, SO_2 will be considered as a surrogate for gaseous SO_x species in this assessment, with the secondarily formed particulate species (i.e., sulfate or SO_4) addressed as part of the particulate matter (PM) NAAQS review.

The planned SO_2 exposure and health risk assessments are designed to estimate very short-term exposures to SO_2 (i.e., 5-minute) and the associated risk of adverse health effects for persons in close proximity to local source emissions. Air quality will be characterized in urban areas along with the associated risk of adverse health effects for 1- and 24-hr averaging times. Risk and exposures will be assessed using a tiered approach where progression to a more sophisticated level of analysis will depend on the availability of data and on the anticipated utility of the results. For example, ambient air quality will initially be used as a surrogate for exposure, while subsequent analyses may involve incorporating human activity data, microenvironmental concentrations, and possibly the development of individual exposure profiles. The exposure assessment will generate ambient concentrations and exposure metrics that are most relevant for addressing concerns about health effects associated with SO_2 exposure.

Health risk will initially be assessed through the identification of exposure concentration levels associated with adverse health effects, termed *potential health effect benchmarks*. These potential health effect benchmarks, based on observed effects from several short-term (i.e., 5-minute) controlled human exposure studies evaluated in the ISA, will be used to determine how often air quality concentrations or estimated exposures exceed exposure concentrations associated with adverse health effects. Thus, the exposure estimates generated will be used to estimate the number of individuals experiencing potential *exposures of concern* (EOC). However, most of the recent supporting evidence for SO_2 health effects is from epidemiological studies, resulting in uncertainties regarding whether the variation in observed health effects is caused by ambient SO_2 concentrations, is from exposure to one or more correlated air pollutants, or the result of differences in individual activity level (i.e., personal activities performed that result in increased ventilation rates). An additional characterization of risk may involve use of concentration-response functions, if and where sufficient and relevant data are identified in the ISA to support development of functions that are related to ambient SO_2 concentrations. These functions typically have averaging times of 1- and 24-hrs and as a result, the ambient concentrations used in this type of risk analysis would have the same averaging times.

This plan is intended to facilitate consultation with the CASAC, as well as for public review, and to obtain advice on the overall scope, approaches, and key issues in advance of the conduct of such analyses and presentation of results in the first draft of the risk/exposure assessments. The risk/exposure assessments together with other information contained in the SO_x ISA, are intended to help inform the Administrator's judgments as to whether the current primary standards are requisite to protect public health with an adequate margin of safety, or whether revisions to the standards are appropriate.

1.2 BACKGROUND ON SO_2 NAAQS

As a first step in formulating the scope and methods plan, a point of reference was developed by extracting key supporting results from the previous review of the NAAQS for SO_2. The most recent review of the SO_2 NAAQS, completed in 1996, evaluated both the existing standards of 0.14 ppm daily average and 0.030 ppm annual average and whether an additional short-term standard (e.g., 5-minute) was necessary to protect against short-term peak exposures. Based on the health evidence at that time, it was determined that repeated exposures to 5-minute peak SO_2 levels (0.60 ppm, noted here as 0.60 ppm-5min) could pose a risk of significant health effects for asthmatic individuals at elevated ventilation rates (e.g., while exercising). Therefore, the air quality and exposure analyses conducted for the previous review focused on the likely frequency of such events using two approaches (US EPA, 1982a; 1982b; 1986a; 1986b; 1994a; 1994b; SAI, 1996).

First, existing ambient monitoring data were analyzed to estimate surrogate exposure metrics. These metrics included the frequency of 5-minute peak concentrations above 0.50, 0.60, and 0.70 ppm, the number of repeated exceedances of these concentrations, and the sequential occurrences of peak concentrations within given a day (SAI, 1996). The results of this analysis indicated that several locations in the U.S. had a substantial number of 5-minute peak concentrations at or above 0.60 ppm, in the vicinity of local sources.

The previous review also included several annual exposure analyses to estimate the likelihood that an asthmatic individual would be exposed to short-term peak SO_2 concentrations while at elevated exertion levels. These analyses generally combined SO_2 emission estimates from targeted utility and non-utility sources with exposure modeling to estimate the probability of exposure to short-term peak concentrations. The first such analysis conducted by the Agency estimated the number of 5-minute exposures ≥0.5 ppm associated with four selected coal-fired power utilities (US EPA, 1986b). An expanded analysis sponsored by the Utility Air Regulatory Group (UARG) also considered the frequency of short-term exposure events that might result from operation of power utility boilers, however the scope of the assessment addressed all power plants across the nation (Burton et al., 1987). The probability of peak concentrations surrounding non-utility sources was the focus of an additional study conducted by the Agency (Stoeckenius et al., 1990). The resultant combined exposure estimates considering these early analyses indicated that between 0.7 and 1.8 percent of the total asthmatic population potentially could be exposed one or more times annually, while outdoors at exercise, to SO_2 concentrations ≥0.50 ppm-5min. It also was noted that the frequency of exposures above the health effect benchmark of 0.60 ppm-5min, while not part of the analysis, would be anticipated to be lower.

Further supporting analyses considered in the prior review included a more recent exposure assessment sponsored by the UARG (Rosenbaum et al., 1992) that centered on emissions from fossil-fueled power plants. That study accounted for the anticipated reductions in emissions after implementation of the acid deposition provisions (Title IV) of the 1990 Clean Air Act Amendments. A 42% reduction in the number of 5-minute exposures to 0.50 ppm for asthmatic individuals was expected (reducing the number of asthmatics exposed from 68,000 sown to 40,000) in comparison with the previous Burton et al. (1987) analysis. In addition, in response to the request for public comment on the 1994 reproposal, a new exposure analysis was submitted by the National Mining Association (Sciences International, Inc. 1995) that reevaluated non-utility sources. Revised exposure estimates were provided for four of the seven non-utility source categories by incorporating new emissions data and using less conservative modeling assumptions in comparison with those used for the earlier Stoeckenius et al. (1990) non-utility analysis. Significantly fewer exposure events (i.e., occurrence of 5-minute 0.50 ppm or greater exposures) were estimated in this industry-sponsored revised analysis, decreasing the range of estimated exposures for these four sources by an order of magnitude (i.e., from 73,000-259,000 short-term exposure events in the original analysis to 7,900-23,100 in the revised analysis).

Based upon the results of each of these analyses, EPA concluded that exposure of asthmatics to SO_2 at concentrations that can elicit adverse health effects is likely to be a rare event when viewed in the context of the entire population of asthmatics (61 FR 25566). Therefore, 5-minute peak SO_2 concentrations were judged not to pose a broad public health threat when viewed from a national perspective, and a 5-minute standard was not promulgated. In addition, the current standards of 0.14 ppm-24hr and 0.03 ppm-annual average were retained (61 FR 25566).

EPA's decision not to establish a 5-minute standard was challenged and, on January 30, 1998, the Court of Appeals for the District of Columbia found that EPA inadequately explained its determination. The court remanded the decision back to EPA, requiring additional rationale to support the Agency judgment that 5-minute peaks of SO_2 do not pose a public health problem even though these peaks would likely cause adverse health outcomes in a subset of asthmatics. In response, EPA has requested and obtained from State air pollution agencies additional 5-minute ambient SO_2 data to support additional analyses that address issues raised in the Court's remand of the Agency's last decision.

The planned exposure analysis and health risk assessment described in this Scope and Methods Plan builds upon the methodology, analyses, and lessons learned from the assessments conducted for the last review. These plans are based on our current understanding of the SO_2 scientific literature and are subject to change as findings of the 1^{st} draft SO_2 ISA are reviewed by the CASAC and the general public. EPA's Office of Research and Development (ORD) National Center for Environmental Assessment (NCEA) has compiled and synthesized the most policy-relevant science available to produce a 1st draft of the ISA (US EPA, 2007b), portions of which have been reviewed and used in the development of the approach below. The approach described in this plan is subject to modification to take into account CASAC and public comments following their review of this document as well as be guided by any additional information contained in the second and final versions of the ISA.

2. AIR QUALITY CONSIDERATIONS

The latest years of SO_2 air quality data available since the previous review (1997-2006) have been assembled for use in the exposure and health risk analyses. Air quality data can be useful in evaluating historic, current, and prospective trends, for the development of statistical relationships, as input to an exposure model, and as input to a risk model based on concentration-response functions. The following air quality scenarios will be considered in this review, the form and use of which is described below:

- "*as is*" represents the 5-minute, 1-hr, 24-hr, and annual average ambient monitoring concentration data reported by US EPA's Air Quality System (AQS). These data will be used for estimating health risks associated with current air quality and for the development of mathematical/statistical relationships among different averaging times (e.g., 5-minute peak to 1-hr mean concentrations).

- "*simulated*" concentrations are *"as is"* air quality data that have been modified by a mathematical or statistical procedure to just meet a particular concentration level for a specific averaging time. These could represent the current primary standards (i.e., 0.14 ppm 24-hr and 0.03 ppm annual averages) and/or potential alternative SO_2 standards that may be under consideration (e.g., a concentration level for a 1-hr average). Simulations of this type would typically use the more recent 1-hr average ambient monitoring data (years 2004-2006). Simulated air quality data are used to estimate health risks associated with air concentrations that deviate from "as is" ambient concentrations. For example, these simulated concentrations would be used in the air quality characterization (Section 3.2) to estimate the number of short-term peak concentrations above a health effect benchmark level (Section 4). In addition, they may be combined with concentration-response functions from epidemiological studies to estimate health risks (Section 4).

Two approaches will be investigated to simulate just meeting the current and potential alternative SO_2 standards, recognizing that currently every location across the U.S. meets both the existing SO_2 annual average and the 24-hr average standards (Figure 1) (US EPA, 2007c). A proportional method is being considered as the primary approach for simulating air quality data. SO_2 concentrations would be adjusted linearly across the entire concentration distribution at the design value monitor to just meet a potential alternative standard. Other ambient monitoring data in the area would then be simulated in proportion to the design value monitor. This general approach (often referred to as a concentration *roll-back*) has been used for evaluating just meeting the current and alternative standards where current air quality monitoring data was above the existing NAAQS (e.g., $PM_{2.5}$ in Abt Associates, 2005).

There are additional considerations for simulating SO_2 concentrations that would just meet the existing standards where recent air quality levels are below the current standard(s). A proportional simulation involving a concentration *roll-up* may be performed to simulate the current and alternative standards that would yield ambient concentrations greater than current air quality. However, EPA has not commonly adjusted ambient concentrations higher to simulate just meeting alternative standards. Therefore, as part of a possible second approach, historical monitoring data may be useful in representing scenarios that are at or near the current and potential alternative SO_2 standards that are above recent air quality, rather than performing the concentration *roll-up* given that the historical data contain higher concentrations than recent air quality. We recognize that it will be important to characterize any analysis involving an upward adjustment in SO2 ambient concentrations as hypothetical scenarios that are very unlikely to occur given current control programs and emission standards.

Another air quality related issue, potentially relevant to characterizing health risks associated with SO_2 ambient standards, is the characterization of policy-relevant background (PRB) levels in the U.S. Policy-relevant background is defined as the distribution of SO_2 concentrations that would be observed in the U.S. in the absence of anthropogenic emissions of SO_2 in the U.S., Canada, and Mexico. Estimates of PRB have been reported in the draft ISA (Section 2.4.3) and Annexes (Section AX2.9), and for most of the continental U.S. the PRB is estimated to be less than 10 parts per trillion (ppt) annual average. In the Ohio River Valley, where present-day SO_2 concentrations are highest (>5 ppb), this amounts to a contribution of less than 1% percent of the total observed ambient SO_2 concentration (AX2.9). In the Northwestern U.S. and Hawaii, where there are geothermal sources of SO_2 (e.g., volcanic activity) the contribution of PRB to total SO_2 can be as high as 70 to 80%. However, since PRB is well below concentrations that might cause potential health effects, PRB will not be considered separately in any estimation of health risk associated with recent air quality or alternative standards.

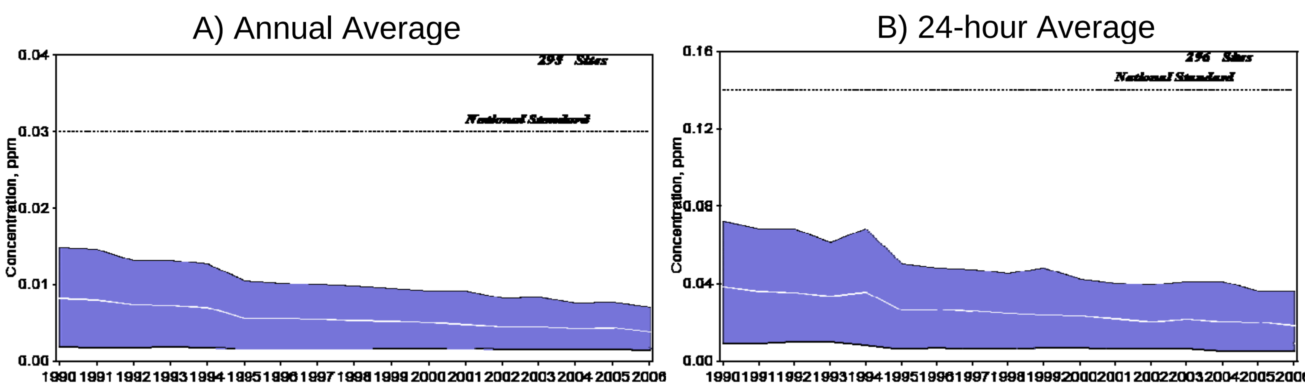

Figure 1. Ambient monitoring site average SO_2 ambient concentrations between 1990 and 2006 (white line), upper and lower shaded regions indicate concentrations for sites within the 90[th] and 10[th] percentiles, respectively. The data were obtained from a both source- and population- oriented ambient monitors.

3. EXPOSURE ASSESSMENT SCOPE AND METHODS

3.1 OVERVIEW

The exposure assessment for SO_2 will estimate short-term human exposures (e.g., 5-minute peak exposures) considering current source emissions and surrogate exposure metrics associated with current ambient levels of SO_2, with ambient levels that just meet the current standard, and with ambient levels that just meet alternative standards that may be under consideration. A two-tiered approach to assessing exposure will be employed, beginning with an air quality characterization and progressing to a more refined analysis, if appropriate. The goals of the SO_2 exposure assessment are: (1) to estimate short-term peak exposures to ambient concentrations through air quality monitoring and modeling analyses, (2) to develop quantitative relationships between time-averaged (1-hr) and short-term peak (5-minute) concentrations, and (3) to identify key assumptions and uncertainties in the exposure estimates. The results from the air quality analysis and exposure assessment will be used to inform the characterization of health risks, as described in Section 4. The assessment approaches and tools to be used in each tier of analysis are summarized in Table 1. Specific objectives, tool applications, assessment inputs, and outcomes of each tier are described in detail below.

At each tier of the exposure assessment, an evaluation of the uncertainties will be performed and the relative degree of confidence in the exposure estimates will be determined. Similar to the exposure assessment approach briefly described above, a tiered approach will be employed that begins with a qualitative uncertainty analysis and progresses to a quantitative analysis if data are available and there is value added to the decision making process to warrant such an analysis. The first step in the uncertainty analysis would be to identify the components of the assessment that do or do not contribute to uncertainty, and provide a rationale for why this is the case. A qualitative evaluation would follow for the uncertain components of the assessment, resulting in a matrix describing, for each area of uncertainty, both the magnitude (minimal, moderate, major) and the direction of influence (under- or over-estimate) on exposure estimates. If sufficient data are available and if the overall magnitude of uncertainty is estimated as high and possibly biased, a quantitative assessment of uncertainty would then be performed for selected components of the assessment.

Table 1. Summary of Metrics and Tools Used for each Tier of the SO_2 Exposure Assessment.

Tier	**Exposure Metrics and Tools Used**
AQ Characterization	AQ, Supplemental Data
Exposure Assessment	AQ, Supplemental Data, SO_2 Emissions, AERMOD, APEX

Notes
AERMOD American Meteorological Society (AMS)/EPA Regulatory Model
APEX EPA's Air Pollutants Exposure Model, version 4
AQ Air quality monitoring data

3.2 TIER I: AIR QUALITY CHARACTERIZATION

The first step in assessing exposure will be to conduct an air quality analysis relying largely on ambient monitoring data and the information provided in the ISA and relevant

Annexes. In this analysis, the ambient SO_2 concentrations will serve as a surrogate for total human exposure and will be used in developing of statistical relationships among various averaging times. This analysis would include information on SO_2 air quality patterns, historic trends, local sources, and any potential concentrations of concern based on the ISA's evaluation of the health effects evidence. The relationships among short-term peak concentrations and various averaging times (e.g., hourly, daily, and annual) will be evaluated and used to inform subsequent analyses (if any) of the current standards and any potential alternative standards that may be under consideration.

The three objectives in this analysis are to: (1) estimate short- and long-term surrogate exposures using available 1-hr average ambient SO_2 monitoring data, (2) develop a statistical model(s) to estimate relevant surrogate short-term peak exposures (5-minute) associated with various averaging times, and (3) estimate quantitative relationships among 5-minute peak and 1-hr average ambient monitoring concentrations in proximity to important local emission sources.

All available ambient monitoring data collected since the prior SO_2 NAAQS review (i.e., both the 1-hr average and 5-minute ambient SO_2 monitoring data from years 1997-2006) have been gathered for use in this assessment and will be used as is for the development of the statistical model(s). Simulation of recent air quality monitoring data will be required to analyze any alternative standards that may be under consideration. While ambient SO_2 concentrations have declined over time and there are no locations that are not meeting the current standard (Figure 1), historical data may be useful for characterizing ambient concentrations that were near or at the current standard levels.

3.2.1 Approach

In general, approximately 300 - 400 ambient monitors collected 1-hr average SO_2 concentrations over the time-period of 1997-2006. The 5-minute monitoring is limited to at most 94 monitors, most of which report the maximum 5-minute concentrations, with only 15 monitors containing continuous monitoring.[2] In addition, while there is some overlap in the monitor siting, not all of the 5-minute monitors have been co-located with hourly monitors. Because of variable coverage in ambient monitors collecting 1-hr average and/or 5-minute SO_2 concentrations across the U.S., some of the proposed air quality analyses may involve either the 1-hr average or the 5-minute data set exclusively.

The analysis of the ambient monitoring data will involve characterizing factors thought to influence ambient SO_2 concentrations. For example, there may be a variable impact on ambient monitoring concentrations from local sources based on the monitor site location. Power generating utilities and related processes are the most significant outdoor emission source of SO_x. Using emissions data provided in the Chapter 2 ISA Annex, Table AX2-3, electric utility fuel combustion is noted as the largest single source category contributing to the total estimated SO_x emissions for the U.S. (Figure 2). Other SO_x emission sources may be identified as being important, based on consideration of local emissions estimates.

[2] The monitor counts are approximate since the number operating monitors can vary from one year to the next.

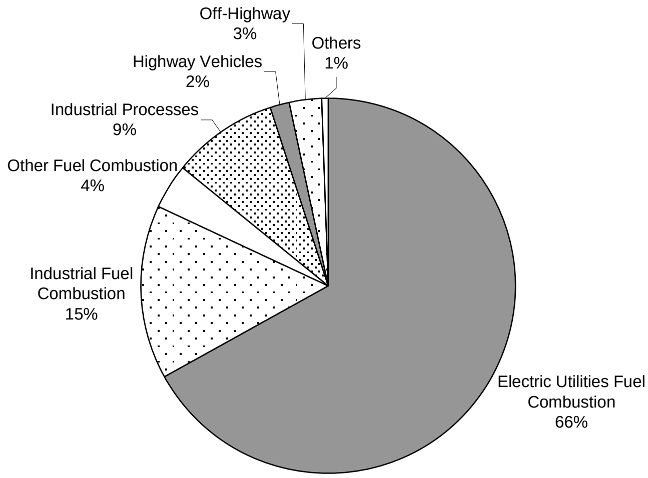

Figure 2. Percent of Total SO_x Emissions in the United States by Major Source Categories.

The air quality characterization also will involve development of mathematical relationships to be used in extrapolating exposure surrogate metrics across different concentration averaging times. This is because the averaging times for the current SO_2 NAAQS (i.e, daily and annual average concentration) and much of the ambient monitoring data (i.e., 1-hr average concentration) are not comparable to the averaging times relevant for much of the health effects data (i.e., 5-minutes). In addition to the analyses addressing concerns about very short-term exposures, all of the hourly monitoring data will be evaluated considering the averaging times related to health effects reported to be associated with 1-hr and 24-hr SO_2 concentrations in urban areas. Where very short-term data are available, the number of 5-minute peak concentrations above a health effect benchmark level would be determined, followed by a derivation of relationships between these very short-term peaks and their corresponding 1-hr concentrations. These relationships will then be used for extrapolation of hourly data to estimate additional 5-minute peak concentrations.

3.2.1.1 1-Hour Average Ambient Monitoring Data Analysis

The following initial analyses will be performed by year at each monitor reporting 1-hr average ambient SO_2 concentrations:

- Identify possible factors that could affect or influence measured concentrations at each monitor, e.g., whether the monitor is in close proximity to a important emission source of SO_2 or could be used to represent background SO_2 concentrations within selected locations;
- Estimate the annual average and daily average ambient SO_2 concentration;
- Calculate surrogate exposure metrics such as the frequency of concentrations above current daily and annual standards and considering alternative averaging times (e.g., estimate the distribution of hourly concentrations in particular urban areas);
- Identify potential factors influencing surrogate exposure estimates.

A preliminary evaluation of the spatial and temporal variability in 1-hr average SO_2 monitoring data is reported in the 1st draft ISA for several U.S. cities[3] (US EPA, 2007b). A strong west-to-east ambient concentration gradient exists across the U.S., with cities in California reporting the lowest mean concentrations, and Pittsburgh and Steubenville in the Eastern U.S. containing the highest. This concentration gradient is consistent with the national pattern in SO_2 emissions. Correlations among multiple monitors within a city are generally low and strength of the correlation decreased with decreasing mean concentrations. This lack of correlation reflects the spatial heterogeneity in ambient SO_2 concentrations and indicates that local sources may influence variability in exposure. Compositing the data to evaluate diurnal variation indicate that, although concentrations below the 95th percentile for each hour are relatively indistinguishable from one another within a day, a pattern may exist for the 1-hr peak concentrations. Most of the highest measured ambient SO_2 concentrations occur either at mid-day or during the middle of the night.

Urban area analyses will be performed in this review considering several averaging times (e.g., 1-hr, 24-hr, annual average) using both the current air quality and air quality adjusted to just meet the current and potential alternative 1-hr, 24-hr, and annual average standards.

3.2.1.2 5-Minute Ambient Monitoring Data Analysis

The following initial analyses will be performed by year at each monitor reporting 5-minute ambient SO_2 concentrations:

- Identify possible factors that could affect or influence measured concentrations at each monitor (e.g., proximity to local source emissions, type of local sources);
- Calculate peak-to-mean ratios (PMRs; 5-minute to 1-hr average concentrations);
- Identify potential factors influencing PMRs;
- Estimate surrogate exposure metrics such as the frequency of concentrations above potential health effect benchmarks including
  - the number of peak concentration exceedances per day or year;
  - the probability of multiple 5-minute exceedances within an hour.

In the prior NAAQS review, two sources of data were identified that contained source-relevant PMR data for use in estimating the probability of 5-minute peak concentrations from 1-hr concentrations. The first study was conducted in Kincaid, Illinois and involved monitoring 5-minute concentrations at 18 sites surrounding a coal-fired power plant (Thrall et al., 1982). The second source of data was generated from two ambient monitors in Billings, Montana, one of which was located 1.6 km from a coal-fired power utility (named 'Coburn Rd.') and the other about 4.8 km from the power utility (named 'Scottish Rites') (Stoeckenius, 1990). Cumulative density functions (CDFs) of the PMRs from each of these sources are summarized in Figure 3. The CDFs from Thrall et al. (1982) were used in the each of the exposure analyses conducted in the previous review and applied universally to both the utility and non-utility sources. The Scottish Rites ratio data were used for estimating the lower bounds of exposure in the non-utility analyses, since the data were noted as likely more representative of PMRs that would occur

[3] Urban areas containing at least 4 ambient monitors include Philadelphia, Washington, Jacksonville, Tampa, Pittsburgh, Steubenville, Chicago, Salt Lake City, Phoenix, San Francisco, Riverside, Los Angeles (US EPA, 2007b; Section 4.1.2) for ambient monitoring conducted during the years 2003-2005.

where individuals reside in surrounding neighborhoods compared to the Kincaid data (Stoeckenius et al., 1990). In review of the prior analyses, the Coburn road data do not appear to have been used for obtaining any estimates of short-term peak concentrations.

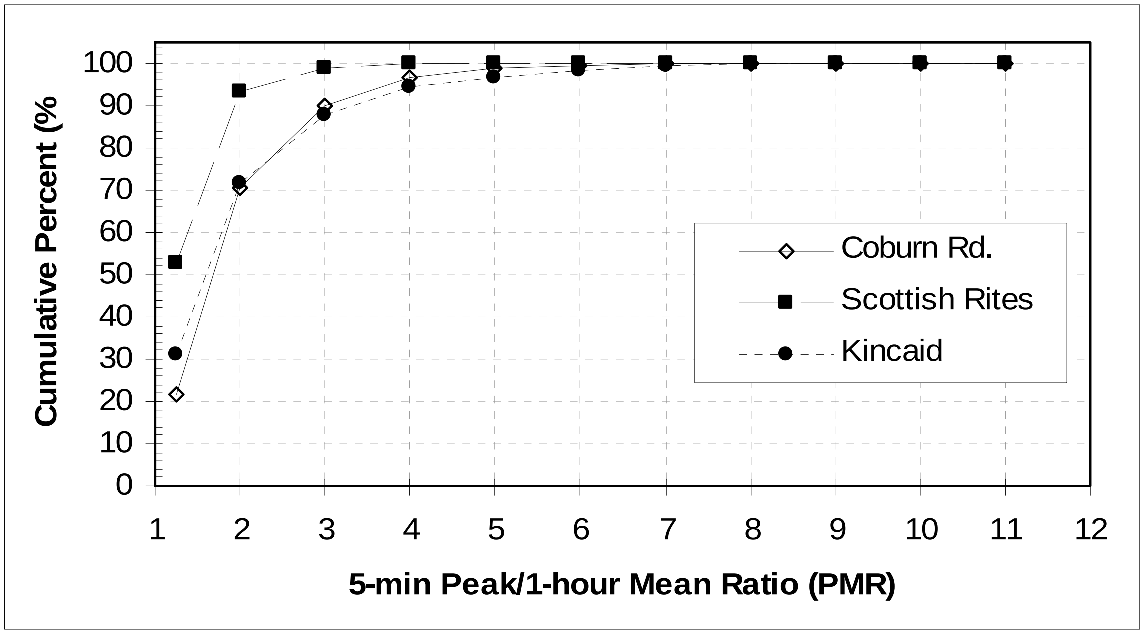

Figure 3. Cumulative density functions (CDF) of 5-minute peak to 1-hr mean ratios for three locations. Data obtained from Stoeckenius et. al (1990) Table 2-18.

Later analyses of PMRs indicated that the ratio is likely influenced by a few factors (SAI, 1995; Thompson, 2000). On average, the PMR is approximately two; however, much higher PMR have been observed. There is greater variability in the ratio at lower 1-hr average concentrations and has been described by an inverse relationship, i.e., there is decreasing variability with increasing 1-hr average concentration. In addition, the location of the monitor can be highly influential. The occurrence of short-term peak concentrations at ambient monitors is likely to be influenced by their distance from local sources and source characteristics including the magnitude of emissions, temporal operating patterns (e.g., seasonal, time-of-day), facility maintenance, and other physical parameters (e.g., stack height, area terrain), as well as by local meteorological conditions. As part of a sensitivity analysis conducted for copper-smelters, the influence of PMRs were evaluated considering the distance from the source stratified by a normalized 1-hr mean concentration (Sciences International, 1995)[4]. Distance was inversely proportional to the PMR in all three of the 1-hr mean stratifications (i.e., ≤0.04 ppm, 0.04 to ≤0.15ppm, and >0.15ppm), with the highest 1-hr category containing the lowest range of PMRs.

The current analysis will examine these issues again, and will benefit from the increased 5-minute monitoring effort that began as a result of negotiations with the American Lung Association (ALA) following the 1998 Court of Appeals remand. Specifically, the current review will have substantially more 5-minute SO_2 concentrations to analyze, and the benefit of some monitors measuring all twelve 5-minute intervals in an hour, rather than just the 5-minute

[4] In this analysis, normalized 1-hr concentrations were obtained by dividing by the maximum hourly concentration.

maximum SO_2 concentration in a given hour. Moreover, the current review will also analyze the continuous monitoring data alone to determine the frequency distribution of 5-minute peaks within a given hour and whether any temporal patterns in peak concentrations (e.g., within an hour, particular hours of the day, etc.). Influential factors described above will be considered in the development of PMR CDFs (e.g., 1-hr concentrations, particular source influence). The approach here also extends the analysis beyond the characterization of the PMRs as done in the previous review, by development of a statistical model to estimate the frequency of short-term peak concentrations at monitors reporting only 1-hr average concentrations.

3.2.1.3 Statistical Model Development

The next step in this tier of the assessment is to develop a statistical model(s) accounting for any important factors identified in the above analyses. The purpose of the model is to estimate the frequency of short-term peak concentrations where only 1-hr average values were reported, and for considering different averaging time scenarios. Thompson (2000) performed an initial analysis of 1990-2000 air quality monitoring data to quantify the relationship between 1-hr mean and 5-minute peak concentrations. A single semi-empirical distribution of PMRs was used based on assumptions regarding independence between the ratio and 1-hr average concentration and grouping the 1-hr average concentrations into 6 bins (Figure 3).

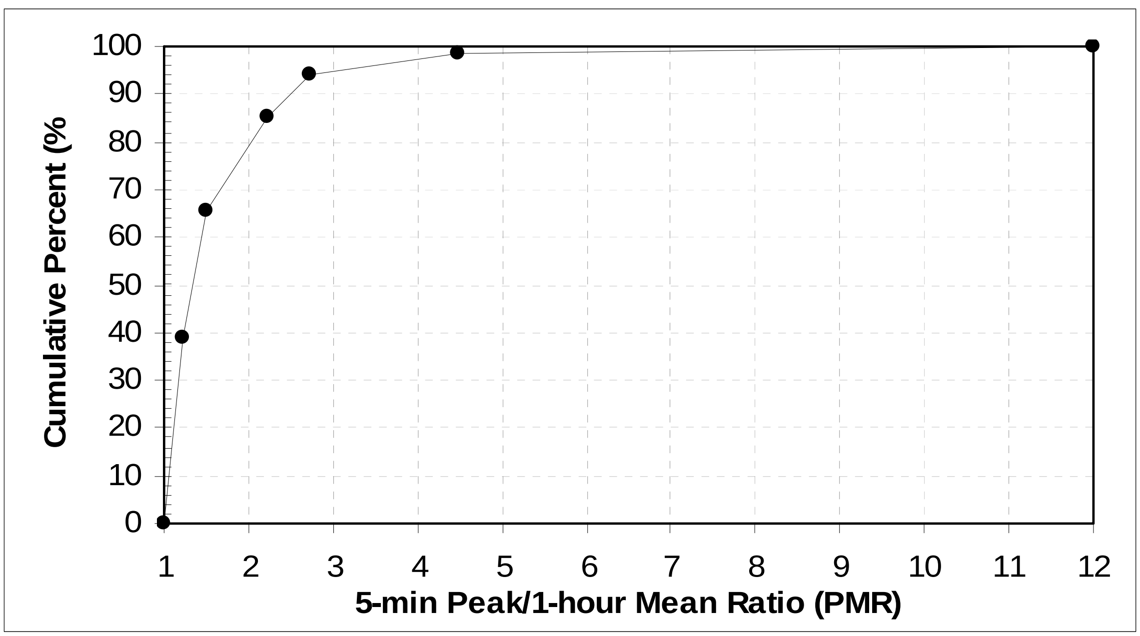

Figure 4. Illustrative example of a semi-empirical cumulative density function (CDF) of peak-to-mean ratios (PMRs). Figure modified using data from Thompson (2000) (Table 5) that were derived from 5-minute ambient monitoring data, years 1990-2000.

The proposed analysis here builds upon that approach and includes the development of PMR cumulative density fuctions (CDFs), including the addition of recent monitoring data and considering any identified influential factors. Rather than assuming a single distribution is representative of all PMRs as was done previously by Thompson (2000), this analysis would include the development of multiple CDFs that account for influential attributes, where appropriate data exist. Currently, the level of the 1-hr mean concentration has been identified as an important consideration in defining a PMR distribution. In addition, the type of source(s) and operating conditions have also been identified as important in influencing temporal variability in concentrations, thus possibly affecting the PMR. To address these issues, it is proposed that the empirically-derived PMR CDFs will be stratified by 1-hr mean concentration ranges (e.g., 0.05 to 0.09 ppm 1-hr, 0.10 to 0.14 ppm 1-hr, etc.) and possibly stratified by a measure of variability in the 1-hr mean concentrations (e.g., standard deviation (SD), coefficient of variation (COV=mean/SD)). Staff will investigate if additional stratification of these distributions is warranted, such as by season or possibly with distance from potential sources (i.e., power utilites, refineries). For example, any 5-minute monitors that are identified in close proximity to important facility types will be evaluated for possible influence by local sources by deriving separate PMR CDFs and to be compared with those at CDFs from monitors at greater distances from local sources. In considering these and any other identified influential factors, there will be consistency in the assignment of PMRs developed from measurement data as applied to the 1-hr average concentrations where 5-minute peak concentrations are not measured and in the dispersion modeled 1-hr concentrations.

3.2.1.4 Statistical Model Application

The expected number of short-term peaks above a particular value can be estimated using a derived ratio CDF as follows.

If c = short-term peak concentration (ppm)
m = 1-hr mean concentration (ppm)
r = peak to mean ratio (PMR), or c/m derived above

then p = probability of an r given all possible r

If interested in a particular peak concentration such as a health effect benchmark level that has the same averaging time as c, then this can be represented as

h = short-term health effect benchmark concentration (ppm)

It follows that since

$$h = c$$

then $r = h/m$

thus, P = probability of $c \geq h$ given m
$= 1\text{-}p$

The appropriate function(s) will be applied to the 1-hr mean ambient monitoring data considering the potential health effect benchmark level of interest and as defined by the stratification variable(s), limited to the criterion that the health effect benchmark is the same averaging time as the PMR. Currently this would be 5-minutes in duration, however if alternative short term peak concentrations and associated averaging times are identified as important (e.g., 10- or 15-min), additional functions would be developed. Regardless, the resultant probabilities are used to determine whether a short-term peak concentration would exceed a health effect benchmark level for each hour given the 1-hr mean concentration (i.e., either there is or is not an exceedance). Once the presence or absence of short-term peaks have been generated for each 1-hr average ambient monitoring concentration, additional relationships can be evaluated that account for longer-term average concentrations (e.g., daily and annual averaged) and the associated frequency of short-term 5-minute peaks. Furthermore, simulated air quality can be used to generate estimates of short-term peak concentrations, considering air quality scenarios that deviate from the existing air quality concentrations.

An additional application of the statistical model and the estimates of short-term peak concentrations would consider population densities within a given distance of the ambient monitor. Thompson (2000) combined the population residing within 5 km of each ambient monitor with the number of 5-minute SO_2 concentrations above 0.6 ppm generated from the available 5-minute ambient monitoring data and those estimated from the 1-hr average ambient monitoring data. Similarly, estimates of the number of short-term peaks using the recent monitoring data could be associated with the population living within 5 km or any alternative distance of interest (e.g., 2 km, 5 km, 10 km) of the ambient monitor, however the analysis here would also account for the fraction of asthmatic individuals rather than considering the entire population. This analysis would serve to place the frequency of peak concentrations in context with possible contact by susceptible populations.

3.2.2 Generated Outcomes

Descriptive statistics (e.g., daily mean ambient concentrations, annual average ambient concentrations, PMRs, their associated percentiles, etc.) will be summarized in tables and figures, accounting for particular factors contributing to their variability (e.g., year, location), where relevant data exist. Newly generated CDFs will then allow for the estimation of the number of exceedances of short-term peak concentrations (e.g., 5-minute exceedances of 0.5 ppm) considering current air quality, upon just meeting the current SO_2 standards (daily and annual) and meeting other potential alternative standards that may be under consideration. All results, including CDFs and exceedance estimates will be compared with that reported by SAI (1996) and Thompson (2000), where appropriate comparisons can be made.

3.2.3 Variability and Uncertainty

One general assumption regarding the air quality characterization is that quality assurance checks have been applied to air quality data. Reported concentrations contain only valid measures, since values with quality limitations are either removed or flagged. Therefore, the quality of the monitoring data used contributes minimally to uncertainty. Depending on the data set used for analysis, the temporal variability in concentrations should be representative of that observed for SO_2. Depending on degree of completeness, the short-term monitoring data should be representative of any longer duration averaging times. However, the limited number of monitors may not account for some of the spatial and perhaps temporal variability in most locations and therefore contribute to uncertainty. Other concerns could result from the exclusion of any unidentified outdoor sources, the ability of ambient monitors to capture the effect of local sources due to their siting location, and the effect of additional local sources on personal exposure estimates. Additionally, there is uncertainty in the application of the identified potential health effect benchmark levels for potentially susceptible populations.

As mentioned in the overview, a tiered approach to assessing uncertainty will be employed with the goal of progressing to a quantitative analysis if warranted and if data are available to support such an analysis. The first step in the uncertainty analysis would be to identify the components of the assessment that do or do not contribute to uncertainty and to provide a rationale for why this is the case. This is described below for this particular tier of the assessment, although the identified components are, in a broad sense, also relevant to subsequent exposure analyses. The following includes a preliminary qualitative evaluation for the uncertain components of the planned Tier I analysis, indicating the direction of influence (under- or over-estimate) on exposure estimates.

- Ambient SO_2 measurement: The draft ISA (Section 2.3) notes various positive and negative sources of interference that could contribute to uncertainty in the measurement of SO_2. Many of the identified sources (e.g., polycyclic aromatic hydrocarbons, stray light, collisional quenching) have limited impact to SO_2 measurement due to the presence of instrument controls that prevent the interference. The actual impact on any individual monitor is uncertain, i.e., the presence of negative and positive interferences has not been quantitated. Therefore, reported ambient monitoring concentrations could be over- or under-estimated, but likely minimally.
- Ambient Monitor Siting: In general, the 5-minute monitors are located in areas impacted by local sources and thus likely capture the anticipated occurrence of peak concentrations well. Many of the 1-hr monitors are not located near large sources of SO_2, thus using the 1-hr monitors for extrapolation may lead to the overestimation of 5-minute peak concentrations. Where such sources exist near 1-hr monitors, the level of uncertainty may be limited by the characterization of factors influencing monitoring concentrations.
- Temporal Representativeness: Data are valid 5-minute and 1-hr average measures and should be of the same temporal scale as identified health effect benchmarks. While there may be missing values within a given year contributing to uncertainty (data will not be interpolated in the Tier I analysis), temporal profiles will be assumed complete and representative. Criteria typically used for establishing a valid year of 1-hr average ambient monitoring data include 75% of valid days in a year, with at least 18 1-hr measurements for a valid day (thus at least 274 valid days, a minimum of 4,932 hours). The 5-minute monitoring has been performed less frequently than the hourly monitoring, generally only a few years of data exist per 5-minute monitor. Due to the limited data available and that they will be used primarily for development of statistical relationships, all 5-minute data will be used as is provided the PMR criteria defined below are met.
- Spatial Representativeness: In general, there are a limited number of SO_2 monitors in a given area, particularly when considering the number of monitors that report 5-minute peaks/values. There may be locations where 5-minute peak concentrations are higher than those measured by a local monitor, e.g., locations in close proximity to a particular source or locations impacted by other nearby sources not represented by the

nearest monitor, or locations where 5-minute peak concentrations occur more frequently above a health effect benchmark compared with the nearest monitor. This may lead to an underestimate of both the frequency and magnitude of peak concentrations.

- Monitor to Exposure Representativeness: Human exposure is characterized by contact of a pollutant with a person, and as such, this analysis contains the broad assumption that the monitoring concentrations are serving as a surrogate for exposure. The ISA reports that personal exposure data are of limited use since ambient concentrations are typically below the detection limit of the personal samplers. There is not a method to quantitatively assess the impact of the uncertain relationship between 5-minute ambient monitoring data and personal exposures for the Tier I estimates, particularly since personal exposures are time-averaged over hours or days, and never by 5-minute averages. Therefore the relationship of short-term peak personal exposure concentrations (i.e., attributed to ambient) to peak-ambient is largely unknown and thus contributes to uncertainty. An evaluation in the ISA indicates the relationship between longer-term averaged ambient monitoring concentrations and personal exposures is reasonably strong, particularly when ambient concentrations are above detection limits, however personal exposure concentrations are reportedly a small fraction of ambient concentrations. This is because outdoor concentrations are typically ½ of the ambient concentrations, and indoor concentrations about ½ of the outdoor concentrations (USEPA, 2007a). Therefore, the use of monitoring data as a surrogate for exposure would likely lead to an overestimate in the number of peak concentrations that people might encounter.
- Peak-to-Mean Ratios: The criterion used previously by Thompson (2000) centered on data that contained a 5-minute peak to 1-hr mean ratio of at least 1 and less than 12. Values <1 would imply the 5-minute peak is less than the 1-hr average, a physical impossibility, and values >12 are a mathematical impossibility. While data can be screened for values outside of these bounds it raises an issue regarding the certainty of values within the range of 1 to 12. Staff is investigating methods for estimating confidence intervals around the number of surrogate peak exposures and possibly performing a cross-validation of the PMRs using subsets of the data used to construct the CDFs. In addition, use of the historical data in developing PMR CDFs carries the assumption that the sources present at that time are similar as current sources, adding uncertainty to results if this were not the case.
- Single vs. Multiple Short-Term Peak Concentrations: The model is primarily designed to estimate the frequency of a single exceedance of a particular health effect benchmark. However, multiple short-term peak concentrations are possible in any hour. Preliminary analysis of the 5-minute continuous monitoring data indicates that multiple occurrences of concentrations above 0.6 ppm-5min within the same hour are common. Using continuous monitoring data obtained from years 1990-2000, multiple peak concentrations (i.e., 2 or more) at or above 0.6 ppm-5min within the same hour occurred with a 70% frequency. Analysis of recent continuous monitoring data (i.e., 1997-2006) indicate that the frequency of multiple peaks within the same hour is still common but less frequent (i.e., about 35%). A single peak approach for estimating surrogate exposures would likely lead to an underestimate in the number of potential exposure events.

- Simulated Air Quality: The proportional simulation procedure assumes that potential pollutant control strategies effect sources equally and that the observed impact at any monitor would also be distributed equally, i.e., the likelihood for reduction in emissions or concentrations is equal for both low and high levels. This would lead to either under- or over-estimates in concentrations if the impact of control strategies is not distributed evenly across the different parts of the air quality distribution. In addition, use of historical data in some of the analyses here carries the assumption that the sources present at that time are similar to current sources, adding uncertainty to results if this is not the case.
- Health Effect Benchmark Representativeness: Potential health effect benchmarks will be based on the assessment of the science as documented in the 1st and 2nd drafts of the ISA. Since potential health effect benchmarks are derived from controlled human exposure studies, the uncertainty about the exposure and resultant response is primarily limited to the extrapolation from the study subjects to the modeled population. For example, uncertainties in the exposure characterization and/or in the susceptibility of specific populations could contribute to the overall uncertainty. As discussed in section 4, uncertainties associated with identification of potential health effect benchmarks will be discussed qualitatively based on information provided in the ISA. In addition, alternative potential health effect benchmark levels will be included in the analysis to illustrate the impact of alternative benchmark levels on the risk characterization.

3.3 TIER II: EXPOSURE ASSESSMENT

The Tier II exposure assessment is intended to build upon exposure analyses conducted for the previous SO_2 NAAQS review (Burton et al., 1987; Stoeckenius et al., 1990; Rosenbaum et al., 1992) and an industry sponsored supplemental exposure analysis (Sciences International, 1995). The objectives of a Tier II exposure assessment would be (1) to improve the spatial/temporal resolution of ambient concentration fields surrounding important local sources of SO_2 considering current emissions, (2) to account for human attributes that influence short-term (e.g., 5-minute) personal exposure, and (3) to account for physical factors that may contribute to lessened or greater personal exposures.

As was done in the previous SO_2 NAAQS review, a combined dispersion modeling and exposure modeling approach would be used to simulate personal exposures of individuals residing in close proximity to important utility and non-utility SO_2 emission sources. The result of this analysis would be the generation of person-based exposure profiles for a given population under direct impact from these local sources of SO_2, centered on the number of 5-minutes peak exposure events in an entire year. General steps are as follows:

1. Estimate 1-hr SO_2 concentrations at receptors with varying distance from selected facilities using the most recent emissions estimates, local meteorology, and facility parameters as input to a dispersion model;
2. Estimate short-term peak (5-minute) concentrations from 1-hr concentrations at modeled receptors using PMRs, accounting for any important influential factors, where possible;

3. Estimate individual exposure concentrations by using the dispersion model receptor concentrations as input to an exposure model accounting for time-location-activity patterns of simulated persons.

While the general approach is similar to that performed in the prior review, there are planned improvements to the approach, models used, and data available for this review. Details of improvements are discussed in the following subsections (3.3.1 through 3.3.3).

3.3.1 Dispersion Modeling Approach

The first component in the Tier II analysis involves estimating local ambient concentrations, given that there may be locations which people reside and visit that are not well represented by ambient monitoring alone. When considering important local sources of SO_2, it is anticipated that short-term peak concentrations will be higher within close proximity (generally within 20 km) of power generating utilities and non-utility emission sources. Due to the large number of power facilities and other emission sources across the U.S., some simplifying assumptions may be applied for simulating concentrations associated with each facility, albeit indirectly using facility prototypes and by considering influential facility attributes and other local features. This may involve grouping facilities into a number of defining bins based on ranges of dispersion characteristics, meteorological/climatic conditions, specific source characteristics, and possibly land use patterns/topography.

For example, previous analyses for power utilities employed 24 bins (Burton et al., 1987; Rosenbaum et al., 1992) defined by dispersion characteristics (ambient concentration-to-source emission rate ratios, or X/Q ratios), atmospheric stability classes (a measure of local atmospheric turbulence and wind speed), and load categories representing general patterns in facility operation (base-load vs. daily cycling or peaking units). Prototype stacks were defined to represent each bin, hourly concentrations were estimated at receptors at a distance from the prototype, followed with an estimation of the frequency of 5-minute peak concentration exceedances of 0.5 ppm.[5] The binning approach and use of prototypes to represent the individual sources at that time was justified by the limited computational resources, availability of emissions estimates, and the capabilities of the dispersion models used (CRSTER, ISCST)[6].

The approach for estimating short-term concentrations in this NAAQS review would instead use AERMOD, the EPA-approved, steady-state, Gaussian plume model (US EPA, 2004). Relevant model input data and other modeling information include, but are not limited to the following:

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[5] Following estimation of peak concentration probabilities, Burton et al. (1987) first extrapolated from the prototype probabilities to the individual stacks based on defining characteristics, then followed with exposure modeling. In a slightly different approach, the occurrence of 5-minute peak exposures were estimated for each prototype using an exposure model in the analysis by Rosenbaum et al. (1992). Then exposures associated with a prototype were then interpolated to the other stacks/facilities in each bin using a functional relationship between the fuel sulfur level and the number of 5-minute peak exposures exceedances. The revised approach resulted in about 13% more exposure events. See Rosenbaum et al. (1992) for a discussion of the differences in the approaches and results.

[6] CRSTER is EPA's Single Source Dispersion Model. ISCST is the EPA's Industrial Source Complex Short Term model.

- The most recent emissions data from the latest National Emissions Inventory (NEI)[7] will be used. Sources identified as contributing greatest to SO_2 emissions will be evaluated (e.g., those contributing to >1,000 tons per year) and may include
  - power-generating facilities (e.g., >25 Megawatt (MW) capacity)
  - coal and oil-fired industrial boilers
  - petroleum refineries
  - pulp and paper mills
  - copper smelters
  - sulfuric acid plants
  - aluminum production facilities.
- The most recent meteorological data contained in the National Climatic Data Center (NCDC) as reported by the National Weather Service (NWS) would be used to perform recent year air quality simulations (e.g., 2004-2006).
- Receptor grids may range from 100 to 500 meter polygons based on estimated spatial variability in SO_2 concentrations and then equally spaced outwards from the facility/stack to a maximum distance of 25 km;
- 1-hr background SO_2 ambient concentrations obtained from local ambient monitoring data and characterized as not directly impacted by any local sources.

A binning approach along with the use of stack/facility prototypes, if determined appropriate, will be employed in this review to best represent the large number of individual emission sources. Simulating each emission source individually, while technically possible, may not be practical given the input data requirements (e.g., site topography, specific release points for certain non-utility sources). Parameters representing site topography will be investigated as an additional binning attribute in this review, rather than assuming flat terrain for all sources as modeled in the prior review. Output from this analysis would include hourly SO_2 concentrations at defined receptor locations in close proximity of selected utility and non-utility sources (i.e., prototypes) over the duration of the simulation.

3.3.2 Approach for Estimating 5-Minute Peak Concentrations

A less intensive post-processing of the dispersion model estimated hourly concentrations may be required compared with that performed for the previous review, due to the current dispersion modeling capabilities (e.g., capable of incorporating fuel sulfur distributions, background concentrations, and varying load levels) and the form of the output data (time series of hourly concentrations for the simulation period). The estimation of 5-minute peak concentrations at receptor points located at a distance from the source is dependent on the development of appropriate PMR CDFs, and is described above in Section 3.2.1.2 in detail.

[7] The NEI is EPA's comprehensive national emission inventory and contains emission measurements and estimates for the criteria air pollutants and others. The NEI includes air pollution emissions from point sources (e.g., electric utilities, petroleum refineries), mobile sources (e.g., cars, trucks, nonroad engines such as construction equipment, etc.), and nonpoint sources (e.g., residential fuel use). The NEI is developed using the latest data and best estimation methods including data from Continuous Emissions Monitors (CEMs), data collected from all 50 States, as well as many local and tribal air agencies, and data using EPA's latest models such as the MOBILE and NONROAD models. See http://www.epa.gov/ttn/chief/net/index.html for more.

Briefly, the 5-minute peak concentrations will be estimated probabilistically considering empirically-derived PMR CDFs obtained from either the historic source-specific data (Stoeckenius et al., 1990) and/or that developed from recent 5-minute ambient monitoring conducted in close proximity to particular SO_2 emission sources, where identified. Compared to what was done in the prior review, the analysis of recent 5-minute monitoring data proposed in this review could result in the development of refined PMR distributions, possibly accounting for influential factors (e.g., considering the relationship between the 1-hr mean concentration level and respective PMRs). Regardless, the peak concentrations associated with all 1-hr average receptor concentrations would be estimated by random sampling from the most relevant and available PMR CDF. Thus for every 1-hr concentration estimated at each receptor, an associated 5-minute peak SO_2 concentration would be generated as the primary output of this analysis.

The approach is designed to generate 5-minute peak concentrations to use in estimating potential exposures of concern (EOC) within an hour. In general, it is not an objective to estimate each of the other eleven 5-minute concentrations within the hour with a high degree of certainty. While the occurrence of multiple peak concentrations is possible, the potential health effect benchmark levels are related to single peak exposures. Currently the exposure model uses 1-hr ambient concentrations, however if all twelve 5-minute values are determined necessary as an input, the additional concentrations within an hour at each receptor could be approximated using the following:

$$X = \frac{n\bar{C} - P}{n - 1} \qquad \text{eq (1)}$$

where,

X = 5-minute concentration in each of non-peak concentration periods in the hour at a receptor (ppm or ppb)

$\bar{C}$ = 1-hr mean concentration estimated at a receptor (ppm or ppb)
P = estimated peak concentration at a receptor (ppm or ppb)
n = number of time periods within the hour (or 12)

In addition to the level of the peak concentration, the actual time of when the contact occurs with a person is also of importance. The ISA indicates that adverse health effects associated with short-term peak exposures occurs with moderate to heavy exertion. Human activities are variable over time, a wide range of activities are possible even within a single hour of the day. The type of activity an individual performs, such as sleeping or jogging, will influence their breathing rate. Therefore, a general strategy is needed to set the 5-minute peak concentrations within the hour. If there are no observed short-term temporal relationships following the evaluation of continuous PMR data, then clock times for peak values would be estimated either randomly (i.e., any one of the 12 possible time periods within the hour) or at an assigned time (e.g., at 35 minutes past the hour).

Multiple peak exposures may be of interest, given that there is a need to match the peak concentration with elevated activity levels. The frequency multiple peak concentrations could be estimated using the appropriate probabilities generated from the PMR analysis, applied here as an additional step in populating 5-minute peak concentrations within the hour, and modification of equation (1).

$$X = \frac{n\overline{C} - \sum_{i=1}^{m} P_i}{n - m} \qquad \text{eq (2)}$$

where,

X = 5-minute concentration in each of the n-m non-peak concentration periods in the hour at a receptor (ppm or ppb)

$\overline{C}$ = 1-hr mean concentration estimated at a receptor (ppm or ppb)
P_i = estimated peak concentration at a receptor (ppm or ppb)
n = number of time periods within the hour (or 12)
m = number of peak concentrations

The outcome of this analysis would be 5-minute ambient SO_2 concentrations for each grid receptor in the facility/stack(s) across the simulation period. This may be in the form of all twelve 5-minute values that would occur within an hour (including the peak concentration(s)) or the 5-minute peak concentration(s) within an hour alone, dependent on the utilization of such data in the exposure model.

3.3.3 Exposure Modeling Approach

The exposure modeling approach would use EPA's Air Pollutants Exposure (APEX) model (US EPA, 2006a; 2006b).[8] APEX is a Monte Carlo simulation model used to simulate a large number of randomly sampled individuals within an area reflecting population demographics, thus generating area-wide estimates of population exposure. The PC-based probabilistic model was recently used to estimate population exposures in 12 urban areas for the O_3 NAAQS review (US EPA, 2007d). The modeling approach and exposure results have been peer-reviewed by the CASAC O_3 panel as part of that NAAQS review.

APEX simulates exposures that occur in indoor, outdoor, and in-vehicle microenvironments (MEs). The model stochastically generates simulated individuals using Census-derived probability distributions from the 2000 Census, typically at the tract level. A national commuting database based on 2000 Census data provides home-to-work commuting flows between tracts. Any number of simulated individuals can be modeled, and collectively they represent a random sample of the study area population in the modeled area.

APEX draws human time-location-activity data from EPA's Consolidated Human Activity Database (CHAD; McCurdy et al., 2000) and generates longitudinal activity sequences to represent the movement of simulated individuals through time and space, accounting for the effects of particular day-types (e.g., weekday versus weekend) and temperature on daily

[8] APEX is also referred to as the Total Risk Integrated Methodology/Exposure (TRIM.Expo) model (see http://www.epa.gov/ttn/fera/trim_gen.html for general details on TRIM).

activities. APEX calculates the concentration in the ME associated with each event[9] in an individual's activity pattern and sums the event-specific exposures by hour to obtain a continuous time series of hourly exposures spanning the time period of interest.

The concentrations in each ME are estimated using either a mass-balance or a factors approach, and the user specifies the probability distributions of the parameters used for the concentration calculations (e.g., indoor-outdoor air exchange rates). These distributions can also depend on the values of other variables in the model. For example, the distribution of air exchange rates in a home, office, or car depends on the type of heating and air conditioning present, which are also stochastic inputs to the model. The user can choose to retain the value of a stochastic parameter constant for the entire simulation (e.g., house volume would remain the same throughout the exposure period), or can specify that a new value shall be sampled hourly, daily, or seasonally from specified distributions. APEX also allows the user to specify diurnal, weekly, or seasonal patterns for certain ME parameters.

The calculation of ME concentrations in APEX is dependent not only on the parameter distributions for the mass balance and factors approaches, but also on the ambient (outdoor) SO_2 concentrations and temperatures. Surface temperatures would be obtained from the NCDC/NWS and spatially interpolated for each study area as input to APEX. For the application to SO_2, MEs such as the following would be modeled, depending on available data:

- Indoors - residence
- Indoors - bars and restaurants
- Indoors - schools
- Indoors - day care centers (commercial)
- Indoors - other (e.g., offices, shopping)
- Outdoors - residence
- Outdoors - other (e.g., playgrounds, parks)
- In vehicles - cars, trucks, others

One particular consideration in this tier of the exposure assessment involves addressing the population fraction living within the tracts containing identified sources and therefore, the assignment of ambient concentrations to individuals in these locations. The receptor grid concentration estimates will be at a finer spatial resolution than that commonly employed in the exposure model, even if the exposure model used the Census scale of block group or block. The proportion of the population in a grid may be defined based on dividing the Census scale (e.g., block) equally by the number of grids falling within that Census scale. The number of grids within the Census scale would be variable since the spatial dimension of the selected census region is also variable. Therefore, individuals residing in a given Census scale will have an equal probability of exposure to any of the grid concentrations estimated for that Census scale.

In addition, the time associated with the input data (i.e., 5-minute) is at a finer scale than used in the APEX (currently it is 1-hr). In the latest review completed in 1994, the Human

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[9] Exposure events are when an individual is in a single microenvironment, exposed to a constant concentration for a definite time duration, and while at a constant activity level. The duration of the event is a maximum of 1-hr due to the structure of the time-location activity diary, but could be as short as 1-minute.

Exposure Model (HEM) was used to estimate the probability of short-term peak exposures. For any given 5-minute period within an hour where a short-term peak concentration of concern was estimated, it was assumed the individual was at moderate or greater exertion for the entire hour. This approach would tend to overestimate the number of short-term peak exposures since it is unlikely that all individuals are at heightened exertion levels for the entire 1-hr period. Staff proposes to address this as part of this review by estimating the peak concentration in a specific 5-minute time period and correlating that with the time-location-activity pattern of the individual within the hour. The result will be more reasonable estimates of the number of EOC compared to those estimated previously, since the occurrence of peak concentrations will be paired with variable breathing rates (as would be expected) within an hour, rather than assuming elevated breathing rates for the entire hour.

Another important consideration in the design of the exposure assessment involves the linking of particular activity levels with the potential EOC. The ISA indicated the requisite for adverse health effects in certain individuals is exposure while performing moderate to heavy exertion activities. Conceptually, the exertion level of an individual engaged in a particular activity can be estimated either by energy expended or associated ventilation rates. In the previous review, the clinical studies indicated that short-term exposures were associated with adverse health effects at breathing rates of 35 L/min or greater. Rather than using specific breathing rates, the exposure model(s) assumed probabilities of persons/cohorts being outdoors performing high-level activities.[10] APEX can estimate an individual's activity-specific metabolic equivalents of work (or METS) which is used in generating associated ventilation rates (e.g., expiratory ventilation (V_E) or oxygen consumption (VO_2)).

Staff is investigating an improved approach to classifying when an individual is performing elevated activities. One method would consider using the exceedance of a set METS value to identify when the simulated individual is at the target activity level. This METS level would be specific for the individual and likely fall between commonly used ranges for moderate (METS from 3.0 to 6.0) and vigorous (>6.0 METS) physical activity (e.g., Ainsworth et al., 2000). A second approach would consider whether an individual's activity-specific rate of VO_2 exceeded a percentage of their normalized VO_2max (mL-O_2/min-kg). Regardless of the approach, the selected target level would correspond to the ventilation or activity level where adverse health effects were observed in the clinical studies. Simulated persons would be assigned variable target levels (one per individual), accounting for any influential factors such as age and gender.

Finally, an extrapolation of exposure estimates to the facilities not modeled would need to be performed. As was done a previous assessment, a relationship would be developed from the prototype emissions parameters (e.g., fuel sulfur level) and estimates of the number of exceedances generated from the exposure model (see Rosenbaum et. al, 1992). Then facility-specific values would be used to generate exposure estimates at each facility where exposure modeling was not conducted.

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[10] The only reference with any detailed classification was Burton et al. (1987). Appendix A notes three activity levels were assigned to a cohort (using NEM), classified as either low (200 cal/hr), med (200-500 cal/hr) and high (>500 cal/hr) for each hour. It is unclear as to how this was proportionally applied to the probability of individuals exercising outdoors at a particular clock hour.

3.3.4 Populations Modeled

A detailed consideration of the population residing in each modeled area would be included, where exposure modeling is performed. The assessment would consider susceptible and vulnerable populations as identified in the ISA, defined from either an exposure or susceptibility perspective. The population subgroups identified by the ISA (US EPA, 2007b) that we plan to include in an exposure assessment include:

- Children (birth to age 18 – subdivided to preschool/school age)
- Asthmatic children (birth to age 18 – subdivided to preschool/school age)
- Asthmatic adults (≥ 19 years)
- Elderly (≥ 65 years)

The proportion of the population of individuals characterized as being asthmatic will be estimated by statistics on asthma prevalence rates recently used in the NAAQS review for O_3 (US EPA, 2007d). Where sufficient data are available, region-specific data would be applied.

3.3.5 Generated Outcomes

Exposure estimates would use the most recent SO_2 emissions data. The exposure assessment would take into account several important factors including the magnitude and duration of exposures, frequency of repeated peak exposures, and breathing rate of individuals at the time of exposure. Estimates of exposure would include (1) temporally and spatially resolved hourly and 5-minute peak ambient concentrations for areas surrounding local stationary sources, (2) counts of people exposed one or more times to a given short-term peak SO_2 concentration at a particular exertion level, and (3) counts of person-occurrences of particular exposures at a given exertion level.

3.3.6 Variability and Uncertainty

The principle objective of a refined exposure assessment would be to estimate exposures by representing the variability in a given population's characteristics that influence its exposure, while minimizing the uncertainties. Variability can be described in terms of the empirical quantities that are important in estimating exposure and are inherently variable across time and space, or when considering a group of individuals (Cullen and Frey, 1999). For example, body mass is a measurable quantity that differs for individuals within a population (depending on a number of factors) and can be represented by a frequency distribution(s). Uncertainty tends to reflect the degree of confidence in the use of or the representativeness of models or model components, for the purposes of which they were designed. For example, uncertainties arise in body mass distributions due to random or systematic measurement error, or perhaps uncertainty is introduced by the application of a body mass distribution obtained using one population of individuals to extrapolate to another distinct population of individuals. In this example using a distribution of measured body mass, uncertainty can be present as apparent variability or exist as unaccounted variability. It is within this general context that variability and uncertainty would be addressed in this tier of the assessment.

Uncertainty would be assessed quantitatively through individual parameter analyses and possibly a unified uncertainty analysis as described previously in the recent O_3 NAAQS review

(US EPA, 2007d; Langstaff, 2007). Briefly, there are two primary sources of uncertainty that would be addressed in this type of a quantitative analysis. The first is uncertainty associated with the modeling inputs (e.g., emissions estimates, peak-to-mean ratios, time-location-activity diaries, microenvironmental factor distributions). The second is uncertainty associated with model formulation (e.g., algorithms included in the model).

For the dispersion modeling, binning and use of prototypes in estimating receptor concentrations carries assumptions regarding similarities in parameters such as meteorology, dispersion characteristics, and load levels to the extrapolated stacks/facilities. This combined with limited data on 5-minute peak to 1-hr average concentrations could result in over or under estimation in concentrations. These and other potential sources of uncertainty could be evaluated to determine the magnitude of impact to receptor concentration estimations through individual sensitivity analyses. In addition, the overall approach may be evaluated by comparing dispersion model concentrations estimates with available 5-minute ambient monitoring data that are located within defined dispersion model grids. Recent 5-minute monitoring conducted in two counties of Missouri (Iron and Jefferson) could provide a benchmark for comparison based on the type of source and monitor proximities.

For APEX, a 2-dimensional Monte Carlo Latin hypercube sampling approach could be used as a combined variability and uncertainty analysis for APEX. A Monte Carlo approach entails performing a large number of model runs with inputs randomly sampled from specified distributions that reflect the variability and uncertainty of the model inputs. The 2-dimensional Monte Carlo method allows for the separate characterization of variability and uncertainty in the model results (Morgan and Henrion, 1990). If this approach were taken, developing appropriate distributions representing both variability and uncertainty in model inputs (e.g., dispersion model input data, air exchange rates, SO_2 decay rates, physiological parameters) would be a key part of the effort.

In the case of model formulation, the preferred approach would be to compare model predictions with measured values; however, according to the draft ISA, these data are limited to a few locations in the U.S., none of which have averaging times of 5 minutes. In the absence of measurements that can be used to estimate model uncertainty, the analysis must rely on informed judgment. The approach would be to partition the model formulation uncertainty into that of the components, or sub-models, of APEX (e.g., microenvironemental concentrations, ventilation estimates). For each of the sub-models, we would discuss the simplifying assumptions and the uncertainties associated with those assumptions. Where possible, we would evaluate these sub-models by comparing their predictions with measured data. Where this is not possible, we would formulate an informed judgment regarding a range of plausible uncertainties for the sub-models.

3.4 CRITERIA FOR DETERMINING APPROACH

Criteria have been developed to determine the tier level of the assessment to be performed. The criteria are designed to determine the value added to the overall assessment as measured by assumptions retained in each tier and, either the reduction of uncertainty or the improved characterization of uncertainty in the exposure estimates. The factors identified below will be considered in the progression from one tier to the next.

- Outcome of the ambient air quality characterization, including the estimated number of peak concentrations using current ambient concentrations and those assuming any potential alternative standards that may be under consideration;
- Availability of information and data defining the potential impact of important local sources on nearby residents (e.g., time spent outdoors while at elevated exertion);
- Existence of the data required to perform the analyses in each subsequent tier of the assessment;
- Representation of identified susceptible populations in the current review.

4. RISK ASSESSMENT SCOPE AND METHODS

4.1 OVERVIEW

A three-tiered approach to characterizing health risks will be utilized. Tier I of the assessment will review the health effects evidence in the 1st and 2nd draft ISA and identify the health endpoints that are judged to be causal or likely causal with respect to ambient SO_2 levels at specific averaging times. A key part of the Tier I assessment will be judgments as to which of the identified health endpoints are likely candidates for progression to a Tier II or III risk characterization.

The Tier II risk assessment would build upon the information gathered in the Tier I assessment. For health endpoints based on findings from controlled human exposure studies identified during the Tier I assessment, a Tier II analysis will first determine whether potential health effect benchmarks can be developed based on the evidence and evaluation presented in the draft ISA. If potential benchmarks can be developed, exceedances of these health benchmarks will be evaluated based on air quality (serving as a surrogate for exposure), or estimates from the exposure assessment described in the previous section.

For health endpoints based on findings from epidemiological studies identified during the Tier I assessment, a Tier II analysis will involve a more extensive evaluation of the ambient air quality levels for SO_2, and co-pollutants where possible, to see if there are any trends or patterns with respect to the effect estimates reported. This evaluation will include examination of whether there are any trends or patterns in the reported concentration-response relationships with respect to the use of different averaging times and air quality metrics as well as the use of single versus multi-pollutant models.

A Tier III risk assessment, if conducted, would involve an estimation of the number of people expected to experience specific health effects and total number of occurrences of these effects. This type of assessment would only be conducted for those health effects identified as having sufficient basis to provide quantitative estimates based on the previous tiers of the assessment. More specifically, a Tier III assessment would estimate the number of people estimated to have one or more occurrences in a year and the total number of annual occurrences of health effects associated with recent ambient SO_2 levels and with SO_2 levels that just meet the current and alternative standards. For health effects based on evidence from controlled human exposure studies, a Tier III risk assessment requires combining estimated exposure-response relationships with exposure estimates for the relevant averaging time(s) and population(s) associated with recent air quality and air quality simulated to just meet the current and potential alternative standards to generate population risk estimates for one or more health endpoints. For health effects based on evidence from epidemiological studies, a Tier III assessment requires combining estimated concentration-response (C-R) relationships with either recent ambient air quality data or simulated ambient air quality data representing just meeting the current or potential alternative standards to generate population risk estimates for one of more health endpoints.

Decisions on whether or not to conduct a Tier III risk assessment will take into account the following considerations: (1) whether the weight of the evidence supports conducting a quantitative assessment for specific health endpoints, (2) whether the data needed to conduct such quantitative assessments are available, (3) the anticipated utility of results to inform decisions on the adequacy of the current SO_2 NAAQS and to provide insights related to potential alternative standards, and (4) whether or not there is adequate time and resources to complete such assessments under the current schedule.

Ultimately, we believe this tiered approach to assessing risk will accomplish the following goals: (1) to provide an overall characterization of the health effects associated with ambient SO_2 exposures including a summary discussion of all significant health effects, including those which are of public health concern but which are not judged appropriate for inclusion in quantitative assessment, (2) to estimate the number of occurrences of short-term air quality events (i.e., on the order of 5 to 10 minutes) at or above potential health effect benchmarks associated with various air quality levels, including recent levels and air quality levels meeting potential alternative SO_2 standards, (3) to estimate the number of people exposed at or above potential health effect benchmarks, for effects based on controlled human exposure studies, associated with recent air quality levels and air quality levels just meeting the current and potential alternative SO_2 standards, (4) to provide insights about whether or not there are patterns of exposure in terms of differences in levels, averaging times, and/or air quality metrics for the health effects based on epidemiological studies, (5) to provide distributions of population health risk estimates for health endpoints based on community epidemiologic studies reporting associations between respiratory effects at ambient SO_2 levels for recent air quality and air quality levels just meeting potential alternative 1-hr, 24-hr, and annual SO_2 standards if a Tier III assessment is judged appropriate and conducted, and (6) to identify and discuss key assumptions, degree of variability, and nature and extent of uncertainties in the estimates and to characterize quantitatively, where feasible, the uncertainties and variability in such estimates.

Conceptually, if there were sufficient scientific data available, the objective of the health risk assessment would be to develop population-based health risks for various health effect endpoints in at-risk[11] population groups associated with recent air quality levels and just meeting the current and potential alternative SO_2 NAAQS. In addition, the health risk assessment would include a quantitative characterization of the uncertainties in those risk estimates and key assumptions underlying such estimates. We recognize that the current state-of-knowledge about SO_2-related health effects, as reflected in the evaluation contained in the first draft ISA, likely precludes the development of quantitative health risk estimates for most health endpoints discussed in the ISA. Our initial judgments about health effect categories and appropriate approaches to conduct the assessments are presented below and are based on the current draft ISA, recognizing that the 1st draft risk assessment will be informed by CASAC and public review of the current draft of the ISA, in addition to the information and evaluation contained in the 2nd draft ISA and associated Annexes.

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[11] *At risk* is used here to include both susceptible populations (i.e., those who are likely to be inherently more sensitive) and vulnerable populations (i.e., those who are at greater risk due to increased exposure).

4.2 TIER I: HEALTH EFFECTS EVALUATION

The Tier I assessment will essentially be a qualitative analysis of the health effects information presented in the 1st and 2nd drafts of the ISA and associated Annexes. The first step will be to identify key studies, both controlled human exposure and epidemiologic studies, that are presented in the ISA and its Annexes as providing evidence for adverse health effects associated with specific averaging times. This includes an analysis of studies that examined SO_2 exposure alone, as well as those that looked for SO_2 associated health effects after adjustment for co-pollutants (e.g., O_3 or PM). Once potential health effect endpoints are identified, the Tier I characterization will involve making judgments as to which of these endpoints are likely candidates for progression to be addressed more quantitatively in Tier II and/or Tier III assessments.

Staff has reviewed the information and evaluation of the health effects evidence presented in the 1st draft of the ISA and we have some initial observations and judgments about potential health effect categories and endpoints that should be considered for Tier II and/or Tier III assessments. The 1st draft ISA identifies several health endpoints from controlled human exposure and epidemiologic studies that are associated with ambient levels of SO_2. The 1st draft ISA notes adverse health effects associated with exposure to short-term peaks (5-10 minutes) of SO_2 based on findings from controlled human exposure studies, most of which were conducted in the 1980's and were evaluated in previous criteria documents. Specifically, the health endpoints identified include changes in respiratory function indicative of bronchoconstriction as measured by specific airway resistance (SR_{aw}) and decreased Forced Expiratory Volume in one second (FEV_1) observed in asthmatic subjects. The draft ISA also identifies asthmatics (children and adults) as the population group most at-risk from respiratory-related effects associated with these short-term peak SO_2 exposures.

The 1st draft ISA also highlights recent epidemiologic studies that provide evidence for an association between 24-hr and 3-hr average SO_2 concentrations and increased respiratory symptoms in children, particularly those with asthma or chronic respiratory symptoms. Additionally, the ISA notes that the SO_2 effect was generally found to be robust after adjusting for particulate matter (PM) and other co-pollutants. Similarly, the ISA presents a large number of epidemiologic studies that provide evidence of positive, but not always statistically significant, associations between ambient 24-hr and 1-hr SO_2 concentrations and ED visits and hospitalizations for all respiratory causes and asthma, particularly among children and older adults. These findings were generally robust when additional co-pollutants are included in the model. Moreover, the 1st draft ISA notes biological plausibility for increased ED visits and hospitalizations is found in both the and human clinical studies (mentioned above) and the epidemiologic studies that observed increased respiratory symptoms and decreased lung function, as well as the animal toxicological studies that observed SO_2-induced altered lung host defense.

In contrast, the 1st draft ISA concludes that the overall epidemiologic evidence is inconclusive regarding the effect of short-term exposures (typically 24-hr) to SO_2 on the cardiovascular and nervous systems. The 1st draft ISA also concludes that the epidemiologic evidence is suggestive of associations between short-term exposures to SO_2 and non-accidental and cardiopulmonary-related mortality, but notes the limited experimental evidence to support judgments about biological plausibility while raising concerns about confounding from other pollutants, including PM and NO_2. The 1st draft ISA also concludes that the evidence is inconclusive regarding the associations between long-term exposure to SO_2 and morbidity and mortality.

Based on the evaluation of the health effects evidence in the 1st draft ISA, the following health effect endpoints are initially judged to be the most appropriate candidates to focus on in Tier II and/or Tier III assessments:

- Changes in respiratory function indicative of bronchoconstriction as measured by SR_{aw} and decreased FEV_1 observed in asthmatic subjects exposed to 5 to 10 minute SO_2 concentrations;
- Respiratory symptoms in children, particularly those with asthma or chronic respiratory symptoms associated with 3- and 24-hr average ambient SO_2 concentrations;
- Respiratory-related emergency department visits, especially for asthmatic children associated with 1- and 24-hr average ambient SO_2 concentrations;
- Respiratory-related hospital admissions, especially for asthmatics associated with 1- and 24-hr average ambient SO_2 concentrations.

Given the conclusion in the 1st draft ISA that the evidence is inconclusive regarding the associations between long-term exposure to SO_2 and morbidity and mortality, we do not anticipate focusing on these long-term exposure-related health effects in the Tier II and/or Tier III assessments.

4.3 TIER II ASSESSMENT

As noted above, the type of health effects evidence providing the basis for concerns about respiratory-related outcomes associated with very short-term (i.e., 5 to 10 minute exposures) are fundamentally different from the type of health effects evidence that serves as the basis for concerns about respiratory-related effects associated with exposures on the order of 1 to 24-hours. More specifically, the evidence finding respiratory effects in asthmatics for very short-term exposures involves controlled chamber studies of exercising subjects generally exposed to SO_2 alone. For this type of evidence, one can more clearly attribute observed effects as being causally related to exposure to SO_2 and these studies also provide direct relationships between exposure to SO_2 and effects. In contrast, for health effects based on findings from epidemiologic studies, it is much more difficult to attribute the effects as being due to exposure to SO_2 and to sort out the relative contribution of SO_2 relative to the many other pollutants and possible contributors in an ambient real world setting. In addition, the epidemiologic studies do not provide a direct relationship between exposure and response, but rather provide relationships between ambient concentrations, as measured at fixed-site monitors, and response, which we refer to in this plan as *concentration-response* (C-R) relationships. Consequently, as described below, the approach to Tier II assessments is fundamentally different depending on whether the health effects identified as candidates for further quantitative treatment are based on evidence from controlled human exposure or epidemiologic studies.

In addition to consideration of the type of health effect relationship provided, there is a difference in the geographic unit of concern that also affects the approach taken in this risk assessment. If very short-term SO_2 exposures are of concern only at levels exceeding 0.5 ppm for 5 minute exposures, current air quality data from the fixed-site monitoring network suggest that these levels are most likely to occur around point sources and will not be observed in the routine urban area-oriented SO_2 monitoring network. Thus, concerns about very short-term peak exposures require a source-oriented focus, in contrast to concerns about 1- to 24-hr averaging time exposures to SO_2 which require a more urban area–oriented focus.

4.3.1 Approaches

Two different approaches to the Tier II assessment, depending on whether the evidence for a given health effect is based on controlled human exposure studies or epidemiologic studies, are described in this section. As noted above, the two different approaches also reflect a different focus in terms of geographic scope.

For respiratory health effects observed in controlled human exposure studies of excerising asthmatics exposed for very short durations (i.e., 5 to 10 minutes) to SO_2, the approach is similar to calculating a hazard quotient, which is the ratio of the air quality concentration or exposure concentration (either population-weighted or individual exposure depending on the Tier exposure assessment output) to the potential health effect benchmark concentration. Counts would be obtained for the number of times the various potential health effect benchmarks are exceeded. The estimation of short-term peak concentrations exceedances at all source- and population-oriented hourly ambient monitors generated from the air quality characterization provides a broad context for potential populations at risk of short-term peak exposures including both urban and non-urban locations (Section 3.2). A refined source-oriented exposure analysis, designed to address the occurrence of short-term peak SO_2 levels in the vicinity of major point sources, is also on a national scale, however would not be considered an urban-oriented analysis.

Based on our initial evaluation of the controlled human exposure studies in the draft ISA, we have identified bronchoconstriction in exercising asthmatics as a candidate health effect category for Tier II assessment. Moreover, we have tentatively identified potential health effect benchmarks in the range of 0.5 to 0.6 ppm (5-minute averaging time), and have identified asthmatics (children and adults) as the population group most at-risk from these potential SO_2 benchmark levels.

As noted in the section on Tier I above, several respiratory health effect categories have been identified as being the most strongly supported effects associated with ambient 1-hr and 24-hr SO_2 concentrations. These health effect categories include: respiratory symptoms, respiratory-related emergency department visits (particularly for asthmatics), and respiratory-related hospital admissions. Since epidemiologic studies generally consider the entire distribution of pollutant levels and report effect estimates in terms of a given response per unit change in pollution, one cannot develop potential health effect benchmarks directly from this type of study. Thus, a Tier II analysis for these health endpoints will involve a more extensive evaluation of the ambient air quality levels for SO_2 and co-pollutants, where possible, to see if there are any trends or patterns in the reported concentration-response relationships. Similar to the approach taken in the recent O_3 and PM NAAQS reviews, EPA will gather additional information to characterize the SO_2 ambient air quality that existed at the time the various key

U.S. and Canadian studies were conducted. The goal is to see if there are any patterns with respect to the levels and associated averaging times and the reported effect estimates across the studies reporting a given health effect. We will also examine the studies addressing these specific health effects to see if there are any differences with respect to geographic location and/or season. In addition, another goal is to evaluate whether there are any patterns in the reported C-R relationships with respect to the inclusion of various co-pollutants in the effect estimate models.

For the respiratory health effects associated with 1- to 24-hr averaging times that are based on the epidemiologic studies conducted in urban areas, the geographic focus of the assessment would use urban area SO_2 concentrations. As part of the air quality characterization, 1-hr ambient monitoring concentrations will be evaluated focusing on urban areas and considering several averaging times (e.g., 1-hr, 24-hr, and annual average concentrations).

4.3.2 Generated Outcomes

For the respiratory-related effects based on evidence from controlled human exposure studies for very short-term SO_2 exposures, outcomes would be the number of occurrences that air quality exceeds a potential health effects benchmark, as well as the number of times a population or an individual experiences an exposure of concern (EOC) in a given year, considering recent air quality levels and air quality levels just meeting the current and potential alternative SO_2 standards that may be considered. Frequencies would be given for each population subgroup analyzed and the particular locations of interest.

The outcome of the Tier II assessment for the respiratory-related effects based on evidence from epidemiologic studies providing effect estimates for 1- to 24-hr averaging time SO2 levels, will be more qualitative. We anticipate the presentation of this part of the assessment will include tables and/or graphs illustrating the existence or absence of any patterns found between concentrations at which various studies were conducted and health effect estimates.

4.3.3 Variability and Uncertainty

Variability in the context of the Tier II risk assessment can be described in terms of the empirical quantities and relationships that are important in estimating health risks and are inherently variable across time and space, or when considering a group of individuals (Cullen and Frey, 1999). For the initial Tier II screening level assessment that estimates the number of exceedances of alternative potential health effect benchmarks across all areas selected for the assessment, results for the individual locations incorporate and illustrate the variability due to differences in air quality patterns and distributions. A second phase of the Tier II level risk assessment would use the results of the Tier II exposure assessment to generate estimates of the number of people exposed to levels at or above the various potential health effect benchmark levels. Results for all areas included in this assessment would incorporate and reflect the variability in air quality and the variability in key inputs that may influence the estimation of population exposures including, but not limited to, the spatial pattern of the population, time-location-activity patterns, and proximity to local sources.

Consistent with the approach described above, a tiered approach to assessing uncertainty will be employed with the goal of progressing to a quantitative analysis if warranted and if data are available to support such an analysis. The first step in the uncertainty analysis would be to identify the components of the assessment that contribute the most to uncertainty. Sections 3.2.3 and 3.3.6 provide a preliminary qualitative evaluation for the uncertain components of the planned air quality analysis and exposure assessment, generally indicating the direction of influence (under- or over-estimate) on air quality concentration and exposure estimates that would be used in a Tier II health risk assessment.

In addition to uncertainties related to the air quality analysis and/or exposure assessment components of a Tier II risk assessment, there is uncertainty related to the potential health effect benchmark levels used in the assessment. The use of any specific potential health effect benchmark assumes that the level is appropriate for application to all susceptible individuals equally, between and within each population subgroup. Recognizing that there is both considerable variability in responsiveness and uncertainty associated with the use of any single potential health effect benchmark, a range of potential health effect benchmarks will be included in the Tier II assessments. This will allow the decision maker to gain insight into the impact that uncertainty about the level at which adverse health effects are likely to occur has on the Tier I estimates. From a directional perspective, we have confidence that higher potential health effect benchmarks are associated with susceptible individuals being adversely affected and that a larger fraction of the population is likely to experience adverse health effects. Conversely, we have less confidence that adverse health effects will occur at lower benchmark levels and a smaller fraction of the population is likely to experience adverse health effects.

4.4 TIER III ASSESMENT

As noted above, based on review of the scientific evidence from controlled human exposure studies regarding respiratory health effects associated with very short averaging times (5-10 minutes), we believe that there is insufficient information to develop credible *exposure-response* relationships for SO_2-related respiratory health effects for use in a quantitative risk assessment. Thus, the discussion below focuses on a possible Tier III assessment which would focus on respiratory health effects associated with 1- and 24-hr ambient SO_2 concentrations in urban areas based on evidence from epidemiologic studies.

As discussed above, based on evidence from epidemiologic studies, health responses most strongly related to SO_2 include respiratory symptoms in asthmatic children, asthma emergency department visits, and respiratory related hospital admissions. A risk assessment based on epidemiologic studies typically requires baseline incidence rates for the specific health endpoints to be analyzed and population data for the specific risk assessment locations.

4.4.1 Approach

As noted earlier in this plan, previous reviews of the SO_2 primary NAAQS completed in 1982, 1986, and 1994 did not include quantitative health risk assessments. Thus, the planned risk assessment described in this Scope and Methods Plan builds upon the methodology and lessons learned from the risk assessment work conducted for the recent PM and current O_3 NAAQS reviews (Abt Associates, 2005; Abt Associates, 2007). Many of the same methodological issues are present for each of these criteria air pollutants where epidemiologic studies provided the basis for the C-R relationships used in the quantitative risk assessment. The plans discussed below are based on the information and evaluation contained in the 1st draft ISA and some aspects of these plans may change based on CASAC and public comments on the 1st draft ISA and changes that will be incorporated in the 2nd draft ISA. The discussion below represents current staff thinking with respect to health effect endpoints that are candidates for inclusion in a possibleTier III risk assessment and those health endpoints for which there is insufficient evidence to warrant inclusion in a Tier III quantitative risk assessment.

4.4.1.1 Selection of Health Effect Endpoints

In selecting potential health endpoints to include in a Tier III risk assessment, staff plans to focus on health endpoints identified during the Tier I and II risk assessment that have well-defined health consequences (i.e., where there is consensus about the degree of response that represents an adverse health effect). In addition, we are focusing on health endpoint categories identified in the ISA where the weight of evidence supports the inference of a likely causal relationship. As discussed below, once we identify candidate health endpoints based on these criteria, there are additional factors that must be considered in deciding whether to proceed with a quantitative Tier III risk assessment. These include: (1) the likely utility of such information in the decision, (2) the availability of sufficient concentration-response data that is relevant to locations in the U.S., and (3) the availability of baseline incidence data for the health effects.

Based on the evaluation of the health effects evidence in the 1st draft ISA, the following health effect endpoints are judged to be the most appropriate candidates for developing quantitative risk estimates:

- Respiratory symptoms (e.g., cough, wheeze), particularly in children and asthmatics
- Respiratory-related hospital admissions, especially for asthmatics
- Respiratory-related emergency department visits, especially for asthmatics

Generally, for a Tier III quantitative risk assessment based on C-R relationships derived from epidemiological studies, it is preferable to use C-R relationships based on studies that were conducted in the same location chosen for the risk assessment. Using C-R relationships from studies conducted in locations different than the risk assessment locations introduces additional uncertainty into the risk assessment due to potential differences in population, SO_2 and co-pollutant air quality patterns, exposure patterns, and other factors that may have influenced the relationship between exposure to the pollutant of interest and the health effect outcome. Following review of the 1st draft ISA and considering any comments and recommendations by CASAC and the public, we plan to evaluate whether the existing epidemiological studies provide C-R relationships that are judged suitable for applying in selected U.S. urban locations.

4.4.1.2 Selection of Concentration-Response Functions

If a Tier III risk assessment is judged to be both feasible and of sufficient utility, then appropriate C-R relationships will have to be selected for inclusion in the assessment. Studies often report more than one estimated C-R function for the same location and health endpoint. Sometimes models include different sets of co-pollutants and/or different time lags. For some health endpoints, there are studies that estimated multi-city SO_2 C-R functions, while other studies estimated single-city functions.

As noted above, all else being equal, staff judges that a C-R function estimated in the assessment location is preferable to a function estimated in some other location, to avoid any uncertainties that may exist due to differences associated with geographic location. There are several advantages, however, to using estimates from multi-city studies versus from studies carried out in single cities. Multi-city studies are applicable to a variety of settings, since they estimate a central tendency across multiple locations. Multi-city studies also tend to have more statistical power and provide effect estimates with relatively greater precision than single-city studies due to larger sample sizes, reducing the uncertainty around the estimated health coefficient. Because single-city and multi-city studies have different advantages, staff plans to include both types of functions, where they are available.

Most SO_2 epidemiological studies include C-R functions in which SO_2 was the only pollutant entered in the model as well as other C-R functions in which SO_2 and one or more co-pollutants (e.g., PM, NO_2, CO, O_3) were entered into the health effects model (i.e., multi-pollutant models). To the extent that any of the co-pollutants present in the ambient air may have contributed to the health effects attributed to SO_2 in single pollutant models, risks attributed to SO_2 might be overestimated where C-R functions are based on single pollutant models. However, if co-pollutants are highly correlated with SO_2, their inclusion in an SO_2 model can lead to misleading conclusions in identifying a specific causal pollutant. When collinearity exists, inclusion of multiple pollutants in models often produces unstable and statistically insignificant effect estimates for both SO_2 and the co-pollutants. Given that single and multi-pollutant models each have both potential advantages and disadvantages, with neither type clearly preferable over the other in all cases, if a Tier III risk assessment is developed, staff plans to report risk estimates based on both types of models where both are available.

4.4.1.3 Baseline Health Effects Incidence Considerations

The most common epidemiological-based health risk model expresses the reductions in health risk (Δy) associated with a given reduction in SO_2 concentrations (Δx) as a percentage of the baseline incidence (y). Thus, information on the baseline incidence of health effects (i.e., the incidence under *as is* air quality conditions) in each location is needed. Where at all possible, staff plans to use county-specific incidences or incidence rates (in combination with county-specific population data). Staff is investigating whether recent baseline incidence data is available for respiratory-related emergency department visits and respiratory-related hospital admissions for potential assessment locations.

For respiratory symptoms, there may be no information on baseline incidence other than that reported in the original epidemiological study. We recognize that lack of recent location-specific incidence data will increase the uncertainty surrounding any risk estimates that may be generated in a Tier III risk assessment for this health endpoint.

4.4.2 Generated Outcomes

If a Tier III risk assessment were to be developed, both central tendency and 95% confidence interval estimates would be provided and such estimates would be expressed using several risk metrics. These risk metrics would include the estimated incidence (i.e., number of cases), percent of total incidence, and incidence per 100,000 relevant population for each health endpoint and location included in the assessment. Results would also be presented for just meeting any potential alternative standards identified for consideration.

4.4.3 Variability and Uncertainty

There are several uncertainties that affect the inputs to any Tier III SO_2 risk assessment based on C-R functions derived from epidemiological studies. These include uncertainties in the procedures used to simulate just meeting the current and potential alternative SO_2 standards, baseline incidence rates, and appropriate model form for the C-R relationships used in a risk assessment. There also is city-to-city variability in C-R relationships due to variability in air quality and exposure patterns and population differences. Presentation of separate risk results for selected example urban areas would incorporate and reflect variability in several key inputs to the health risk assessment (e.g., variability in air quality patterns and baseline incidence data).

Consistent with the approach used in the recent O_3 and PM NAAQS risk assessments, the uncertainty resulting from the statistical uncertainty associated with the estimate of the SO_2 health coefficient in the C-R function can be characterized by confidence intervals around the corresponding point estimates of risk. However, these confidence intervals only address sampling error and do not address broader uncertainties concerning the overall shape or form of the C-R relationships. As noted above, if a Tier III assessment is conducted, staff plans to include results using both single- and multi-city models, and single- and multi-pollutant models and C-R functions based on different epidemiological studies. Presentation of a range of results would provide decision makers with some perspective on the impact of alternative models and the degree of uncertainty associated with any risk estimates.

4.4 CRITERIA FOR DETERMINING APPROACH

The factors identified below will be considered in deciding whether to conduct a Tier III quantitative risk assessment.

- Outcome of the Tier I and Tier II risk assessments with respect to the magnitude of the estimated number of concentrations and/or exposures exceeding several potential health effect benchmark levels associated with current ambient concentrations and with SO_2 levels just meeting the current and any potential alternative standards that may be considered and kind and extent of the uncertainties associated with these estimates;
- Availability of information and data required to conduct a Tier III risk assessment, including baseline incidence data and concentration-response relationships that are judged suitable for applying in several example U.S. urban areas;
- The utility or value-added to the decision process of a Tier III risk assessment, beyond that provided by the Tier I and II assessments. For example, is a Tier III risk assessment likely to reduce or better characterize uncertainties in the characterization of SO_2-related health risks;
- The feasibility of conducting a credible Tier III risk assessment within the consent decree schedule and available resources.

4.5 BROADER HEALTH RISK CHARACTERIZATION

The exposure/health risk assessment document will include both summary air quality information for the U.S. and summary information and discussion of the various health effects identified in the 2nd draft ISA to help provide a broad context for the quantitative exposure and risk estimates that are provided in the Tier II and/or Tier III exposure and risk assessments. Thus, air quality statistics for all areas with SO_2 monitoring data will be presented to provide a broad perspective of potential populations at risk, considering several potential health effect benchmark levels for short-term peak concentrations. National scale information on the size of various at-risk populations will also be presented for where short-term peak concentrations/exposures may be of greatest concern, namely those individuals residing in close proximity to fossil-fueled emission sources.

5. SCHEDULE AND MILESTONES

Table 6 lists the key milestones for the risk/exposure assessment that will be conducted as part of the current SO_2 NAAQS review. Consultation with the CASAC NO_x/SO_x Panel is planned for December 5-6, 2007 to obtain input on the 1st draft ISA and this draft Scope and Methods Plan. Staff will then proceed to develop exposure and health risk estimates associated with recent SO_2 ambient concentrations and levels representing just meeting the current SO_2 standard. These estimates and the methodology used will be presented in the first draft SO_2 risk/exposure assessment and technical support documents. The draft report will be released for CASAC and public review in May 2008. EPA will receive comments on these draft documents from the CASAC NO_x/SO_x Panel and general public at a meeting in July 2008. A revised assessment, including assessment for just meeting potential alternative standards will be released in October 2008 for review by CASAC and public at a meeting to be held in December 2008. Staff will consider these review comments and prepare a final risk/exposure assessment by January 2009.

Table 2. Key Milestones for the Exposure and Health Risk Assessment for the SO_2 NAAQS Review.

Milestone	Date
Release 1st draft SO_x ISA	September 2007
Release 1st draft SO_2 Risk/Exposure Scope and Methods Plan	November 2007
CASAC/public review and meeting on 1st draft SO_x ISA	December 5-6, 2007
CASAC consultation on 1st draft SO_2 Risk/Exposure Scope and Methods Plan	December 5-6, 2007
Release 2nd draft SO_x ISA	April 2008
Release 1st draft of the SO_2 Risk/Exposure Assessment	May 2008
CASAC/public review and meeting on 2nd draft SO_x ISA and 1st draft of the Risk/Exposure Assessment	July 2008
Final SO_x ISA	September 2008
Release 2nd draft of the SO_2 Risk/Exposure Assessment	October 2008
CASAC/public review and meeting on 2nd draft of the SO_2 Risk/Exposure Assessment	December 2008
Final SO_2 Risk/Exposure Assessment	January 2009

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