Responses to Significant Comments on the 2009 Proposed Rule on the Primary National Ambient Air Quality Standards for Sulfur Dioxide (December 8, 2009; 74 FR 64810)

Docket Number OAR-2007-0352

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Table of Contents

Frequently Cited Documents

The following documents are frequently cited throughout EPA's response to comments, often by means of the short names listed below:

Integrated Science Assessment (ISA):

> EPA. (2008). ISA for Oxides of Sulfur - Health Criteria. National Center for Environmental Assessment, Research Triangle Park, NC. Available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=198843

Preamble to the final rule (final notice):

> Preamble to the Final Rule on the Review of the Primary National Ambient Air Quality Standards for Sulfur Dioxide; to be published in the *Federal Register* in June of 2010.

Proposal notice:

> Primary National Ambient Air Quality Standard for Sulfur Dioxide: Proposed Rule. 74 FR 64810, December 8, 2009.

Risk and Exposure Assessment (REA):

> EPA. (2009a). Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standard. Office of Air Quality Planning and Standards, Research Triangle Park, NC. Available at: http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_cr_rea.html

Acronyms and Abbreviations

A&B	Alexander & Baldwin, Inc.
AA	The Aluminum Association
ABR	Association of Battery Recyclers, Inc.
ACC	American Chemistry Council
AECT	Association of Electric Companies of Texas
AEPSC	American Electric Power Service Corporation
AERR	Air Emissions Reporting Requirements
AFPA	American Forest & Paper Association
AirQuality	AirQuality Research and Logistics
ALA	American Lung Association
ALA-SC	American Lung Association State Chapters
Alaska	Alaska Department of Environmental Conservation
Alexandria	City of Alexandria, Virginia
ACSBPP	Annapolis Center for Science-Based Public Policy
API	American Petroleum Institute
AQCD	Air quality criteria document
AQI	Air quality index
AQS	Air quality system
ASARCO	American Smelting And Refining Company
ASC	The Amalgamated Sugar Company
ATS	American Thoracic Society
BART	Best available retrofit technology
CAA	Clean Air Act
CAIR	Clean Air Interstate Rule
CASAC	Clean Air Scientific Advisory Committee
CBSA	Core-based statistical area
CE	Consumers Energy
CEM	Continuous emission monitor
CFR	Code of Federal Regulations
CIBO	Council of Industrial Boiler Owners
City of New York	City of New York Law Department, Environmental Law Division
CMAQ	Community multi-scale air quality
CO	Carbon monoxide
CRA	Corn Refiners Association
Delaware	Delaware Department of Natural Resources and Environmental Control
Dow	The Dow Chemical Company
DRSI	Dominion Resources Services, Inc.
Duke Energy	Duke Energy Corporation
ED visits	Emergency department visits
EDEC	Empire District Electric Company
EDF	Environmental Defense Fund
EEI	Edison Electric Institute
EGU	Electric generating unit, or electricity generating utility

EPA	Environmental Protection Agency
EPRI	Electric Power Research Institute
ExxonMobil	ExxonMobil Corporation
FEM	Federal equivalent method
FEV_1	Forced Expiratory Volume in the first second
First Energy	FirstEnergy Corporation
Florida	Florida Department of Environmental Protection
FR	Federal Register
FRM	Federal reference method
GAM	Generalized Additive Model
GCLC	Gulf Coast Lignite Coalition
GDI	Green Dubuque Inc.
Georgia	Georgia Department of Natural Resources
Golder	Golder Associates Inc.
Hamilton	Pepper Hamilton
Harris County	Harris County Public Health and Environmental Services
H-GAC	Houston-Galveston Area Council
Houston	City of Houston, TX
Illinois	Illinois Environmental Protection Agency
Indiana	Indiana Department of Environmental Management
Iowa	Iowa Department of Natural Resources/Iowa Department of Public Health
ISA	Integrated Science Assessment
JRSC	J.R. Simplot Company
KUC	Kennecott Utah Copper, LLC
KYDEP	Kentucky Department for Environmental Protection
LAER	Lowest Achievable Emission Rate
LEC	Lignite Energy Council
Louisiana Chemical	Louisiana Chemical Association, Louisana Mid-Continent Oil and Gas Association, and Louisana Pulp and Paper Association
Marathon Petroleum	Marathon Petroleum Company
MDUC	Montana-Dakota Utilities Co.
MIDNRE	Michigan Department of Natural Resources and Environment
Missouri	Missouri Department of Natural Resources, Air Pollution Control Program
MSCC	Montana Sulphur and Chemical Company Inc.
MWV	MeadWestvaco Corporation
NAAQS	National Ambient Air Quality Standards
NACAA	National Association of Clean Air Agencies
NAM	National Association of Manufacturers
NEI	National Emissions Index
NESCAUM	Northeast States for Coordinated Air Use Management
New Mexico	New Mexico Environment Department, Air Quality Bureau
NMA	National Mining Association
NO_2	Nitrogen dioxide
North Carolina	North Carolina Department of Environment and Natural Resources

NO_x	Nitrogen oxides
NPRA	National Petrochemical & Refiners Association
NRDC	Natural Resource Defense Council
NRECA	National Rural Electric Cooperative Association
NSR	New Source Review
Nucor	Nucor Corporation
NYSDEC	New York State Department of Environmental Conservation
NYDOH	New York State Department of Health
O_3	Ozone
Ohio	Ohio Environmental Protection Agency
PCA	Portland Cement Association
PE	Progress Energy
Pennsylvania	Pennsylvania Department of Environmental Protection
Pepper Hamilton	Pepper Hamilton
PM	Particulate matter
PM_{10}	Particulate matter with an aerodynamic diameter of less than 10 micrometers
$PM_{2.5}$	Particulate matter with an aerodynamic diameter of less than 2.5 micrometers
ppb	parts per billion
PPLC	PPL Corporation
ppm	parts per million
PSD	Prevention of significant deterioration
PWEI	Population weighted emissions index
RA	Regional administrator
RACT	Reasonable available control technology
REA	Risk and Exposure Assessment
RIA	Regulatory Impact Analysis
Rio Tinto	Rio Tinto Corporation
RMA	Rubber Manufacturers Association
RRI	RRI Energy, Inc.
RTA	Rio Tinto Alcan Sebree Works
RTC	Response to Comment
SC	Sierra Club
SER	Significant emission rate
SIDS	Sudden infant death syndrome
SIL	Significant impact level
SIP	State implementation plan
SMC	Significant monitoring concentration
SO_2	Sulfur dioxide
South Carolina	South Carolina Department of Health and Environmental Control
South Dakota	South Dakota Department of Environment and Natural Resources
SO_x	Sulfur oxides
Springfield	City of Springfield, MO
SAP	Ad Hoc Committee of Sulfuric Acid Producers
sRaw	Specific Airway Resistance

TAB	Texas Association of Business
Texas	Texas Commission on Environmental Quality
TXOG	Texas Oil and Gas Association
TFI	The Fertilizer Institute
tpy	tons per year
UARG	Utility Air Regulatory Group
URL	Upper range limit
USDOI	United States Department of Interior
Vermont	Vermont Air Pollution Control
WEACT	WE ACT for Environmental Justice (West Harlem Environmental Action, Inc.)
WHO	World Health Organization
Wisconsin	Wisconsin Department of Natural Resources

I. Introduction

This document, together with the preamble to the final rule on the review of the primary national ambient air quality standards (NAAQS) for sulfur dioxide (SO_2), presents the responses of the Environmental Protection Agency (EPA) to the public comments received on EPA's proposal of December 8, 2009, proposing revisions to the primary NAAQS for SO_2, as well as related proposed changes to the ambient air monitoring, reporting, and network design requirements for the primary SO_2 NAAQS. 74 FR 64810. All significant issues raised in timely public comments have been addressed. Where comments were submitted after the close of the public comment period, EPA has responded to the extent feasible.

Due to the number of comments that addressed similar issues, this response-to-comments document does not generally cross-reference each response to the commenter(s) which raised the particular issue involved, although commenters are identified in some cases where they provided particularly detailed comments that were used to frame the overall response on an issue.

The responses presented in this document are intended to augment the responses to comments that appear in the preamble to the final rule or to address comments not discussed in the preamble to the final rule. Although portions of the preamble to the final rule are paraphrased in this document where useful to add clarity to responses, to the extent any (unintended) ambiguity is introduced by this paraphrasing, the preamble itself remains the definitive statement of the rationale for the positions adopted in the final rule.

In many instances, particular responses presented in this document include cross references to responses on related issues that are located either in the preamble to the SO_2 primary NAAQS final rule, or in this Response to Comments document. In other instances the comment is appropriately addressed by the Agency's discussion in other parts of the record. All issues on which the Administrator is taking final action in the SO_2 primary NAAQS final rule are addressed in the SO_2 NAAQS rulemaking record.

Accordingly, this Response to Comments document, together with the preamble to the SO_2 primary NAAQS final rule and the information contained in the Integrated Science Assessment (ISA) (EPA, 2008), the Risk and Exposure Assessment (REA) (EPA, 2009a), and the Notice of Proposed Rulemaking should be considered collectively as EPA's response to all of the significant comments submitted on EPA's 2009 SO_2 primary NAAQS proposed rule. This document incorporates directly or by reference the significant public comments addressed in the preamble to the SO_2 NAAQS final rule as well as other significant public comments that were submitted on the proposed rule.

Consistent with the final decisions presented in the notice of final rulemaking, comments on the following topics are addressed in this document: the scientific evidence and exposure/risk information (section II); the adequacy of the current SO_2 standard to protect public health (section III); revisions to the current standard in terms of indicator (section IV.A), averaging time (section IV.B), form (section IV.C), level (section IV.D) and

retaining or revoking the current standards (section IV.E); revisions to the SO_2 monitoring network (section V); the air quality index (VI); the process for reviewing the standard (section VII); interpretation of the Clean Air Act (section VIII); implementation, designations, and exceptional (section IX); and on data handling (section X). Finally, comments related to the Regulatory Impact Analysis are addressed (section XI).

II. Responses to Significant Comments on the Scientific Evidence and Exposure/Risk Information

A. Comments on the controlled human exposure evidence

(1) ***Comment:*** Several industry groups (e.g., API, UARG, ACC, ASC, CE, AEPSC, ASARCO, NMA, EEI, RTA) commented that EPA does not provide justification for changing the conclusion in the 1996 review that adverse effects were based on SO_2 exposure concentrations that resulted in large decrements in lung function and moderate to severe respiratory symptoms in exercising asthmatics. That is, industry groups do not believe EPA has provided an adequate rationale for focusing the current review on moderate to severe decrements in lung function and/or respiratory symptoms ranging from mild (perceptible wheeze or chest tightness) to severe (breathing distress requiring the use of a bronchodilator). For example, UARG comments state:

> The genesis of this change is obscure. First, the Proposed Rule seems to postulate that the health risk to asthmatics who experience lung function effects without symptoms might be greater than the health risk to those who experience both symptoms and lung function decrements. See id. at 64816/2. It is simply implausible that a failure to experience symptoms is worse than having them. Second, the Proposed Rule points to advice from CASAC as justification for the focus on moderate as well as large lung function decrements. Id. at 64817/3. But the Administrator culls this advice from comments of individual CASAC members in the transcript of a CASAC meeting; it is not reflected in the letter from the complete CASAC that followed that meeting. Finally, the Administrator simply provides no explanation of why she now considers mild symptoms to be adverse health effects. Clearly, this does not constitute a reasoned analysis in support of the change to the definition of adversity (see comments provided by UARG, p.10).

Response: The commenters are correct that the ISA, and this review, focused on moderate or greater decrements in lung function in the presence or absence of respiratory symptoms in exercising asthmatics. With respect to the ISA, from individual level response data derived from controlled human exposure studies, the ISA characterized the number and percent of exercising asthmatics experiencing a $\geq$ 100% increase in specific airway resistance (sRaw) or $\geq$ 15% decline in forced expiratory volume in the first second (FEV_1). The results of this analysis indicated that exposure to SO_2 concentrations as low as 200 -300 ppb for 5 - 10 minutes resulted in approximately 5 - 30% of exercising asthmatics experiencing moderate or greater decrements in lung function (ISA, Table 3-1). In addition, at SO_2 concentrations $\geq$ 400 ppb, 20 - 60% of exercising asthmatics experienced moderate or greater decrements in lung function. Notably, at SO_2 concentrations $\geq$ 400 ppb the ISA noted that moderate or greater decrements in

lung function are frequently accompanied with reparatory symptoms, while at 200 – 300 ppb there is limited evidence of respiratory symptoms.

The decision in the ISA to focus on moderate or greater decrements in lung function with or without accompanying respiratory symptoms was *not*, as commenters contend, based solely on the advice of individual CASAC panel members. In part, as noted on page 3-4 of the ISA, this judgment reflects recent guidance provided by the American Thoracic Society (ATS, 2000). That is, the ISA states: "In their official statement, the ATS concluded that an air pollution-induced shift in a population distribution of a given health-related endpoint (e.g., lung function in asthmatic children) should be considered adverse, even if this shift does not result in the immediate occurrence of illness in any one individual in the population (ISA, p.3-4)." Thus, the ISA concluded that these updated ATS guidelines could reasonably be interpreted to indicate that moderate or greater decrements in lung function, even without respiratory symptoms, could be of public health significance. (See also response #5 below, explaining that EPA would reach the same conclusion without reference to the ATS Guidelines.) Notably, this focus was also in agreement with CASAC comments. In their consensus letter to the Administrator dated August 8, 2008, CASAC advised EPA to place more of an emphasis on SO_2 concentrations below 0.4 - 0.6 ppm (i.e. below 400 – 600 ppb), stating, *"The clinical and epidemiological studies warrant a stronger conclusion about health effects at lower levels."* This counsel was based in part on the fraction of asthmatics shown to experience *"…**moderate or greater decrements in lung function** at SO_2 concentrations as low as 0.2 – 0.3 ppm."* (Emphasis added.) Moreover, we note that this is in agreement with previous CASAC recommendations (Henderson 2006) and NAAQS review conclusions (EPA 2006, EPA 2007) indicating that moderate decrements in lung function can be clinically significant in some asthmatics. See Coalition of Battery Recyclers Association v. EPA, No. 09-1011 (D.C. Cir., May 14, 2010), slip opinion at 9 (reasonable for EPA to conclude that two IQ point loss is an adverse effect based in part on CASAC advice that such a decrement is significant).

The commenter's assertion that EPA's interpretation of the controlled human exposure studies is grounded in the view that not having symptoms is worse than having them is misplaced. First, neither EPA nor the ISA made that statement. That language does not appear at 74 FR 64816 (the citation given by the commenter). Nonetheless, EPA believes that focusing on only more severe respiratory symptoms observed in controlled human exposure studies would be inappropriate and not protective of public health. As discussed in the final ISA (p. 3-4 to 3-5), symptom perception is highly variable among asthmatics. This is particularly true in children, and may result in an increased risk of respiratory morbidity and mortality in those individuals who are poor perceivers of changes in pulmonary function, as they will be less likely to seek treatment. That is, individuals who experience moderate or greater decrements in lung function, but only mild or perhaps no respiratory symptoms at all are potentially at greater risk of developing hypoxia because they are less likely to seek medical treatment (as

noted by clinicians on the CASAC panel). Thus, it is possible that in some instances, a failure to have respiratory symptoms can lead to a more serious health outcomes.

(2) ***Comment:*** Several industry groups (e.g., API, UARG, ACC, ACSBPP, Nucor, AEPSC, ABR, ASARCO, NMA, Dow, NRECA, NPRA, A&B) generally commented that the effects reported in exercising asthmatics following exposure to 200 - 300 ppb SO_2 for 5-10 minutes should not be considered adverse by the Administrator. Commenters indicate that at 200 – 300 ppb, decrements in lung function reported in controlled human exposure studies in exercising asthmatics are not statistically significant, and they are not frequently accompanied by respiratory symptoms. Many of these groups indicate that EPA relied upon the advice of select CASAC members rather than consensus CASAC letters in determining adverse effects at 200 - 300 ppb SO_2.

Response: The commenters are correct that following 5-10 minute SO_2 exposures at 200- 300 ppb, the moderate or greater decrements in lung function experienced by some exercising asthmatics are not statistically significant at the group mean level or frequently accompanied by respiratory symptoms**.** However, we strongly disagree that these effects are not adverse to the health of asthmatics. EPA's rationale for considering health effects associated with 5-10 minute SO_2 exposures from 200- 300 ppb as adverse is based on consensus CASAC advice and recommendations, EPA's conclusions in previous reviews of other NAAQS, as well as ATS guidelines of what constitutes an adverse effect of air pollution. These considerations and similar comments are thoroughly described in sections II.B.1.a, II.E.2.b and II.F.4.b of the preamble to the final rule.

(3) ***Comment:*** A number of industry groups stated that it is inappropriate to analyze the effects of SO_2 in terms of percentage of asthmatics affected, and that it is better to conduct analyses on group mean data. Industry groups (e.g., API, MSCC, ACSBPP) also stated that effects below 400 ppb should not be considered adverse because compared to the number of asthmatics experiencing *decrements* in lung function, there were similar numbers of asthmatics experiencing *increases* in lung function. For example API states:

> EPA's conclusions about adverse effects in this range of SO_2 exposure relies on selective consideration of negative responses in lung function in only a few individuals from one tail of the tail response distribution while ignoring similar positive and apparently beneficial responses in lung function, an approach that is not scientifically defensible (see comments provide by API; p. 14).
>
> Similarly, ACSBPP commented that:
>
> …day-today variation in pulmonary function test results, with a small portion of increases and decreases that are as large as the metric uses for

moderate decrements. EPA needs to consider the day-to-day variation in pulmonary function for asthmatics that may be affected by changes in meteorology, personal activities, exposure to indoor irritants and allergens, etc. in the analysis (see comments provide by ACSBPP; p. 6).

Response: EPA strongly disagrees with the assertion that the analysis of percentage of asthmatics experiencing moderate or greater SO_2-induced decrements in lung function reflects only normal variation in lung function unrelated to SO_2 exposure. This analysis clearly shows an increase in the fraction of asthmatics affected with increasing SO_2 concentrations, an effect which has been consistently demonstrated across studies. EPA further notes that both the ISA and REA have specifically considered and discussed statistical analyses of mean changes (group data) in lung function resulting from controlled exposures to SO_2. See ISA at page 3-33, "Statistically significant decrements in lung function accompanied by respiratory symptoms including wheeze and chest tightness have been clearly demonstrated following exposure to 0.4-0.6 ppm SO_2. Although studies have not reported statistically significant respiratory effects following exposure to 0.2-0.3 ppm SO_2, some asthmatic subjects (5-30%) have been shown to experience moderate to large decrements in lung function at these exposure concentrations." In addition, in comments prepared and submitted to the docket for API, William Linn's analysis shows that, "…it is possible to pick out response data and statistical results from our studies that show significant ($P < 0.05$) pulmonary function changes at 0.2 ppm relative to control (filtered air, 0.0 ppm SO_2)," although Dr. Linn did not consider these effects to be clinically significant. EPA's conclusions from controlled human exposures to SO_2 have been drawn from an evaluation of both individual and group mean response data. As stated on page 3-9 of the ISA, "Among asthmatics, both the magnitude of SO_2-induced decrements in lung function and the percent of individuals affected have consistently been shown to increase with increasing exposure to SO_2 concentrations between 0.2 and 1.0 ppm."

The commenters correctly point out that at the lowest concentration tested in free-breathing chamber studies (0.2 ppm), there are a similar number of asthmatics experiencing a moderate or greater decrease in lung function (i.e., ≥ 100 increase in sRaw or ≥ 15 decrease in FEV_1) and experiencing what might be called a moderate improvement in lung function (i.e., ≥ 100 decrease in sRaw or ≥ 15 increase in FEV_1). This observation is consistent with data presented in Figures 4-2 and 4-3 of the ISA showing essentially no SO_2 -induced change in lung function at 0.2 ppm when averaged across asthmatics participating in the three cited studies conducted by William Linn**.** However, these figures also demonstrate that asthmatics who are sensitive to SO_2 at a higher concentration (0.6 ppm) experience, on average, a greater decrement in lung function at lower concentrations, including 0.2 ppm, when compared with all subjects combined. Therefore, while some asthmatics are relatively insensitive to SO_2-induced respiratory effects even at concentrations ≥ 0.6 ppm, there is clear empirical evidence that others experience significant bronchoconstriction following

exposures to both relatively high (0.6 ppm) and low (0.2 ppm) SO_2 concentrations. Among these SO_2-sensitive asthmatics, Figures 4-2 and 4-3 show a clear increase in bronchoconstriction with increasing SO_2 concentration from 0.2 - 0.4 ppm. Given this clear relationship of exposure and effect at all levels in the sensitive asthmatics (i.e. those who experienced significant decrements in lung function at the highest exposure concentration used (600 ppb)), EPA does not accept the commenter's premise that the results of the study do not demonstrate adverse effects. It should also be noted that significant effects have been observed at concentrations as low as 0.1 ppm (the lowest concentration tested) using mouthpiece exposure systems. Although these results cannot be compared directly with free-breathing chamber studies, they nonetheless provide valuable information regarding respiratory effects following exposures to low concentrations of SO_2. These studies provide evidence of bronchoconstriction directly attributable to SO_2 at the lowest concentrations tested among mild and moderate asthmatics**.** We further note that severe asthmatics could experience greater effects. See CASAC's consensus letter to the Administrator dated August 8, 2008, advising EPA to focus more on concentrations < 0.4 ppm, in part because, *"…severe asthmatics were not part of these clinical studies, but it is not unreasonable to presume that they would have responded to even a greater degree."*

EPA also notes that a variety of factors such as variability in baseline conditions, time of day, exercise, and the laboratory exposure setting itself may affect lung function responses in subjects participating in controlled human exposure studies. Recognizing the potential of these factors to alter pulmonary function, investigators expose study participants to pollutant(s) of interest and a control atmosphere, typically filtered air. Exposures are conducted at the same time of day under the same laboratory conditions. By randomly assigning the order of these exposures, bias in response is distributed between the exposure days and improves the ability to discern the "true" effect of a pollutant exposure. Therefore, the other factors affecting lung function mentioned by the commenter are, to the extent possible, already controlled for by the design of these studies (see ISA, p.1-4).

(4) ***Comment:*** Several industry groups (e.g., UARG, API, ACC, Nucor) and organizations (e.g., EPRI) generally argue that EPA is not applying the 2000 ATS adversity guidelines (ATS 2000) with respect to population risk appropriately. These groups argue that since the effects of SO_2 are transient and reversible within an hour, there is little chance of an asthmatic affected by these low levels of SO_2 having diminished reserve lung function when confronted by another stimuli (e.g. viral infection). Groups also argue that variations in lung function is a hallmark of asthma and that there is no indication that the most sensitive exercising asthmatics represent a distinct subpopulation that may be affected in the manner described in the ATS Statement.

Response: ATS guidelines were not meant to provide strict rules related to the differentiation between adverse and non-adverse health effects of air pollution. As stated in the guidelines, *"…the placement of dividing lines should be a societal judgment and consequently this committee does not propose specific boundaries for separating adverse from nonadverse effects."* Therefore, judgments regarding the adversity of effects following exposure to specific concentrations of SO_2 represent EPA's interpretation of the ATS guidelines. These judgments also reflect CASAC recommendations and conclusions drawn by EPA in previous NAAQS reviews (as described in final rule preamble sections II.B.1.a, II.E.2.b and II.F.4.b; see particularly final rule preamble section II.E.2.b and the response to Comment 5 in this section).

Moreover, although it is correct that the decrements in lung function caused by exposure to SO_2 in controlled human exposure studies have been shown to be transient, EPA disagrees with the assertion that there is little chance that an asthmatic would simultaneously be confronted by a secondary agent. Such exposure could very well occur, particularly considering the myriad of other stimuli known to affect lung function in asthmatics (e.g., allergens, cold air, coexposures to other pollutants—not just viral infections). In addition, those asthmatics with diminished reserve lung function caused by other factors such as an existing respiratory infection would be at higher risk of experiencing adverse respiratory effects if subsequently exposed to SO_2 notwithstanding the transient nature of SO_2-induced effects.

(5) ***Comment:*** Multiple groups (e.g., ACSBPP) indicated that the ATS guidelines (ATS 2000) regarding adversity due to a population shift for a given health endpoint do not apply to SO_2 effects because the ATS was referring to **permanent** decrements in lung function in a population.

Response: EPA disagrees with the commenters' interpretation of the ATS guidelines at the population level. The example given of an adverse effect at the population level given in the ATS Guidelines is as follows:

> A population of children with asthma could have a distribution of lung function such that no individual child has a level associated with significant impairment. Exposure to air pollution could shift the distribution toward lower levels without bringing any individual child to a level that is associated with clinically relevant consequences. Individuals within the population would, however, have diminished reserve function and are at potentially increased risk if affected by another agent, e.g., a viral infection. Assuming that the relationship between the risk factor and the disease is causal, the committee considered that such a shift in the risk factor distribution, and hence the risk profile of the exposed population, should be considered adverse, even in the absence of the immediate occurrence of frank illness (ATS, 2000; p. 668).

EPA does not believe that the above example was referring to a permanent loss in lung function. The Guidelines refer to permanent loss in lung function specifically when permanent effects are at issue, and further state that any permanent loss of lung function in an individual, or at the population level, is by definition an adverse effect:

> There is also epidemiologic evidence that air pollution may adversely affect lung growth or accelerate the age-related decline of lung function. Epidemiologic studies are limited in their power to detect such permanent effects and any evidence of association between air pollution exposure and permanent loss of function is indicative of an adverse effect at the population level. Some individuals may sustain clinically relevant, permanent losses of lung function. This committee considered that any detectable level of permanent lung function loss attributable to air pollution exposure should be considered as adverse. (ATS 2000; p. 671).

The example quoted above (p. 668) does not mention permanent effects, "diminished reserve function" is not an inherently permanent effect, and, since any permanent effect is already deemed adverse under the Guidelines, EPA believes that the example would have no point if it was referring only to permanent effects. Thus, EPA is reasonably interpreting this part of the Guidelines to indicate that certain non-permanent effects at the population level may be considered to be adverse.

Even without considering the 2000 ATS guidelines mentioned above, EPA would consider the asymptomatic decrements in lung function associated with 5- 10 minute SO_2 exposures as low as 200 ppb to be adverse. As described in the preamble to the final rule in sections II.B.1.a, II.E.2.b and II.F.4.b, these reasons include the conclusions drawn by EPA and CASAC in previous NAAQS reviews regarding the significance of decrements in lung function. That is EPA has stated that similar moderate or greater decrements in lung function (e.g., a $\geq$15% decline in FEV_1 and/or $\geq$ 100% increase in sRaw) in people with pre-existing respiratory disease could result in clinical outcomes such as increased medication usage and/or disruption of normal activities (see REA, section 4.3, p. 35-36) which would also be considered adverse effects of air pollution under ATS guidelines (ATS 1985). In addition to these conclusions and CASAC advice from previous NAAQS reviews, EPA considered the consensus advice from CASAC in the current SO_2 NAAQS review (Henderson 2008a; Henderson 2008b; Samet 2009; and final rule preamble sections II.B.1.a, II.E.2.b and II.F.4.b), as well as comments from individual clinicians on the CASAC panel during the current review (see final rule preamble sections II.B.1.a, II.E.2.b and II.F.4.b). See Coalition of Battery Recyclers Association v. EPA, No. 09-1011 (D.C. Cir., May 14, 2010), slip opinion at 9 (reasonable for EPA to conclude that two IQ point loss is an adverse effect based in part on CASAC advice that such a decrement is significant).

EPA finally notes that the current ISA also indicated that asymptomatic decrements in lung function can be clinically significant. The ISA states:

> …it is important to note that symptom perception is highly variable among asthmatics even during severe episodes of asthmatic bronchoconstriction. An asymptomatic decrease in lung function may pose a significant health risk to asthmatic individuals as it is less likely that these individuals will seek treatment (ISA, section 3.1.3; p. 3-4).

Taken together, along with the consideration that severe asthmatics were not included in the controlled human exposure studies described in the ISA, the Administrator would have reasonably considered moderate or greater decrements in lung function in exercising asthmatics to be adverse, even without considering the 2000 ATS guidelines mentioned above. That being said however, she finds that the 2000 ATS guidelines provide strong support for considering these decrements in lung function, even without accompanying respiratory symptoms, as adverse. In addition, for the reasons outlined above, the Administrator further notes that she does not believe that only repeated exposures to SO_2 should be considered adverse to the health of asthmatics.

(6) ***Comment:*** Several industry groups (e.g., API, UARG, ACC, CE) commented that EPA is incorrect in assuming that severe asthmatics would likely have a more pronounced response to SO_2 exposures at a given level, or would respond to even lower levels of SO_2. As support for their assertion multiple industry groups cite studies in the ISA stating that they included "severe asthmatics" as well as a study by Linn et al. (1987) concluding that among asthmatics, responses to SO_2 exposure are not dependant on the clinical severity of asthma and that "the subjects with the highest risk [of temporary respiratory disturbances from ambient SO_2] can be identified only be actually measuring their responses to SO_2."

Response: We disagree with the assertion that severe asthmatics have been evaluated in 5 - 10 minute controlled human exposure studies. These comments and EPA responses are discussed in detail in section II.E.2.b of the preamble to the final rule.

(7) ***Comment:*** EPRI generally commented that EPA is assuming that severe asthmatics were not included in controlled human exposure studies. However, EPRI contends that it is unlikely severe asthmatics would be exercising with the ventilation rates needed to be affected by SO_2.

Response: EPA strongly disagrees with the assertion that the most SO_2-sensitive asthmatics have been included in controlled human exposure studies. EPA recognizes that it is possible that the most severe asthmatics would be less likely to experience SO_2-induced bronchoconstriction due to exercise limitations. However, it is also possible that these asthmatics experience respiratory effects of SO_2 exposure at lower ventilation than is required to produce a response in

individuals with less severe disease. In addition, there is clearly a continuum of disease severity in the general population above the level of disease among those asthmatic subjects who participated in studies involving controlled exposures to SO_2. It is therefore very possible that a significant fraction of these more severe asthmatics would be capable of experiencing increases in minute volume which would increase the fraction of SO_2 reaching the tracheobronchial airways. This legitimate inference is supported by CASAC's consensus advice that, *"…severe asthmatics were not part of these clinical studies, but it is not unreasonable to presume that they would have responded to even a greater degree."* Henderson (2008b; p. vi).

(8) ***Comment:*** Multiple groups (e.g., ACSBPP, MWV, EPRI, Golder, AFPA, EEI, A&B) indicated that the respiratory effects of SO_2 are not adverse because they are transient, reversible and/or can be alleviated through the use of medication. Moreover, they are similar to the effects experienced by asthmatics in response to common stimuli such as cold air, or psychological stress.

Response: We agree that the respiratory effects of SO_2 are transient and reversible. However, we strongly disagree that this indicates that such effects are not adverse to the health of asthmatics. EPA further disagrees that effects following SO_2 exposure should not be considered adverse because they are similar to the effects experienced by asthmatics in response to common stimuli such as cold air. As noted above, judgments regarding the adversity of effects following SO_2 exposure are described in detail in sections II.B.1.a, II.E.2.b, and II.F.4.b of the preamble to the final rule. However, additional information is provided below.

Simply because the respiratory effects of SO_2 in exercising asthmatics are transient and similar to those experienced by asthmatics in response to commonly encountered stimuli (e.g., cold air), it does not mean that such effects should not be considered adverse to the health of asthmatics. That is, following SO_2 exposures $\geq$ 400 ppb, transient moderate or greater decrements in lung function are frequently accompanied by respiratory symptoms and this combination of effects would clearly be considered adverse under ATS guidelines (ATS 1985, ATS 2000). The observation that these respiratory effects are similar to those in response to commonly encountered stimuli does not change this conclusion.

In addition, following SO_2 exposures in the range of 200 - 300 ppb, controlled human exposure studies indicate that exposure to SO_2 can result in an appreciable percentage of exercising asthmatics experiencing moderate or greater decrements in lung function. Notably, CASAC indicated that such decrements in lung function can be clinically significant in some asthmatics. As with exposures at higher levels, the observation that these respiratory effects are similar to those in response to commonly encountered stimuli does not change the following conclusions: 1) these respiratory effects are the direct result of exposure to SO_2; and 2) these effects can be clinically significant in exercising asthmatics. We

finally note that any respiratory effect experienced by exercising asthmatics in response to SO_2 exposure would likely be in addition to those respiratory effects resulting from exposure to commonly encountered stimuli (that is, if co-exposure occurred). Thus, SO_2 exposure could reasonably be judged to increase the risk of a more serious respiratory outcome (e.g., an asthma attack) because it could potentially reduce even further, an asthmatic's lung function that has already been reduced by one or more commonly encountered stimuli.

With respect to the respiratory effects of SO_2 being alleviated through the use of medication, we note as discussed in the ISA (ISA, section 3.1.3.2), that some asthma medications have been shown to significantly reduce SO_2-induced bronchoconstriction. However, the ISA further notes that even among severe asthmatics, the disease is often poorly controlled *"…due to inadequate drug therapy or poor compliance among those who are on regular medication."* Furthermore, EPA agrees with the statement from the 1985 ATS guidelines that medication usage in potentially susceptible populations should not be used as a justification to allow for increased pollutant concentrations. In addition, the ATS has recommended that detectable effects of air pollution on clinical measures (e.g., medication use) be considered adverse effects of air pollution (ATS, 1985)

(9) ***Comment:*** Some health and environmental groups wanted more emphasis placed on mouthpiece studies at 100 ppb. For example ALA et al., stated:

> In its analysis of data from chamber studies in the ISA and in the REA, EPA focuses on studies of "free breathing" exposure. In doing so, EPA improperly and arbitrarily downplays important evidence that reported increased airway resistance, a measure of bronchoconstriction, in subjects with mild asthma at concentrations of 100 ppb. Regrettably, EPA does not rely on the mouthpiece studies in formulating its proposed standards (see comments provided by ALA et. al., p. 15)…. In downplaying the mouthpiece studies, EPA ignores the large segment of people who rely on oral or oronasal breathing some or all of the time (see comments provided by ALA et. al., p. 16).

Moreover, health and environmental groups note that effects at 100 ppb are backed up by studies in laboratory animals.

Response: These comments and EPA's responses were initially discussed in section II.F.4.b of the preamble to the final rule. However, EPA provides additional details below.

EPA carefully considered the mouthpiece studies and continues to believe that these studies are not a reasonable proxy for actual exposure. In these studies, SO_2 is delivered directly through the mouth, typically in conjunction with nasal occlusion. This allows a greater fraction of the inhaled SO_2 to reach the tracheobronchial airways. Although we agree with commenters that some

individuals do breathe oronasally both while at rest and during exercise, nasal ventilation still constitutes a significant percentage of total ventilation. The consequence is that individuals exposed to SO_2 through a mouthpiece are likely to experience greater respiratory effects from a given SO_2 exposure than they would in real life. Thus, as noted in the REA (REA, section 6.2) and in the proposal preamble (see section II.B.1.b), these mouthpiece studies only provide very limited evidence of decrements in lung function following exposure to 100 ppb SO_2. Therefore, the Administrator reasonably did not place great weight on these mouthpiece studies when considering the appropriate level of a 1-hour SO_2 standard. The commenters correctly point out that animal toxicology studies provide some evidence of an SO_2-induced increase in airway hyperresponsiveness at concentrations of 100 ppb. However, these effects were observed in only one species, and only following repeat SO_2 exposures.

(10) ***Comment:*** MSCC generally commented that while annual and daily SO_2 concentrations have fallen dramatically over the last 20 years, asthma prevalence has steadily increased. Thus, additional reductions in SO_2 are unlikely to produce additional public health benefits.

Response: EPA acknowledges that the etiology of asthma is complicated and likely involves multiple factors. However, EPA strongly disagrees with the assertion that additional reductions in SO_2 will not benefit the health of asthmatics. Numerous controlled human exposure studies have consistently demonstrated that exposure to 5-minute peaks of SO_2 causes decrements in lung function and/or respiratory symptoms in exercising asthmatics. Thus, limiting those 5-minute concentrations is very likely to produce public health benefits.

In addition, as noted throughout this NAAQS review, numerous epidemiologic studies have reported associations between SO_2 and markers of respiratory morbidity such as emergency department visits for asthma. Thus, it is similarly likely that limiting SO_2 concentrations to below those in the locations these studies were conducted will produce public health benefits.

(11) ***Comment:*** Rio Tinto generally commented that the ATS concept of enhancing the risk to a population to an unacceptable degree, without shifting the risks of any one individual to an unacceptable level is impractical. They note that taken to its logical conclusion, any concentration of SO_2 would decrease reserve lung function and be unacceptable.

Response: As noted in previous responses, ATS guidelines were not meant to provide strict rules related to the differentiation between adverse and non-adverse health effects of air pollution. As stated in the guidelines, *"…the placement of dividing lines should be a societal judgment and consequently this committee does not propose specific boundaries for separating adverse from nonadverse effects."* Therefore, EPA's judgments regarding the adversity of effects following exposure to specific concentrations of SO_2 represent our interpretation of the ATS

guidelines along with CASAC recommendations and conclusions drawn by EPA in previous NAAQS reviews (as described in final rule sections II.B.1.a, II.E.2.b and II.F.4.b and responses to comments in this document). Moreover, the effects involved in the clinical studies are not minimal. Exposure at the 200 ppb benchmark can result in moderate or greater decrements in lung function, evidenced by a ≥15% decline in FEV_1 and/or ≥ 100% increase in sRaw in an appreciable percentage of exercising asthmatics. As to the asserted inability to draw a line at any lung function decrement, the Administrator has rejected use of a 100 ppb benchmark and has placed minimal reliance on the (equivocal) evidence of lung function decrements associated with exposure at that benchmark level. The explanation for doing so (see section II.F.4.b of the preamble to the final rule) illustrates that there are reasonable means of differentiating between exposures which raise public health concern and those which do not.

B. Comments on the epidemiology

(1) ***Comment:*** A number of commenters (e.g., API, UARG, ACSBPP, MSCC, Springfield, NPRA) indicated that EPA relies on only 10 epidemiologic studies as a basis for its proposed revisions to the SO_2 NAAQS. Moreover, commenters indicated that the effects reported in these studies are small, sometimes null or negative and largely not statistically significant (ACSBPP specifically identifies studies by Peel et al., 2005, and Tolbert et al., 2007).

Response: First**,** EPA disagrees with the commenters that the Agency relied on only ten epidemiologic studies as a basis for the proposed revisions to the primary SO_2 NAAQS. Notably, the ISA's conclusion that there was sufficient evidence to infer a causal relationship between respiratory morbidity and short-term (5-minutes to 24-hours) exposure to SO_2 (ISA, section 5.2) is based on the consistency, coherence, and plausibility of findings observed in controlled human exposure studies of 5 - 10 minutes, epidemiologic studies mostly using 1-hour daily maximum and 24-hour average SO_2 concentrations, and animal toxicological studies using exposures of minutes to hours (id.).

With respect to the epidemiologic evidence, EPA notes that since the last review of the SO_2 NAAQS, there have been more than 50 peer-reviewed studies examining the relationship between SO_2 concentrations and emergency department visits and hospital admissions for respiratory causes published worldwide. Taken together, the ISA concluded that these studies provide evidence to support an association between ambient SO_2 concentrations and respiratory morbidity heath outcomes. (ISA, section 5-2, p. 5-5; see also ISA at p. 3-24) ["studies generally observed small, positive associations between ambient SO_2 concentrations and ED visits and hospitalizations, particularly among children and older adults"]; ISA, p. 3-27 ["In summary, small, positive associations were observed between ambient SO_2 concentrations and ED visits and asthma hospitalizations"]. The evidence from these studies is supported by additional panel studies of respiratory symptoms and medication use that demonstrate "consistent evidence of an association between ambient SO_2 exposure and increased respiratory symptoms in children, particularly those with asthma or chronic respiratory symptoms" (ISA p. 5-11). The ISA concluded that these epidemiologic studies were consistent and coherent. This evidence was consistent in that associations were reported in studies conducted in numerous locations and with a variety of methodological approaches (ISA, section 5.2; p. 5-5). It was coherent in that respiratory symptom results from epidemiologic studies of short-term (predominantly 1-hour daily maximum or 24-hour average) SO_2 concentrations were generally in agreement with respiratory symptom results from controlled human exposure studies of 5 - 10 minutes. These results were also coherent in that the respiratory effects observed in controlled human exposure studies of 5 - 10 minutes provided a basis for a progression of respiratory morbidity that could lead to the emergency department visits and hospital admissions observed in epidemiologic studies (ISA, section 5.2; p. 5-5).

In addition, the ISA found that when evaluated as a whole, SO_2 effect estimates in multi-pollutant models generally remained positive and relatively unchanged when co-pollutants were included. Id. Therefore, although recognizing the uncertainties associated with separating the effects of SO_2 from those of co-occurring pollutants (e.g., $PM_{2.5}$), the ISA concluded that the limited available evidence indicates that the effect of SO_2 on respiratory health outcomes appears to be generally robust and independent of the effects of gaseous co-pollutants, including NO_2 and O_3, as well as particulate co-pollutants, particularly $PM_{2.5}$ (ISA, section 5.3; p. 5-9; see also id. at p. 5-5).

Given the conclusions discussed above, the Administrator reasonably considered relevant air quality information available from locations where epidemiologic studies were conducted in determining the level of a revised standard. More specifically, in assessing the extent to which these studies and their associated air quality information could inform the level of a new 99th percentile 1-hour daily maximum standard for the U.S., air quality information from the U.S. and Canada was considered most relevant since these areas have similar monitor network designs and patterns of air quality. However, as described in proposal section II.F.4.a, SO_2 concentrations reported for Canadian studies were not directly comparable to those reported for U.S. studies due to the use of different monitoring protocols in those studies. Thus, the Administrator focused on 99th percentile air quality information available from locations where ten U.S. emergency department/hospitalization studies were conducted. However, we disagree with these commenters that the air quality information mentioned above was the sole basis for the range of levels proposed. The Administrator also considered the extent to which the level of a new 1-hour standard limited 5-minute concentrations/exposures of concern identified from controlled human exposure studies. Thus, in considering a reasonable range of levels to propose and in adopting the ultimate 75 ppm 1-hour standard, the Administrator considered the epidemiologic and controlled human exposure evidence, as well as the air quality, exposure and risk information.

We also generally disagree that epidemiologic effect estimates have to be large and/or statistically significant in order to be considered. When examining a large body of epidemiologic evidence, such as is available for the association of ambient SO_2 concentrations and respiratory morbidity, it is appropriate to evaluate the trend of the direction and magnitude of effect estimates and evaluate the consistency of the directions and magnitudes of these effect estimates when determining evidence for causality, rather than focus on the statistical significance of each individual effect estimate. As noted above, the ISA concluded that these epidemiologic studies were consistent and coherent (including the results from Peel et al., 2005 and Tolbert et al., 2007). Additionally, it is not necessary for the effect estimates to be large in magnitude to be considered to have a relevant public health impact. For example, a 1% increase in daily ED visits or hospital admissions in a single urban area due to increased ambient SO_2 concentrations translates into millions of annual excess ED visits and hospital admissions when

applied to the entire US population. Such increases are clearly relevant to public health. See Coalition of Battery Recyclers Association v. EPA, No. 09-1011 (D.C. Cir., May 14, 2010), slip opinion at 8 ("This assertion confuses the 'critical distinction between population and individual risk', wherein a small change … at the level of an individual is a substantial change at the level of a population").

(2) ***Comment:*** A number of commenters (e.g. API, UARG, ACC, ACSBPP, ABR, GCLC, CIBO, EEI) generally indicated that the results of epidemiologic studies are confounded by co-pollutants, and thus EPA cannot confidently identify SO_2 as the causative agent of the resulting health outcome (e.g., ED visits).

Response: EPA notes the response to this comment in section II.E.2.a of the preamble to the final rule. However, EPA provides additional information below.

EPA consistently recognizes that other pollutants are also associated with health outcomes, as is reflected in the fact that EPA has established regulations to limit emissions of the particulate criteria pollutants as well as other gaseous criteria pollutants. In its assessment of the health evidence regarding SO_2, EPA has carefully evaluated the potential for confounding, effect measure modification or other interactions between SO_2 and other criteria pollutants, and concluded that the results attributable to SO_2 are robust. See, e.g. ISA at pages 5-5 and 5-9.

To evaluate the potential for confounding in the epidemiologic evidence, EPA focused especially on studies which used two-pollutant models (SO_2 plus one other pollutant) as the inclusion of each additional pollutant in the model can decrease model stability and affect the precision of the effect estimate. This decrease in model stability is often reflected in wider confidence intervals, making it less likely for a statistically significant result to be observed. Thus, when a statistically significant effect estimate observed in a single pollutant model is no longer statistically significant in a copollutant model (even though the magnitude and direction of the effect estimate has not changed substantially), this may be an artifact of model instability.

Although the presence of other pollutants in the ambient air mixture complicates efforts to quantify specific SO_2-related health effects, a number of epidemiologic studies have evaluated associations with SO_2 in models that also include co-occurring pollutants such as PM, O_3, CO, and/or NO_2. The evidence summarized in the ISA indicates that SO_2 associations generally remain robust in these multi-pollutant models and supports a direct effect of short-term SO_2 exposure on respiratory morbidity (see ISA Figure 3-8). This evidence supports the effects observed in experimental (i.e., controlled human exposure) studies that have evaluated respiratory symptoms and lung function (see ISA section 3.1.6), which provide plausibility and coherence of these effects. As noted, the ISA (section 5.2) concluded that the robustness of epidemiologic findings to adjustment for co-pollutants, coupled with data from human experimental and animal studies,

support a determination that the relationship between SO_2 and respiratory morbidity is causal.

(3) ***Comment:*** Industry commenters indicate that many epidemiologic studies relied upon by EPA did not employ multi-pollutant models to address potential confounding. Several groups indicated that lack of potential confounding by PM was especially problematic. Some commenters (e.g., ASARCO) also indicated out of the over 50 peer reviewed epidemiologic studies evaluated by EPA, only two found a statistically significant association between SO_2 and emergency department visits when other pollutants were considered.

Response: Results in ISA Figure 3-8 indicate that the association of SO_2 with respiratory morbidity is robust to the addition of copollutants, including PM. While some individual studies may report specific findings that are more influenced by copollutants, Figure 3-8 clearly demonstrates the reasonableness of EPA's conclusion of robustness. See Schwartz (1995), Burnett et al., (1997), NY DOH (2006), Lin et al., ((2003), Sunyer et al., (1997), Anderson et al., (1998), Ito et al., (2007), Hajat et al., (1999), Tsai et al., (2006), all of which are studies showed results which remained statistically significant for SO_2 in two-pollutant models, many of which included PM.

(4) ***Comment:*** A number of industry commenters (e.g., API, UARG) indicate that EPA failed to discuss the only epidemiologic study looking at associations between hospital admissions for asthma, wheeze or shortness of breath and 5-minute SO_2 peaks (Donoghue and Thomas; 1999). Moreover, UARG indicates that EPA failed to account for a study by Erbas and Hyndman finding that "the effects of…sulfur dioxide were highly sensitive to model specification for both COPD and asthma [HAs]." UARG further states:

> The fact that EPA has failed to examine, or even acknowledge the existence of these studies after they were pointed out in public comments, is a striking indication that EPA has not fulfilled its duty under the CAA (see comments provided by UARG; p. 20).

Response: EPA has reviewed both of the studies identified by commenters. The first, by Donoghue and Thomas (1999) is riddled with a number of limitations that in EPA's view made it too unreliable to include in the ISA and REA. The limitations of this study include: 1) the statistical analysis included Poisson regression, and used GAM models and was conducted with S-Plus software. The study was published before Dominici et al. (2002) identified default GAM convergence issue and never reanalyzed, making it likely to be GAM impacted and hence unreliable (see EPA (2004), Air Quality Criteria for Particulate Matter, section 8.1.3.1 and 8.4.2 (EPA/600/P-99/002bF)); 2) The failure to present average, median, minimum or maximum SO_2 concentrations. Instead only the percent of days when the maximum 5-minute SO_2 concentration at any of the 10 SO_2 monitors exceeded 3 benchmark levels (800, 2145, and 5434 $\mu g/m^3$) is

presented. 3) The failure to present the number of hospital visits or hospital admissions included in analyses. 4) The temporal scale of the exposure data is 5-minute concentration, but temporal scale of outcome data is a 24 hour period. Thus, the precision of the 5-minute SO_2 concentrations is lost on the less precise 24-hour outcome data. For example, it isn't clear if the hospital visit or hospital admission occurred before or after the 5-minute SO_2 concentration was measured. 5) A seasonal effect (by month) was observed, but the study authors did not adjust for influenza hospital visits to account for this potential confounder/effect modifier.

Similarly, the study by Erbas and Hyndman (2005) was viewed by EPA to be too unreliable to include in the ISA and REA. The authors provide no information on the number of hospital admissions observed for COPD or asthma during the 3.5 year study period. Additionally, there is no information that characterizes the concentration of SO_2 during the study period.

(5) ***Comment:*** A number of commenters (e.g., API) indicate that EPA did not account for publication bias in the review of the SO_2 NAAQS

Response: EPA recognizes the possibility of publication bias, which can potentially occur in any field of study. In the discussion of the evaluation of epidemiologic studies, EPA observed that one of the advantages of multi-city studies is that "by their very nature can reduce uncertainty related to publication bias" (ISA, p. 3-1).

EPA does not agree that reported associations between SO_2 and health effects are an artifact of publication bias. EPA acknowledges that publication bias can result in potential overestimation of the estimated risk in a body of literature. However, for an individual study, factors such as exposure error or selection of results from an individual lag period from among several positive associations can result in underestimation of an effect estimate (i.e. a more pronounced bias in the other direction).

(6) ***Comment:*** A number of industry commenters indicated that EPA selectively presented results of epidemiologic studies. For example, API indicated that in the NYDOH (2006) analysis EPA selectively considered the positive associations in the Bronx NY, while not considering the negative associations in Manhattan (see comments by API; p. 17).

Response: EPA disagrees that the results of the NYDOH (2006) from the Bronx and Manhattan were presented selectively. Effect estimates from both locations are presented in Figures 3-7 (p. 3-26) and 3-8 (p. 3-29) of the ISA. Additionally, on page 3-25, the ISA states, "Another study conducted in New York City (NYDOH, 2006) found a 10% (95% CI 5, 15) excess risk in asthma hospital admissions per 10 ppb increase in 24-hour average SO_2 for Bronx residents, but a null association for the residents of Manhattan (-1% [95% CI: -11, 11])." EPA

fails to see how presenting effect estimates from both locations in the text and figures of the ISA constitutes a selective portrayal of the results. In addition, EPA notes that the REA and proposal included figures (see REA figures 5-2 and 5-3 and proposal figures 2 and 3) with results from both the Bronx and Manhattan study areas.

(7) ***Comment:*** A number of commenters (e.g., ACSBPP) argue that it is inappropriate for EPA to use the same epidemiologic analyses to suggest causal associations in reviews for multiple criteria pollutants. In general, these groups argue that the same epidemiologic analyses have been used to attribute health effects to O_3, PM, NO_2 and now, SO_2. This is likely leading to double, triple, or quadruple counting of health effects.

Response: EPA strongly disagrees that the agency is "double or triple counting" by attributing effects to SO_2 in the current review that are attributed to different pollutants in other NAAQS reviews. EPA consistently recognizes that other pollutants are also associated with health outcomes, as is reflected in the fact that EPA has established regulations to limit emissions of the particulate criteria pollutants as well as other gaseous criteria pollutants. In its assessment of the health evidence regarding SO_2, EPA has carefully evaluated the potential for confounding, effect measure modification or other interactions between SO_2 and other criteria pollutants, and concluded that the results attributable to SO_2 are robust (See Figure 3-8 on page 3-29 of ISA). The combination of this epidemiologic evidence with evidence from controlled human exposure and animal toxicological studies provides clear and convincing evidence of the specificity of these adverse respiratory effects to SO_2 exposure. Together, these lines of evidence are consistent and coherent, explain the temporal and biologic gradients observed, and provide biological plausibility for the observed effects. See also Air Quality Criteria for Particulate Matter (EPA, 2004) at 8-254, indicating how EPA distinguishes effects attributable to PM from those attributable to SO_2: "In many of these studies, PM with and without added components of gases thusly appears to be a key putative agent. However, care must be exercised in interpreting such results, taking into account what is known about the toxicology and clinical studies of the gases. It is often clear that these gases, at concentrations present of given the nature of the effects, do not carry sufficient biologic plausibility to substantially affect the results seen. For example, SO_2 is mostly absorbed in upper airways under normal breathing conditions and, although it might affect airway neural reflexes to contribute to asthma exacerbation at typical U.S. ambient levels, it is not likely to exert sufficient effects on COPDS or CVD to contribute to excess morbidity and mortality."

(8) ***Comment:*** Some industry groups (e.g., API, UARG, ExxonMobil) commented that reliance on central monitors in epidemiologic studies leads to a high degree of exposure misclassification. For example, UARG states: "when all of the co-pollutants are measured with error, robustness of the association of one pollutant

in multi-pollutant models is not sufficient to infer an absence of confounding (see comments provided by UARG; p. 18)

Response: As noted in Section 2.6.4 of the ISA, although EPA agrees that SO_2 measurements from central monitors is subject to potentially large measurement error when used to reflect population exposures in epidemiologic studies, the Agency disagrees with the suggestion that statistically significant associations between centrally monitored air quality concentrations and adverse health effects measured in these studies are invalid as a result. This section concluded that such measurement errors in community time-series and panel epidemiologic studies are more likely to underestimate the strength and the significance of any association between SO_2 and any adverse health effects observed in the study, thereby decreasing the likelihood of an association reaching statistical significance and likewise decreasing the possibility of a false identification of an association (Section 2.6.4.4, p. 2-63). Thus, the measurement error makes it more difficult to detect a positive and statistically significant effect estimate, even when such an association exists. Moreover, the signal that drives statistical associations between ambient concentrations and health effects in time-series studies is the day-to-day changes in concentration, not the absolute daily values. Appropriately located central SO_2 monitors can adequately characterize such day-to-day changes. Exposure studies have found statistically significant regression slopes between personal exposure to SO_2 and ambient SO_2 concentrations at fixed-site monitors (see ISA section 2.6.3.2, p. 2-56), indicating that fluctuations in ambient concentration are an important driver of fluctuations in SO_2 exposure.

Time-series epidemiologic studies evaluate associations between day-to-day changes in air pollution and health outcomes. Therefore, the measurement error argument cannot be used to nullify an effect that has been observed. If anything, as noted, it is likely that the real effects are likely to be larger than those that were estimated. Therefore, for the purposes of determining whether public health protection is warranted in light of the available evidence, EPA believes that it has interpreted the evidence from these epidemiologic studies reasonably.

(9) ***Comment:*** Some industry groups (e.g., UARG) indicate that there is no evidence from controlled human exposure studies to suggest that brief exposures to low concentrations of SO_2 could lead to hospital visits. For example, UARG states:

> Although no one would suggest that clinical studies could or should be conducted with the intent of sending people to the hospital, there is also no indication from the clinical studies of any population that would be susceptible to SO_2 such that a brief exposure to a low concentration could lead to hospital visits (see comments provided by UARG; p. 16)

Response: As described in Section 5.2 of the ISA (p. 5-2), the evidence from controlled human exposure, toxicological and epidemiologic studies for the respiratory health effects of SO_2 are consistent with the mode of action of SO_2 as

it is currently understood. The immediate effect of SO_2 on the respiratory system is bronchoconstriction. This response is mediated by chemosensitive receptors in the tracheobronchial tree. These receptors trigger reflexes at the central nervous system level resulting in bronchoconstriction, mucus secretion, mucosal vasodilation, cough and apnea followed by rapid shallow breathing. Asthmatics are more sensitive to the effects of SO_2 likely resulting from preexisting inflammation associated with this disease. This inflammation may lead to enhanced release of mediators, alterations in the autonomic nervous system and/or sensitization of the chemosensitive receptors. These biological processes are likely to underlie decreased lung function and increased hyperresponsiveness observed in response to SO_2 exposure.

The asthmatics participating in studies involving controlled exposures to SO_2 must be relatively healthy, and do not likely represent the most sensitive individuals in the population. Controlled human exposure studies include very small numbers of subjects, particularly when compared to the large populations considered in epidemiologic investigations. These populations do include the most sensitive individuals who are not eligible or willing to participate in controlled human exposure studies either due to study-specific inclusion or exclusion criteria, or self-selection. In addition, as presented in the ISA (p. 5-5) it is quite possible that effects observed in epidemiologic studies could be driven in large part by higher peak exposures within a 24-hour period. Thus, as noted in the ISA (id.), the effects of SO_2 on respiratory symptoms, lung function, and airway inflammation observed in the controlled human exposure studies provide a basis for the progression of respiratory morbidity resulting in increased ED visits and hospital admissions, especially among susceptible populations (i.e., asthmatics).

(10) ***Comment:*** Several industry commenters (e.g., UARG) indicated that there is a disconnect between effects seen at higher SO_2 concentrations in controlled human exposure studies and those observed at lower concentrations in epidemiologic analyses. For example, UARG states:

> EPA recognizes that human clinical studies 'provide directly applicable information for determining causality'" while for epidemiological studies "the degree of uncertainty introduced by confounding variables (e.g., other pollutants) affects the level of confidence that the health effects being investigated are attributable to SO_2 exposures." 74 Fed. Reg. at 64815/3 - 64816/1. Thus, the discrepancy between the nature of effects attributed to SO_2 in epidemiologic studies at ambient levels and those in clinical studies at much higher SO_2 concentrations must call into question the reliability of the epidemiological studies as evidence of effects from SO_2 exposure (see comments provided by UARG; p.17)

Response: Please see the response to the previous comment that characterizes the progression from the respiratory effects observed in controlled human exposure studies to those observed in epidemiologic studies. In addition, although the

concentrations investigated in controlled human exposure studies are higher than the mean concentrations reported in epidemiologic studies, it is important to note that epidemiologic studies conducted in the United States have reported associations between ambient SO_2 concentrations measured at area-wide monitors in the current network and increased respiratory symptoms, emergency department visits, and hospital admissions.

As noted in the ISA (Table 2-8, p. 2-33), 1-hour SO_2 concentrations measured at area-wide monitors in the United States have been observed in the range of 50 to 100 ppb, with maximum concentrations between 600 and 700 ppb. In addition, a very limited number of U.S. monitors report 5-minute SO_2 concentrations, and upper-percentile 5 minute concentrations at these monitors can be 200-300 ppb or higher (ISA, Figure 2-31, p. 2-44). Based on these considerations, EPA believes that the SO_2 concentrations that occurred in the locations of epidemiologic studies may have included concentrations that overlapped with those reported to cause respiratory effects in controlled human exposure studies.

(11) ***Comment:*** Several industry commenters (e.g. ACSBPP) indicated that EPA downplayed major findings regarding uncertainty due to model selection. For example, ACSBPP states:

> Model selection uncertainty relates to confounding of air pollutant associations by temporal trends, weather and co-pollutants. During the last ozone review, EPA acknowledged that the uncertainties in the estimates of pollutant effects are understated by consideration of the statistical uncertainty of the fitted model alone. Much more uncertainty arises from the lack of information regarding the choice of appropriate models for adjusting confounding by other covariates, and the choice of appropriate lag structures (see comments provided by ACSBPP; p.8).

Response: EPA has not ignored issues related to model specification for epidemiologic studies, such as selection of models and approaches to adjust for meteorological and temporal variables. As observed in the ISA (p. 3-1), extensive discussions of the issues surrounding model selection and model specification have been presented in the PM AQCD (EPA, 2004**)** and the O_3 AQCD (EPA, 2006) and are thus not reiterated at length in the ISA. The SO_X ISA makes clear, however, that these issues were carefully considered in selecting studies for inclusion in the ISA and interpreting the results of the body of epidemiologic evidence. Indeed, EPA went to great lengths to do so, placing special emphasis on the epidemiologic studies which remained statistically significant in two-pollutant models which included PM. See section II.F.4.e in the preamble to the proposed rule and section II.F.4.c in the preamble to the final rule.

(12) ***Comment:*** Several commenters (e.g. ACSBPP) indicate that EPA chose the best lag times from studies with multiple lag times to support it's assertion of a causal relationship between short-term SO_2 exposure and adverse respiratory effects.

Response: EPA reiterates that it believes in the importance of a comprehensive evaluation that considers and weighs a variety of evidence, including biological plausibility of associations between the various pollutants and health outcomes, and focuses on the stability of the size of the effect estimates in time-series studies considering both single- and multi-pollutant models, rather than just looking at statistical significance in a large number of alternative models as a basis to delineate between real and suspect associations. EPA finds that the approach of simply counting the number of statistically significant results across all models does not give adequate weight to important statistically significant results as a consequence. This has the effect of weighting all models equally, regardless of plausibility or statistical power, and it allows a lack of statistically significant results for one lag structure to essentially cancel out statistically significant results based on another lag structure. That is, EPA does not agree, for example, that a statistically significant association between emergency department visits for asthma and same day exposure to SO_2 should be completely discounted by a finding in the same study that an association between emergency department visits for asthma and SO_2 exposure several days prior to the ED visit is not statistically significant. Health effects associated with relatively more immediate exposures could well be the consequence of a biological mechanism that would not reasonably be expected to result in the same health effect several days after exposure. Thus, EPA does not believe that it is appropriate to simply average out statistically significant and nonsignificant results derived from models with different lags.

EPA has an established hierarchy for choosing which effect estimates will be presented in the text and figures of the ISA when effect estimates from multiple lag days are presented: (1) effect estimates from distributed lags; (2) effect estimates for the average of multiple days (e.g., 0-2); (3) a priori lag days selected by the study authors; (4) if only individual lag days were presented, the estimate with the highest magnitude and level of statistical significance is selected from among the biologically plausible lag days available.

(13) ***Comment:*** Commenters (e.g. ACSBPP) indicated that EPA did not discuss all of the results and/or all of the authors conclusions presented in the original publication (with regard to Sheppard 2003, Jaffe et al., 2003, Schwartz et al., 1996, Wilson et al. 2005, Anderson et al. 1998)

Response: EPA may not discuss the author's conclusions presented in the original publications because the interpretation of the results of a single study may differ greatly from the interpretation of a large body of evidence, which is what is evaluated and serves as the basis for causal determinations in the ISA. As mentioned in the response to epidemiology Comment 1, EPA evaluates the trend of the direction and magnitude of effect estimates and evaluates the consistency of the directions and magnitudes of these effect estimates when determining

evidence for causality, rather than focusing on the statistical significance of each individual effect estimate.

(14) ***Comment:*** ACSBPP indicated that there is a biologically implausible wide range of effect estimates in epidemiologic studies

Response: In responding to similar comments made with regard to the 2004 PM AQCD, EPA has recognized that in the expansive body of literature, especially in the multi-city studies, there appears to be spatial heterogeneity in city-specific excess risk estimates for relationships between short-term ambient SO_2 concentrations and acute health effects. The reasons for variation in effect estimates are not well understood. Factors likely contributing to the apparent heterogeneity include geographic differences in air pollution mixtures, and personal and sociodemographic factors potentially affecting SO_2 exposure.

The commenters focused on multi-city results (e.g., Sunyer et al., 2003; Barnett et al., 2005; Ballester et al., 2006), and raised a series of technical issues with the analytical approaches used, including the use of a standard analytical approach that did not allow for city-specific modeling of factors such as meteorology that likely vary from city to city, and the fact that many multi-city studies have combined results from communities with fewer available data that would likely not have been considered adequate for use in single-city analyses. Beyond the fact that these studies were conducted in Europe (Sunyer et al. 2003), Australia (Barnett et al. 2005), or focused on cardiac hospital admissions (Ballester et al. 2006), and thus did not play a large role in the current regulatory process, the EPA does not agree that the issues raised diminish the value of these analyses.

Another key factor that contributes to heterogeneity or variation between areas is a study's statistical power. EPA observes the importance of statistical power for interpreting these results, and EPA agrees that it is reasonable to focus on results from studies with greater power. Despite there being some evidence for greater variation in magnitude and precision of SO_2-health associations between geographic areas, EPA concluded in the ISA that the extensive body of epidemiology evidence demonstrated "an association between ambient SO_2 concentrations and ED visits and hospitalizations for all respiratory causes, in particular among children and older adults (65+ years), and for asthma." (EPA, 2008, p. 3-28)

(15) ***Comment:*** Some groups generally remarked that the term "robust" in the ISA is not used consistently or systematically across NAAQS reviews. For example, ACSBPP stated:

> In one instance, the ISA indicates that the term robust is used to indicate that there was little change in the magnitude of the central estimate, though statistical significance may have been lost. Since EPA is using similar methods to evaluate the epidemiology for other criteria pollutants,

it is appropriate to consider the criterion for robustness used in other ISAs. In the draft CO ISA, EPA uses the fact that the association remains positive in copollutant models to define robustness. (see comments provided by ACSBPP; p. 19)

Response: The term "robust" is used consistently throughout NAAQS reviews to indicate that results were essentially the same regardless of the manner in which the statistical models were specified. Statistical significance of the results is not considered in the application of the term "robust".

(16) ***Comment:*** EPRI generally commented that EPA should consider that all of the epidemiologic studies employed linear models that do not examine the possibility of a threshold at which health responses may occur.

Response: EPA evaluated the concentration-response function and potential thresholds in Section 4.1 (p. 4-1 to 4-7) of the ISA. The ISA concluded that a clear increase in the magnitude of respiratory effects was observed with increasing exposure concentrations between 0.2 and 1.0 ppm during 5-10 minute SO_2 exposures in controlled human exposure studies. The ISA also noted that the concentration-response function between short-term exposure to SO_2 and respiratory morbidity could not be distinguished from linear across the entire concentration range. Population-level studies did not indicate a possible threshold, though due to limitations associated with observing a possible threshold in these studies the limited evidence was determined to be inconclusive regarding the presence of an effect threshold at current ambient levels.

(17) ***Comment:*** With respect to the epidemiologic evidence, MSCC commented:

> There are other factors that may positively associate with increased levels of admissions and with increased levels of SO_2 (if SO_2 is present) – gusty, windy days, particulate loads, pollen, ambient temperature effects, patient activities, even days of the week, to name a few. Further, for such studies, the monitored levels, do not likely indicate the concentrations of actual SO_2 exposure for the population, but at best a subset of any constrained very near the monitor(s). **An association that is sometimes negative, sometimes positive, and rarely significant, is not compelling to use to conclude a direct cause/effect relationship** (see comments provided by MSCC; p.5)

Response: EPA evaluates each of the epidemiologic studies to ensure that potential confounding variables, including meteorological variables and day of week, are included in time-series studies of ED visits and hospital admissions to determine whether observed health effects are associated with air pollutant concentrations and not with these potential confounders. A time-series study that does not account for these potential confounders would have a difficult time

getting accepted for publication in the peer-reviewed literature, and if it did, would not be included as evidence in the ISA.

EPA disagrees that exposure measurement error is cause to ignore the observational evidence from epidemiologic evidence, and again reiterates (see response to epidemiology Comment 1) that the ISA's conclusion that there was sufficient evidence to infer a causal relationship between respiratory morbidity and short-term (5-minutes to 24-hours) exposure to SO_2 (ISA, section 5.2) is based on the consistency, coherence, and plausibility of findings observed in controlled human exposure studies of 5 - 10 minutes, epidemiologic studies mostly using 1-hour daily maximum and 24-hour average SO_2 concentrations, and animal toxicological studies using exposures of minutes to hours (id.).

(18) ***Comment:*** Some groups indicate that there is no evidence to suggest that children or older adults may be at increased risk of experiencing adverse respiratory effects following SO_2 exposure.

Response: The ISA concludes that there is "limited epidemiologic evidence to suggest that children and older adults (65+ years) are more susceptible to the adverse respiratory effects associated with ambient SO_2 concentrations when compared to the general population" (ISA, pg. 4-14). Specifically, on page 4-12, the ISA states:

> "A number of studies, investigating the association between ambient SO_2 levels and ED visits or hospital admissions for all respiratory causes or asthma, stratified their analyses by age group. Figure 4-6 summarizes the evidence of age-specific associations between SO_2 and acute respiratory ED visits and hospitalizations. Several studies demonstrated that excess risk of ED visits or hospitalizations for all respiratory causes was higher for children (e.g., Atkinson et al., 1999a; 1999b; Petroeschevsky et al. 2001) and older adults (e.g., Petroeschevsky et al., 2001; Wilson et al., 2005; Wong et al., 1999) when compared to the risk for adults or all ages together. This is more clearly depicted in the summary density curves in Figure 4-7 and Figure 4-8, created using the effect estimates presented in Figure 4-6. As shown in these two figures, the effect estimates for children and older adults are slightly larger than that for adults or all ages for both all respiratory diseases and asthma ED visits and hospitalizations."

C. Comments on the air quality, exposure, and risk analyses

(1) ***Comment:*** Several commenters (e.g., API, UARG, ACSBPP, ACC, JSRC, ABR, ASARCO, GCLC) indicated that it was inappropriate for EPA to 'degrade" current air quality to just meet the current 24-hour and/or annual standards. Industry groups argue that there is no plausible scenario that could lead to current

air quality, which is well below the current standards, regressing back to "just meeting" the current standards.

Response: EPA disagrees with the commenters. In determining whether the current primary standards are requisite to protect public health with an adequate margin of safety, EPA finds that it is appropriate to consider exposures and risk associated with air quality that has been adjusted to just meet the current standards. Similar comments and EPA's responses are discussed in detail in section II.E.2.c of the final rule preamble.

(2) ***Comment:*** Several commenters (e.g., API, UARG, ACSBPP, ACC, CE, TXOG, JRSC, ABR, ASARCO, NRECA) indicated that it was inappropriate for EPA to compare exposure and risks associated with just meeting alternative 1-hour standards to those just meeting the current SO_2 standards. These groups argue the more relevant comparison to just meeting alternative 1-hour standards (or the current standards) is to the exposure and risk associated with "as is" air quality, which is well below the current SO_2 standards. Moreover, these groups argue that if this comparison is done, there is little to no benefit to public health by adopting a 1-hour standard in the proposed range.

Response: The response to this comment follows the same logic as that outlined in the preceding comment. Thus, EPA disagrees with the commenters that it is inappropriate to consider exposures and risk associated with air quality that has been adjusted to just meet the potential alternative standards in assessing what potential NAAQS could protect public health with an adequate margin of safety. Similar comments and EPA's responses are discussed in detail in section II.E.2.c of the final rule preamble.

(3) ***Comment:*** Several commenters (e.g., API, UARG, FE, MSCC, AECT, NAM) indicated that the proposed alternative standards are not necessary because SO_2 emissions and/or ambient levels have fallen dramatically over the years and will continue to do so. Many of these groups also point out this will result in diminished risk estimates associated with ambient SO_2 concentrations as well (which industry groups point out are already small).

Response: As described in detail in final rule section II.E.2.c, EPA is required to review whether the present standards – not present air quality – are requisite to protect public health with an adequate margin of safety. Section 109 (b) (1). Similarly, EPA may not consider projected future air quality and its associated risks when reviewing the adequacy of the current standards to protect public health with an adequate margin of safety.

(4) ***Comment:*** Several commenters (e.g., ACSBPP) generally indicated that the only relevant approach to assessing risks associated with SO_2 exposure are those in the risk assessment chapter of the REA (Chapter 9). These groups argue that the air quality and exposure analyses presented in Chapters 8 and 9 of the REA

substantially overestimate risks associated with SO_2 exposure because they do not account for the fact that not all exposed asthmatics at elevated ventilation rates will experience a lung function response. Moreover, if only the results of the risk assessment are taken into account, one would see that there is very little risk of a lung function response in exposed asthmatic children at 150 ppb and above.

Response: EPA disagrees with the commenters that primary emphasis should be placed on the results of the quantitative risk assessment when assessing the extent to which the current and potential alternative standards limit 5-minute benchmark exposures of potential concern and their associated health effects. As described in the REA (Chapters 7-9) and the proposal (section II.C), EPA used three different approaches (i.e., air quality analysis, exposure analysis, and quantitative risk assessment) for assessing exposures and risks associated with these 5-minute benchmarks identified from controlled human exposure studies. Rather than relying on just one of these approaches, EPA recognized that each of these analyses has strengths and limitations (see proposal preamble section II.C) and thus, reasonably considered the results of all of these analyses (albeit to different extents, see below) to evaluate the extent to which the current, and potential alternative 1-hour standards limit exposure and risks associated with these 5-minute benchmark concentrations (see proposal preamble sections II.E.1.b and Tables 2 – 4).

As noted in the final rule's preamble (section II.E.2.c) however, the Administrator did place relatively more weight on the results of the St. Louis exposure analysis than she did on the results of the St. Louis quantitative risk assessment. EPA notes the results of the quantitative risk assessment likely have greater uncertainty than the results of the exposure analysis considered alone. That is, because the results of the exposure analysis are used as inputs into the quantitative risk assessment, the risk assessment will have all the uncertainties of the exposure analysis (see proposal preamble section II.C; 74 FR at 64823 and REA, section 8.11), as well as the additional uncertainties inherent in the quantitative risk assessment (see proposal preamble section II.C; 74 FR at 64823 and REA, section 9.4). EPA finally notes that the Administrator's proposed and final decisions with regard to the adequacy of the current standards and the elements of a new short-term standard appropriately placed substantial weight on the epidemiologic and controlled human exposure evidence presented in the ISA.

As discussed above, EPA believes that it would be inappropriate to consider only the results of the quantitative risk assessment. Thus, we believe the commenter's contention of relatively little risk of an adverse lung function response given a 1-hour standard level of 150 ppb is not compelling in isolation. We believe that this is especially true given that the St. Louis exposure analysis estimates that a 1-hour standard at 150 ppb would only protect about 88 percent of asthmatic children at moderate or greater exertion in that city from experiencing at least one exposure per year greater than or equal to the 200 ppb 5-minute benchmark exposure of concern.

(5) ***Comment:*** Several commenters (e.g. ACSBPP) generally indicated that the risk estimates presented in Chapter 9 of the REA and in the proposal are substantially overestimated because they only consider decrements in lung function, independent of whether there were accompanying respiratory symptoms.

Response: EPA disagrees that the quantitative risk estimates presented in Chapter 9 are substantially overestimated because they only consider decrements in lung function, independent of whether they were accompanied by respiratory symptoms. As noted above (see section II.A), and in detail in final rule preamble section II.E.2.b, EPA considered moderate or greater decrements in lung function, even without accompanying respiratory symptoms to be adverse effects of SO_2 exposure. Thus, EPA believes that it was reasonable to consider the decrements in lung function health endpoint in its quantitative risk assessment.

(6) ***Comment:*** Some commenters generally indicated (e.g., ACSBPP, TAB) that the scenarios under which an asthmatic at elevated ventilation (e.g., while exercising) is likely to come into contact with an SO_2 benchmark concentration of concern is exceedingly rare and therefore not a public health issue appropriate for a NAAQS. In addition, some of these groups indicated that there were few monitored 5-minute SO_2 levels above 5-minute benchmark concentrations of concern. For example, ACSBPP indicates that Figure 7-19 of the REA shows that only a portion of the available monitors with 5-minute concentrations have exceedences of the various benchmarks, and at monitors with these exceedences, values above 400 ppb are very rare (comments by ACSBPP; p. 27).

Response: EPA disagrees with these comments. EPA first notes the results of the St. Louis exposure analysis indicating that numerous asthmatic children at moderate or greater exertion (e.g., while exercising) in St. Louis are estimated to experience at least one exposure per year above the 5-minute benchmark concentrations of concern identified from controlled human exposure studies (see REA Figure 8-19 and proposal Table 3 at 74 FR 64841). For example, if air quality is simulated to just meet the current standards in St. Louis, approximately 24% and 73% of asthmatic children at moderate or greater exertion are estimated to experience at least one exposure per year above the 400 and 200 ppb benchmark exposures of concern, respectively. Id.

In addition, the figure referenced by the commenter describes the number of days/year measured 5-minute SO_2 concentrations from 98 monitors in 13 states from 1997 -2007 exceeded 5-minute benchmark concentrations identified from controlled human exposure studies. We first note that this subset of monitors that reported measured 5-minute SO_2 concentrations was relatively small. That is, over the same time frame, there were 933 monitors in 49 states, the District of Columbia, Puerto Rico and the Virgin Islands measuring 1-hour SO_2 concentrations. In addition, most of the monitors that did measure 5-minute concentrations only did so for a limited span of time, ranging from only several

hundred, to at most, a few thousand hours in a year. REA Appendix A, Table A.5-1. Furthermore, it is important to consider that those monitors reporting 5-minute concentrations do not represent data from a dedicated 5- minute monitoring network, but rather a voluntary submission of 5-minute values from existing monitors placed for the purpose of evaluating attainment of the 24-hour and annual average SO_2 NAAQS, which does not require monitoring at locations of expected maximum concentrations (much less maximum 5-minute concentrations). Thus, there is considerable uncertainty that the relatively few monitors reporting 5-minute SO_2 concentrations were sited in the proper locations to record 5-minute peaks of SO_2 above benchmark values.

Notwithstanding these decidedly non-optimized monitoring conditions, approximately 2% of the monitored days (approximately one week in a year) exceeded the 200 ppb benchmark. REA p. 120. EPA regards this amount of potential exposure to be significant. See also American Lung Ass'n v. EPA, 134 F. 3d 388, 392 (D.C. Cir. 1998) (noting facts in previous review that "'repeated' exposure is 'significant' and that thousands of asthmatics are exposed more than once a year"). Indeed, this comment appears to raise the same issue as that presented in the previous review: are repeated SO_2 exposures resulting in adverse effects to a susceptible population a public health problem, even if the exposures are confined to relatively localized areas. American Lung Ass'n v. EPA, 134 F. 3d at 392. The D.C. Circuit rejected the argument that such exposures were not a public health problem by virtue of being localized and infrequent, noting that hundreds of thousands of asthmatics were exposed to these events annually, and remanded the standard to EPA for want of a satisfactory explanation. The facts here, as set out in the REA, indicate that the current standard allows exposures exceeding health benchmarks (the benchmarks of 200 ppb and 400 ppb), in multiple areas and occurring on multiple days. See, e.g. REA Figure 7-19; see also CASAC letter of May 18, 2009 at p. 15 ("The panel agrees that the current 24-hour and annual standards are not adequate to protect public health, especially in relation to short term exposures to SO_2 (5-10 minutes) by exercising asthmatics.") This risk-based information is one of the reasons EPA is determining that the present standards are not requisite to protect public health with an adequate margin of safety

(7) ***Comment:*** UARG commented on the documentation and replicability of the data set used for the air quality data analyses. Concern was expressed regarding the number of monitors available and number of 5-minute and hourly measurements used in their analyses versus those used by EPA.

Response: We have responded to this comment on the 1st draft REA by improving the documentation of the raw data sets used and the screening procedure to generate the final data set used for developing the PMR statistical model. See REA section 7.2.1, pages 73-766. In this section, there are descriptions regarding the types of data used for the air quality analyses including: 1) monitors reporting 5-minute maximum SO_2, 2) monitors reporting continuous

5-minute SO_2 concentrations and, 3) monitors reporting 1-hour SO_2 concentrations. Briefly, all ambient monitoring data were downloaded from EPA's Air Quality System (AQS). The processing of each data set is then adequately described given criteria for inclusion or exclusion from the final data set used for analysis. A final combined data set was constructed by EPA to maximize the number of 1-hour measurements that also had corresponding 5-minute maximum concentrations. It was this final data set that was used to construct a statistical model used to predict 5-minute maximum concentrations from 1-hour concentrations.

(8) ***Comment:*** A few commenters (ACC, UARG, API) requested improved documentation of and justification for the approach used to adjust ambient air quality data to simulate just meeting the current and alternative standards.

Response: EPA has expanded the discussion regarding the proportional method used to adjust the air quality data (REA, section 7.2.4) and benchmark levels (REA, section 8.8.3), each justified by analyses conducted by Rizzo (2009). A comparison between historical, high concentration monitor data and recent, low concentration monitor data indicated that changes have occurred in a mostly proportional manner, giving support for the proportional method used to simulate alternative air quality scenarios.

(9) ***Comment:*** ABR and ASARCO commented on the approach used to estimate 5-minute maximum concentrations from 1-hour average SO_2 concentrations. More specifically, concern was expressed regarding the peak-to-mean (PMR) ratios developed from a subset of ambient monitors and their application to the broader ambient monitoring network. These commenters claim that "if the characteristics and micro-scale conditions of the small subset of 5-minute concentration monitors, which significantly influence measured concentrations, differ from the broader monitoring network, then the estimated exposures are not accurately represented." Differences in two identified ambient monitor characteristics (i.e., monitor objective and surrounding emission sources) are described by the commenters as either "increasing the uncertainty" in applying calculated PMRs to the broader monitoring network and leading "to an overestimation of exposures to SO_2."

Response: EPA evaluated the attributes of both the ambient monitors that report 5-minute SO_2 concentrations and those monitors that report only 1-hour average concentrations (REA, section 7.2.2) and did so using several physical characteristics including monitor objective, scale, land-use, and setting; types of emission sources within 20 km of a monitor; and the population residing with 5, 10, 15, or 20 km of a monitor. EPA acknowledged any differences where present, though in general, the composition of monitors from the two data sets was very similar regarding each of these physical attributes. EPA feels that the qualitative evaluation performed was a reasonable and informative comparison.

EPA is well aware of the greater percentage of monitors identified as having a source-oriented objective among the monitors that reported 5-minute concentrations. EPA also recognizes that there can be high concentrations and significant concentration variability measured at these source-oriented monitors. This is the primary reason for developing a statistical model based on an ambient monitor's concentration variability and the 1-hour concentration level (REA, section 7.2.3). The statistical model was designed to use information and relationships derived from the 5-minute measurements and appropriately assign PMRs to 1-hour concentration measurements. EPA calculated the coefficient of variation (COV) at each ambient monitors and used that to categorize every monitor into one of three COV categories (≤100%, <100-≤200%, and >200%). Then, distributions of PMRs were calculated from the available 5-minute measurement data to also reflect the differences in concentration levels as well as the concentration variability expected to occur at each of the monitors REA, section 7.2.3.2). Hence, our method is in agreement with the ABR/ASARCO comments made regarding the potential link between source characteristics, concentration variability, and 1-hour average concentration.

(10) ***Comment:*** UARG commented that the coefficient of variation (COV) is an inappropriate summary statistic for the monitor data. They argue that the "COV measure is generally reserved for normally distributed data, which SO_2 concentrations certainly are not."

Response: The COV statistic was not used by EPA as a descriptor to define a monitor's ambient concentration distribution. It was used to categorize the monitor into one of three variability groups (low – ≤100% COV; medium <100-≤200% COV, and high >200% COV). EPA acknowledges that measured ambient concentrations at a monitor may not necessarily reflect that of a normal distribution, and in fact considered this in the development of the PMR statistical model. An alternative approach was used that incorporated the geometric standard deviation (GSD) in categorizing the ambient monitors (i.e., a statistic more appropriate in describing the variability associated with a lognormal distribution). Five-minute maximum SO_2 concentrations were estimating using a PMR statistical model that either used COV or GSD as the categorical variable. Results demonstrated that the PMR model using COV to define a monitor's variability performed better than that using GSD (REA, section 7.2.3.4).

(11) ***Comment:*** A few commenters (e.g., API, UARG, ASARCO) generally indicated that exposures and risk estimates presented in the REA and proposal are over estimates because they rely on emissions estimates from 2002 and that information on the stack emission characteristics (i.e., stack location, stack height, stack diameter, stack flow rate and stack temperature) are uncertain. For example, API points out that: "SO_2 emissions fell from 111,057 thousand short tons nationally in 2002 to 77,685 thousand short tons nationally in 2008 (see comments provided by API; p.22)

Response: We first note that values API cited are the 2002 and 2008 emission estimates for CO rather than SO_2**.** Total SO_2 emissions fell from 14,774 thousand short tons nationally in 2002 to 11,429 thousand short tons nationally in 2008, a national reduction of about 23%.[1]

EPA acknowledges there is uncertainty in using the 2002 NEI emissions data. EPA has appropriately characterized both the exposure and risk results associated with the "as is" modeling scenario as reflective of year 2002. No adjustment was made to reflect any apparent emission reductions (i.e., post-2002) in either study area. Therefore, the "as is" 2002 exposure and risk results should not necessarily be interpreted as those that might result from using current air quality conditions (e.g., year 2008). If there have been reductions to the specific SO_2 emission sources modeled in these study areas relative to the 2002 emissions used, then the estimated exposure and risk results would likely be an overestimate of exposure and risk associated with recent year (e.g., 2008) emissions.

However, as discussed above in the response to comments C(1) through C(3), EPA is interested in evaluating the risk of adverse health effects associated with a variety of air quality conditions including just meeting the current and alternative standards. Just as adjustments were made to 2001-2006 ambient monitor concentrations (REA, section 7.2.4), adjustments were made to the exposure benchmark level (REA, section 8.8.3) to reflect air quality just meeting the current or alternative standards. These hypothetical scenario-based investigations are independent of what current air quality conditions or emissions levels might actually be, assuming that the variability in measured ambient concentrations (and hence their emission sources) remain relatively stable. To justify this assumption as appropriate, EPA evaluated historical trends in ambient air quality (REA, section 7.4.2.5).

EPA judged the 2002 NEI to be the most accurate, comprehensive SO_2 emissions data base available for use in the exposure and risk analyses. As noted in the REA, the 2002 NEI emissions data were not used alone but were supplemented with Clean Air Markets Division (CAMD) Unit Level Emissions Database of continuous emissions monitoring (CEM) emissions data where available and Emissions Modeling System for Hazardous Pollutants model (EMS-HAP) data to specify temporal profiles. Because of the importance of accurate locations of emission sources relative to population receptors for exposure assessment, the locations of all emitting stacks were verified and corrected where necessary, based on GIS analysis, as described in the REA (section 8.4.3.1). In addition all port-related emission sources, which were characterized as nonpoint area emissions, had boundaries specified based on GIS analysis of aerial photographic images.

[1] 1970 - 2008 Average annual emissions, all criteria pollutants in MS Excel - June 2009. http://www.epa.gov/ttn/chief/trends/.

(12) ***Comment:*** The REA included exposure analyses that were performed in the greater St. Louis metropolitan area and Green County, MO using U.S. EPA's promulgated air quality dispersion model AERMOD (AERMIC MODEL) to estimate 1-hour ambient SO_2 concentrations at the census block level. ABR and ASARCO commented that the model evaluation performed when AERMOD was originally developed showed that for short-term averages the ratio of the predicted concentration to the observed concentration ranged up to 1.35, and speculated that the discrepancies were due to the "conservativeness" of AERMOD in certain situations.

Response: AERMOD has been evaluated against several data sets of observed concentrations. The results of the AERMOD development model evaluation showed, for short-term average concentrations, an overall average predicted-to-observed ratio of 1.03 with a range among sites from 0.76 to 1.35.[2] Thus, this evaluation does not provide evidence that AERMOD is inherently "conservative", but rather suggests somewhat variable but unbiased model performance.

A more relevant assessment of how AERMOD performed is provided by the comparison of model predicted to ambient monitor measured concentrations (REA, section 8.4.5). Two types of predicted-to-measured comparisons were made: (a) predicted and measured concentration distributions for a particular location were matched by percentile and compared, and (b) diurnal patterns of predicted and measured concentrations were compared by averaging concentrations for each hour of the day, e.g., the concentrations for the first hour of the day were averaged across all simulated days. Recognizing that uncertainties in model inputs can result in uncertainties in model predictions, particularly with respect to location, for both types of comparisons the predicted concentrations were processed for all modeling receptors within 4 km of the monitor site so that the observed values could be compared to both the predictions at the exact location of the monitor, as well as the range of predictions in the vicinity. The AERMOD 1-hour concentration predictions showed good agreement with measured concentrations, particularly for those at the upper end of the concentration distribution, concentrations most likely to be associated with 5-minute benchmark level exceedances.

(13) ***Comment:*** ASARCO commented that a substantial fraction of the SO_2 emissions in Greene County were characterized as nonpoint sources, and generally questioned the approach and data used by EPA to model these nonpoint emission sources (e.g., the accuracy of the emissions estimates, assuming uniform emission densities across a census tract, and selection of emission release heights).

Response: First of all, EPA has adopted the term "nonpoint" to refer to all stationary emission sources that are not inventoried at the facility-level, and hence these sources are not incorporated into the point source component of the NEI.

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[2] See *AERMOD: Latest Features and Evaluation Results*. EPA-454/R-03-003. http://www.epa.gov/ttn/scram/7thconf/aermod/aermod_mep.pdf

Rather these emissions are specified at the county-level. For the Greene County study area, to improve the spatial resolution of the nonpoint source emissions, the county level aggregate emissions data provided in the NEI were allocated to census tracts based on land use. For example, the county total of nonpoint industrial emissions was allocated to tracts in proportion the amount of industrial land use in each tract. Given the time, resources, and data available to conduct this exposure and risk assessment, it was not feasible to estimate the locations of these facilities any more precisely. Therefore, it was assumed for modeling purposes, that the emissions were released uniformly over the tract.

When considering SO_2 emissions, the majority of these nonpoint sources are comprised of small industrial and commercial/institutional facilities combusting fuels. For the fuel combustion categories, NEI estimates were derived from state level fuel consumption data, and allocated to counties based on employment data for appropriate sectors. In the case of industrial nonpoint sources, the fuel combustion data was first corrected for an estimate of fuel consumption by industrial point sources to avoid double-counting.[3]

As noted above, given the lack of location data for nonpoint sources, it was not feasible to specify the locations any more precisely than census tracts. If there are only a small number of nonpoint sources in a tract, this approach would tend to reduce the spatial variance of the concentration predictions compared to specifying precise locations for each small facility. The result could be either an over- or under-estimate of the number of exceedances at the population receptors. However, if there are numerous such facilities dispersed throughout the tract, this approach will provide a reasonable characterization of the spatial pattern of the emissions.

EPA selected release heights for non-point area sources as 10.0 m for rural tracts and 20.0 m for urban tracts. Although no data were identified by EPA to estimate release heights for these nonpoint sources, the release heights were not selected "arbitrarily" as mentioned by the commenter. First, engineering judgment was used to estimate the release height for a small industrial or commercial/institutional facility of 2 to 3 stories. Then an estimate of plume rise was added, since AERMOD does not apply a plume rise algorithm to area sources. Finally a series of sensitivity simulations were conducted to characterize model performance at the ambient monitor locations in order to make final estimates for release parameters.

Again, the model evaluation discussed in REA section 8.4.5 suggests that the approaches to modeling the nonpoint sources in both Greene County and the St. Louis metropolitan study areas resulted in acceptable model performance,

[3] See *Documentation for the Final 2002 Nonpoint Sector (Feb 06 Version) National Emission Inventory for Criteria and Hazardous Air Pollutants.* ftp://ftp.epa.gov/EmisInventory/2002finalnei/documentation/nonpoint/2002nei_final_nonpoint_documentation0206version.pdf .

especially in the upper end of the concentration distribution, where exceedances of concentration thresholds of concern are most likely to occur.

(14) ***Comment:*** UARG suggested that some of the exposure analysis could not be replicated with the data provided in the first draft REA. In particular they questioned the specification of block receptors within 20 km of major point sources, given a discrepancy between the number of block receptors stated in the draft report for the Southwest and James River Power Plants in Greene Co MO and the number they calculated based on location coordinates they derived from visual inspection of Google Earth. They suggest that the discrepancy may be due to a discrepancy in the location coordinates used for the REA and those they derived.

Response: The UTM coordinates of each stack modeled for the final REA are listed in Appendix B, Table B.3-1. The discrepancy in the number of block receptors stated in the draft report and that found by the commenter is likely due to a discrepancy in the number of release points used to characterize the James River Power Plant. For this study we characterized the James River Power Plant with 10 emission release points, each with unique location parameters, while the commenter used only two. Hence, we found slightly more Census blocks within 20 km of the plant than reported by the commenter.

(15) ***Comment:*** Several commenters (e.g., API, UARG, Dominion) indicated EPA did not properly consider the exposure and risk results for Greene County rather, EPA focused on the larger risk estimates presented for St. Louis.

Response: EPA acknowledges that more weight was placed on the exposure and risk results in St. Louis compared to Greene County. EPA believes this to be a reasonable approach: the St. Louis information provided more probative information as to the adequacy or inadequacy of the current standards. As stated in the REA:

> Exposures and risks have been estimated for two study areas in Missouri (i.e., Greene County and several counties representing the St. Louis urban area) which have significant emission sources of SO_2. As noted in section 8.10, there were differences in the number of exposures above benchmark values when the results of the Greene County and St. Louis exposure assessments were compared. Moreover, given that the results of the exposure assessment were used as inputs into the quantitative risk assessment, it was not surprising that there were also far fewer asthmatics at elevated ventilation rates estimated to have a moderate or greater lung function response in Greene county when compared to St. Louis. The difference in the St. Louis and Greene County exposure and quantitative risk results are likely indicative of the different types of locations they represent (see section 8.10). Greene County is a rural county with much lower population and emission densities, compared to the St. Louis study area which has population and emissions density similar to other urban

areas in the U.S. It therefore follows that there would be greater exposures, and hence greater numbers and percentages of asthmatics at elevated ventilation rates experiencing moderate or greater lung function responses in the St. Louis study area. Thus, when considering the risk and exposure results as they relate to the adequacy of the current standards (as well as the need for considering potential alternative standards), the St. Louis results are more informative in that they suggest that the current standards may not adequately protect public health. Moreover, staff judges that the exposure and risk estimates for the St. Louis study area provide useful insights into exposures and risks for other urban areas in the U.S. with similar population and SO_2 emissions densities (REA, p. 364).

(16) ***Comment:*** JRSC referenced prior comments by UARG stating that the individual data from controlled human exposure studies used in the quantitative risk assessment had significant errors associated with it, and that it was unclear if these errors had been corrected (comments by JRSC, p. 2).

Response: EPA conducted a full quality assurance review of the controlled human exposure data, which included personal communication and technical guidance from the principal investigator of the original studies, William Linn. This review, presented in Johns and Simmons (2009), found a very limited number of minor errors in the original individual subject lung function data presented in the ISA. However, the results of the review did not change the conclusions presented in the ISA. In fact, the quality assurance review resulted in an *increase* in the percentage of responders reported in Table 3-1 of the ISA and 9-3 of the REA.

(17) ***Comment:*** UARG generally concluded that under all air quality scenarios EPA's quantitative risk assessment substantially overestimated risk because EPA did not use proper methods to estimate the parameters of the exposure-response functions used in its analyses. UARG contends this is because many of the subjects in the controlled human exposure studies from which EPA's exposure-response functions were derived (see REA, Table 9-3) were exposed to more than one SO_2 concentration, yet EPA treated each exposure event as being independent (e.g., if the same subject was exposed to 200 and 300 ppb SO_2, EPA considered these as representing two independent exposure events). UARG contends that observations from the same subject exposed to different SO_2 concentrations are not independent observations and should not be treated as such. Notably, when UARG derived their own exposure-response functions taking into account that observations from the same subject exposed to different SO_2 concentrations are not independent of each other, they estimated appreciably less risk than that estimated by EPA.

Response: EPA notes that it is true that observations for the same subject across the different SO_2 concentrations to which the subject was exposed are not

completely independent observations – although for any given SO_2 concentration, the observations are (mostly) independent.[4] The important question is what effect not considering the dependence of intra-subject observations across SO_2 concentrations has on the estimated exposure-response relationship.

To address this perceived problem of dependent observations, UARG estimates subject-specific exposure-response functions.[5] Based on these subject-specific exposure-response functions, UARG estimates the two parameters in the (population-level) logistic and probit exposure-response functions necessary for use in the risk assessment. EPA plotted the logistic and probit exposure-response functions estimated by UARG along with the logistic and probit exposure-response functions estimated by EPA, as well as the underlying data.[6,7] These are shown in Figure 1.

As Figure 1 shows, the logistic and probit exposure-response functions estimated by UARG (the blue curves) do not fit the underlying data (the proportions of subjects who responded at each exposure level) nearly as well as the functions estimated by EPA (the black curves). This suggests that, even though it deals with the "dependency problem," the UARG approach has its own problems.

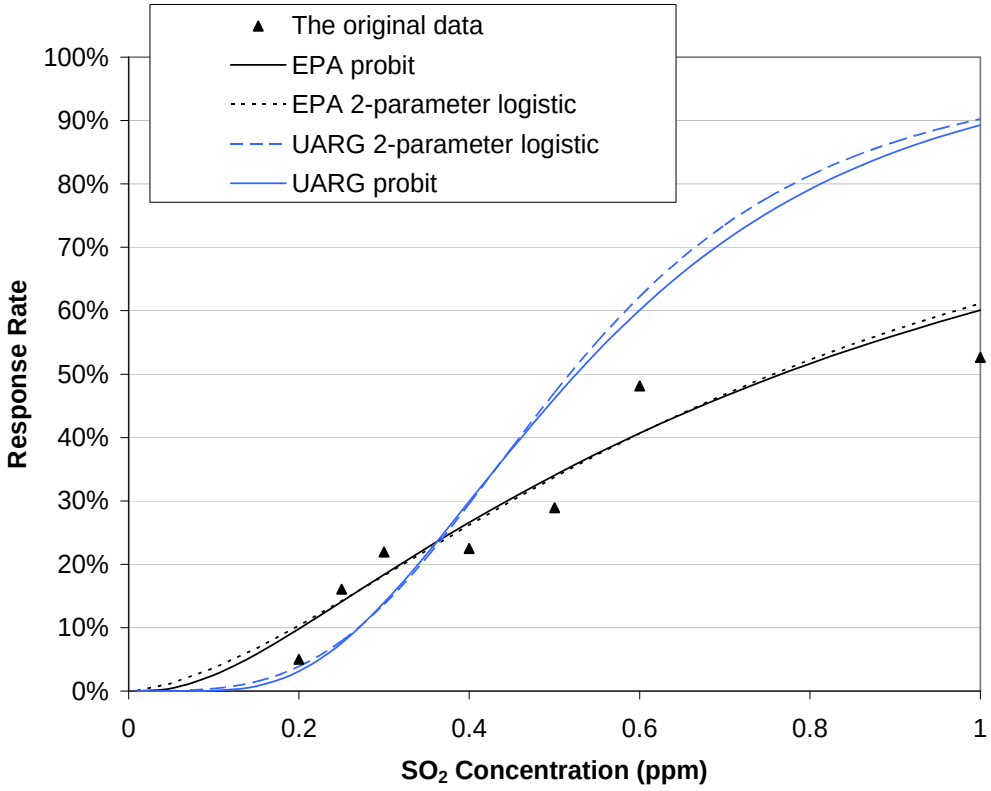
[4] There were a few instances where a subject was exposed to the same SO_2 concentration more than once. EPA noted this in the REA, stating the following: "Some subjects in the controlled human exposure studies participated in more than one study and were exposed to a given SO_2 concentration more than once. However, because there were insufficient data to estimate subject-specific response probabilities, we assumed a single response probability (for a given definition of response) for all individuals and treated the repeated exposures for a single subject as independent exposures in the binomial distribution."

[5] UARG first claims that "the correct likelihood for such a case [in which there are several observations per subject] would be multinomial" and they set up a multinomial likelihood function. However, UARG appears not to use it.

[6] The UARG curves are based on the estimated values given for the two parameters in each function presented in Table 4 of "Technical Comments on the Primary National Ambient Air Quality Standard for Sulfur Dioxide. Proposed Rule Docket no. EPA-HQ-OAR-2007-0352, by Edmund A.C. Crouch, Ph.D. and Laura C. Green, Ph.D., D.A.B.T. Cambridge Environmental Inc. Cambridge, Massachusetts. February 8, 2010 (Docket No. EPA-HQ-OAR-2007-0352-1061.1) Corrected April 6, 2010.

[7] The functional forms for the logistic and probit functions are given in (equation 9-3) and (equation 9-4), respectively, on p. 327 of the REA. The EPA-estimated curves and the underlying data are shown in Figure 9-2 on p. 330 of the REA.

Figure 1. EPA- and UARG -Estimated Logistic and Probit Exposure-Response Functions (for Lung Function Response Defined as an Increase in sRaw of ≥100%) and Underlying Data



UARG is not specific about the nature of the problems that will result from using a likelihood function that does not consider intra-subject dependencies. They note only that "the consequence of using this incorrect likelihood for common subjects was to decrease (in the REA analysis) the estimated slope of the population E_{100} distribution function (the magnitude of the γ parameter in both [the logistic and probit exposure-response] models), and increase the estimated population fraction responding at low exposures (in the extrapolated region below 0.2 ppm SO_2)."[8] They note in a footnote that "this consequence was evaluated by performing the calculations both ways [i.e., the way EPA estimated the parameters and the way UARG estimated them]." That is, they concluded that EPA's estimated curves are "wrong" because they differ markedly from their own curves. This presumes, however, that UARG's curves are indeed "correct." The comparison of how each of the curves reflects the underlying data (Figure 1) suggests otherwise.

[8] From: Comments of the Utility Air Regulatory Group on the Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standards: Second Draft (March 2009). Docket ID No. EPA-HQ-OAR-2007-0352. June 11, 2009. Attachment 1 (Technical Comments by Edmund A. C. Crouch, Ph.D., Laura C. Green, Ph.D., D.A.B.T. and Joshua M. Galanter, M.D. on the SO_2 REA (June 10, 2009), p. 12.

While their approach of estimating subject-specific exposure-response functions addresses the issue of intra-subject dependencies, EPA notes that it creates other serious problems. In particular, EPA notes that there do not appear to be sufficient data for any of the subjects to estimate a subject-specific exposure-response function.[9] The form of the individual-specific exposure-response function they chose is a quadratic function with three parameters. Thus for each subject they presumably had to estimate the subject-specific values of these three parameters. However, none of the subjects in the seven controlled human exposure studies on which EPA relied were exposed to more than three non-zero SO_2 levels: over half were exposed to only one or two non-zero SO_2 levels.

Thus, EPA notes that it appears that the data for estimating these subject-specific exposure-response functions were severely limited, especially given that a large percentage of the total number of subjects had fewer exposures than the number of parameters UARG was attempting to estimate. UARG attempted to estimate three parameters in its exposure-response functions, but over fifty percent of subjects had only one or two exposures. It appears, moreover, that UARG's population-level exposure-response function estimates depended on these subject-specific exposure-response function estimates, and this could explain why UARG's estimated population-level exposure-response functions do not fit the underlying controlled human exposure data nearly as well as the EPA-estimated functions. In attempting to address the problem of intra-subject dependencies, UARG seems to have created different problems. It is not surprising, then, that neither their estimated logistic function nor their estimated probit function fit the underlying data very well.

There are other approaches to dealing with the intra-subject dependency issue that avoid the problem associated with the UARG approach. Not considering intra-subject dependencies is effectively omitting an individual-level effect from the model. This would be a problem if the omitted individual-level effect were correlated with the assignment of exposures (for example, if the hyper-responsive subjects were disproportionately exposed to the lowest levels), but there is no reason to suppose this is the case. Moreover, any possible bias in the estimated logit or probit model parameters is likely to be minor, since the majority of the subjects had only one or two exposures, so the degree of intra-subject dependencies is small; indeed, visual inspection of the EPA fitted curves in Figure 1 does not suggest any substantial biases.

EPA further notes that the approach we used to estimate the parameters of the exposure-response functions was not first introduced in this SO_2 risk assessment; it was previously used in the O_3 risk assessment completed in 2008, which used data from controlled human exposure studies much like the data used in the SO_2 risk assessment. This approach was suggested to EPA by an applied statistician

[9] This was noted in the Risk and Exposure Assessment, see http://www.epa.gov/ttn/naaqs/standards/so2/data/200908SO2REAFinalReport.pdf, p. 328.

serving on the CASAC which at the time was overseeing the O_3 NAAQS review. Notably, this approach allowed EPA to use all of the individual subject data. Consequently, as noted in section II.E.2.c of the preamble to the final rule, EPA does not accept UARG's view that the methodology used in EPA's quantitative risk assessment was inappropriate.

(18) ***Comment:*** UARG generally concluded that the risk estimates presented in Chapter 9 of the REA and in the proposal are substantially overestimated because of the use of 50 ppb bins by EPA.

More specifically, in their original comments submitted on June 11, 2009, UARG noted that EPA's approach:

> …serves to overestimate the number of annual 'events' (defined as an increase in corrected relative sRaw of ≥100% among asthmatics in St. Louis). This is primarily because the REA analysis bins SO_2 exposures into 50 pbb-wide bins. An accurate calculation must take into account the distribution of values, particularly in the lowest bin — wherein (i) ambient air concentrations range from zero to 50 ppb, and (ii) the REA predicts 95% of the sRaw events.[10]

That is, UARG concluded that the use of 50 ppb bins, combined with assigning all exposures within a bin the probability of an adverse lung function response at the midpoint of that bin (e.g., all exposures from 0 - 50 ppb were assigned the probability of an adverse lung function response at 25 ppb), resulted in a substantial overestimate of the total number of occurrences of lung function responses in asthmatics at moderate or greater exertion. UARG concludes that this is because the vast majority of exposures are occurring below the midpoint of the 0 - 50 ppb exposure bin (i.e., most exposures are occurring below 25 ppb), yet EPA is assigning these very low SO_2 exposures the higher probability of a lung function response associated with the midpoint of the 0 -50 ppb exposure bin (i.e., the great majority of exposures were < 25 ppb but were assigned the probability of an adverse lung function response at 25 ppb).

In follow-on comments submitted in February 2010,[11] UARG takes advantage of a technique EPA used to streamline the estimation of exposures under the

[10] "Comments of the Utility Air Regulatory Group on the Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standards: Second Draft (March 2009)." Docket ID No. EPA-HQ-OAR-2007-0352. June 11, 2009. Attachment 1: "Technical Comments by Edmund A. C. Crouch, Ph.D., Laura C. Green, Ph.D., D.A.B.T. and Joshua M. Galanter, M.D. on the SO_2 REA (June 10, 2009), p. 31.

[11] "Technical Comments on the Primary National Ambient Air Quality Standard for Sulfur Dioxide. Proposed Rule Docket No. EPA-HQ-OAR-2007-0352, by Edmund A.C. Crouch, Ph.D. and Laura C. Green, Ph.D., D.A.B.T. Cambridge Environmental Inc. Cambridge, Massachusetts. February 8, 2010 (Docket No. EPA-HQ-OAR-2007-0352-1061.1) Corrected April 6, 2010.

different air quality scenarios considered. As described in Section 8.8.3 of the July 2009 Final SO_2 REA,

> … instead of proportionally adjusting the ambient concentrations, [EPA] proportionally adjusted the health effect benchmark levels used in each exposure modeling domain. The benchmark levels were adjusted rather than the air quality to reduce the processing time associated with the modeling of several thousands of receptors in each of the large exposure modeling domains. A proportional adjustment of the selected benchmark level (i.e., division by the adjustment factor) is mathematically equivalent to a proportional adjustment of the air quality concentration (i.e., multiplication by the adjustment factor). Therefore, the end effect of adjusting the exposure model input concentrations upward versus adjusting exposure model benchmark levels downward is identical.

This "walkway" between SO_2 concentrations under each alternative SO_2 standard and SO_2 concentrations under recent conditions allowed EPA to carry out the exposure analysis for all the different air quality scenarios in a single APEX run, resulting in an APEX output table with many SO_2 exposure levels under year 2002 "as is" air quality conditions. UARG used these many exposure levels under "as is" conditions and EPA's factors for converting from recent conditions to each of the alternative air quality scenarios to create much smaller "bins." Applying EPA's approach of calculating the expected number of lung function responses at the midpoint of each "bin" to these much smaller "bins," UARG showed that use of 50-ppb "bins" does indeed overstate the total number of occurrences of lung function response under each air quality scenario. UARG further notes that this methodological concern was raised in its comments on the second draft REA, but EPA failed to address this issue and relied heavily on this metric in the proposal with respect to the adequacy of the current and potential alternative standards.

Response: EPA generally agrees with UARG's technical comments that there is a substantial overestimation of the total occurrences of lung function responses because of the binning issues described above. However, we strongly disagree that: 1) this issue was not acknowledged in the final REA; and 2) the metric of total occurrences was relied on heavily in the policy assessment chapter of the REA (REA, chapter 10) and in the Administrator's rationale with respect to the adequacy of the current and potential alternative standards. First, EPA did respond to this concern in the final REA. More specifically, page 344 of the final REA states:

> As noted in public comments on the 2nd draft SO_2 REA, the assignment of response probability to the midpoint of the exposure bin combined with the lack of more finely divided intervals in this range can lead to significant overestimation of risks based on total occurrences of a defined lung function response. This is because the distribution of population

> exposures for occurrences is not evenly distributed across the bin, but rather is more heavily weighted toward the lower range of the bin. Thus, combining all exposures estimated to occur in the lowest bin with a response probability assigned to the midpoint of the bin results in a significant overestimate of the risk. Therefore, staff places less weight on the estimated number of occurrences of lung function responses.

Thus, as noted in the final REA, less weight was placed on this metric in the quantitative risk assessment chapter (REA, chapter 9), and importantly, no weight was placed on this metric in either the policy assessment chapter of the REA (REA, chapter 10) or in the Administrator's rationale sections of the proposal preamble. Rather, the policy assessment chapter of the REA and the Administrator's rationale at the proposal considered the percent of exposed asthmatic children at moderate or greater exertion estimated to have at least one defined lung function response per year in St. Louis. Importantly, this metric is not appreciably affected by the binning issue raised in UARG's comments. As stated on page 344- 345 of the final REA:

> This overestimation of total occurrences does not impact the risk metric expressed as incidence or percent incidence of a defined lung function response 1 or more times per year because the bulk of the exposures contributing to these risk metrics are not skewed toward the lower range of the reported exposure bins.

This is confirmed by using the same technique used by UARG, described above, but applying it to this metric. The results, for asthmatic children in St. Louis, are shown in Table 1 below using the original 50-ppb bin approach and the more disaggregated bins identified by UARG.

Table 1. Estimates of the Number of Asthmatic Children in St. Louis with at Least One Lung Function Response (Defined as an Increase in sRaw>=100%) Under Different Air Quality Scenarios Using 50 ppb Bins Compared with Estimates Using More Disaggregated Bins

Air Quality Scenario	Number of Asthmatic Children Who Respond at Least Once		New Result as a Percent of Original Result	Percent of Asthmatic Children Who Respond at Least Once*	
	Using 50 ppb Bins	Using More Disaggregated Bins		Using 50 ppb Bins	Using More Disaggregated Bins
Recent conditions	588	591	100.5%	1.41%	1.42%
Current Standard	8021	8090	100.9%	19.23%	19.39%
Alternative Std: 99/50	396	406	102.5%	0.95%	0.97%
Alternative Std: 99/100	1221	1204	98.6%	2.93%	2.89%
Alternative Std: 99/150	2243	2214	98.7%	5.38%	5.31%
Alternative Std: 99/200	3369	3346	99.3%	8.08%	8.02%
Alternative Std: 99/250	4555	4541	99.7%	10.92%	10.89%

*There were 41714 asthmatic children in St. Louis in this analysis.

As Table 1 shows, the use of 50 ppb bins does not result in overestimates of the number or percent of asthmatic children in St. Louis with at least one lung function response across the air quality scenarios. While in some air quality scenarios the estimate based on the 50-ppb bin approach is slightly greater than the estimate based on more disaggregated bins, in others the estimate based on the 50-ppb bin approach is slightly less than the estimate based on more disaggregated bins. The differences appear to be random and are judged not significant from a policy perspective.

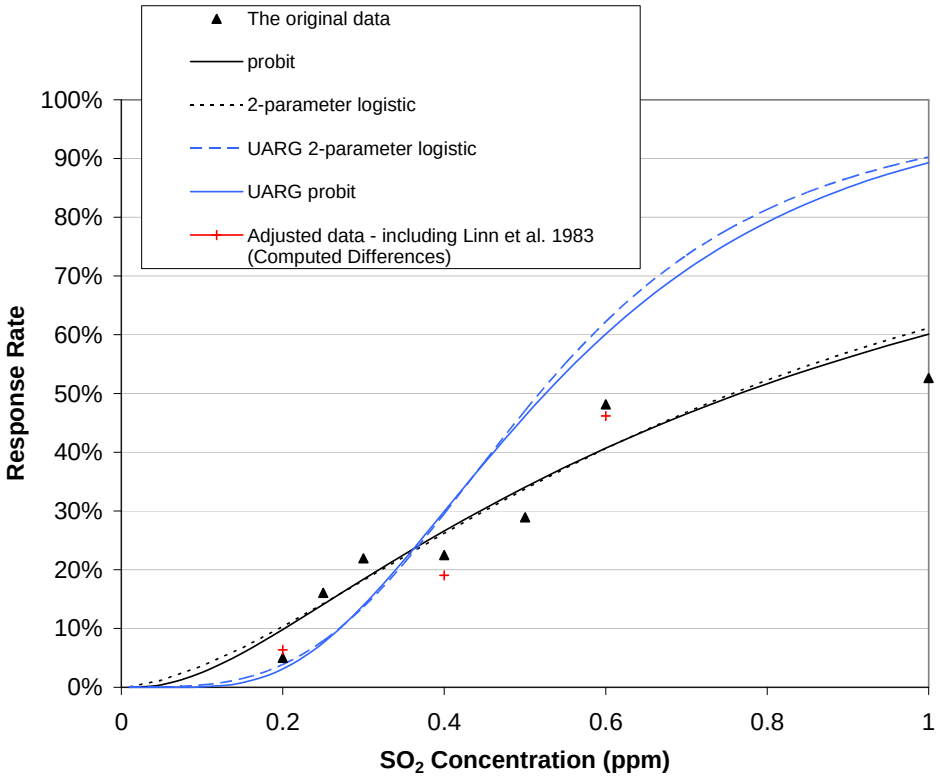
Finally, it is important to note that the Administrator's rationale in the proposal regarding the adequacy of the current and potential alternative standards in general placed only limited reliance on the results of the quantitative risk assessment in St. Louis, with no reliance on the estimates of total occurrences. Rather, in addition to the substantial weight that she placed on the scientific evidence as described in the ISA, the Administrator placed relatively more weight on the results of the St. Louis exposure analysis (see section II.E.2.c of the preamble to the final rule for more information).

(19) ***Comment:*** In their comments submitted on April 6, 2010, UARG notes that "the Final REA also omitted to take account of the additional information available on the experiments of Linn et al. (1983) that became available between the Draft REA and Final REA, another 69 samples with 14 positive results."[12]

[12] "Technical Comments on the Primary National Ambient Air Quality Standard for Sulfur Dioxide. Proposed Rule Docket No. EPA-HQ-OAR-2007-0352, by Edmund A.C. Crouch, Ph.D. and Laura C. Green, Ph.D., D.A.B.T. Cambridge Environmental Inc. Cambridge, Massachusetts. February 8, 2010 (Docket No. EPA-HQ-OAR-2007-0352-1061.1) Corrected April 6, 2010, p. 15.

Response: While it was not possible to re-estimate the exposure-response functions incorporating this additional data mentioned by UARG, EPA did create a new graph showing the original and adjusted data as well as the EPA-estimated and the UARG-estimated logistic and probit exposure-response functions (based on the original set of data) for lung function response defined as an increase in sRaw of ≥100%. Shown below are all the original data points (black triangles) as well as the adjusted data points (red crosses) incorporating the additional data from Linn et al. (1983) for the three SO_2 exposures for which that study provided data (0.2, 0.4, and 0.6 ppm). As shown in Figure 2 below, the three adjusted data points are all quite close to the original data points used to develop the exposure-response functions; it is therefore highly unlikely that the incorporation of the Linn et al. (1983) data would alter the estimated exposure-response functions appreciably.

Figure 2. EPA- and UARG (Crouch/Green)-Estimated Logistic and Probit Exposure-Response Functions (for Lung Function Response Defined as an Increase in sRaw of ≥100%), Underlying Original Data, and Data Incorporating Linn et al. (1983)



(20) ***Comment:*** Springfield pointed out that Table 10-5 of the REA contained an error. The 1-hour SO_2 concentrations reported for Greene County were not from the monitor that recorded the highest SO_2 concentrations in the county. Springfield was concerned that the exposure and risk estimates presented in the REA for

Greene County were based on erroneous data, and thus did not accurately represent the impacts of SO_2.

Response: Springfield is correct that REA Table 10-5 identified the incorrect monitor as that recording the highest 1-hour daily maximum SO_2 concentrations in Greene County. We note that Table 10-5 was only used to demonstrate that in most counties, the 99^{th} percentile 1-hour daily maximum SO_2 concentration corresponded to the 4^{th} highest 1-hour daily maximum SO_2 concentration and that the 98^{th} percentile 1-hour daily maximum SO_2 concentration corresponded to the 7^{th} -8^{th} highest 1-hour daily maximum SO_2 concentration. Thus, the results of the air quality, exposure and risk assessment for Greene County were not affected by this error. In addition, we note that in general, as noted above in response 8 of this section, the results of the Greene County exposure and risk assessments were not considered as informative as those in St. Louis.

(21) ***Comment:*** Springfield commented:

> Springfield is the seat of Greene County, Missouri, a locale mentioned several times in the proposal and in the supporting Risk Exposure Analysis. Understandably, we noted with considerable interest the discussion of EPA's exposure modeling for this area. We find it especially telling that the model returned exposure results that apparently were too inconsequential for further consideration (see, for example, p.64827, "(t)hus, when considering the risk and exposure results as they relate to the adequacy of the current standards, the REA concluded that the St. Louis results were more informative [than Greene County]…"). Despite this lack of any cogent exposure findings for our "rural" (population 270,000) county, the proposed standard could very well place Greene County in nonattainment (see comments provided by Springfield, section II.d.ii)

Response: Springfield is correct that EPA found the exposure and risk results for St. Louis more informative than those in Greene County for informing the adequacy of the current and potential alternative standards. As stated in the REA (and is quoted in the earlier response):

> Exposures and risks have been estimated for two study areas in Missouri (i.e., Greene County and several counties representing the St. Louis urban area) which have significant emission sources of SO_2. As noted in section 8.10, there were differences in the number of exposures above benchmark values when the results of the Greene County and St. Louis exposure assessments were compared. Moreover, given that the results of the exposure assessment were used as inputs into the quantitative risk assessment, it was not surprising that there were also far fewer asthmatics at elevated ventilation rates estimated to have a moderate or greater lung function response in Greene county when compared to St. Louis. The

> difference in the St. Louis and Greene County exposure and quantitative risk results are likely indicative of the different types of locations they represent (see section 8.10). Greene County is a rural county with much lower population and emission densities, compared to the St. Louis study area which has population and emissions density similar to other urban areas in the U.S. It therefore follows that there would be greater exposures, and hence greater numbers and percentages of asthmatics at elevated ventilation rates experiencing moderate or greater lung function responses in the St. Louis study area. Thus, when considering the risk and exposure results as they relate to the adequacy of the current standards (as well as the need for considering potential alternative standards), the St. Louis results are more informative in that they suggest that the current standards may not adequately protect public health. Moreover, staff judges that the exposure and risk estimates for the St. Louis study area provide useful insights into exposures and risks for other urban areas in the U.S. with similar population and SO_2 emissions densities (REA, p. 364).

That being said, it is important to note several points. First, these analyses only estimated exposure and risks associated with modeled 5-minute benchmark concentrations of concern identified from the controlled human exposure literature: thus these considerations alone do not take into account 1-hour SO_2 levels in U.S. locations epidemiologic studies reported positive effects between ambient SO_2 and emergency department visits and/or hospitalizations (i.e., epidemiologic considerations taken into account by the Administrator in setting a new 1-hour standard at 75 ppb). In addition, Tables 7-12 to 7-14 of the REA indicate that when air quality is adjusted to just meet the current standards, Greene County had an appreciable number of days per year on average when 5-minute SO_2 concentrations exceeded 5-minute benchmark levels. This indicates 5-minute concentrations of concern could be present in Greene County under the current standards, and it is thus possible with increased population growth and/or shifts in activity patterns, a greater number of SO_2 exposures above 5-minute benchmark levels could result (if air quality just met the current standards). Finally, EPA notes that the NAAQS are national standards meant to provide protection in both rural and urban areas.

(22) ***Comment:*** UARG generally commented that the risk and exposure assessment did not take into account the 3-hour secondary standard when estimating the extent to which the current standards limit 5-minute peaks above benchmark levels of concern.

Response: Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on [the air quality] criteria and allowing an adequate margin of safety, are requisite to protect the public health." Section 109(b)(1). In contrast, a secondary standard, must "specify a level of air quality the attainment and maintenance of which, in the

judgment of the Administrator, based on [the air quality] criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such pollutant in the ambient air."[13] Thus, EPA found it reasonable when considering the adequacy of the current standards to protect public health, to only consider the primary SO_2 standards in its air quality, exposure and risk analyses.

III. Responses to Significant Comments on the Adequacy of the Current Standards

(1) ***Comment:*** Many industry groups (e.g., API, UARG, ACC, DRSI, ExxonMobil, PE, CIBO, TFI, EEI, Dow, MWV, NMA, Duke Energy, GCLC) commented that, given the presence of numerous co-pollutants in the air, the epidemiologic studies do not support the contention that SO_2 itself is causing health effects. For example, UARG stated:

> The epidemiological evidence cannot determine that SO_2 is a cause of or a contributor to hospital admissions ("HA"), emergency department ("ED") visits or respiratory symptoms, the effects cited in the Proposed Rule (see comments provided by UARG; p.3)

Thus, these groups generally conclude that the epidemiologic evidence should not be considered when evaluating the adequacy of the current standards

Response: These comments and EPA's responses were presented in detail in section II.E.2.a of the preamble to the final rule. EPA also provided additional information on similar comments above in section II.B

(2) ***Comment:*** Many industry groups (e.g., API, ACC, PE, EEI, CIBO) commented that adverse health effects do not occur following 5 - 10 minute SO_2 exposures < 400 ppb. In addition, some groups (e.g., UARG, Duke Energy) commented that adverse respiratory effects do not occur in exercising asthmatics following SO_2 exposures below 600 ppb. The disagreement is not whether effects occur in exercising asthmatics at these exposure levels and exposure durations. Rather, the issue is whether the effects experienced can properly be regarded as adverse. In general, these groups conclude that EPA's judgment of adverse health effects at SO_2 exposure levels below 600 or 400 ppb is inappropriately based on an unsound interpretation of ATS guidelines. More specifically, these groups generally contend that decrements in lung function without accompanying respiratory symptoms are not adverse effects of SO_2 exposure, and that decrements in lung function in a percentage of exercising asthmatics does not represent a shift in lung function at the population level. Some of these groups also contend that EPA

[13] EPA is currently conducting a separate review of the secondary SO_2 NAAQS jointly with a review of the secondary NO_2 NAAQS (see http://www.epa.gov/ttn/naaqs/standards/no2so2sec/index.html for more information).

followed the advice of individual CASAC members, rather than consensus CASAC written comments on the ISA and REA when concluding respiratory effects associated with SO_2 exposures below 600 or 400 ppb are adverse. Thus, these groups generally conclude that 5-minute benchmark levels less than 600 or 400 ppb should not be considered when evaluating the adequacy of the current standards.

In addition to disagreeing with EPA's proposed finding of adverse health effects following 5 - 10 minute SO_2 exposures as low as 200 ppb, many industry groups (e.g., API, UARG, ACC, ExxonMobil) also disagreed with EPA that severe asthmatics were not included in controlled human exposure studies. That is, these groups contend that EPA is incorrect in assuming that severe asthmatics would likely have a more pronounced response to SO_2 exposures at a given level, or would respond to even lower levels of SO_2 and that this should be taken into account when judging the adequacy of the current standards.

Response: EPA disagrees with these comments, and believes (as does CASAC) that the clinical evidence also supports the conclusion that the current standards are not requisite to protect public health with and adequate margin of safety. These comments and EPA's responses were presented in detail in section II.E.2.b of the final rule. Similar comments and EPA responses were also discussed above in section II.A of this document.

(3) ***Comment:*** Several commenters discussed the analyses of SO_2-associated exposures and health risks presented in the REA. As in past reviews (e.g., EPA 2005, EPA 2007), EPA has estimated risks associated with the current standards to inform judgments on the public health risks that could exist under different standard options. Some industry commenters (e.g., API, UARG, LEC, ASARCO, NRECA) concluded that when considering the adequacy of the current standards, the Administrator should consider exposures and risks associated with actual SO_2 air quality rather than air quality allowed by the current NAAQS. These groups also note adjusting air quality to just meet the current and potential alternative standards is highly uncertain. They consequently challenged the relevance and appropriateness of EPA's use of SO_2 concentrations that have been simulated to just meet the current standards in assessing the adequacy of the current standards.

Response: EPA disagrees with these comments. These comments and EPA's responses were presented in detail in section II.E.2.c of the preamble to the final rule. Similar comments and EPA responses were also discussed above in section II.C.

(4) ***Comment:*** UARG generally concluded that under all air quality scenarios, the results of EPA's quantitative risk assessment (the third of the analyses conducted in the REA (chapter 9) are substantially overestimated because EPA did not use proper methods to estimate the parameters of the exposure-response functions used in its analyses. UARG contends this is because many of the subjects in the

controlled human exposure studies from which EPA's exposure-response functions were derived (see REA, Table 9-3) were exposed to more than one SO_2 concentration, yet EPA treated each exposure event as being independent (e.g., if the same subject was exposed to 200 and 300 ppb SO_2, EPA considered these as representing two independent exposure events). UARG contends that observations from the same subject exposed to different SO_2 concentrations are not independent observations and should not be treated as such. Notably, when UARG derived their own exposure-response functions taking into account that observations from the same subject exposed to different SO_2 concentrations are not independent of each other, they estimated appreciably less risk than that estimated by EPA.

Response: EPA presented this comment and provided an initial qualitative response in section II.E.2.c of the preamble to the final rule. A more detailed technical response to this comment is discussed above in section II.C.

(5) ***Comment:*** UARG concluded that EPA further overestimates the total number of occurrences of an adverse lung function response (i.e., total number of occurrences of increases in sRaw ≥100 or 200% and/or declines in $FEV_1 \geq 15$ or 20%) in its quantitative risk assessment. More specifically, UARG concluded that the use of 50 ppb bins, combined with assigning all exposures within a bin the probability of an adverse lung function response at the midpoint of that bin (e.g., all exposures from 0 - 50 ppb were assigned the probability of an adverse lung function response occurring at 25 ppb), resulted in a substantial overestimate of the total number of occurrences of lung function responses in asthmatics at moderate or greater exertion. UARG generally concludes that this is because the vast majority of exposures of asthmatics at moderate or greater exertion are occurring below the midpoint of the 0 - 50 ppb exposure bin (i.e., most exposures are occurring below 25 ppb), yet EPA is assigning these very low SO_2 exposures the higher probability of a lung function response associated with the midpoint of the 0 -50 ppb exposure bin. UARG contends that this results in a substantial overestimation of the total number of occurrences of lung function response in asthmatics and asthmatic children at moderate or greater exertion. UARG further notes that this methodological concern was raised in its comments on the second draft REA, but EPA failed to address this issue and relied heavily on this metric in the proposal with respect to the adequacy of the current and potential alternative standards.

Response: EPA presented this comment and provided an initial qualitative response in section II.E.2.c of the preamble to the final rule. A more detailed technical response to the binning issue discussed in this comment can be found above in section II.C.

IV. Comments on A New Short-Term SO_2 Primary Standard

This section discusses comments received on EPA's proposed 1-hour standard. Some commenters provided comments on the cost or economic impact of monitoring, implementation, or compliance associated with the proposed SO_2 NAAQS. As noted in section I.B of the preamble, the Clean Air Act bars consideration of costs in setting the NAAQS, and accordingly EPA has not considered costs, including the costs or economic impact of monitoring, implementation or compliance, in revising the primary SO_2 NAAQS.

A. Indicator

Few public commenters directly addressed the issue of the indicator for the standard. These commenters generally endorsed the proposal to continue to use SO_2 as the indicator for ambient SO_x.

B. Averaging time

(1) ***Comment:*** As discussed above, industry commenters who disagreed with setting a new 1-hour standard generally based this conclusion on their interpretation of the scientific evidence and their conclusion that this evidence does not support the proposed revisions to the current SO_2 NAAQS.

Response: These comments and EPA's responses were presented in detail in sections II.E.2.a and II.E.2.b of the preamble to the final rule.

(2) ***Comment:*** Some industry commenters (e.g. ASARCO, RTA, ABR, Nucor, KUC) and South Dakota expressed that EPA should have considered longer averaging times (e.g., 3-hour, 8-hour, 24-hour). In general, these groups concluded that a standard with a longer averaging time could potentially provide the same public health protection as a 1-hour standard, while also providing a more stable regulatory target. For example, in its comments, South Dakota states: "DENR recommends EPA evaluate a 3-hour or 8-hour standard to determine if these averaging periods are also protective of the public health. If they are, EPA should propose a 3-hour or 8-hour sulfur dioxide standard instead of a 1-hour standard. A longer averaging period would smooth out the variability of the upper range measurements and provide a more stabile standard" (see comments provided by South Dakota; p. 1) Similarly, RTA stated in its comments: "the short-term averaging period defined by EPA (i.e., 5-minutes to 24-hours) is not limited to only 5-minute, 1-hour and 24-hour averaging periods. EPA could explain in more detail why these three averaging periods were examined when considering appropriate averaging periods to limit short-term peaks of SO_2...a longer term average could provide additional stability to the standard, while at the

same time effectively protecting public health" (see comments provided by RTA; p. 3)

Response: These comments and EPA's responses were presented in detail in section II.F.2.b of the final rule

(3) ***Comment:*** Although health and environmental groups were supportive of setting a new 1-hour standard to protect against short-term exposures to SO_2 (depending on the level of the 1-hour standard selected), these groups generally commented that a 5-minute standard to protect against health effects associated with 5-minute peaks would be optimal (e.g., ALA, Sierra Club, EDF). For example, in its comments ALA et al., stated: "We need a short-term SO_2 standard, optimally a 5-minute standard, to protect against bursts of pollution that can result from start-up, shutdown, upset, malfunction, downwash, complex terrain, atmospheric inversion conditions, and other situations" and that "EPA has over emphasized a concern about the stability of a 5-minute standard… The record does not show that any alleged instability of a 5-minute standard has any relevance to whether such a standard is requisite to protect public health (see comments provided by ALA et al., p. 11-12)

Response: These comments and EPA's responses were presented in detail in section II.F.2.b of the preamble to the final rule. We also again emphasize CASAC's conclusion that "that a one-hour standard is the preferred averaging time". Samet (2009) at p. 15.

(4) ***Comment:*** ALA generally commented that EPA was not setting a 5-minute standard because of concerns over the number of monitors needed. ALA notes that this concern is not lawful under the CAA.

Response: As noted in final rule preamble sections II.F.2.b and II.F.2.c, EPA is not setting a 5-minute standard because of concerns over the stability of a 5-minute standard, and the deleterious effects an unstable standard could have on public health protection. The number of monitors needed should a 5-minute standard be adopted was not a consideration in the Administrator's rationale for not setting a 5-minute standard.

In addition, as noted in final preamble section II.F.2.b, a 1-hour standard to protect against 5-minute exposures is in agreement with CASAC advice and recommendations. That is, CASAC stated that they were "in agreement with having a short-term standard and finds that the REA supports a 1-hour standard as protective of public health" (Samet 2009, p. 1). Similarly, in a CASAC statement addressing whether a 1-hour averaging time can adequately control 5 - 10 minute peak exposures and whether there should be a 5-minute averaging time, CASAC stated that the REA had presented a "convincing rationale" (Samet 2009, p. 16)

for a 1-hour standard, and that "a one-hour standard is the preferred averaging time" (Samet 2009, p. 15).

(5) ***Comment:*** ALA favored a rolling average rather than a block average for determining compliance with the NAAQS. That is, ALA stated:

> EPA has proposed a block average to determine compliance with the one-hour daily maximum standard. That is, compliance would be measured against concentrations recorded in each hour of the day. However, this method of measuring compliance misses high concentrations that span the top of the hour. Our lungs do not differentiate between high concentrations that occur during hours beginning at the top of the hour, and all other hours in the day. To provide requisite health protection from short term exposures, EPA must base compliance on a rolling average for the one-hour standard. Such a rolling average would be consistent with a not to be exceeded form of the standard (see comments provided by ALA et. al., p. 14)

Response: EPA acknowledges that there are multiple ways of potentially determining compliance with the SO_2 NAAQS. However, we disagree that a rolling average is needed to provide requisite protection against short-term SO_2 exposures. The form of the standard being finalized is the 99th percentile of the distribution of 1-hour daily maximum SO_2 concentrations averaged over 3 years. Thus, since EPA is already considering the 99th percentile of the distribution of the highest 1-hour SO_2 concentrations in each day of the year, we believe that using a rolling average as opposed to a block average would result in negligible, if any, additional public health benefits. Moreover, we note that a rolling average for the 1-hour standard was not proposed

C. Form

(1) ***Comment:*** A number of industry groups (e.g., NAM, ASARCO) and South Dakota preferred a 98th percentile form. In general, their preference for a 98th percentile form was based on their conclusion that a form based on the 98th percentile would be more stable than a form based on the 99th percentile, and that a 98th percentile form is consistent with the forms selected in recent NAAQS reviews (i.e. $PM_{2.5}$ and NO_2). For example AirQuality stated:

> The Administrator should reconsider her proposal and choose instead the 98th percentile (or equivalent nth highest value) form of the standard for the added reliability and stability it offers in determining compliance or progress towards attainment. This approach has been promulgated for recent revisions of the $PM_{2.5}$ and NO_2 standards and this consistency should be maintained with SO_2 (see comments provided by AirQuality; p. 1).

Some groups also maintained that a 98th percentile form should be selected since a 98th percentile form is consistent with the forms selected in recent NAAQS reviews (i.e. $PM_{2.5}$ and NO_2).

Response: These comments and EPA's responses were presented in detail in section II.F.3.b of the preamble to the final rule

(2) ***Comment:*** Dow commented that "using the 99th percentile could still cause an area to be considered a non-attainment area for an unusual event in one year, using the 98th percentile would, with the 3 year rolling average reduce this possibility and allow better identification of real issues where resources need to be deployed."

Response: EPA disagrees with this comment. The form of the standard is the 3-year average of the 99th percentile of the annual distribution of 1-hour daily maximum SO_2 concentrations. Moreover, analyses in the REA indicate that in most locations analyzed, the 99th percentile corresponds to the 4th highest SO_2 concentration. Thus, an unusual event in one year would have to occur over at least four days, or at least on four different occasions (and each occasion would have to be on a different day). Moreover, as noted by the commenter, the use of the 3-year average will also mitigate this possibility. Finally, it is possible an unusual natural event could be considered an exceptional event and not result in an area being designated as being in nonattainment (see preamble to the final rule section VII.B).

(3) ***Comment:*** MSCC commented that:

> In place of the 99th percentile, 3 year/1hour average proposed, consideration should reasonably be given instead to a standard that is reasonably protective of the 400 ppb threshold above, more directly related to it, and which recognizes that not every measured exceedence of a threshold concentration represents the failure of a feasible control strategy. This could take the form of a standard that, for example, identified 400 ppb as the excessive concentration for a 5-10 minute period in given hour, and required hourly compliance at the 97th, 98th or 99th percentile level for a given year, in conjunction with a requirement for reasonable data completeness in each calendar quarter. Replication should be required to eliminate flukes that could and do arise from measurement errors, random events such as fires, accidents, natural events, and other circumstances beyond reasonable human control, as well as predictable spikes arising from deliberate cultural events such as fireworks displays (see comments provided by MSCC; p. 6).

Response: EPA disagrees with the commenter. As noted throughout the preamble to the final rule (e.g. see section II.E.2.b) and this RTC document (e.g.,

see section II.A), EPA considers the respiratory effects associated with 5- 10 minute SO_2 exposures as low as 200 ppb to be adverse to the health of asthmatics. Thus, we reject the idea that the form of the standard should be targeted to limit 5-minute peaks above the 400 ppb threshold. Moreover, the form of the standard is the 3-year average of the 99th percentile of the annual distribution of 1-hour daily maximum SO_2 concentrations. Thus, it is extremely unlikely that areas would be designated as nonattainment due to cultural events such as fireworks displays.

(4) ***Comment:*** A number of health and environmental groups supported a 99th percentile form, but expressed that they would prefer a more restrictive form, such as a no-exceedence based form. In addition, the Alexandria Department of Transportation and Environmental Services only recommended a no, or one exceedence based form. In general, these groups concluded that a more restrictive form would further limit the: 1) number of days an area could exceed the standard level and still attain the standard; and 2) the occurrence of 5-minute peaks of SO_2 above benchmark levels.

Response: These comments and EPA's responses were presented in detail in section II.F.3.b of the preamble to the final rule

(5) ***Comment:*** ALA generally commented that EPA favors a percentile form because it provides more stability than a more restrictive exceedence based form. Moreover, ALA indicates that EPA's concerns over stability have no basis in fact and no relevance under the CAA.

Response: ALA is incorrect in their suggestion that the primary reason EPA is setting a percentile based form is because of standard stability. The rationale for a percentile based form is discussed in detail in section II.F.3.b and II.F.3.c of the preamble to the final rule. In brief, this decision was based on multiple considerations including selecting a form of a new 1-hour standard that reflected that health evidence in the ISA indicating that the percentage of asthmatics affected and the severity of the response increases with increasing SO_2 concentrations. Thus, a percentile form is appropriate in order to give due weight to years when 1-hour SO_2 concentrations are well above the level of the standard, than to years when 1-hour SO_2 concentrations are just above the level of the standard. Moreover, we note that a concentration based form is in agreement with CASAC advice that: "there is adequate information to justify the use of a concentration-based form averaged over 3 years" (Samet 2009, p. 16).

(6) ***Comment:*** The CBD commented that:

> As a logical matter, it seems odd that EPA would reject an exceedance-based form due to its tendency to give less weight to years when concentrations are well above the standard, but would propose a three-year averaging period that could do the same thing, i.e., give diminished weight

to years with high concentrations (see comments provided by the CBD p. 6; note: footnotes have been omitted).

CBD also commented that:

> EPA does not explain its three-year averaging proposal except to state that it "increases the stability of the standard." Under the Clean Air Act, however, a NAAQS must be requisite to protect public health with an adequate margin of safety, regardless of cost and implementation issues. 42 U.S.C. § 7409(b)(1); see also Whitman, 531 U.S. at 464-71. Therefore, if EPA in fact believes that a stable regulatory standard is requisite to protect public health, EPA should explain in its responses to comments why this is so, and further should explain why a three-year averaging period would be required to produce a stable regulatory standard (see comments provided by the CBD p. 7; note: footnotes have been omitted).

Response: The commenter is correct that in part, EPA selected a concentration based form in order to give due weight to years when 1-hour SO_2 concentrations are well above the level of the standard than to years when 1-hour SO_2 concentrations are just above the level of the standard. However, EPA also considered that a concentration based form, averaged over three years, would likely be appreciably more stable than an exceedence based form. Selecting a form that is relatively stable is important to prevent locations from frequently shifting in and out of attainment thereby reducing public health protection by disrupting an area's ongoing implementation plans and associated control programs. Thus, EPA notes that this decision is based on more stable standards providing increased public health protection and not on implementation or cost issues. See American Trucking Assn's v. EPA, 283 F. 3d at 374-75.

(7) ***Comment:*** Some groups preferred the 4th highest form to the 99th percentile. For example, AirQuality stated that **if** a 99th percentile or 4th highest form is chosen over a 98th percentile or 7-8th highest form, than a 4th highest form is preferable. AirQuality states:

> The "4th" highest daily maximum concentration is preferable to the "99th" form in that it can provide an unambiguous determination of a "design value" in the face of missing data if concentrations are high. The 99th percentile form does not provide that certainty if data are missing (see comments provided by AirQuality, p.2).

Response: Appendix T Section 3.c describes two ways that a design value can still be considered valid even though it is incomplete. Section 3.c.i explains that even if the days are incomplete but the quarters are complete then the design value that is above the standard is valid. Also Section 3.c.ii provides for two diagnostic data substitution tests for use with data sets that do not meet the 75% requirement. These tests are complicated and may not be perceived as transparent to all the public, but EPA believes that this complexity is necessary and

appropriate given the usefulness of the tests in allowing at least some areas to be clearly determined to be meeting or not meeting the NAAQS despite the data incompleteness.

In addition, EPA notes that the 99th percentile was favored over the 4th highest form since it results in a sampling from the same part of the annual distribution of 1-hour daily maximum SO_2 concentrations regardless of the number of 1-hour daily maximum concentrations reported in a given year for a particular location.

D. Level

(1) ***Comment:*** Many industry groups (e.g., NAM, Golder, AFPA, AA, Marathon Petroleum) indicated that other environmental/health agencies (e.g., California Air Resource Board, World Health Organization (WHO)) have used the same health information from controlled human exposure and epidemiologic studies to set a 1-hour SO_2 standard at a level higher than the proposed range of 50 - 100 ppb. Thus, these groups generally contend that EPA is interpreting the health information too stringently.

Response: EPA disagrees with these comments. The California Air Resource Board adopted its 1-hour standard in 1984 and retained this standard in 1995 (see http://www.arb.ca.gov/research/aaqs/caaqs/so2-1/so2-1.htm), while the WHO guidelines were last updated in 2005 (see http://www.euro.who.int/Document/E90038.pdf). Thus, especially with respect to the California 1-hour standard, it is highly unlikely that all the health information available in the current SO_2 NAAQS review was available in these previous reviews.

We also note that there are significant differences in the 1-hour standard being finalized by EPA and the existing WHO 10-minute recommendation. For example, the WHO recommendation is a ten minute recommendation equal to approximately 190 ppb (see http://www.euro.who.int/Document/E90038.pdf). Because of the difference in averaging times, in order for EPA to protect against similar 5-10 minute SO_2 concentrations of concern with a 1-hour standard, that necessarily means that a 1-hour standard would have to be lower than the 190 ppb WHO guidelines. The WHO also has a 24-hour SO_2 recommendation while EPA is revoking its 24-hour standard and using a 1-hour standard to protect against health effects associated with averaging times from 5-minutes to 24-hours.

In addition, we note that the form of the standard EPA is finalizing differs from that of the California 1-hour standard. While the 1-hour standard EPA is finalizing is the 99th percentile of the distribution of 1-hour daily maximum SO_2 concentrations averaged over 3 years, the California standard is more restrictive. That is, the form of the California standard indicates that the level is not to be exceeded (see http://www.arb.ca.gov/research/aaqs/aaqs2.pdf). Moreover, in

addition to a 1-hour standard, California also has a 24-hour standard at a level of about 40 ppb. Thus, comparing only the levels of different short-term standards is often misleading.

Finally, we note that the CAA entrusts the EPA Administrator to set standards for criteria pollutants that are in her judgment, adequate to protect public health with an adequate margin of safety, and that these standards are to be based on air quality criteria, not on standards established by other entities.

(2) ***Comment:*** With regard to the controlled human exposure evidence, health and environmental groups generally concluded that a 1-hour SO_2 standard no higher than 50 ppb is needed to protect against 5-minute SO_2 benchmark exposures as low as 100 ppb identified from mouthpiece exposure studies, rather than the 200 ppb 5-minute SO_2 benchmark identified from "free breathing" controlled human exposure studies. More specifically, in their combined comments, ALA et. al., stated:

> In its analysis of data from chamber studies in the ISA and in the REA, EPA focuses on studies of free breathing exposure. In doing so, EPA improperly and arbitrarily downplays important evidence that reported increased airway resistance, a measure of bronchoconstriction, in subjects with mild asthma at concentrations of 100 ppb. Regrettably, EPA does not rely on the mouthpiece studies in formulating its proposed standards (see comments provided by ALA et. al., p. 15)…In downplaying the mouthpiece studies, EPA ignores the large segment of people who rely on oral or oronasal breathing some or all of the time (see comments provided by ALA et. al., p.16)

Response: These comments and EPA's responses were presented in detail in section II.F.4.b of the preamble to the final rule. Similar comments and EPA responses were also discussed above in section II.A.

(3) ***Comment*:** Health and environmental groups (e.g., ALA, ATS, EDF, NRDC, Sierra Club, CBD) and the Alexandria Department of Transportation and Environmental Services generally concluded that the epidemiologic evidence indicates that a standard no higher than 50 ppb is required to protect public health. For example, it its comments the CBD stated:

> Epidemiologic studies referenced in the Proposed Rule showed positive, and in many cases statistically significant, relationships between ambient SO_2 concentrations and hospital admissions where 99th percentile 1-hour concentrations ranged from 50 - 460 ppb. Of these studies, two showed positive and sometimes statistically significant relationships in single-pollutant models at 50 ppb, and three studies showed statistically significant correlations at 78- 150 ppb in multi-pollutant models. These three multipollutant studies, moreover, "lend[] strong support . . . to the conclusion that SO_2 effects are generally independent" of those of co-

pollutants like particulate matter. Giving these studies their proper weight, and allowing for an adequate margin of safety, EPA should set a one-hour NAAQS at a level no higher than the lowest concentration at which positive, adverse relationships have been demonstrated: 50 ppb (note that footnotes were omitted; see comments provided by CBD p.5).

Response: These comments and EPA's responses were presented in detail in section II.F.4.b of the preamble to the final rule. We also again emphasize CASAC's view that a 50 ppb 1-hour standard (99^{th} percentile form) is by no means compelled, that no level lower than 50 should be considered, and that EPA could legitimately consider standards with higher levels. Samet (2009) at p. 16. EPA's final determination as to level is consistent with this advice

(4) ***Comment:*** A number of industry groups did not support setting a new 1-hour SO_2 standard. However, several of these groups (e.g., UARG, API, ASARCO) and the SC Chamber of Commerce concluded that, if EPA does choose to set a new 1-hour standard, the level of that standard should be $\geq$ 150 ppb. In addition, South Dakota and Ohio recommended standard levels at 150 ppb. As a basis for this recommendation, these groups generally emphasized uncertainties in the scientific evidence. As noted above, these commenters typically concluded that the available epidemiologic studies do not support the conclusion that SO_2 causes the reported health effects. This was based on their assertion that the presence of co-pollutants in the ambient air precludes the identification of a specific SO_2 contribution to reported effects.

Response: These comments and EPA's responses were presented in detail in section II.F.4.b of the preamble to the final rule.

(5) ***Comment:*** Industry groups (e.g., API, ABR, ASARCO) had several comments with respect to the epidemiologic study conducted by the NYDOH (NYDOH, 2006). First, these groups generally concluded that the results of this study are mixed. That is, while SO_2 effect estimates were positive and statistically significant even in multipollutant models with $PM_{2.5}$ or NO_2 in the Bronx, SO_2 effect estimates were actually negative in Manhattan in both single and multipollutant models. These groups also contend that this report was not peer-reviewed and that the authors of this study indicated that high correlations among pollutants in the Bronx made it difficult to confidently identify which pollutants are actually increasing risks. For these reasons, industry groups generally concluded that this study should not be relied upon by the Administrator in considering the appropriate level of anew 1-hour standard.

Response: These comments and EPA's responses were presented in detail in section II.F.4.b of the preamble to the final rule. Other comments and EPA responses with respect to this study are presented below.

(6) ***Comment:*** Some groups (e.g., ASARCO, ABR) also commented that the NYDOH (NYDOH, 2006) results are uncertain because it was noted by the authors that the SO_2 concentrations used to estimate relative risk associated with SO_2 exposure were arbitrary (see ASARCO comments, p.6). Others commented (e.g., ACSBPP) that the lack of association in Manhattan is not consistent with a causal SO_2 impact. Furthermore, others commented that the discrepant results in the Bronx and Manhattan could be explained by residual confounding by other factors such as correlation with other pollutants or smoking prevalence, which was not controlled for in the analysis.

Response: These commenters misconstrued or misunderstood the text when they claimed the SO_2 concentrations used to estimate the relative risk associated with SO_2 exposure were arbitrary. On Page 21 of the NYDOH study (2006), the authors state, "It should be noted that the choice of concentration increments used to compute the RRs is an arbitrary one." The commenters failed to include the word "increments" in their comments. What the study authors are referring to is that they present their results per some incremental change in exposure concentration. The ISA standardizes all of the studies so that effect estimates describing 24-hour average SO_2 concentrations all have an incremental change of 10 ppb and effect estimates describing 1-hour maximum SO_2 concentrations all have an incremental change of 40 ppb. It is also common in the peer-reviewed literature to see investigators use the mean concentration, the interquartile range of concentrations, or the standard deviation as the incremental change. In this case, the authors use the mean SO_2 concentration averaged over the two study sites (11 ppb; See Table 3, page 50 of NYDOH, 2006). What's more, they present a comparison of relative risks computed using alternative concentration increments in Table 4b (page 52 of NYDOH, 2006). No where do the authors claim that the SO_2 concentrations themselves were arbitrary.

With respect to the lack of association in Manhattan, EPA notes that there were 29,987 asthma visits in the Bronx during the study period, and only 5,014 asthma visits in Manhattan during this same period (See Table 1, page 38 of NYDOH, 2006). The much smaller sample size in Manhattan makes it more difficult to detect a statistically significant association when compared to the sample size available in the Bronx. Additionally, the demographics of the population in the Bronx and Manhattan differ by age, race and socioeconomic status, all of which may be susceptibility factors that would explain why an association was observed in the Bronx and not Manhattan.

In addition, we note that the authors acknowledge that "Variation in effects of unmeasured co-pollutants, such as indoor allergens, environmental tobacco smoke or local traffic and industrial emissions, might also influence the apparent differences in acute asthma ED responses to ambient air pollution observed in the two communities. Increased exposure to such local measured pollutants could directly increase baseline asthma morbidity and might also indirectly increase the response to changes in ambient air pollutants by increasing airway inflammation

and hyper-responsiveness to acute airway irritants. Data were not available to address these possible effects in this report." In fact, by the nature of the study design, these potential confounders are not able to be measured on an individual level in any time-series studies of ED visits or hospital admissions. Thus this limitation applies to all time-series studies and is not specific to NYDOH, 2006. In light of this limitation, the authors still conclude that "The results suggest that the criteria pollutants $PM_{2.5}$, SO_2, O_3 and NO_2 had a statistically detectable impact on acute asthma ED visits in a community with a relatively high baseline rate of acute asthma exacerbations. In two-pollutant and three-pollutant regression models, O_3 and SO_2, and to a lesser extent maximum one-hour $PM_{2.5}$, were the most robust pollutants. In other words, these pollutants exhibited less change in their effect estimates as additional pollutants were added to the models."

Additional discussion with respect to the apparent discrepancy in results in the Bronx and Manhattan study areas can be found in section II.F.4.b of the preamble to the final rule.

(7) ***Comment:*** Some groups (e.g., ASARCO, ABR) also commented with respect to the NYDOH (NYDOH, 2006) analysis that the Administrator failed to note that the positive association in the Bronx was observed at biologically implausible lag times of 3 or 4 days but not at 0-2 days.

Response: The commenters are incorrect in stating that the associations observed in the Bronx were observed at "biologically implausible lag times of 3 or 4 days, but not at 0-2 days". In Table 4a (page 51, NYDOH, 2006) the authors present the relative risk for the "5-day mean" which is the average of days 0, 1, 2, 3, and 4. As noted in the response to Comment 12 in section II.B, EPA relies heavily on the effect estimates for the average of multiple days. Perhaps the commenters were referring to Figure 8 (page 71, NYDOH, 2006) which presents the relative risk for each of the single day lags from 0 to 4. Here, there are elevated relative risks on lag day 0, 2, 3, and 4 with the ones on days 2, 3, and 4 appearing to be statistically significant. Single lag day 2 is statistically significant and has the relative risk of greatest magnitude. This response is not biologically implausible.

(8) ***Comment:*** With respect to Ito et al., (2007), industry groups generally commented that since the SO_2 effect estimate did not remain statistically significant in multipollutant models with NO_2, this study does not indicate an independent effect of SO_2 on emergency department visits in the NYC study area. API specifically commented:

> The RR for an increase of 6 ppb SO_2 was statistically significant (1.20; 95% CI: 1.13, 1.28) and remained so when $PM_{2.5}$, O_3, or CO was included in the model, but became nonsignificant when NO_2 was included in the model (RR not provided, 95% CI: 0.9, 1.1). Because associations with SO_2 could be attributable to NO_2, this study cannot be used to assess the effects

> of SO_2 on health effects with small incremental increases in exposure (see comments provided by API; p. B-4).

Response: These comments and EPA's responses were presented in detail in section II.F.4.b of the preamble to the final rule

(9) ***Comment:*** With respect to Ito et al., (2007), ABR commented that the authors state: "

> SO_2 and CO showed lower monitor to monitor correlation and low within-city precision of the mean levels, indicating that these pollutants' risk estimates could be biased in short term health effects models (see comments by ABR; p.5)

ABR also notes that the authors concluded the study with a precaution against using multipollutant models in health analyses.

Response: EPA agrees with Ito et al. (2007) that the lower monitor correlations and within-city precision could bias short-term health effects models. But as addressed in the response to other comments (see section II.B), EPA maintains that measurement errors in community time-series and panel epidemiologic studies are more likely to underestimate the strength and the significance of any association between SO_2 and adverse health effects, thereby decreasing the likelihood of an association reaching statistical significance and likewise decreasing the possibility of a false identification of an association (Section 2.6.4.4, p. 2-63). Thus, the measurement error makes it more difficult to detect a positive and statistically significant effect estimate, even when such an association exists. Moreover, the signal that drives statistical associations between ambient concentrations and health effects in time-series studies is the day-to-day changes in concentration, not the absolute daily values. Appropriately located central SO_2 monitors can adequately characterize such day-to-day changes. Exposure studies have found statistically significant regression slopes between personal exposure to SO_2 and ambient SO_2 concentrations at fixed-site monitors (Section 2.6.3.2, p. 2-56), indicating that fluctuations in ambient concentration are an important driver of fluctuations in SO_2 exposure.

EPA agrees that multipollutant models should be used and interpreted cautiously in health analyses. Currently, these multipollutant models are the most common tools used by investigators to try to disentangle the effects of individual criteria pollutants. When examined across the body of evidence, EPA believes that the results of the multipollutant models can be informative about the robustness of associations observed in epidemiologic studies.

(10) ***Comment:*** With respect to Schwartz (1995), industry groups generally commented that the results of this study are mixed, and therefore should not be

considered by the Administrator. More specifically, these commenters noted that although the results in New Haven remained statistically significant in the presence of PM_{10}, the SO_2 effect estimate in Tacoma was reduced and no longer statistically significant in the presence of PM_{10}. Commenters also noted that in both cities, the SO_2 effect estimate was reduced and no longer statistically significant in the presence of O_3.

Response: These comments and EPA's responses were presented in detail in section II.F.4.b of the preamble to the final rule

(11) ***Comment:*** Some commenters indicated that because EPA did not find the epidemiologic evidence adequate enough to support a quantitative risk assessment based on epidemiology, then these studies should not be relied upon for informing the level of a standard.

Response: EPA disagrees with this comment. Using epidemiologic studies for the purpose of a quantitative risk assessment is a separate issue from using air quality information from locations in which epidemiologic studies were conducted to help inform the level of a new 1-hour standard. EPA judged that a quantitative risk assessment using concentration-response functions derived from any one epidemiologic study would not produce quantitative results that would be particularly useful in the decision making process. However, although no one epidemiologic study was appropriate for use in a quantitative risk assessment, EPA concluded that looking at SO_2 air quality in the ten locations U.S. epidemiologic studies reported positive associations between ambient SO_2 and emergency department visits or hospitalizations was informative with respect to setting the level of a new 1-hour standard.

(12) ***Comment:*** Dow commented that "if EPA opts to set a 1-hour NAAQS for SO_2, the expected difference between "monitor locations of expected maximum short-term concentration" and area-wide concentrations should be considered in establishing the standard (see comments provided by Dow; p.2).

Response: EPA set the level of a new 99^{th} percentile 1-hour daily maximum SO_2 standard at 75 ppb. In doing so, EPA considered that the monitors in three locations where epidemiologic studies (i.e., NYDOH (2006), Ito et al., (2007), Schwartz (1995)) reported statistically significant associations in multipollutant models with PM may not have recorded the highest 99^{th} percentile 1-hour daily maximum SO_2 concentration across a given study area. This consideration is described in section II.F.4.c of the preamble to the final rule.

(13) ***Comment:*** In general, EPRI commented that using the epidemiology to set a 1-hour standard is problematic because few of these studies considered a 1-hour averaging time

Response: EPA acknowledges that many of the epidemiologic studies considered in the ISA and REA used longer averaging times than 1-hour (e.g., 24-hour, 3-hour). However, we disagree with that using 1-hour air quality information from the areas these epidemiologic studies were conducted to inform a new 1-hour standard is problematic. EPA notes that just because a particular epidemiologic study used a longer averaging time, it does not rule out the possibility that the effects reported in those studies may be associated with shorter-term SO_2 concentrations. In fact, when describing epidemiologic studies observing positive associations between ambient SO_2 and respiratory symptoms, the ISA stated "that it is possible that these associations are determined in large part by peak exposures within a 24-hour period" (ISA, section 5.2 at p. 5-5). EPA notes that this assertion is based on both the large body of controlled human exposure studies reporting respiratory effects following 5 - 10 minute SO_2 exposures, as well as a body of epidemiologic studies reporting positive associations between < 24-hour ambient SO_2 concentrations and respiratory morbidity endpoints.

(14) ***Comment:*** In addition to generally concluding that the epidemiology is too uncertain to demonstrate that SO_2 has an independent effect on the respiratory effects reported in those studies, many industry groups (e.g., API, ACC, PE, EEI, CIBO, CRA, Pepper Hamilton, RMA, Louisiana Chemical, A&B, TFI) also generally commented that adverse health effects do not occur following 5-10 minute SO_2 exposures < 400 ppb in controlled human exposure studies (an issue also discussed above in final rule section II.E.2). Thus, these groups generally maintained that the level of a 1-hour standard should not take into account limiting 5-minute peaks ≤ 200 ppb. From this argument, many of these groups further maintained that 1-hour standard levels ≥ 150 ppb are requisite to protect public health with an adequate margin of safety.

Response: These comments and EPA's responses were presented in detail in section II.F.4.b of the preamble to the final rule.

(15) ***Comment:*** Both industry (e.g., Rio Tinto) and environmental/health groups (e.g., ALA et al.,) referenced the 5-minute peak to 1-hour mean ratios in REA Table 10-1 as a rationale for selecting a specific level for a 1-hour SO_2 standard to adequately protect against 5-minute SO_2 concentrations of concern (notably, industry was generally opposed to a new 1-hour standard, but they still suggested standard levels in the event the Administrator chose to adopt such a standard).

Response: EPA did not use the 5-minute peak to 1-hour mean ratios from REA Table 10-1 in its consideration for the level of a new 1-hour SO_2 standard. Rather, EPA used these ratios as an initial consideration for an appropriate averaging time for a new short-term SO_2 standard. As noted in the proposal, this information suggested that a 1-hour averaging time was likely to be more efficient at limiting 5-minute concentrations of concern than a 24-hour averaging time. As stated in footnote 19 of the preamble to the proposal:

> The analysis of peak to mean ratios was used as an initial screen to evaluate which averaging times could be suited to control 5-minute peaks of SO_2. The more sophisticated analysis for ultimately determining that a one-hour averaging time set at an appropriate level could effectively limit these 5-minute peaks was the air quality, exposure, and risk analyses discussed in section II.F.4. (74 FR 64831)

That is, EPA reasonably based its decision on the appropriate level for limiting 5-minute concentrations of concern identified from controlled human exposure studies on the sophisticated air quality, exposure, and risk analyses presented in detail in chapters 7 – 9 of the REA and the summary of the estimates from those analyses presented in sections II.F.4.b and II.F.4.c of the preamble to the proposal (see especially Tables 2 - 4). However, as previously noted EPA did not place the same weight on all of these analyses. For example, EPA placed relatively more weight on the St. Louis exposure analysis than it did on the St. Louis quantitative risk assessment (see final rule preamble section II.E.2.c).

We also note that the ratios presented in Table 10-1 are from a small number of monitors in areas voluntarily reporting 5-minute SO_2 concentrations from the years 2004 -2006. Moreover, not all the monitors in Table 10-1 reported 5-minute concentrations during the entire three year period (see REA, Table 10-1). Thus, while EPA finds this data was reasonable to use as an initial screen for an appropriate averaging time, we do not think it is a sufficient basis for selecting the level of a new 1-hour standard to protect against 5-minute concentrations of concern. Again, EPA relied on the more sophisticated air quality, exposure, and risk analyses as they indicate the extent to which a given level of a 1-hour standard limited 5-minute concentrations of concern.

E. Retaining or revoking the current SO_2 NAAQS

(1) ***Comment:*** Public health (e.g., ALA, ATS) and environmental organizations (e.g., CBD, WEACT) were generally opposed to revoking the current 24-hour and annual standards. These groups generally concluded that the 24-hour standard should be revised while the annual standard should be retained. In support of this position, ALA et al., cited air quality information from the REA indicating that if air quality was simulated to just meet a 99^{th} percentile 1-hour daily maximum standard in the proposed range of 50 – 100 ppb, then in some locations analyzed, 99^{th} percentile 24-hour average SO_2 concentrations would be above concentrations (i.e., above 99^{th} percentile 24-hour average concentrations) in cities where U.S. emergency department visit and hospital admission studies reported positive associations with SO_2. In addition, many of these groups were opposed to revoking the current annual standard. In general, these groups concluded that given the uncertainties associated with SO_2 exposure and long-term health effects, EPA should err on the side of being health protective and retain the existing annual standard.

Response: These comments and EPA responses are discussed in detail in final rule section II.F.5.b.

(2) ***Comment:*** NAACA, NESCAUM, and Vermont, while supportive of revoking the existing standards, also suggested EPA explore setting a new 24-hour standard to minimize the potential that multiple hours within a day would exceed a 1-hour standard

Response: EPA generally agrees with the commenters that given the form of the standard selected, a 99th percentile daily maximum, there is potential for multiple hours within a day that would exceed the 1-hour level selected for that standard. However, given typical patterns in air quality data, the frequency of days having multiple hours above a given 1-hour level is likely rare. We also again emphasize CASAC's conclusion that "that a one-hour standard is the preferred averaging time." Samet (2009) at p. 15.

(3) ***Comment:*** The CBD commented that:

> In proposing to revoke the 24-hour standard, EPA appears to assume that health effects found in epidemiologic studies based on 24-hour exposures are driven entirely or primarily by very short-term (five- to ten-minute) peak exposures. This assumption, however, is not borne out by the evidence (see comments provided by the CBD p. 7).

Response: EPA provided a response to similar comments in final rule preamble section II.F.5.b. We further note that EPA's rationale does not assume that all 24-hour associations in epidemiologic studies are primarily being driven by 5- 10 minute peak SO_2 concentrations. Rather, it reasonably considers that the overall body of health evidence suggests that respiratory effects following SO_2 exposure may be most related to averaging times $\leq$ 1-hour (see preamble section II.F.5.b).

(4) ***Comment:*** The CBD commented that EPA should better explain why it proposed to revoke the current annual standard. The CBD also noted that:

> CASAC points out that EPA has not focused on causality in the same way in reviewing the health effects of other pollutants. EPA's proposal also may run afoul of a long line of cases holding that a NAAQS must not only protect against known hazards, but also must protect against uncertain and incompletely understood hazards. See Am. Trucking Ass'ns, 283 F.3d at 369; Am. Lung Ass'n, 134 F.3d at 389; Lead Indus. Ass'n, 647 F.2d at 1152-55. (see comments provided by the CBD p. 8; note: footnotes have been omitted)

Response: EPA provided its rationale for revoking the annual standard in final rule preamble section II.F.5.b. We note further, that although the commenter is

correct that the adequate margin of safety standard affords authority to EPA to act to protect against uncertain or incompletely understood hazards, EPA is not compelled to act when there is evidence that no hazard exists. The ISA finds that there is inadequate evidence to infer a causal relationship between morbidity and mortality from long-term SO_2 exposure. ISA p. 5-6; see also ISA p. 5-13 explaining the lack of evidence of causality between long-term SO_2 exposure and particular health end points. See American Farm Bureau Federation v. EPA, 559 F. 3d 512, 538-39 (D.C. Cir. 2009) ("The EPA reasonably decided that an annual coarse particle standard is not necessary because, as the Criteria document and the Staff paper make clear, the latest scientific data do not indicate that long-term exposure to coarse particles poses a health risk").

With respect to CASAC, the CBD provided the following information in a footnote:

> See Samet 2009 at 9 ("Some discussion is needed that indicates why the risk assessment for this pollutant, in contrast to others, is limited only to health effects that are classified as sufficient to infer causality.").

EPA notes that we placed primary emphasis on those health endpoints for which the ISA concluded the strongest evidence. More specifically, the preamble to the final rule states (see introduction to section II):

> In reaching this decision, EPA has drawn upon an integrative synthesis of the entire body of evidence on human health effects associated with the presence of SO_2 in the ambient air, and upon the results of quantitative exposure and risk assessments reflecting this evidence. As discussed below, this body of evidence addresses a broad range of health endpoints associated with exposure to SO_2 in the ambient air. In considering this entire body of evidence, EPA chose to focus most on those health endpoints for which the ISA found the strongest evidence of an association with SO_2 (see section II.B below). Thus, the rationale for this final decision on the SO_2 NAAQS focused primarily on respiratory morbidity following short-term (5-minutes to 24-hours) exposure to SO_2, for which the ISA found a causal relationship.

(5) ***Comment:*** Amanda L. Matthews urged EPA to retain the annual standard in order to protect against long-term SO_2 effects on prenatal/neonatal health outcomes. She contends that EPA ignored several key long-term SO_2 exposure studies with regard to these health outcomes. In particular: Hoppenbrouwers (1981) with regard to Sudden Infant Death Syndrome (SIDS); Liu et al., (2003) with regard to increases in pre-term delivery and low birth weight; and Dales et al., (2004) with regard to SIDS

Response: As noted by the commenter, EPA found the association between ambient SO_2 and long-term health effects to be inadequate to infer the presence or

absence of a causal relationship. That is, the ISA found the long-term health evidence to be of insufficient quantity, quality, consistency, or statistical power to make a determination as to whether SO_2 was truly associated with these health outcomes (ISA, Table 1-2). Notably, this included an evaluation of the possible associations between long-term (weeks to year) exposure to SO_2 and adverse prenatal and neonatal outcomes. EPA further notes that the general scientific conclusions of the ISA were reviewed and accepted by CASAC. With regard specifically to the studies mentioned above, EPA did consider Liu et al., (2003) as well as Dales et al., (2004), but still found the overall breadth of the information relating long-term exposure to SO_2 and adverse prenatal and neonatal outcomes inadequate to infer the presence or absence of a causal relationship. With respect to the study by Hoppenbrouwers et al. (1981), this study was not included in the final ISA because the focus of the document was on recent scientific studies, and re-evaluation of only some key older studies (primarily key older controlled human exposure studies). Additionally, the lag time used in the Hoppenbrouwers et al. (1981) study was 7 weeks, which is not consistent with any known mechanism by which SO_2 may cause adverse health outcomes. That being said, EPA can confidently state that inclusion of this study in the ISA would not have changed the final conclusion with respect to prenatal and neonatal outcomes.

(6) ***Comment:*** Amanda L. Matthews urged EPA to retain the annual standard generally commenting that a 1-hour standard in the proposed range will likely not prevent annual SO_2 concentrations from exceeding the level of the current annual standard.

Response: EPA disagrees with this comment. Table 10-4 of the REA gives a clear indication that 99th percentile 1-hour daily maximum standards in the range of 50 -100 ppb (and indeed up to 150 ppb) will likely prevent annual SO_2 concentrations from exceeding the level of the current annual standard (i.e. approximately 30 ppb). In fact, Table 10-4 estimates that given a 100 ppb standard, the highest annual SO_2 concentration in any county analyzed in this table would only be 15.5 ppb. Thus, a standard level of 75 ppb would be expected to keep annual SO_2 concentrations even lower. EPA notes that REA Appendix Tables D-5 and D-6 show similar information.

(7) ***Comment:*** Health and environmental groups urged EPA to maintain or lower the existing 24-hour standard. As evidence that both a standard designed to limit 5-10 minute peaks of SO_2 and a standard to limit 24-hour average concentrations of SO_2 is needed, some of these groups cite SO_2 WHO guidelines and standards in SO_2 standards in California. For example, ALA states:

> …both World Health Organization and the state of California recommend or maintain both a short-term (hourly or 10-minutes) and a 24-hour standard. The World Health Organization has recommended both a 10 minute standard and a 24-hour standard. Their 24- hour standard recommendation is for a standard of 7 ppb, far more stringent than the

U.S. standard, and their recommendation for a 10-minute standard is 175 ppb. The California Air Resources Board has established a 24-hour standard of 40 ppb, not to be exceeded. This standard is in addition to the state's one-hour standard for SO_2 (note that footnotes have been omitted; see comments provided by ALA et. al., p. 9).

Response: As noted above, the CAA entrusts the EPA Administrator to set standards for criteria pollutants that are in her judgment, adequate to protect public health with an adequate margin of safety, and that these standards are to be based on air quality criteria, not on standards established by other entities.

That being said, EPA notes that a 99^{th} percentile 1-hour daily maximum standard set at a level of 75 ppb is expected to limit 5-minute to 24-hour SO_2 concentrations associated with respiratory morbidity effects in both epidemiologic and controlled human exposure studies. See sections II.F.2.b, II.F.2.c, II.F.4.b and II.F.4.c of the final rule preamble for more detail.

V. Technical Issues with Monitoring Requirements

(1) ***Comment:*** LEC expressed concern that EPA's proposed two-pronged monitoring network based on the Population Weighted Emissions Index (PWEI) metric and a state's contribution to the national SO_2 emissions inventory would likely result in monitors near major sources where SO_2 "hot spots" are likely and fail to provide sufficient monitors in non-urban and rural areas to appropriately characterize background concentrations for permitting purposes. LEC suggests that EPA encourage states to site area-wide monitors to establish background concentration for use in permitting and to track air quality trends. When a state does not have an appropriate background monitor, LEC included suggestion on using source-oriented monitoring data to estimate background.

Response: As explained in sections III and IV of the preamble to the final rule, EPA intends to use a hybrid approach that combines monitoring and modeling, using each of these analytic tools where they are most appropriate and effective. As a result, EPA has revised the scope of the monitoring network is revised so that it is no longer required to be source-oriented in nature (i.e., "hot-spot" monitoring only). Instead the final monitoring network design now has the flexibility to address multiple monitoring objectives including source characterization, highest concentration, population exposure, general background, or regional transport. As a result of this flexibility, the commenter's concern should be alleviated because, as part of the required monitoring network, states may site monitors to address the need for measuring background concentrations.

(2) ***Comment:*** RRI recommended EPA change its monitoring guidance in order to "allow the use of emission distributions in a probabilistic implementation of compliance modeling for short-term probabilistic standards such as the 1-hour SO_2 NAAQS."

Response: Under a hybrid analytical approach, EPA anticipates using both ambient monitoring and the modeling of SO_2 sources in the implementation of the revised NAAQS. EPA anticipates that dispersion modeling will be used to assess impacts of large and medium sized sources. Therefore, as indicated in the final rule, EPA intends to develop guidance for the use of refined air quality dispersion modeling in implementing the new SO_2 1-hour NAAQS and the issue of how to appropriately characterize emissions will be addressed in that guidance, as needed.

(3) ***Comment:*** NACAA provided comments urging EPA to provide greater flexibility in the siting requirements for new SO_2 monitors in order to avoid requiring the installation of redundant SO_2 monitors and allow for states to use a broader range of criteria to determine the best locations for SO_2 monitors. NACAA also included suggestions on when duplicative monitors could be removed. NYSDEC also noted that the two prong approach could result in duplicative monitoring.

Response: Under a hybrid analytical approach, introduced in section III of the preamble to the final rule, the monitoring network is no longer required to be source-oriented in nature. As further explained in section IV.B of the preamble, the required monitoring network has the flexibility to have monitoring sites characterizing one or more of the following objectives: source characterization, highest concentration, population exposure, general background, or regional transport (discussed in section IV.B.3 of the preamble). EPA believes this flexibility alleviates much of the concern raised over redundant or unnecessary monitoring and, therefore, it is unnecessary to address the specific suggestions on reducing such duplicative monitoring.

IV.A: Comments on Proposed Monitoring Program

(1) ***Comment:*** NYSDEC, noting the significant shift in SO_2 emissions over the last three decades away from small and mobile emitters of SO_2 to large, stationary sources, expressed concern in its comments that the "proposed SO_2 monitoring network design does not adequately address this source transition and will not ensure that the largest point sources are adequately characterized." To address this source transition effectively, NYSDEC recommended using a CBSA emissions threshold (50,000 tpy) and a point source emissions threshold (20, 000 tpy) instead of a PWEI or state's contribution to SO_2 emissions approach for siting monitors. NESCAUM made similar threshold recommendations.

Response: Under a hybrid analytical approach, introduced in section III of the preamble to the final rule, and further explained in section IV,V, and VI of the preamble, EPA anticipates using both ambient monitoring and the modeling of SO_2 sources to assess compliance with the new 1-hour SO_2 NAAQS. We believe that for a short-term 1-hour standard it is more technically appropriate, efficient, and effective to use modeling as the principal means of assessing compliance for medium to larger sources, and to rely more on monitoring for groups of smaller sources and sources not as conducive to modeling. As a result, EPA anticipates that SO_2 sources will be adequately characterized by either, or both of, ambient monitoring and source modeling.

(2) ***Comment:*** Indiana urged EPA to emphasize the placement of SO_2 monitors in "areas that record higher values and away from those found to be below the level of the proposed NAAQS."

Response: Under EPA's anticipated use of a hybrid analytical approach, as introduced in section III of the preamble to the final rule and the monitoring network design described in section IV, the final monitoring network design is more flexible than the proposed network design. The monitor objectives of the final network design are broadened in the final rule to include assessment of population exposure, general background concentrations, SO_2 transport, long-term trends, and source oriented and/or highest concentration data. This increased

flexibility gives states the ability to select areas where they believe ambient monitoring is most warranted. As a result, we believe that the final network design allows states to emphasize placement of SO_2 monitors in "areas that record higher values and away from those found to be below the level of the proposed NAAQS" as the commenter suggested.

(3) ***Comment:*** The City of Alexandria expressed concern in its comments that, while an increased focus on monitoring SO_2 concentrations in high impact areas is a positive change by EPA, Alexandria's own experience in air quality monitoring "shows that local monitoring should only be used as a backstop, in order to assist in compliance verification, and only after air quality model-based limitations are developed and implemented by the large stationary sources that have the potential to contravene NAAQS protections." Under the proposed network design, while new SO_2 monitors could be placed to identify areas of localized nonattainment caused by discrete stationary sources, the commenter believes that sole reliance on these locally-sited monitors is misplaced. The commenter contends this is because monitoring methods cannot fully and comprehensively identify all areas of non-compliance caused by a single source's maximum potential emissions, for all of the possible local meteorological conditions. Instead, the commenter suggests using modeling major sources to demonstrate compliance with the SO_2 NAAQS.

Response: Partly in response to these and other comments, and a re-examination of our historical approach to SO_2 NAAQS implementation, we now anticipate using a hybrid analytic approach combining the use of monitoring and available modeling to assess compliance with the new 1-hour SO_2 NAAQS. EPA discusses its revised intended approach in chapters III, IV, V, and VI of the preamble to the final rule, EPA believes that under a hybrid analytical approach, the commenter's concerns should be addressed.

(4) ***Comment:*** NACAA stated that "EPA and NACAA jointly developed a National Monitoring Strategy that provided a framework for operation and maintenance of the national air monitoring networks. The primary purpose of the National Monitoring Strategy was to gain a better understanding of the relationships and potential reaction in the atmosphere of various pollutants, develop a strategy to apply the lessons learned and use the information developed for a variety of purposes, not just for determining attainment/non-attainment." NACAA concluded that it is "…concerned that EPA appears to be changing the focus of the monitoring program as currently described in the National Monitoring Strategy from recording ambient measurements to measuring emissions from sources, based on the more source-oriented monitoring lead, NO_2 and SO_2 proposals."

Response: Under a hybrid analytical approach, introduced in section III of the preamble to the final rule, EPA anticipates using both ambient monitoring and source modeling in implementing the SO_2 NAAQS (fully discussed in sections

III, IV, V and VI of the preamble). As a result, the required monitoring network is no longer required to be source-oriented in nature, as explained in section IV.B of the preamble. The required monitoring network has the flexibility to have monitoring sites serve multiple monitoring objectives. EPA believes that under this approach, there is no longer cause for concern that SO_2 monitoring sites can not be used in the multi-pollutant paradigm that the monitoring strategy promotes, and that the NCore network exemplifies. Further, NCore monitoring sites that measure SO2 are allowed to satisfy minimum monitoring requirements resulting from this rulemaking.

(5) ***Comment:*** Several commenters (ALA/EDF/NRDC/SC, CBD, and Missouri) urged EPA to revise its approach to determining how many SO_2 monitors are required in each state to require more monitors. These commenters asked that more SO_2 monitors be required in order to more directly monitor air quality around the nation's many large SO_2 emission sources. For example, ALA/EDF/NRDC/SC argues that "the proposed 348 monitors are grossly inadequate to detect peak concentrations from the 4,400 stationary sources, and an unknown number of area sources, which emit more than 50 tons of sulfur dioxide per year."

Response: To address these and other comments, EPA re-examined its proposed monitoring-focused approach and its historical approach to SO2 NAAQS implementation. As a result, EPA intends to use a hybrid analytical approach, as introduced in section III of the preamble to the final rule. Under this approach, EPA anticipates using both ambient monitoring and source modeling thus allowing more individual sources to be addressed, while maintaining a stable monitoring network, which can serve multiple monitoring objectives. EPA believes a hybrid analytical approach as described in sections III, IV, V, and VI addresses the concern raised by these commenters that the proposed monitoring network would be inadequate to detect peak concentrations from a large number of stationary sources.

(6) ***Comment:*** NESCAUM commented that it does "not support EPA's proposed requirement that any PWEI- or CBSA-triggered monitors 'shall not count toward satisfying any required monitors resulting from the state emissions triggered requirements' (74 FR 64880). Additional SO_2 monitors should only be required if the CBSA-triggered monitor count is less than the state emissions triggered count." NESCAUM also recommended exempting states from the emissions-triggered monitoring requirement if they had SO_2 inventory of less than 0.1% of the national inventory.

Response: In this comment, NESCAUM refers to the second prong of the proposed monitoring network which required minimum number of monitors based on the state's contribution to the national SO_2 emissions inventory. In the final monitoring network design, explained in section IV.B.4 of the preamble to

the final rule, EPA did not retain this second prong to the network design. As a result, the concerns raised by this commenter should no longer exist.

(7) ***Comment:*** South Carolina submitted comments noting that the agency "believes the number of monitors, distributed as proposed, is greater than needed to provide a network sufficient to provide reporting to the general public and support compliance with the standards in areas where there is a reasonable potential to exceed the proposed standard…The number and allocation of monitors in the proposal using the PWEI appears to miss some high emission density areas and require monitoring in many locations unlikely to experience significant impact."

Response: The statement that "…the number of monitors, distributed as proposed, is greater than needed…" implies that the proposed network was viewed to be redundant and would have required unnecessary monitoring in certain areas. Under a hybrid analytical approach, introduced in section III and further explained in section IV.B of the preamble to the final rule, the number of required monitors is lessened, the monitoring network is no longer required to be source-oriented in nature, and the network objectives of the final network design are now broadened to include assessment of population exposure, general background concentrations, SO_2 transport, long-term trends, and source oriented and/or highest concentration data. As a result, the required monitoring network has the flexibility to have monitoring sites characterizing one or more of these objectives. EPA believes this flexibility alleviates the concern raised over redundant or unnecessary monitoring.

The commenter also suggested that the proposed allocation of monitors based on the use of the PWEI may "…miss some high emission density areas and require monitoring in many locations unlikely to experience significant impact." As explained in the preamble, EPA believes where high emissions density occurs due to large sources, the modeling component of our anticipated hybrid approach would be more technically appropriate and effective in assessing ambient SO_2 concentrations and compliance with the SO_2 NAAQS. In addition, states always have the prerogative to monitor where they believe monitoring is warranted above minimum monitoring requirements. Further, as discussed in section IV.B.6 of the preamble to the final rule, EPA Regional Administrators (working with states) may require additional monitoring above the minimum requirements if they believe monitoring objectives remain unfulfilled in an area even though a state may be satisfying minimum monitoring requirements. The commenter also suggested that the proposed monitoring approach could lead to "…monitoring in many locations unlikely to experience significant impact." The final network design, discussed in section IV.B.4 in the preamble to the final rule, utilizes the PWEI, but with some changes in the breakpoints used to require monitors, ultimately requiring lesser number of monitors in the final network than by the proposed use of the PWEI. EPA believes that the anticipated use of modeling, the states and RA's authority to require monitoring above the minimum requirements, and the changes to the PWEI breakpoints addresses the commenters concern.

(8) ***Comment:*** City of New York commented that New York City presently has three SO_2 monitors located in its metropolitan area and urges EPA to ensure that the final SO_2 monitoring plan does not reduce the number of required monitors in the New York City area.

Response: Under the final network design, discussed in section IV.B.4 in the preamble to the final rule, and based on the 2005 NEI and 2008 Census data, EPA estimates that the New York City CBSA has a PWEI value that will require it to operate at least 3 monitors within the CBSA.

IV.B: Comments on Monitoring Method

(1) ***Comment:*** Two industry groups provided comments noting that, while EPA is proposing a significant change in the permitted total interferent limit for the new FRM, the interferent limits need to be further tightened in order to reduce the potential for false positive exceedances of the SO_2 NAAQS. Given the stringent SO_2 standards being proposed, AirQuality recommends "a more realistic specification would limit each interferent to no more than 3 ppb and total interference to no more than 12 ppb." UARG recommends EPA "further limit the total of all interferents" without providing a specific number. NESCAUM also submitted a comment requesting EPA "tighten the NO interference metric for the new SO_2 Federal Reference Method from 100 to 300 to 1. The proposed value of 100 results in substantial NO interference at sites with low SO_2 levels in urban areas, such as NCORE sites."

Response: As discussed in section IV.A.2.b of the preamble to the final rule, EPA reconsidered what is reasonably feasible with current technology to determine the final interferent equivalent limit requirements. In evaluating the limits, we must keep in mind that the test concentrations specified for most of the interferents (in Table B-3) are substantially higher than the concentrations normally observed in ambient air. A review of test data submitted for numerous SO_2 FEM applications showed that it is not feasible to further lower the limit requirement of each interferent. However, in response to the NESCAUM comment, EPA has concluded that that the limit requirement for NO interferent for SO_2 analyzers can be lowered to ±3 ppb (167:1) for the lower measurement range to reduce possible NO interference at sites in urban areas with low SO_2 levels. In reconsidering the requirement for the total of all interferents, we also reassessed the high probability that many of the test interferents would not coexist in ambient air at these test concentrations. Therefore, we concluded that the limit requirement for total interference equivalent for SO_2 analyzers can be eliminated entirely.

(2) ***Comment:*** UARG requested that EPA provide additional information to prove that existing FEMs qualify as FRM and FEM under the proposed new definitions as EPA stated without providing supporting information.

Response: As explained in section IV.A.1.b of the preamble to the final rule, there is no legal impediment to continued use of SO_2 FEMs without redesignation pursuant to the new automated SO_2 FRM. With respect to the technical issue raised by the commenter, these automated continuous monitoring methods have been tested against the test and performance requirements of 40 CFR Part 53, which are designed specifically to test such continuous methods. For decades, these FEMs have been gathering and reporting hourly averages (almost exclusively) for monitoring agencies and so are technically sound to provide monitoring data for determining compliance with the new one-hour NAAQS. EPA has clarified the proposed regulatory text so that the rules state unambiguously that both FRMs apply to the new one-hour standard (as well as to the 24-hour and annual standard so long as they are retained), as do all presently designated FEMs.

(3) ***Comment:*** AirQuality requested EPA to reevaluate its decision to not change the span drift requirement at the 80% URL which EPA left at +5.0%. "Ambient air monitors in the 21st century should be able to hold span drift to no more than +2.5% under the conditions specified in EPA testing and EPA should adjust the span drift specification (at 80% URL) accordingly."

Response: In response to this comment, EPA has reevaluated the span drift limits. Based on information from FEM testing and manufacturers' data (EPA, 2009c), EPA has concluded that the span drift requirement at 80% URL can be lowered to ±3%, as stated in section IV.A.2.b of the preamble to the final rule.

(4) ***Comment:*** ExxonMobil expressed support for EPA "allowing monitoring agencies to choose mobile monitoring that meets monitoring quality requirements. This would, over time, expand geographic coverage and be responsive to changes in roadway emissions and community co-location relationships, while facilitating optimal deployment of monitoring resources."

Response: EPA appreciates the corroboration expressed in this comment and agrees with ExxonMobil that the revised performance specifications of automated SO_2 methods included in Table B-1 of 40 CFR Part 53 for noise, lower detection limit, interference equivalent, zero drift, span drift, lag time, rise time, fall time, and precision (discussed in section IV.A.2.a and A.2.c of the preamble of the final rule) will allow for monitoring that meets various quality requirements and will be responsive to changing needs.

(5) ***Comment:*** Missouri provides recommendations for several technical changes to EPA's proposed monitoring method. These changes are:

- Page 64870 Appendix A-1, section 2.4, Sampling considerations – "While the use of a particulate filter can be a good practice it can also cause problems. Whether or not a sample line filter is required has normally been spelled out in the reference and equivalency descriptions; some require the filter and some don't. The wording here seems to make it a

universal requirement. We suggest changing the wording or removing this section and referencing the List of Designated Reference and Equivalent from EPA's National Exposure Research Laboratory."

- Page 64871 Appendix A-1, sections 4.1 .1 and 4.1 .2. – "These two sections cause confusion. Since the goal is to control the flow outputs of the dilution system to within 2% of a NIST traceable standard, we propose combining the two sections and making this concept clearer. For example: 'The air and standard gas combined dilution system shall measure and control both the air and standard gas flows. Each of these flows will be calibrated to a NIST traceable standard to deliver flows accurate to within +/- 2% of the NIST traceable standard.'"
- Page 64871 Appendix A-1, section 4.1 .6.1 – "We have not seen problems with using cylinders with concentrations below 50 parts per million (ppm). A problem with using cylinders with concentrations of 50 ppm and greater is that, in order to dilute to a concentration approximately equal to the standard, e.g., 0.055 ppm, requires using the normal 10 liters per minute (lpm) air flow controller and 100 cubic centimeters per minute (cc/min) gas flow controller at less accurate limits of their design range, 9 lpm and 10 cc/m. Unless this section is based on recent study, we recommend consulting with manufacturers."

Response: 1**)** The use of a particulate filter on the sample inlet line may or may not be required for existing specific FRM or FEM analyzers, depending on manufacturer requirements, which are reflected in EPA/ORD's List of Designated Reference and Equivalent Methods. Missouri's suggestion is a reasonable one. However, for new SO_2 FRM analyzers, EPA believes that the benefits of an inlet line particulate filter and the uniformity provided by a mandatory filter requirement outweigh possible disadvantages of using such a filter. Therefore, the particulate filter requirement of section 2.4 of the FRM has not been changed.

2) Sections 4.1.1 and 4.1.2 of the FRM described the separate required functions of (1) flow regulation and (2) flow measurement. These separate functions correspond to the separate schematic boxes for each of these two functions shown in Figure 2 of the FRM. However, both functions are often combined in a single device, such as a mass flow controller. In response to this comment to reduce possible confusion regarding flow control and measurement, the language of these sections has been revised to describe both the flow rate regulation and flow rate measurement functions together for the SO_2 standard gas (4.1.1) and for the dilution air (4.1.2). This arrangement is appropriate because the flow rate measurement devices may need to be calibrated differently and specifically for nitrogen (standard gas) and for air.

3) In response to this comment, which we believe is very appropriate, the minimum concentration requirement for the SO_2 calibration standard, specified in section 4.1.6.1 of the FRM, was re-evaluated. EPA has concluded that this requirement can be changed to 10 ppm. The language of section 4.1.6.1 has been

revised to incorporate this change. These changes to the language of the FRM are discussed in Section IV.A.1.b of the preamble.

(6) ***Comment:*** A number of organizations expressed support for EPA's proposed FRM using UVF as a means of both improving the accuracy of monitoring data and reducing the operational cost of FRMs. (AirQuality, CE, H-GAC, Houston, KYDEP, MSCC, North Carolina, Pennsylvania, South Carolina, South Dakota, UARG, and Wisconsin)

Response: EPA appreciates the corroboration expressed in these comments. As discussed in section IV.A.1.c of the preamble to the final rule, we are finalizing the new automated SO_2 FRM based on UVF technology as Appendix A-1 to 40 CFR Part 50, titled "Reference Measurement Principle and Calibration Procedure for the Measurement of Sulfur Dioxide in the Atmosphere (Ultraviolet Fluorescence Method)."

(7) ***Comment:*** Both North Carolina and South Carolina urge EPA to retain existing FRM and FEM standards so that monitoring agencies can avoid additional monitoring expenditures and continue to utilize existing equipment as long as the data produced from the instruments can meet the monitoring and data quality objectives. Similarly, NYSDEC recommended EPA permit "existing FEMs to be retained while superseding the existing FRM" rather than keep the existing FRM for a number of years. NYSDEC also commented that the existing FEMs should be retained because "the existing standard range FEMs typically used by State and Local monitoring agencies are acceptable for SO_2 monitoring for comparison to the range of the proposed standard." In addition, AirQuality also expressed support for utilizing "existing FEM monitors for initial attainment designation (before they are phased out)" even if they "may create some difficulties" because "there is no real alternative."

Response: EPA concurs with these comments. Section IV.A.1.b of the preamble to the final rule explains that there are sound reasons for not withdrawing the existing FRM at this time, as doing so would result inappropriately in cancellation of existing FEM designations as well. The consequent costs and disruptions to State and Local monitoring networks are clearly unwarranted given that existing FEMs (and the existing FRM as well) accurately measure ambient one-hour SO_2 concentrations. Because supersession of an FRM, as defined in §53.16, requires cancellation of FEMs based on the superseded FRM, EPA is exercising its discretion not to supersede the existing FRM but rather to simply add a second FRM for SO_2. As described in section IV.A.1.c of the preamble, EPA plans to rescind the original manual FRM at a future time when the new FRM analyzers have permeated the network.

(8) ***Comment:*** UARG's comments included the claim that EPA is violating the CAA by proposing to have multiple FRM standards effective at the same time.

According to UARG's interpretation of the CAA, EPA is only allowed to have one operational FRM standard at a time for a NAAQS.

Response: As discussed in section IV.A.1.b of the preamble to the final rule, there is nothing in the Act which mandates a single FRM for each NAAQS. There are sound policy reasons for not withdrawing the existing FRM at this time, as this would result in cancellation of all existing SO_2 FEM designations as well. See § 53.16 (b). Cancellation of the FEM designations of all these SO_2 analyzers now would be potentially very disruptive to State, Local, and other monitoring networks, and is technically unwarranted given that existing FEMs and the existing FRM accurately measure ambient one-hour SO_2 concentrations. Therefore, EPA is exercising its discretion not to supersede the existing SO_2 FRM and add a second FRM.

(9) ***Comment:*** Center for Biological Diversity recommends in its comments that "EPA should move more expeditiously in phasing out the existing FRM and implementing new performance standards."

Response: In section IV.A.1.b of the preamble to the final rule, we describe how withdrawing the existing FRM at this time would result in cancellation of existing FEM designations as well and so would be potentially very disruptive to State, local, and other monitoring networks. We have identified no negative impact from retaining the existing FRM for some period of time to support the approval of existing FEMs. However, as stated in section IV.A.1.c of the preamble, EPA plans to rescind this manual method at a future time when the new FRM analyzers have permeated the network.

(10) ***Comment:*** AirQuality submitted comments supportive of EPA for "seeking to upgrade the performance specifications for both FRM and FEM SO_2 monitors.

Response: EPA appreciates the corroboration expressed in these comments. As discussed in section IV.A.2.a and A.2.c of the preamble of the final rule, EPA has included revised performance specifications for automated SO_2 methods in Table B-1 of 40 CFR Part 53 for noise, lower detection limit, interference equivalent, zero drift, span drift, lag time, rise time, fall time, and precision. In addition, to address the need for more sensitive lower measurement ranges for SO_2 analyzers, EPA has added a separate set of performance requirements that would apply specifically to narrower measurement ranges, i.e. ranges extending from zero to concentrations less than 0.5 ppm.

(11) ***Comment:*** Wisconsin recommends EPA revise its monitoring requirements "to specifically recognize digital recorders rather than maintaining the tie to analog technology" in Section 53.21 in order to increase the time resolution of SO_2 monitoring data.

Response: In section IV.A.2.b of the preamble of the final rule, EPA acknowledges that industry has moved away from strip chart recording technology to digital data recording. The language of §53.21 calls for a graphic representation of analyzer responses to test concentrations to facilitate visual examination of test results. It allows any "alternative measurement data recording device" as long as it can provide such a graphic representation. Describing the analog strip chart recorder in this section provides a clear and appropriate model to help define the type of graphic representation needed for the Part 53 tests. EPA believes that the language of §53.21 is adequately broad to permit digital or other types of data recording devices. With regard to acquisition of field monitoring data, there is no requirement for use of chart recorders in lieu of digital or other types of data recorders as long as hourly (or shorter time) averages can be accurately recorded.

IV.C: Comments on deadlines for monitoring plans and deployment

(1) ***Comment:*** Louisiana Chemical requested EPA provide 6 additional months "for states to submit a monitoring plan (i.e. until January 1, 2012)."

Response: The final network design, discussed in section IV.B.4 of the preamble to the final rule, requires fewer monitors than proposed. Further, states have the flexibility to use required monitors to serve multiple monitoring objectives, as discussed in section IV.B.3 of the preamble. As a result, EPA believes that much of the existing monitoring network will be able to satisfy minimum monitoring requirement promulgated in this rule. EPA roughly estimates that 41 CBSAs will have to establish a new site, or insert an SO_2 analyzer into existing sites within those CBSAs that currently do not have an SO_2 analyzer operating. As a result, and as discussed in section IV.B.7 of the preamble, EPA does not believe extra time for network plan development or deployment is necessary.

(2) ***Comment:*** South Carolina requested revisions to the expectations for the proposed monitoring plan such that "the Annual Monitoring Plan due July 1, 2011, should only be expected to contain a general description of the expected SO_2 monitoring network unless the monitoring organization plans to implement some SO_2 monitoring as part of the calendar year 2012 Annual Monitoring Plan. The 2013 Annual Monitoring Plan (due to EPA by July 1, 2012) is the appropriate document for review and comment of any additions or modifications required for the January 1, 2013 implementation of the SO_2 required monitoring."

Response: The final network design, discussed in section IV.B.4 of the preamble to the final rule, requires fewer monitors than proposed. Further, states have the flexibility to use required monitors to serve multiple monitoring objectives, as discussed in section IV.B.3 of the preamble. As a result, EPA believes that much of the existing monitoring network will be able to satisfy minimum monitoring requirements promulgated in this rule. EPA roughly estimates that only 41

CBSAs will have to establish a new site, or insert an SO_2 analyzer at existing sites, within those CBSAs that currently do not have an SO_2 analyzer operating. Therefore, as discussed in section IV.B.7 of the preamble, EPA believes that states will have sufficient time to develop annual monitoring plans that include the requirements of this rulemaking by July 1, 2011.

(3) ***Comment:*** Ohio provided comments on the proposed monitoring plan that expressed significant skepticism that large SO_2 emitter states would be able to complete all the necessary work before the July 1, 2011 deadline for state monitoring plans. Ohio points out that a state-wide analysis that distributes 18 PWEI monitors in 10 counties and 9 emissions triggered monitors (under the proposed network design) within the state is a large undertaking requiring significant analysis and resources.

Response: EPA believes that states will have sufficient time to develop annual monitoring plans that include the requirements of this rulemaking by July 1, 2011 because the final network design, discussed in section IV.B.4 of the preamble to the final rule, requires fewer monitors than proposed. Further, states have the flexibility to use required monitors to serve multiple monitoring objectives, as discussed in section IV.B.3 of the preamble. As a result, EPA believes that much of the existing monitoring network will be able to satisfy minimum monitoring requirements promulgated in this rule.

(4) ***Comment:*** ALA/EDF/NRDC/SC recommended EPA accelerate the deployment schedule for SO_2 monitors because "the sooner monitors are in place, the sooner the public will experience the health benefits of the new standard."

Response: Rather than a monitoring-focused approach to assess ambient SO_2 concentrations and compliance with the SO_2 NAAQS, EPA anticipates using a hybrid analytic approach that combines monitoring and modeling, using each of these analytic tools where they are most appropriate and effective. We anticipate placing greater emphasis on modeling than did the proposed rule as the most technically appropriate, efficient, and readily available method for assessing short-term ambient SO_2 concentrations in areas with point sources. This projected change in approach would necessarily result in a lesser emphasis on the less appropriate, more expensive, and slower to establish monitoring sites than did the proposed rule. Therefore, the minimum requirements for the SO_2 monitoring network is of a smaller scale than proposed, and we do not expect monitoring to become the primary method by which ambient concentrations are compared to the new 1-hour SO_2 NAAQS. States have the flexibility to use required monitors to serve multiple monitoring objectives, as discussed in section IV.B.3 of the preamble. As a result, EPA believes that much of the existing monitoring network will be able to satisfy minimum monitoring requirement promulgated in this rule. However, EPA received comment from some states urging us to consider their burden (both financially and with regard to personnel) of implementing multiple rulemakings with overlapping schedules. With this

consideration in mind and the anticipated use of modeling described above, EPA does not believe there is sufficient reason to accelerate the deployment of SO_2 monitors sooner than the proposed schedule. As discussed in section IV.B.7 of the preamble, the schedule requires submission of annual monitoring plans that will reflect the requirements of this rulemaking by July 1, 2011, and is further requiring that the network deployment be complete by January 1, 2013.

(5) ***Comment:*** Louisiana Chemical requested EPA provide a one-year extension to the proposed SO_2 monitor deployment deadline so that state agencies would have until January 1, 2014 to install the required SO_2 monitors.

Response: The final network design, discussed in section IV.B.4 of the preamble to the final rule, requires fewer monitors than proposed. Further, states have the flexibility to use required monitors to serve multiple monitoring objectives, as discussed in section IV.B.3 of the preamble. As a result, EPA believes that much of the existing monitoring network will be able to satisfy minimum monitoring requirement promulgated in this rule. EPA roughly estimates that 41 CBSAs will have to establish a new site, or insert an SO_2 monitors into existing sites within those CBSAs that currently do not have an SO_2 analyzer operating. As a result, and as discussed in section IV.B.7 of the preamble, EPA does not believe extra time for network plan development or deployment is necessary.

(6) ***Comment:*** Three state agencies requested EPA allow state agencies to deploy SO_2 monitors on a phased schedule. Wisconsin's comments requested that state agencies be allowed to install half of the requisite SO_2 monitors by the proposed deadline of January 1, 2013 with the second half of the required SO_2 monitors being installed by January 1, 2014. According to Wisconsin, the phased installation schedule is necessary because "state and local agencies will need more time to establish the network because establishing new sites near point sources is time-consuming, and expensive." South Carolina provided comments requesting that, if EPA was going to move forward with the proposed SO_2 monitoring plan, it allow state agencies phase in the implementation of SO_2 monitors "with the largest source/highest probability population exposure areas designated for implementation in 2013 (some proportion of the highest PWEI monitors) and establishment of the remaining PWEI and the state level emissions triggered monitoring required by the following year." Finally, Iowa also requests a phased implementation schedule for all states required to install more than four SO_2 monitors that would extend the final deadline for all SO_2 monitors to be deployed by two years (January 1, 2015).

Response: The final network design, discussed in section IV.B.4 of the preamble to the final rule, requires fewer monitors than proposed. Further, states have the flexibility to use required monitors to serve multiple monitoring objectives, as discussed in section IV.B.3 of the preamble. As a result, EPA believes that much of the existing monitoring network will be able to satisfy the minimum

monitoring requirement promulgated in this rule. EPA roughly estimates that 41 CBSAs will have to establish a new site, or insert an SO_2 monitor into existing sites within those CBSAs that currently do not have an SO_2 monitor operating. As a result, and as discussed in section IV.B.7 of the preamble, EPA does not believe extra time for network plan development or deployment is necessary.

(7) ***Comment:*** Both NYSDEC and MIDNRE provided comments arguing that EPA's implementation deadline for SO_2 monitors was not realistic given the scope of the work, limited state funding, and the implementation of other monitoring programs during the same time period.

Response: The final network design, discussed in section IV.B.4 of the preamble to the final rule, requires fewer monitors than proposed. Further, states have the flexibility to use required monitors to serve multiple monitoring objectives, as discussed in section IV.B.3 of the preamble. As a result, EPA believes that much of the existing monitoring network will be able to satisfy minimum monitoring requirement promulgated in this rule. EPA roughly estimates that 41 CBSAs will have to establish a new site, or insert an SO_2 analyzer into existing sites within those CBSAs that currently do not have an SO_2 analyzer operating. Given the fewer number of required monitors and the flexibility of monitoring objectives discussed in section IV.B.7 of the preamble, EPA does not believe extra time for network plan development or deployment is necessary.

(8) ***Comment:*** Four state agencies expressed support for the proposed 5-year network review process being linked with SO_2 network adjustments (Indiana, South Carolina, South Dakota, and Wisconsin). South Carolina and South Dakota also recommended that network adjustments also be allowed on an annual basis as part of the annual monitoring plan.

Response: In section IV.B.7 of the preamble to the final rule, EPA has clarified that existing requirements for both annual and 5-year reviews are appropriate tools to ensure that the SO_2 network is sited and operated appropriately. In response to the comments, adjustments to the network may be made on annual basis as part of annual network plans required in 40 CFR §58.10. However EPA does not intend for required monitors to move from spot to spot on a frequent (i.e. annual) basis. In particular, annual monitoring plans would be expected to identify, for example, if an area has minimum monitoring requirement where it previously did not as a result of updated PWEI calculations.

(9) ***Comment:*** North Carolina recommended that "if the EPA is going to base the monitoring requirements on emission inventories, then it would make sense to make adjustments to the monitoring network on the same cycle that the statewide emissions inventories are updated, i.e., either every 3 years or 6 years to coincide with AERR inventory requirements."

Response: In section IV.B.7 of the preamble to the final rule, EPA has clarified that existing requirements for both annual and 5-year reviews are appropriate tools to ensure that the SO_2 network is sited and operated appropriately. Regarding network adjustments, annual adjustments to the network may be made, and documented in annual monitoring plans. However EPA does not intend for required monitors to move from spot to spot on a frequent (i.e. annual) basis. Annual monitoring plans would be expected to identify, for example, if an area now has minimum monitoring requirement where it previously did not as a result of updated PWEI calculations. EPA notes that the Air Emissions Reporting Requirement (AERR) requires full inventory updates every three years. However, as discussed in section IV.B.5 of the preamble, EPA believes that the NEI is an appropriate tool by which to calculate PWEI values that are used to determine minimum monitoring requirements for SO_2 monitoring. The process by which the NEI will be updated is being adjusted (by use of the Emissions Inventory System [EIS]) in a manner that will allow for more frequent insertion of state-supplied emissions data, resulting in a more up-to-date inventory. Any introduction of actual reductions that may be occurring (such as federally enforceable reductions, like MACT rules) will therefore be reflected more quickly in the inventory. EPA believes that the NEI is limited only if states choose not to submit data for inclusion, or in a timely manner, and thus, strongly encourages states to submit all available emissions data as frequent as feasible to ensure the NEI is as accurate as possible.

(10) ***Comment:*** Five organizations opposed EPA's proposed five-year update schedule for SO_2 monitors. NYSDEC saw no need for an every five-year update if state agencies were "permitted to use the best available data to determine where and how many monitors are needed." Alaska opposed the proposal on the grounds that the update process was not necessary if EPA followed Alaska's other recommendation to allow state agencies to remove SO_2 monitors that no longer demonstrate concentrations of concern." Ohio opposed the proposal, because as the proposal is currently being interpreted, states will be required to duplicate "the same analysis every five years under the network assessment. Such a requirement would be duplicative, unnecessary, and overly burdensome." NACAA and Illinois both considered the five-year siting update process to be duplicative given the annual and 5-year network reviews that are already in place.

Response: As discussed in section IV.B.7 of the preamble to the final rule, EPA has clarified that existing requirements for both annual and 5-year reviews are appropriate tools to ensure that the SO_2 monitoring network will be sited and operated appropriately, per 40 CFR §58.10. EPA did not intend for states to execute a parallel, and duplicate review, every 5-years solely for the SO_2 network. Annual adjustments to the network may be made, and documented in annual monitoring plans, however EPA does not intend for required monitors to move from spot to spot on a frequent (i.e. annual) basis. Annual monitoring plans would be expected to identify, for example, if an area now has minimum

monitoring requirement where it previously did not as a result of updated PWEI calculations.

Regarding Alaska's recommendation to allow state agencies to remove SO_2 monitors that no longer demonstrate concentrations of concern, EPA notes that existing rules (40 CFR § 58.14 (c)) allow states to remove any monitors above minimum monitoring requirements if certain conditions are met, and provided Regional Administrator approval.

IV.D: Comments on Population Weighted Emissions Index (PWEI) monitors

(1) ***Comment:*** Four state agencies provided comments criticizing EPA's PWEI metric as too simplistic and/or flawed to be the only tool for determining where prong 1 SO_2 monitors are to be located (Iowa, NESCAUM, NYSDEC, and Wisconsin). Wisconsin "believes that modeling, population distribution, and local conditions must be considered in determining whether monitoring is required."

Response: Under a hybrid analytical approach, introduced in section III of the preamble to the final rule, EPA anticipates using both ambient monitoring and source modeling in implementing the SO_2 NAAQS (discussed in sections III, IV, V and VI of the preamble). As a result, the required monitoring network is no longer required to be source-oriented in nature, as explained in section IV.B of the preamble. The required monitoring network has the flexibility to have monitoring sites characterizing one or more of the following objectives: source characterization, highest concentration, population exposure, general background, or regional transport. EPA believes that the flexibility of how monitors may serve varied monitor objectives in the final network design is balanced by the continued use of the PWEI to require them. The use of the PWEI provides a mechanism to focus required monitoring in areas where there is an increased coincidence of population and SO_2 emissions.

(2) ***Comment:*** Four commenters expressed concern with the use of CBSAs for determining the number and location of SO_2 monitors. Delaware does not favor EPA's proposed CBSA/PWEI metric for SO_2 monitors because it does not properly take into account interstate CBSAs that require special consideration "for determining the need for additional monitors beyond the current PWEI calculation method."

Response: There is precedent for using CBSAs (which encompasses both Metropolitan Statistical Areas [MSAs] and Micropolitan Statistical Areas) as a means to identify urban areas (e.g. the requirement of NO_2 monitors in CBSAs based on population [40 CFR Part 58 Appendix D, section 4.3]). EPA believes that in situations where a CBSA covers more than one state, or monitoring agency, those entities are in a position to negotiate with each other (and with EPA Regional assistance) how best to satisfy minimum monitoring requirements for

that CBSA. In all cases, states always have the prerogative to conduct additional monitoring above the minimum requirements for an area as they see fit.

(3) ***Comment:*** NESCAUM provided comments seeking EPA clarification on how monitoring issues will be resolved for CBSAs that span across EPA regions and consequently have separate Regional Administrators.

Response: EPA believes that in situations where a CBSA covers more than one state, or monitoring agency, those entities are in a position to negotiate with each other (and with EPA Regional assistance) how best to satisfy minimum monitoring requirements for that CBSA. Similarly, EPA expects that the Regional Administrators, and possibly EPA Headquarters, would also work together as necessary in dealing with any cross boundary issues that may arise.

(4) ***Comment:*** South Carolina and Missouri requested in their comments that EPA relax the requirement that SO_2 monitors be located within the boundaries of the assigned CBSA in order "to allow monitoring organizations the ability to best address sources and potential maximum impacts associated with an area without unnecessary restrictions."

Response: EPA intends to use a hybrid analytical approach, introduced in section III of the preamble to the final rule, that combines monitoring and modeling, using each of these analytic tools where they are most appropriate and effective. In addition, the scope of the monitoring network is revised so that it is no longer required to be source-oriented in nature (i.e., "hot-spot" monitoring only). Instead the final monitoring network design now has the flexibility to address multiple monitoring objectives including source characterization, highest concentration, population exposure, general background, or regional transport. Thus the final monitoring network design is more flexible than the proposed network design as discussed in section IV.B of the preamble. This increased flexibility gives states the ability to select areas where they believe ambient monitoring is most warranted within a CBSA with required monitoring. However, EPA believes that requiring monitors in CBSAs by using the PWEI metric appropriately focuses monitors into areas with increased population and SO_2 emissions. EPA has also included a provision to allow a required monitor to be sited outside of its parent CBSA. As explained in section IV.B.3 of the preamble, a source-oriented/high concentration monitor may be placed outside of its parent CBSA if it is sited to characterize a source inside that parent CBSA whose PWEI value triggered minimum monitoring requirements. Further, as discussed in section IV.B.6, EPA Regional Administrators (working with states) may require additional monitoring above the minimum requirements if they believe monitoring objectives remain unfulfilled in an area (including areas outside of CBSAs) even though a state may be satisfying minimum monitoring requirements. Finally, states always have the prerogative to conduct additional monitoring above the minimum requirements for an area as they see fit.

(5) ***Comment:*** South Carolina commented that EPA "needs to develop a better definition for Core-Based Statistical Areas (CBSA) which is not explicitly defined by the U.S. Census Bureau." In addition, South Carolina "strongly encourages EPA to specifically seek public comment on the definition and use of CBSA, to include an annual list of counties comprising each CBSA in the context of the standard implementation and monitoring requirements."

Response: EPA believes that the term CBSA is adequately defined by the U.S. Office of Management and Budget (OMB). OMB defines metropolitan and micropolitan statistical areas according to published standards that are applied to Census Bureau data. The general concept of a metropolitan or micropolitan statistical area is that of a core area containing a substantial population nucleus, together with adjacent communities having a high degree of economic and social integration with that core. Currently defined metropolitan and micropolitan statistical areas are based on application of 2000 standards (which appeared in the *Federal Register* on December 27, 2000) to 2000 decennial census data. Current metropolitan and micropolitan statistical area definitions were announced by OMB effective June 6, 2003 (http://www.census.gov/population/www/metroareas/aboutmetro.html).

(6) ***Comment:*** Both South Carolina and LEC provided comments noting that the use of PWEI as the metric for locating prong 1 SO_2 monitors will emphasize urban areas at the expense of non-urban and rural areas which will be left with few if any SO_2 monitors. Without an area-wide monitoring network, state agencies will find it difficult conduct SO_2 permitting in these areas (LEC) and will "lose the broader context needed to evaluate" SO_2 concentration data (South Carolina).

Response: : Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble. The scope of the monitoring network is revised so that it is no longer required to be source-oriented in nature (i.e., "hot-spot" monitoring only). Instead, the final monitoring network design now has the flexibility to address multiple monitoring objectives including source characterization, highest concentration, population exposure, general background, or regional transport. This increased flexibility gives states the ability to select areas where they believe ambient monitoring is most warranted within a CBSA with required monitoring. As a result, states may site monitors to address the need to measure background concentrations or to provide data for a broader context to evaluate ambient SO_2 concentrations. EPA notes that it currently has no minimum monitoring requirements (except for NCore) for SO_2, but as of the 3rd quarter of 2009, EPA estimated that approximately 433 SO_2 sites were operating nationwide, based on data states have submitted to AQS. Under the final network design, and including monitors required at NCore sites, EPA estimates that 191 monitors would be required to be

operational by January 1, 2013. That number is well short of the 433 analyzers operating in late 2009. EPA believes that states have and likely will continue to place SO_2 monitors in various locations (including non-urban areas) to produce information upon which PSD permitting determinations may be based.

(7) ***Comment:*** Wisconsin commented that "if EPA is intent on placing monitors in areas of higher population, it may be useful to establish a population threshold for evaluating exposure potential within a CBSA to ensure that monitoring is directed toward the higher priority locations." Wisconsin's recommendation is that EPA should "consider allowing monitoring agencies the flexibility, under the first prong, to determine whether SO_2 monitors would be suitable in metropolitan statistical areas with populations between 50,000–350,000" or "in rural areas, if necessary, and that such monitors would fulfill prong 1 requirements."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble. This increased flexibility gives states the ability to select areas where they believe ambient monitoring is most warranted within a CBSA with required monitoring. EPA's contemplated use of the hybrid analytical approach, results in a lesser emphasis on the monitoring network design to assess compliance with the SO_2 NAAQS than did the proposed rule. Therefore, the minimum requirements for the SO_2 monitoring network are smaller than those proposed. EPA does not believe that the minimum monitoring requirement should be further relaxed than the final network design, in order to have a monitoring network coupled with source modeling under a hybrid analytical approach, which is focused to provide information to support protecting public health, in this case by focusing monitoring in areas where there is an increased coincidence of population and SO_2 emissions. In regard to monitors being necessary in more rural areas, states always have the prerogative to conduct additional monitoring above the minimum requirements for an area as they see fit. Further, as discussed in section IV.B.6 of the preamble, EPA Regional Administrators (working with states) may require additional monitoring above the minimum requirements if they believe monitoring objectives remain unfulfilled in an area (including areas outside of CBSAs) even though a state may be satisfying minimum monitoring requirements.

(8) ***Comment:*** Iowa requested that EPA consider supplementing the "2005 NEI with the most recent and representative point source emissions inventory data available, using both CEMs data and emissions reports from Type A major emitting facilities. Additionally, recent federally enforceable reductions not reflected in current emissions inventories, such as may be expected from Best Available Retrofit Technology (BART) requirements, should be considered."

Response: EPA believes that the NEI is an appropriate tool by which to calculate PWEI values that are used to determine minimum monitoring requirements for

SO_2 monitoring. As discussed in section IV.B.5 in the preamble to the final rule, the process by which the NEI will be updated is being adjusted in a manner that will allow for more frequent insertion of state supplied emissions data, resulting in a more up-to-date inventory. Any introduction of actual reductions that may be occurring will therefore be reflected more quickly in the inventory, a result that the commenter appears to desire. EPA believes that the NEI is limited only if states chose not to submit available information timely for inclusion, and thus, we strongly encourage states to submit all available emissions data as frequent as feasible to ensure the NEI is as accurate as possible.

(9) ***Comment:*** Pennsylvania provided comments recommending that thresholds be included within the PWEI calculation method to focus monitoring in high population areas that could potentially violate the proposed new one-hour SO_2 standards. Pennsylvania recommended that prong one monitors be limited to "urbanized areas with a population of at least 50,000 people or greater where there is a sulfur dioxide source or combination of sources within 50 miles emitting a total of at least 20,000 tons of SO_2 per year."
NYSDEC comments included remarks that "the PWEI calculation method should be changed to remove or reduce the influence of population in the calculation," and "because the PWEI approach does not appear to be more predictive, the Department does not recommend a PWEI breakpoint. Instead, the Department recommends a CBSA emissions value of 50,000 tpy as a threshold where monitoring would be required. In addition, if the site has a 3 year design value that is less than ½ of the standard, that monitor should no longer be required." (.0145) Similarly, NESCAUM recommended EPA "adopt an emissions-only approach, resulting in fewer CBSA monitors" including the use of a "threshold of 50,000 tpy CBSA SO_2 emissions to trigger the first CBSA monitor, and a second CBSA monitor required when emissions exceed 200,000 tpy. CBSAs with emissions under these thresholds could be monitored under the state emissions triggered prong."

Response: EPA discusses this issue and the examples for alternative thresholds in section IV.B.5 of the preamble to the final rule. As explained there, EPA believes that these thresholds neither provide an adequate number of monitors nor do they include an adequate number of CBSAs that should have monitors. Using the commenters' thresholds would result in too sparse a network to meet the appropriate monitoring objectives. EPA believes that the broader scope of the monitoring objectives of the network is best served by using the PWEI metric to focus ambient monitoring into areas where there is an increased coincidence of population and SO_2 emissions.

(10) ***Comment:*** Center for Biological Diversity complained that EPA's proposed PWEI calculation method is too weighted towards monitoring high population areas and "could effectively deny the health benefits of a short-term SO_2 standard to residents of areas with some of the nation's highest total SO_2 emissions" because they live in rural areas.

Response: Partly in response to these and other comments and an examination of our historical approach to SO_2 NAAQS implementation, we now anticipate using a hybrid analytic approach combining the use of monitoring and available modeling to assess compliance with the new 1-hour SO_2 NAAQS. Rather than a monitoring-focused approach EPA anticipates using each of these analytic tools where they are most appropriate and effective. We anticipate placing greater emphasis on modeling than did the proposed rule as the most technically appropriate, efficient, and readily available method for assessing short-term ambient SO_2 concentrations in areas with point sources. This projected change in approach would necessarily result in a lesser emphasis on the monitoring network than did the proposed rule. Therefore, the minimum requirements for the SO_2 monitoring network is of a smaller scale than proposed, and we do not expect monitoring to become the primary method by which ambient concentrations are compared to the new 1-hour SO_2 NAAQS. EPA discusses its intended approach in sections III, IV, V, and VI of the preamble to the final rule. EPA believes that under a hybrid analytical approach, the commenter's point about the lack of monitoring in CBSAs with low populations but with high emissions, (e.g., greater than 100, 000 tpy) is no longer a concern. EPA notes that states always have the prerogative to conduct additional monitoring above the minimum requirements in any area they see fit.

(11) ***Comment:*** Missouri's comments included the recommendation that EPA adopt the alternative PWEI equation PWEI = [Population + Emissions (TPY) * 100] / 100 because this equation "allows for highly populated areas with lower emissions to have necessary monitoring while emphasizing areas with lower populations that have higher emissions. The thresholds for this proposal would be PWEI over 225,000 - three monitors, PWEI over 75,000 - two monitors, and PWEI over 15,000 - one monitor. The new approach would require any area with over 15,000 tons per year of $S0_2$ to have at least one monitor." According to Missouri's calculations, "the total number of required monitors using the revised PWEI would be 250 including 187 CBSAs as compared to 231 monitors in 131 CBSAs under EPA's proposal."

Response: EPA anticipates using a hybrid analytic approach, as introduced in section III of the preamble to the final rule, combining the use of monitoring and available modeling to assess compliance with the new 1-hour SO_2 NAAQS. Rather than a monitoring-focused approach, EPA anticipates using each of these analytic tools where they are most appropriate and effective. This projected change in approach would necessarily result in a lesser emphasis on monitoring than did the proposed rule. EPA has adjusted the final network design, discussed in section IV.B.4 in the preamble to the final rule, which uses the PWEI metric, but with some changes in the breakpoints used to require monitors, which ultimately results in requiring fewer monitors than the number proposed (discussed in section IV.B.5 of the preamble). EPA believes that fewer monitors are needed to serve monitoring objectives under a hybrid analytical approach, as

compared to either the proposed number or in the example provided by the commenter

(12) ***Comment:*** Three organizations recommended EPA revise the PWEI calculation method in order to reduce the number of SO_2 monitors that would be placed in areas unlikely to have SO_2 concentrations violating EPA's proposed new SO_2 standards (Illinois, NACAA, and North Carolina). According to NACAA, "EPA should limit the total number of monitors required in CBSAs based on additional metrics, such as total number of monitors, historical data, area, trends analysis and/or modeling, and allow for removal of monitors" if SO_2 concentrations prove to not be close to violating the SO_2 NAAQS. Similarly, South Carolina finds fault with the proposed PWEI equation because it doesn't take into consideration "the area of the CBSA, relative distribution of population or emissions within or outside the boundaries" which can "lead to inconsistency and possibly inefficient use of resources across the CBSAs." South Carolina's recommended solution to this problem is for EPA to "develop a refined Index incorporating the proposed PWEI population and emissions elements, but truly normalizing the result to better account for the differences in CBSAs. CBSA area, population distribution and source categories in and near the CBSAs are among the possible factors that should be considered"

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network, as discussed in section IV.B of the preamble. The final network design, discussed in section IV.B.4 in the preamble to the final rule, utilizes the PWEI metric, but with some changes in the breakpoints used to require monitors, resulting in fewer required monitors than proposed. Under our current approach, states are free to use such metrics suggested above to aid in siting their required monitors within a given CBSA. One commenter states that the use of PWEI can "…lead to inconsistency and possibly inefficient use of resources across the CBSAs." On a national scale, EPA believes that no nationally applied network will always perfectly fit every area of the country. EPA has finalized a minimally required network which we believe is necessary to ensure that a network of adequate size and focus will be operated. The number of minimally required monitors in this rule is much less than the number estimated to be in operation at the time of this rulemaking. EPA does not believe that the application of the PWEI will lead to an inefficient use of resources. Further, the final network design allows states more flexibility in monitor siting than that proposed (as discussed in section IV.B.3 of the preamble), which should further prevent states from operating a minimally required monitor in a fashion that they would consider to be inefficient.

(13) ***Comment:*** MIDNRE's comments included a recommendation that EPA modify the PWEI calculation method to take advantage of natural break points between the PWEI values of CBSAs when determining how many SO_2 monitors are required in an area so that CBSAs with almost identical PWEI scores are not

arbitrarily required to have different numbers of SO_2 monitors deployed. Similarly, South Carolina commented that the "break points in the PWEI approach for the number of monitors (1,000,000, 10,000 and 5,000) are arbitrary. Any index developed to determine potential for population exposure and the number of required monitors should have a logical and documented basis for the breakpoints used to determine the minimum monitoring requirements." South Carolina also recommended "the PWEI be truly normalized to better address the differences in area, population and source type and distribution between CBSAs."

Response: Under a hybrid analytical approach, introduced in section III of the preamble to the final rule, the final network design (discussed in section IV.B.4) still uses the PWEI as a means by which to require monitoring. However, the application of the PWEI has been adjusted, as discussed in section IV.B.5 of the preamble, where EPA did consider the MIDNRE suggestion in the final rule.

(14) ***Comment:*** Both Florida and Louisiana Chemical recommended that EPA revise its PWEI calculation method to take into account the impact of stack heights on SO_2 concentrations when calculating the number of SO_2 monitors required for a CBSA and their location.

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble. The required monitoring network no longer must be wholly source-oriented in nature, but rather can serve multiple monitoring objectives, as discussed in section IV.B.3. As a result EPA does not believe it necessary for states to consider individual source characteristics when requiring a given number of monitors for an area. Further, states now have increased flexibility in deciding the location of required monitors, which should address the commenter's concerns.

(15) ***Comment:*** Iowa commented that EPA should "abandon use of the PWEI in designing the monitoring network. The PWEI is scientifically unsound as it fails to address: 1) the characteristics of the dominant SO_2 source type, 2) population distributions, 3) recent and representative emissions data, 4) the number of SO_2 sources in a state, and 5) the role of atmospheric dispersal in relating emissions to ambient impacts."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble. EPA expects the hybrid analytical approach to combine modeling and monitoring, using each where they are most appropriate and effective. The required monitoring network is no longer wholly source-oriented in nature, and can now serve multiple monitoring objectives, as discussed in section IV.B.3. However, EPA is retaining the use of the PWEI metric to appropriately focus monitoring resources into areas with increased coincidence of population and SO_2 emissions.

As states decided where to place their required monitoring, under the final network design requirements, they can consider the characteristics of the dominant SO_2 source type in that area, population distributions, and the role of atmospheric dispersal in relating emissions to ambient impacts. For some of these, modeling may be a more appropriate and effective tool. If a state feels that more monitors are required, above the minimum requirements, to address any one of a myriad of issues, EPA notes that states always have the prerogative to conduct additional monitoring in any locations they see fit consistent with the overall monitoring objectives.

With regard to 'recent' emissions data being utilized in the PWEI, as discussed in section IV.B.5 of the preamble, EPA believes that the NEI is an appropriate tool by which to calculate PWEI values. The process by which the NEI will be updated is being adjusted in a manner that will allow for more frequent insertion of state-supplied emissions data, resulting in a more up-to-date inventory. Any introduction of actual reductions that may be occurring will therefore be reflected more quickly in the inventory. EPA believes that the NEI is limited only if states choose not to submit data for inclusion, or in a timely manner, and thus, strongly encourages states to submit all available emissions data as frequent as feasible to ensure the NEI is as accurate as possible.

(16) ***Comment:*** Wisconsin remarked in its comments that, "in states such as Wisconsin, with large CBSA containing relatively small population centers and large, dispersed sources, placing monitors at the maximum downwind location does not necessarily result in effective protection of public health. Some CBSAs may have excess monitors and others may have inadequate coverage based on local conditions. The maximum hourly downwind locations may not correlate well with population centers."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, EPA anticipates using both modeling and monitoring where each of these is most appropriate and effective. In the example that Wisconsin gives of small population centers with large sources, Wisconsin's concern could be addressed by using modeling rather than monitoring as it may be more conducive in assessing ambient SO_2 concentrations and compliance with the SO_2 NAAQS. In addition, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble. The required monitoring network is no longer wholly source-oriented in nature, and can now serve multiple monitoring objectives, as discussed in section IV.B.3, including monitors sited to specifically characterize population exposure.

(17) ***Comment:*** Many commenters expressed concerns about inaccuracies in the 2005 NEI data and recommended that states be permitted to utilize the "best available emissions data when selecting the sources where monitors will be established" rather than being limited to the NEI inventory. (DSRI, MIDNRE, NESCAUM,

NYSDEC, North Carolina, South Carolina, South Dakota, UARG, and Wisconsin)

Response: In response to the comments, EPA recognizes that states do receive and submit emissions information for some sources on an annual basis, but PWEI calculations must be made using the most recent NEI data. As discussed in section IV.B.5 of the preamble, EPA believes that the NEI is an appropriate tool to calculate PWEI values that are used to determine minimum monitoring requirements for SO_2 monitoring. The process by which the NEI will be updated is being adjusted in a manner that will allow for more frequent insertion of state supplied emissions data, resulting in a more up-to-date inventory. Any introduction of actual reductions that may be occurring (such as federally enforceable reductions, like MACT rules) will therefore be reflected more quickly in the inventory. EPA believes that the NEI is limited only if states choose not to submit data for inclusion, or in a timely manner, and thus, strongly encourages states to submit all available emissions data as frequent as feasible to ensure the NEI is as accurate as possible.

(18) ***Comment:*** Delaware expressed concern that basing monitor allocation and siting on emissions inventories "may not be the most relevant method for source-oriented monitoring network design. Facilities with large emissions at high elevations often have a much smaller impact on 1-hour concentrations than smaller facilities with low level emissions. Unless the site allocation method can incorporate critical information such as stack height, this method is unlikely to produce the most meaningful results."

Response: Rather than the proposed monitoring-focused approach to assess compliance with the SO_2 NAAQS, EPA anticipates using a hybrid analytical approach, introduced in section III of the preamble to the final rule, which combines monitoring and modeling using each of these where they are most appropriate and effective which should address the commenters concerns. As further explained in sections IV, V, and VI of the preamble, EPA anticipates that both ambient monitoring and the modeling of SO_2 sources would play a role in the implementation of the revised SO_2 primary NAAQS. Since it is anticipated that dispersion modeling will be used to assess impacts of individual SO_2 sources, the required monitoring network is no longer required to be wholly source-oriented in nature, and now can serve multiple monitoring objectives as discussed in section IV.B.3 of the preamble.

(19) ***Comment:*** Pennsylvania, concerned about EPA's over-reliance on the NEI for determining SO_2 monitor locations, proposed "that if the emission inventory is to be used, that a source threshold be developed, similar to lead, where modeling would be used to determine if the expected maximum one-hour SO_2 concentration is at least 50 percent of the NAAQS for those facilities emitting 50,000 tons per year based on the most recent inventory available at the time of final rule…. The determination of facilities should also take into account the installation of control

devices (scrubbers) that would reduce SO_2 emissions to less than 50,000 tons per year if the installation of the devices would occur prior to January 1, 2013…. This approach would allow states and regions to analyze the effect of stack height on local ambient concentrations."

Response: Pennsylvania's suggestion is similar in some regards to the alternative network design, described which was provided in the proposed rule for comment. In the proposed rule, EPA took comment on alternative network design; however it is not adopting that alternative network design which should alleviate the concerns expressed by the commenter. Instead, EPA anticipates using a hybrid analytical approach, as introduced in section III of the preamble to the final rule. The final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble. The required monitoring network is no longer wholly source-oriented in nature, as modeling of source may in effect provide source-oriented concentration data. We now anticipate using a hybrid analytic approach combining the use of monitoring and available modeling to assess compliance with the new 1-hour SO_2 NAAQS. We anticipate placing greater emphasis on modeling than did the proposed rule as it is technically appropriate, efficient, and readily available method for assessing short-term ambient SO_2 concentrations in areas with large point sources. Thus the alternative network design or the approach suggested by Pennsylvania, where modeling informs where monitoring is to occur is not necessary and the projected change in our approach should address the commenters' concerns. .

IV.E: Comments on State-Level Emissions Monitors

(1) ***Comment:*** H-GAC commented that it supports EPA's proposed state-level emissions monitoring plan of locating monitors in areas where maximum SO_2 concentrations are expected. NESCAUM also supports source-oriented SO_2 monitoring but with the caveat that state agencies ought to have the authority to remove SO_2 monitors after three-years of deployment if the design value is less than 50% of the standard. NESCAUM also supports "a minimum number of sites within a state, based on the state emissions triggered monitor count as proposed by EPA."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble. The final network design does not retain the proposed requirement for monitors based solely on state level emissions (the second prong of the proposed network design), as discussed in section IV.B.4 of the preamble. The required monitoring network is no longer wholly source-oriented in nature, and can now serve multiple monitoring objectives, as discussed in section IV.B.3. EPA believes state and local air agencies should consider monitoring, as appropriate, those sources which are not as conducive to dispersion modeling. Such sources include (1) sources classified as non-point sources.("area-sources") such as shipping

ports, (2) a source situated in area of complex terrain and/or situated in a complex meteorological regime, (3) locations that have multiple, relatively small sources with overlapping plumes. EPA also notes that existing rules (40 CFR § 58.14 (c)) allow states to remove any monitors above minimum monitoring requirements if certain conditions are met, and provided Regional Administrator approval.

(2) ***Comment:*** Pennsylvania commented that it opposes the proposed design of the state-level emissions monitoring program and requests that EPA remove the program in favor of allowing Regional Administrators and state and local air pollution control agencies "to determine the number and location of any additional SO_2 monitors." Similarly, South Carolina commented that state-level emissions monitors are unnecessary and redundant if EPA allows state agencies more flexibility in siting PWEI monitors such as by allowing the monitors to be located outside the boundaries of the CBSA.

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble. The final monitoring network design does not retain the proposed requirement for monitors based solely on state level emissions (the second prong of the proposed network design), as discussed in section IV.B.4 of the preamble.

(3) ***Comment:*** Several organizations provided comments in opposition to EPA's proposed requirement that every state have at least one state-level emissions monitor. South Carolina recommended that "EPA should not require one monitor in every state unless the NCore site can serve as the sole monitor." AirQuality recommended EPA not require state-level emissions monitors for any states that contribute less than 0.5% to the nation's total SO_2 emissions. In addition, Vermont recommended that state's that emit less than 0.1% of the nation's total SO_2 emissions should be permitted to site their one required state-level emissions monitor at the state's discretion rather than at an in-state SO_2 emissions source since no emissions sources in such a state would be likely to generate an SO_2 concentration of concern.

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design no longer requires monitors based solely on state level emissions (the second prong of the proposed network design), as discussed in section IV.B.4 of the preamble. The removal of the second prong of the monitoring network in the final network design should address the commenters' concerns.

(4) ***Comment:*** Both Delaware and South Dakota provided comments in support of EPA's "requirement that each state have at least one monitor" in the state-level emission monitor prong of the network design. (Delaware and South Dakota)

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble, and no longer will require monitors based solely on state level emissions (the second prong of the proposed network design), as discussed in section IV.B.4 of the preamble. However, if a state feels that more monitors are required, above the minimum requirements, to address any one of a myriad of issues, EPA notes that states always have the prerogative to conduct additional monitoring in any locations they see fit consistent with overall monitoring objectives.

(5) ***Comment:*** Iowa expressed concern that "it will be difficult to obtain an accurate picture of the attainment status of the ambient air in any state based on the number of monitors allocated in the proposed rule."

Response: Rather than the proposed monitoring-focused approach to assess compliance with the SO_2 NAAQS, EPA anticipates using a hybrid analytical approach, introduced in section III of the preamble to the final rule, which combines monitoring and modeling using each of these where they are most appropriate and effective. As further explained in sections IV, V, and VI of the preamble, EPA anticipates that both ambient monitoring and the modeling of SO_2 sources would play a role in the implementation of the revised SO_2 primary NAAQS and provide more accurate information on what areas may or may not be in attainment than the proposed monitoring-focused approach.

(6) ***Comment:*** NYSDEC recommended that state-level emissions monitors be used exclusively for source-oriented monitoring but also be permitted "to replace PWEI monitors if the source is within a CBSA."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble, and no longer requires monitors based solely on state level emissions (the second prong of the proposed network design), as discussed in section IV.B.4 of the preamble.

(7) ***Comment:*** NYSDEC recommended "that monitoring be considered for any point source with greater than 20,000 tpy SO_2 emissions."

Response: Under a hybrid analytical approach, introduced in section III of the preamble to the final rule, and further explained in sections IV, V, and VI of the preamble, EPA anticipates using both ambient monitoring and the modeling of SO_2 sources to play a role in the implementation of the revised NAAQS. If a state believes that monitoring is necessary to evaluate source impacts (whether sources have been modeled or not), the state may focus its required monitors for that purpose (for sources inside CBSAs which have minimum monitoring requirements). If a state believes that a source outside of a CBSA with minimum

monitoring requirements warrants ambient monitoring resources to characterize source impacts, EPA notes that states always have the prerogative to conduct monitoring above the minimum requirements as they see fit consistent with the over all monitoring objectives. Further, Regional Administrators also have the authority (as discussed in section IV.B.6 of the preamble) to require additional monitors above the minimum requirements, if monitoring objectives are not being met in an area although the state may be fulfilling minimum monitoring objectives. EPA expects Regional Administrators to work with states to address in such circumstances.

(8) ***Comment:*** NACAA and North Carolina commented that for siting state-level emissions monitors, "EPA must allow agencies to determine the most scientifically defensible location, while taking into account potential exposures and access to locations with adequate siting." (NACAA and North Carolina) Similarly, Dow commented "that EPA's final rule should provide additional flexibility with respect to locating monitors within state boundaries solely based on their contribution to annual SO_2 emissions."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble. The required monitoring network is no longer wholly source-oriented in nature, and can serve multiple monitoring objectives, as discussed in section IV.B.3. The greater flexibility to site monitors to meet different and varied monitoring objectives should address the concerns expressed by these commenters. If a state believes that monitoring resources outside of a CBSA with minimum monitoring requirements are warranted, EPA notes that states always have the prerogative to conduct monitoring above the minimum requirements as they see fit consistent with the overall monitoring objectives.

(9) ***Comment:*** RRI and API cautioned that "if a state's SO_2 monitoring network does not include suitably sited background monitors, but instead only includes source-oriented monitors, specific EPA guideline methods for using this source oriented monitoring data to estimate background for compliance modeling need to be developed." (API and RRI)

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble. The required monitoring network is no longer wholly source-oriented in nature, and now can serve multiple monitoring objectives, discussed in section IV.B.3, including non-source oriented monitors such as those characterizing general background. However, EPA does not intend for the required network to be shifted to only provide 'background' values for modeling purposes, as we believe that such an action would be at the expense of other monitoring objectives. EPA encourages states to consider monitoring near sources which are not conducive to

modeling, such as (1) sources classified as non-point sources (. "area-sources") such as shipping ports, (2) a source situated in area of complex terrain and/or situated in a complex meteorological regime, (3) locations that have multiple, relatively small sources with overlapping plumes, and also consider monitoring for population exposures. Because monitoring objectives can be broader now and include monitoring for background, EPA believes the commenters concern is addressed and specific guideline methods to estimate background from source-oriented monitoring data are not needed at present.

(10) ***Comment:*** Ohio criticized EPA's proposed monitoring plan for being too state-oriented in its monitor allocation process. Ohio recommended that "allocation of monitors based on emissions should not be based upon state borders but rather areas of highest concentration regardless of boundaries…. An analysis, based upon the final level of the standard, should be conducted to determine what level of emissions have an impact on achieving the standard followed by an analysis nationally to determine which areas of emissions necessitate monitors (again, regardless of boundaries). States are capable of working with our neighbors to determine which state would be in the best position to site and operate a monitor." Dow expressed a similar view in noting that "assigning monitors based on which state has the most emissions may be inconsistent with the 'area of highest concentration' criteria" given that the emissions from major SO_2 sources "are more likely to impact distant areas than local areas and the resultant ground level concentrations are often minimal."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble, and no longer requires monitors based solely on state level emissions (the second prong of the proposed network design), as discussed in section IV.B.4 of the preamble. The final network design is intended to focus the minimally required monitors into areas that have an increased coincidence of population and SO_2 emissions through the use of the PWEI, as discussed in sections IV.B.4 and IV.B.5 of the preamble. As states decide where to place their required monitoring, under the final network design requirements, they can consider a number of monitoring objectives, including identifying the highest concentrations. States may find modeling more useful and appropriate to meet certain objectives such as identifying peak concentrations near large sources. EPA also notes that states always have the prerogative to conduct additional monitoring in any locations they see fit consistent with the overall monitoring objectives.

IV.F: Comments on siting requirements and requesting waivers

(1) ***Comment:*** City of New York supports EPA's position that SO_2 monitors should be focused on measuring "maximum ground-level concentrations in areas of both higher population and higher emissions."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is more flexible than the proposed network design, as discussed in section IV.B of the preamble. The required monitoring network is no longer wholly source-oriented in nature, as modeling of source may be more appropriate, efficient, and effective in providing information on source-oriented concentration data. However, EPA notes that as explained in section IV.B.3, states should consider monitoring near sources which are not as conducive to modeling, such as (1) sources classified as non-point sources ("area-sources") such as shipping ports, (2) a source situated in area of complex terrain and/or situated in a complex meteorological regime, (3) locations that have multiple, relatively small sources with overlapping plumes, and also to consider monitoring for population exposures.

(2) ***Comment:*** Multiple organizations provided comments in support of EPA focusing the SO_2 monitoring program on measuring maximum concentrations of SO_2 in the ambient air near major sources of SO_2 emissions. (ATS, Center for Biological Diversity, Harris County, Houston, and NYSDEC). As ALA/EDF/NRDC/SC notes, "People in rural areas have long been neglected by a monitoring network strategy that places most monitors in large cities. Large SO_2 sources such as smelters and power plants have created pollution hotspots in less populated areas. The people who live, work, and breathe in the vicinity of these sources are those most in need of protection from SO_2 air pollution." In addition, NYSDEC argued that "by adequately monitoring significant sources of SO_2 we expect that we will be protecting more populated areas."

Response: In response to these and other comments and an examination of our historical approach to SO_2 NAAQS implementation, we anticipate using a hybrid analytical approach, as introduced in section III of the preamble to the final rule which combines the use of monitoring and available modeling to assess compliance with the new 1-hour SO_2 NAAQS. The final monitoring network design is focused, through use of the PWEI, into areas where there is increased coincidence of population and SO_2 emissions (section IV.B.4 and IV.B.5 of the preamble). Under this approach, EPA expects many SO_2 sources in more rural areas to be modeled to characterize their ground-level impacts which should address the concerns expressed by the commenters. In addition, there are provisions that allow monitoring outside of urban areas where minimum monitoring requirements are focused. First, states always have the prerogative to conduct monitoring above the minimum requirements as they see fit consistent with the overall monitoring objectives (see 40 CFR Part 58, Appendix D, section 1.1). Second, as discussed in section IV.B.6, EPA Regional Administrators (working with states) may require additional monitoring above the minimum requirements if they believe monitoring objectives remain unfulfilled in an area (urban or rural) even though a state may be satisfying minimum monitoring requirements.

(3) ***Comment:*** A number of organizations expressed a preference for EPA to use population exposure to high ambient air SO_2 concentrations as the primary criterion for determining where SO_2 monitors would be located. Many organizations provided comments similar to NPRA's that for the "purposes of designing a monitoring system to support implementation of a NAAQS, monitoring plans should not include locations where there is little or no prospect of public exposure, but must be broadly related to ambient air conditions faced by the public at large." (ABR, Exxon Mobil, Golder, NPRA, PCA, Rio Tinto, RTA, UARG, Delaware, Indiana, North Carolina, South Carolina, South Dakota, and, Wisconsin)

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is focused, through use of the PWEI, into areas where there is increased coincidence of population and SO_2 emissions (section IV.B.4 and IV.B.5 of the preamble). We now anticipate using an approach combining the use of monitoring and available modeling to assess compliance with the new 1-hour SO_2 NAAQS. Therefore, the required monitoring network is no longer wholly source-oriented in nature, and can now serve multiple monitoring objectives, as discussed in section IV.B.3, including population exposure. Further, EPA encourages states to consider monitoring near sources which are not as conducive to modeling, such as (1) sources classified as non-point sources (i.e., "area-sources") such as shipping ports, (2) a source situated in area of complex terrain and/or situated in a complex meteorological regime, (3) locations that have multiple, relatively small sources with overlapping plumes, and also to consider monitoring for population exposures.

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(4) ***Comment:*** Five organizations requested that state and local agencies be provided the authority to remove SO_2 monitors: "based on an assessment of local conditions and risks (Wisconsin), "if the ambient data is not likely to violate the NAAQS" (MIDNRE), "if measured design values at the site are less than 75% of the selected standard level" (AirQuality), or if "the data show that the concentrations in the area are <75% of the NAAQS" in a CBSA with only one monitor or "concentrations are <80% of the NAAQS" for a CBSA with more than one monitor (Alaska and NACAA). AirQuality also remarked that the decision to remove SO_2 monitors should "include relevant stakeholder input that includes consideration of continuing monitoring of a 'clean air' area because the monitor provides the community confidence the operations of nearby sources are well within health protective limits."

Response: Under existing regulation (40 CFR 58.14(c)), there is a process states may utilize to receive EPA Regional Administrator approval to shut down an existing SO_2 monitoring site. However, EPA notes that this applies to monitors in excess of the established minimum monitoring requirements in 40 CFR Part 58 Appendix D.

(5) ***Comment:*** Several organizations requested EPA provide greater flexibility for state agencies in the siting and operation of monitoring stations and conducting network reviews in order to protect the public health as well as possible (Iowa, MIDNRE, and South Carolina).

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design has greater flexibility than the proposed network design, as discussed in section IV.B of the preamble. The final monitoring network design now has the flexibility to address multiple monitoring objectives including source characterization, highest concentration, population exposure, general background, or regional transport (discussed in section IV.B.3 of the preamble).

(6) ***Comment:*** South Carolina commented that EPA's "monitoring requirement must include the ability for states to address the needs for area and regional background concentration measurements" by allowing for at least some area-wide monitoring stations to stay in there current locations.

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design has greater flexibility than the proposed network design, as discussed in section IV.B of the preamble. The required monitoring network is no longer wholly source-oriented in nature, and now can serve multiple monitoring objectives, as discussed in section IV.B.3, including siting of non-source oriented monitors such as those characterizing background concentrations (within a CBSA where monitoring is required). If a state believes that monitoring resources outside of a CBSA with minimum monitoring requirements are warranted, EPA notes that states always have the prerogative to conduct monitoring above the minimum requirements as they see fit consistent with the overall monitoring objectives.

(7) ***Comment:*** MIDNRE requested that state agencies "have the flexibility to substitute a nearby pre-existing monitoring station that may be located at a population-oriented location if its location is within a prescribed distance (e.g., three kilometers)."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design has greater flexibility than the proposed network design, as discussed in section IV.B of the preamble. The required monitoring network is no longer wholly source-oriented in nature, and now can serve multiple monitoring objectives, as discussed in section IV.B.3. Regarding the commenter's specific suggestion of allowing existing monitors to be used, this comment was directed at the proposed network design's requirement that all minimally required monitors be source-oriented. Under the more flexible final network design, EPA believes the commenter's concern should be alleviated.

(8) ***Comment:*** RRI commented that EPA "should encourage states to provide a stakeholder process so that affected emission sources can be consulted in the state's planning process for the monitor placement, which may include a dispersion modeling analysis conducted by the state."

Response: Under a hybrid analytical approach, a state's monitoring network plan, including any source-oriented monitoring that might be conducted under the plan will go through a public notice process. As required in 40 CFR 58.10, states develop an annual monitoring network plan, which would describe its monitoring network including any proposed or forthcoming changes to the monitoring network, which is available for public inspection prior to submission to EPA. RRI's comment regarding the use of a dispersion modeling analysis to determine monitor placement is directed at the proposed and alternative network design on which EPA took comment but is not adopting in the final rule.

(9) ***Comment:*** City of New York requested EPA "require that states provide an opportunity for affected municipalities to provide relevant information and suggestions about monitor locations, and that states shall consider such information in their proposals to the EPA" because oftentimes local agencies have information useful to the siting of air quality monitors such as the "location of existing sensitive populations, future demographic shifts, and the scope of planned developments, and other governmental initiatives."

Response: Monitoring network plans that states develop for the SO_2 monitoring network will go through a public notice process. As required in 40 CFR §58.10, states develop an annual monitoring network plan, which would describe its monitoring network including any proposed or forthcoming changes to the monitoring network, which is available for public inspection prior to submission to EPA.

(10) ***Comment:*** MIDNRE recommended EPA conduct a feasibility study to justify "the need for multiple SO_2 monitors within a single CBSA and the need for new monitoring stations." In the feasibility study, "the maximum modeled concentrations should be compared with the design values generated by urban areas that already operate a rich density of SO_2 monitors. By comparing the ambient data and isopleths created from it with dispersion modeling outputs, relationships between monitoring and modeling data can be estimated for CBSAs. This could provide insights into how ambient stations can be substituted for maximum concentration sites, leveraging the infrastructure. The level of the NAAQS may need to be adjusted downward to retain the same level of protection as if a maximum concentration site were used."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is focused on, through use of the PWEI, into areas where there is increased coincidence of population and SO_2 emissions (section IV.B.4 and IV.B.5 of the preamble).

Under this approach we anticipate combining the use of monitoring and available modeling to assess compliance with the new 1-hour SO_2 NAAQS. Therefore, the required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring objectives, as discussed in section IV.B.3, while the modeling of sources in effect provide source-oriented concentration data. EPA believes the more flexible final network design addresses the concerns raised by the commenter, significantly relieving what some considered a redundant or unnecessary monitoring burden on states, reducing the need for new monitoring sites that would have been required under the proposal, and only requiring multiple monitors in urban areas where the relatively highest coincidences of population and SO_2 emissions are occurring.

(11) ***Comment:*** API and RRI commented that "EPA should explicitly consider the needs of compliance modeling in siting monitors," making sure to "avoid double-counting regional background concentrations to be obtained from appropriate monitors, which are added to modeled impacts from a specific facility" (API and RRI).

Response: We recognize the need for and distinct role that representative background monitored concentrations play in support of modeling demonstrations for compliance with the standards. However, we feel the monitoring language in this final rule as written appropriately addresses the needs of compliance modeling by including the measurement of background concentrations as one of the monitoring objectives. Further, we believe the monitoring rule is not an appropriate regulatory forum to address the needs identified in the comment further. As indicated in the final rule, EPA intends to develop guidance for the use of refined air quality dispersion modeling in implementing the new SO2 1-hour NAAQS and the issue of how to appropriately define background concentrations will be addressed in that guidance, as needed.

(12) ***Comment:*** RRI and LEC suggested EPA develop a more robust method for calculating background concentrations of SO_2 by "assigning background on an hour-by-hour basis from one or more monitors, accounting for wind direction and excluding hours when a monitor is directly downwind of the its existing source. Another approach could be the development of SO_2 background climatology according to wind direction and season, based upwind monitors that are not influenced by local sources." RRI continued by stating that "refined modeling approaches that consider realistic combinations of source impacts and regional background concentrations are critical to avoid false identifications of non-existent non-attainment areas."

Response: EPA recognizes the technical challenges associated with conducting a cumulative ambient air quality impact analysis given the 1-hour averaging time and the statistical form of the new standard. Existing guidance for demonstrating compliance with NAAQS through dispersion modeling is expected to be generally applicable and adequate for the new hourly SO2 standard, and that guidance

provides an appropriate amount of flexibility to address specific issues that may arise on a case-by-case basis. However, EPA expects to develop additional modeling guidance to support the proper implementation of the new standard. Further, we believe the monitoring rule is not an appropriate regulatory forum to address the needs identified in the comment further.

(13) ***Comment:*** RRI urged EPA not to allow "states to use 'hot spot' monitors to characterize regional background concentrations that are needed for comprehensive modeling analyses." In addition, RRI requested EPA allow states to permit "affected facilities to conduct refined modeling to determine whether there is a need for monitoring near these facilities, and where any monitor should be placed."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is focused, through use of the PWEI, into areas where there is increased coincidence of population and SO_2 emissions (section IV.B.4 and IV.B.5 of the preamble). Under this approach we anticipate combining the use of monitoring and available modeling to assess compliance with the new 1-hour SO_2 NAAQS. Therefore, the required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring objectives, as discussed in section IV.B.3, while the modeling of sources in effect provide source-oriented concentration data. Because of the greater flexibility of the final monitoring network to address multiple monitoring objectives including general background (discussed in section IV.B.3 of the preamble), EPA expects that non-source oriented monitoring data will be available for use as background concentration input for modeling analysis. Regarding the "need for monitoring" near facilities, states should consider monitoring near sources which are not as conducive to modeling, such as (1) sources classified as non-point sources (i.e., "area-sources") such as shipping ports, (2) a source situated in area of complex terrain and/or situated in a complex meteorological regime, (3) locations that have multiple, relatively small sources with overlapping plumes.

(14) ***Comment:*** Louisiana Chemical recommends that the placement of SO_2 monitors "be based on projected emissions rather than historical data" since "significant reductions in levels of sulfur dioxide emissions have occurred since 2005 and these will continue to decrease. Decisions on monitor locations should be based on enforceable agreements, permits and regulations in the process of implementation."

Response: Rather than the proposed monitoring-focused approach to assess compliance with the SO_2 NAAQS, EPA anticipates using a hybrid analytical approach, introduced in section III of the preamble to the final rule, which combines monitoring and modeling using each of these where they are most appropriate and effective which should address the commenters concerns. Since it is anticipated that dispersion modeling will be used to assess impacts of

individual SO_2 sources, the required monitoring network is no longer wholly source-oriented in nature, and now can serve multiple monitoring objectives, as discussed in section IV.B.3, while the modeling of sources in effect provide source-oriented concentration data. This approach should address the commenter's concerns regarding the appropriate location of monitors.

(15) ***Comment:*** MSCC requests "greater consideration…be given so that the limited monitoring resources are placed in the areas judged most likely to benefit from the measurements–most likely to a) have populations at risk, b) have concentrations above the threshold of the standard, and c) most likely to have a feasible means of correcting any problem found."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is focused, through use of the PWEI, into areas where there is increased coincidence of population and SO_2 emissions (section IV.B.4 and IV.B.5 of the preamble). The required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring objectives, as discussed in section IV.B.3, while the modeling of sources in effect provide source-oriented concentration data. EPA believes the final network design, in combination with the projected use of modeling, alleviates the concerns raised by the commenter.

(16) ***Comment:*** Dow recommended EPA relocate "only a portion of the current monitors during the first few years of short term data collection" in order that data from the new monitoring stations can be compared with the pre-existing monitoring stations and community monitors to gain a better understanding of the strengths and weaknesses of the new monitoring system. Dow also expressed concern that "the new monitoring network could result in some monitoring results that are variable and responsive to small changes in placement."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is focused, through use of the PWEI, into areas where there is increased coincidence of population and SO_2 emissions (section IV.B.4 and IV.B.5 of the preamble). Under this approach we anticipate combining the use of monitoring and available modeling to assess compliance with the new 1-hour SO_2 NAAQS. Thus, the required monitoring network is no longer wholly source-oriented in nature, and now can serve multiple monitoring objectives, discussed in section IV.B.3, while the modeling of sources may be more efficient and effective in providing source-oriented concentration data. EPA believes the final network design, in combination with the projected use of modeling, should alleviate the concerns raised by the commenter.

(17) ***Comment:*** City of Alexandria commented that, based on its own monitoring experiences, "local monitoring should only be used as a backstop, in order to assist in compliance verification, and only after air quality model-based

limitations are developed and implemented by the large stationary sources that have the potential to contravene NAAQS protections."

Response: Partly in response to these and other comments and an examination of our historical approach to SO2 NAAQS implementation, we now anticipate using a hybrid analytic approach, as introduced in section III of the preamble to the final rule, combining the use of monitoring and available modeling to assess compliance with the new 1-hour SO_2 NAAQS. Rather than a monitoring-focused approach EPA anticipates using each of these analytic tools where they are most appropriate and effective. We anticipate placing greater emphasis on modeling than did the proposed rule as the most technically appropriate, efficient, and readily available method for assessing short-term ambient SO2 concentrations in areas with large point sources. Under this approach, the required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring objectives, as discussed in section IV.B.3, while the modeling of sources in effect provide source-oriented concentration data. EPA believes states should consider monitoring in areas or near sources that are not conducive to modeling, such as (1) sources classified as non-point sources ("area-sources") such as shipping ports, (2) a source situated in area of complex terrain and/or situated in a complex meteorological regime, (3) locations that have multiple, relatively small sources with overlapping plumes. This approach should address the commenter's concern.

(18) ***Comment:*** AirQuality recommended EPA "consider adding simple particle detectors to SO_2 sites to further characterize the nature of the plume. If other such parameters are to be required at SO_2 sites EPA should be prepared to fund the capital cost of the equipment involved."

Response: While EPA does not disagree with the reasoning of the commenter's suggestion, EPA is only addressing the SO_2 monitoring network design here. Particulate matter is a separate NAAQS pollutant which is on another time-line for review. However, EPA encourages and applauds state efforts to make monitoring sites multi-pollutant.

(19) ***Comment:*** Wisconsin requested "a clarification on the minimum monitoring requirements presented on page 64850. When EPA discusses minimum SO_2 monitoring requirements, the third requirement is 'any ongoing SO_2 monitoring must have a least one monitor sited to measure the maximum concentration of SO_2 in that area.' Further clarification is requested for the term 'area'. What is the special extent that one existing monitor must measure?"

Response: Due to the change of approach from proposal, this comment is now moot.

(20) ***Comment:*** Several organizations provided comments in support of granting SO_2 monitor waivers when violation of the SO_2 NAAQS has been proven to be

unlikely. Iowa recommended that "existing monitors that record low values" continue to be considered "subject to removal in accordance with existing regulations contained in 40 CFR 58 Subpart B paragraph 58.14" as well as being considered for a waiver when "there are no monitoring locations in the prescribed area where site specific ambient impact analyses predict a NAAQS violation, there are no monitoring locations available in the modeled "hot spot" that meet EPA siting requirements, or the modeled "hot spot" occurs in an area that is inaccessible or unpopulated." MIDNRE recommended EPA permit a monitoring requirement to be waived "if modeling shows maximum concentrations are less than 50 percent of the NAAQS" so that state agencies can efficiently use their limited budgets. (Iowa, MIDNRE, and South Carolina)

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring objectives, as discussed in section IV.B.3, while the modeling of sources we believe would be more efficient and effective in providing source-oriented concentration data. Further, fewer monitors are required in the final network design versus that number which was proposed. Due to the flexibility in the monitoring network design and the adjustments made to the PWEI thresholds by which monitoring is required (discussed in section IV.B.4 and IV.B.5), EPA does not believe that a waiver provision is necessary. Regarding site shutdown, 40 CFR 58.14(c) explains how a state can seek EPA Regional Administrator approval to shut down an existing SO_2 monitoring site. However, EPA notes that this applies to monitors in excess of the established minimum monitoring requirements in 40 CFR Part 58 Appendix D.

(21) ***Comment:*** Three commenters expressed concern that the "two pronged approach in the proposed regulation will lead to duplicative monitoring in some areas and require monitors in areas where monitors are not needed" and recommend EPA allow monitors to be removed "(1) where there is only one monitor for a given source or Core Based Statistical Area (CBSA) and data show that the concentrations in the area are less than 75 percent of the National Ambient Air Quality Standards (NAAQS); or (2) where there is more than one monitor in a given CBSA or for a given source and data show that concentrations are less than 80 percent of the NAAQS." (North Carolina, NACAA, and Ohio)

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring objectives, discussed in section IV.B.3, while the modeling of sources would be more efficient and effective in providing source-oriented concentration data. EPA believes an approach that combines use of monitoring and modeling and not requiring monitors under a second prong as proposed alleviates the commenters' concerns regarding duplicative monitoring. In addition, due to the flexibility in the monitoring network design and the adjustments made to the PWEI thresholds

by which monitoring is required (discussed in section IV.B.4 and IV.B.5), EPA does not believe that a waiver provision is necessary.

(22) ***Comment:*** Wisconsin recommends that the "proposed rule should provide flexibility for states to eliminate monitors from CBSAs based on an assessment of local conditions and risks and EPA Regional Directors should have the ability to approve waivers or exceptions to the monitoring requirements in the rule." Wisconsin also recommends "EPA allow flexibility for monitor siting in rural areas, if necessary, and that such monitors would fulfill prong 1 requirements."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring objectives including siting monitors in rural areas consistent with the monitoring objectives, as discussed in section IV.B.3, while the modeling of sources in effect provide source-oriented concentration data. Due to the flexibility in the monitoring network design and the adjustments made to the PWEI thresholds by which monitoring is required (discussed in section IV.B.4 and IV.B.5), EPA does not believe that a waiver provision is necessary. Regarding the request for "…EPA Regional Directors should have the ability to approve waivers or exceptions to the monitoring requirements in the rule", EPA disagrees with such a concept. The minimum monitoring requirements are a 'minimum' to ensure that a network of sufficient size and focus is maintained to support the NAAQS.

IV.G: Comments on Proposed Alternative Network

(1) ***Comment:*** Five commenters expressed support for the proposed alternative monitoring network and the use of dispersion modeling to determine where SO_2 monitors should be located. For instance Iowa recommended "that the final rule contains provisions that require monitors to be sited only at locations where dispersion modeling indicates that the NAAQS is violated" (Alexandria, Delaware, South Dakota, and Center for Biological Diversity). Delaware's support for the alternative monitoring network did come with the recommendation that EPA revise its approach to "include the impact of modeled concentrations on populated areas, and not rely on modeled ambient concentrations alone to determine the number or location of monitoring sites."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is focused, through use of the PWEI, into areas where there is increased coincidence of population and SO_2 emissions (section IV.B.4 and IV.B.5 of the preamble). Under this approach, we anticipate combining the use of monitoring and available modeling to assess compliance with the new 1-hour SO_2 NAAQS. Thus, the required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring objectives, discussed in section IV.B.3, while the modeling of sources we believe would be more efficient and effective in

providing source-oriented concentration data. EPA believes that at hybrid analytical approach is superior to both the proposed network design and the alternative network design because redundant and/or unnecessary monitoring is reduced, required monitoring can serve multiple monitoring objectives, and modeling can provide data that would have otherwise only been collected by a relative fewer number of source-oriented monitors compared to the number of sources that can be modeled. EPA's reasons for believing that modeling SO_2 sources is more effective than just source-oriented SO_2 monitoring is discussed in detail in section IV.B.2 of the preamble.

(2) ***Comment:*** Five commenters expressed opposition to EPA's proposed alternative monitoring network with three of the organizations opposing the proposed alternative network design because it "would not distinctly use population as a factor in deciding where monitors should be placed." (AirQuality, South Carolina, and UARG). In addition, NPRA opposed EPA's proposed alternative network because it would "effectively make the SO_2 NAAQS a "source oriented" NAAQS" which is "not supported by the clear language of the CAA." Finally, Indiana opposed the alternative network because the state agency preferred "to determine placement of the monitors" rather than have the monitor locations determined strictly from dispersion modeling.

Response: In the final rule, EPA is not adopting the alternative monitoring network. Instead, under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the final monitoring network design is focused, through use of the PWEI, into areas where there is increased coincidence of population and SO_2 emissions (section IV.B.4 and IV.B.5 of the preamble). Under this approach, we anticipate combining the use of monitoring and available modeling to assess compliance with the new 1-hour SO_2 NAAQS. Thus, the required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring objectives, as discussed in section IV.B.3, while the modeling of sources we believe could be more appropriate, efficient, and effective in providing source-oriented concentration data. EPA believes that a hybrid analytical approach is superior to both the proposed network design and the alternative network design because redundant and/or unnecessary monitoring is reduced, required monitoring can serve multiple monitoring objectives, and modeling can provide data that would have otherwise only been collected by a relative fewer number of source-oriented monitors compared to the number of sources that can be modeled. EPA's reasons for believing that modeling SO_2 sources is more effective than just source-oriented SO_2 monitoring is discussed in detail in section IV.B.2 of the preamble.

(3) ***Comment:*** API provided comments recommending that if dispersion modeling was used in the monitor location process that "EPA should encourage states to provide a stakeholder process so that affected emission sources can be consulted in the state's planning process for the monitor placement…If an affected source does not agree with the state's analysis on the placement of one or more SO_2

monitors, they should have the right to provide their own study for state review and consideration if they choose to do so."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring objectives, as discussed in section IV.B.3, while the modeling of sources we believe would be more efficient and effective in providing source-oriented concentration data. EPA is encouraging states to consider monitoring in areas or near sources that are not conducive to modeling, such as (1) sources classified as non-point sources (i.e., "area-sources") such as shipping ports, (2) a source situated in area of complex terrain and/or situated in a complex meteorological regime, (3) locations that have multiple, relatively small sources with overlapping plumes. The decision on the appropriate locations for the required monitors falls on the states, who will detail such decisions in their annual monitoring network plan. States must develop annual monitoring network plans under 40 CFR §58.10, and the plan must be available to the public prior to submission to EPA.

(4) ***Comment:*** UARG opposes the proposed use of AERMOD for any requisite dispersion modeling because it would "simply not be appropriate for siting a monitor at the likely site of the expected maximum 1-hour concentration–the model has been validated by comparing it with observed high ambient concentrations, but its performance for matching concentrations at a specific time or location has not been evaluated."

Response: The revised approach for monitoring shifts the focus of monitoring toward characterizing ambient concentrations that are best achieved through ambient monitoring, such as areas with a large number of smaller SO_2 sources or areas with complex meteorological influences, such as coastlines, that may be more difficult to characterize through modeling. Under a hybrid analytical approach (as introduced in section III of the preamble to the final rule), modeling will typically not be relied upon to site a single source-oriented ambient monitor. The limitation of a single monitor to adequately account for peak hourly SO_2 ambient concentrations in the vicinity of SO_2 emission sources, even if dispersion modeling was conducted to site the monitor, is part of the rationale for revising the focus and objectives for the ambient monitoring network.

(5) ***Comment:*** NYSDEC expressed concern in its comments that "using AERSCREEN or SCREEN3 may not be the most practical approach for determining the number and location of required monitors" because "the data required to run the models are only readily available for permitted facilities," which would result in incomplete and inaccurate dispersion models.

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring

objectives, as discussed in section IV.B.3, while the reliance on appropriate refined dispersion modeling would be used to provide source-oriented concentration data.

(6) ***Comment:*** RRI and LEC suggested EPA develop a more robust method for calculating background concentrations of SO_2 by "assigning background on an hour-by-hour basis from one or more monitors, accounting for wind direction and excluding hours when a monitor is directly downwind of the its existing source. Another approach could be the development of SO_2 background climatology according to wind direction and season, based upwind monitors that are not influenced by local sources." (RRI (.0388), LEC (.0257)) RRI continued by stating that "refined modeling approaches that consider realistic combinations of source impacts and regional background concentrations are critical to avoid false identifications of non-existent non-attainment areas." (RRI (.0389))

Response: EPA recognizes the technical challenges associated with conducting a cumulative ambient air quality impact analysis given the 1-hour averaging time and the statistical form of the new standard. Existing guidance for demonstrating compliance with NAAQS through dispersion modeling is expected to be generally applicable and adequate for the new hourly SO2 standard, and that guidance provides an appropriate amount of flexibility to address specific issues that may arise on a case-by-case basis. However, EPA expects to develop additional modeling guidance to support the proper implementation of the new standard.

(7) ***Comment:*** NYSDEC recommended that if the alternative monitoring network approach is pursued, potential monitoring should be limited "to the source types of highest concern (e.g. smelters, coal burning plants, >20,000 tpy emission sources). In addition, modeling can be used in areas of uncertainty, as an auxiliary or complementary tool to other methods for assessing the likelihood of NAAQS exceedance."

Response: EPA has not pursued the alternative network design. The final network design is discussed in section IV.B of the preamble to the final rule.

(8) ***Comment:*** North Carolina made several recommendations for how the alternative monitoring network proposal could be improved. First, North Carolina suggested that any "facility whose smokestack SO_2 emissions are above a determined emission rate would be required to perform modeling to demonstrate that the SO_2 concentration at the fence-line does not exceed whatever ambient standard EPA establishes. If modeling does not demonstrate compliance, the facility could then be required to reduce emissions from the stack, install continuous emissions monitoring (CEM) in the stack itself, or require a fence-line monitor at the target facility. This will allow flexibility to work with facilities to determine if monitoring is required and will reduce the cost and consequences of nonattainment." Second, EPA could create a monitoring approach similar "to the lead network where modeling can be used to demonstrate whether the facility

impacts the NAAQS. Facilities where the model indicates the ambient air is a certain amount below the NAAQS" would not have to monitor. "This approach would also reward states that have taken actions to reduce SO_2 emissions from their facilities and place the monitoring burden on states that have more significant SO_2 emissions."

Response: EPA has not pursued the alternative network design, but instead has identified a hybrid analytical approach, as introduced in section III of the preamble to the final rule, where the required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring objectives, as discussed in section IV.B.3, while the modeling of sources we believe would be more efficient and effective in providing source-oriented concentration data. This combination of monitoring and modeling is anticipated to provide the data for implementation of and designations under the revised primary SO_2 NAAQS. EPA believes that a hybrid analytical approach embodies much of the suggestions made by North Carolina, thus addressing their concerns.

(9) ***Comment:*** Missouri recommended "EPA should not require states to conduct refined modeling in every case that the screening tools show a violation. Many times, the screening tools are overly conservative and might lead to analysis in areas that is not warranted. Many states will have a better indication of areas that might violate the new NAAQS without this type of screening approach due to previous permit modeling exercises or additional ambient monitoring data collected by third parties."

Response: This comment is no longer relevant under a hybrid analytical approach, as discussed in sections III, IV, V, and VI in the preamble to the final rule.

IV.H: Comments on data reporting

(1) ***Comment:*** Iowa commented that EPA will need to emphasize that "long term monitoring commitments are required, as computation of design values at a monitoring site requires at least three years of data."

Response: EPA concurs with Iowa that monitoring sites are long term commitments. EPA expects that many of the existing sites in urban area with required minimum monitors will be used to meet minimum monitoring requirements of this final rule, thus continuing operation of some sites that could be already considered 'long-term' sites.

(2) ***Comment:*** NESCAUM recommended if a "source-oriented site has or is expected to have SO_2 levels at 75% or more of the NAAQS… that five-minute wind data also be collected at the site."

Response: EPA did not propose, and is not finalizing a requirement for wind data at source oriented monitoring sites. EPA encourages states, as appropriate, or possible, to collect meteorological data at such sites in order to better characterize source impacts on the monitoring site.

(3) ***Comment:*** Both Alaska and NACAA oppose requiring states to measure and report data at increments below one hour. In Alaska's comments, the Department notes that upgrading its "current data collection infrastructure to capture, store and review data on a smaller time scale than one hour would impose substantial costs" because Alaska does not currently possess monitors capable of reporting five-minute SO_2 concentrations. Similarly, NACAA commented that while report five-minute SO_2 concentrations "may be easily achievable for some agencies with the appropriate data collection infrastructure, requiring all agencies to perform these duties impose significant costs."

Response: EPA notes that all continuous UVF analyzers produce readings that can be aggregated into time intervals as short as 1-minute. Such units should easily be capable of reporting 5-minute averages. EPA believes that the prevalence of data acquisition systems that can acquire monitor output signals and formulate averages as short as 1-minute is nearly ubiquitous among state, local, and tribal agencies. Such data systems can typically be configured to store and report 1-minute averages to a central database which subsequently can be configured to aggregate data into the desired averaging period (e.g., 5-minute, 15-minute, and 60-minute). Although agencies may be most familiar with reporting averages over 60-minute periods, the capability to create alternative average periods and report such averages in AQS compatible formats likely resides within most current data systems. EPA acknowledges that some investment may be necessary for those few agencies whose data systems cannot currently meet the required reporting requirements for SO_2; however, EPA also believes that the investment in such systems will provide efficiencies in data handling across all continuous measurements that will outweigh the initial cost.

(4) ***Comment:*** Missouri recommends EPA require SO_2 concentrations to be reported in ppm rather than ppb in order to be consistent with other the reporting of other pollutants and the Air Quality Index.

Response: Since the standard itself is expressed in parts per billion (rather than in fractional parts per million), EPA believes it appropriate for SO_2 concentrations to be reported the same way.

(5) ***Comment:*** Seven organizations submitted comments in opposition to EPA proposal to require state and local agencies to report the maximum 5-minute block average because the reporting requirement would represent too great a burden on state finances and labor and because the additional reporting requirements would not be necessary in order to demonstrate compliance with the proposed new SO_2 standard. (Iowa, NYSDEC, LEC, RRI, South Carolina, and KYDEP)

Response: EPA has finalized the requirement to report the maximum 5-minute data block occurring in each hour. EPA's reasons for this requirement are discussed in detail in section IV.C of the preamble to the final rule.

(6) ***Comment:*** AirQuality recommended "hourly met data should be reported to EPA while the maximum 5-minute block average met data should be reported at the State's option" so that EPA will be able "to accurately determine the source of the measured SO_2."

Response: EPA did not propose, and is not finalizing a requirement for wind data at source oriented monitoring sites. EPA encourages states, as appropriate, or possible, to collect meteorological data at such sites in order to better characterize source impacts on the monitoring site.

(7) ***Comment:*** Six organizations provided comments supporting the requirement that state agencies submit all 12 5-minute block SO_2 concentrations to EPA along with the 1-hour average either because the organization considered reporting all 12 5-minute concentrations "less resource intensive than selecting the 5-minute max for each hour" (NYSDEC) or because it "will provide higher quality data for future NAAQS reviews" (AirQuality). Center for Biological Diversity, Wisconsin, ATS, and ALA/EDF/NRDC/SC)

Response: EPA has finalized the requirement to report the maximum 5-minute data block occurring in each hour. EPA's reasons for this requirement are discussed in detail in section IV.C of the preamble to the final rule.

(8) ***Comment:*** Three organizations submitted comments opposing the requirement that state agencies provide all 12 5-minute block SO_2 concentrations because the requirement would create too great a reporting burden for financially strapped state agencies. (Missouri, South Carolina, and South Dakota)

Response: EPA has finalized the requirement to report the maximum 5-minute data block occurring in each hour, as discussed in detail in section IV.C of the preamble to the final rule.

(9) ***Comment:*** Both ALA/EDF/NRDC/SC and South Dakota provided comments supporting the requirement that state agencies report the highest 5-minute rolling average SO_2 concentration from each hour. In its justification for supporting a highest 5-minute rolling average reporting requirement, ALA/EDF/NRDC/SC noted "the rolling average will yield data more appropriate to the evaluation of health concerns than block averaging which is arbitrary and does not actually report the highest 5-minute concentration." (South Dakota and ALA/EDF/NRDC/SC) In addition, Center for Biological Diversity expressed support for EPA requiring states to report the highest 5-minute rolling average SO_2 concentration for each hour at SO_2 monitors where possible.

Response: EPA has finalized the requirement to report the maximum 5-minute data block occurring in each hour. See discussion in section IV.C of the preamble to the final rule.

(10) ***Comment:*** Three organizations provided comments opposing the requirement that state agencies report highest 5-minute rolling average SO_2 concentrations because the use of rolling averages would be burdensome to financially strapped state agencies in charge of the SO_2 monitoring network. (North Carolina, Indiana, and South Carolina)

Response: EPA has finalized the requirement to report the maximum 5-minute data block occurring in each hour, as discussed in detail in section IV.C of the preamble to the final rule.

IV.I: Comments on Cost of Monitoring Changes

(1) ***Comment:*** Numerous commenters expressed serious concern about large the cost of the ambitious monitoring network EPA is proposing and how it will be funded. These commenters said that state governments are already struggling with budget cuts and the addition of a new SO_2 monitoring program on top of other monitoring program expansions is likely to result in cuts to state air quality monitoring programs, regardless of federal requirements, without federal funding assistance. Many comments called on the federal government to significantly increase federal funding for the development and operation of the proposed SO_2 monitoring network in general terms. (NYSDEC, Delaware, Indiana, AEPSC, NESCAUM, Illinois, South Carolina, Texas, Wisconsin, CE, Ohio). Others explicitly requested that EPA fund the new SO_2 monitoring program with Section 103 funds rather than leave the monitoring network unfunded or funded with Section 105 funds (which require matching state and local funds). (Florida, Iowa, Pennsylvania , MIDNRE , North Carolina , Alaska, NACAA, KYDEP, and Vermont)

Response: EPA notes that $15 million in new STAG funding has been proposed in the President's budget for fiscal year 2011 for the purpose of supporting new monitoring equipment purchases related to the NAAQS. EPA also notes that additional STAG funding was proposed to support "core" programs which can include activities such as ambient monitoring. EPA will work with the Regional Offices, NACAA, and monitoring agencies to develop a plan for allocating these funds to the new monitoring needs related to recent NAAQS revisions.

(2) ***Comment:*** Several commenters expressed concern that EPA significantly underestimated the deployment and operation costs for new SO_2 monitors. For example Vermont estimated that the associated costs for a source-oriented monitor would “be at least 30 to 40 percent higher than EPA's estimates.” (NYSDEC, Delaware, Alaska, NACAA, and Vermont).

Response: EPA uses its best available estimation in determining costs for network deployment and operations, as required for inclusion the Information Collection Review (ICR) that accompanies each rulemaking.

(3) ***Comment:*** NACAA and Vermont suggested in their comments that EPA consider "promulgating regulations that make the sources pay directly for the monitoring efforts carried out by state and local agencies" as a means of addressing the funding crisis for SO_2 monitoring and other NAAQS monitoring. (NACAA and Vermont).

Response: EPA is not in a position to address or execute such an action as part of this rulemaking. EPA notes that $15 million in new STAG funding has been proposed in the President's budget for fiscal year 2011 for the purpose of supporting new monitoring equipment purchases related to the NAAQS. EPA also notes that additional STAG funding was proposed to support "core" programs which can include activities such as ambient monitoring. EPA will work with the Regional Offices, NACAA, and monitoring agencies to develop a plan for allocating these funds to the new monitoring needs related to recent NAAQS revisions.

(4) ***Comment:*** Georgia requested in its comments that EPA withdraw its proposed monitoring program proposal "until a holistic analysis of the total costs is conducted and adequate new funding is identified and assured."

Response: EPA understands that each individual NAAQS review is not occurring in a vacuum. However, EPA will not suspend the promulgation of monitoring rules that directly support revised NAAQS. EPA notes that $15 million in new STAG funding has been proposed in the President's budget for fiscal year 2011 for the purpose of supporting new monitoring equipment purchases related to the NAAQS. EPA also notes that additional STAG funding was proposed to support "core" programs which can include activities such as ambient monitoring. EPA will work with the Regional Offices, NACAA, and monitoring agencies to develop a plan for allocating these funds to the new monitoring needs related to recent NAAQS revisions.

(5) ***Comment:*** Several commenters suggested that EPA should not implement any new FRM or FEM changes until sufficient new funding is procured to fund the deployment of the entire new SO_2 monitoring network because the funding challenge for the SO_2 monitoring network will only be made worse by the forced retirement of functional SO_2 monitors that no longer meet the new FRM and FEM standards. (MIDNRE, AEPSC).

Response: Under this rulemaking, there will not be an entirely new monitoring network. The promulgation of a new FRM, which coexists with the existing FRM and FEMs, will not force the retirement of functional and currently operating FEMs.

(6) ***Comment:*** Several commenters recommended that, because of the limited funds for deploying a new SO_2 monitoring network, dispersion modeling should be utilized along with other criteria (i.e. population exposure) to determine which SO_2 monitors are the highest priorities to deploy so that a smaller, but still health protective, SO_2 monitoring network can be deployed. (North Carolina, South Carolina, Vermont)

Response: As discussed in section IV.B.3 and IV.B.4 of the preamble to the final rule, the final monitoring network design calls for less monitoring sites and is more flexible than the proposed network design. As a result, EPA anticipates that only 41 new monitors will need to be deployed to satisfy minimum monitoring requirements. Therefore, we believe that the final network design alleviates the commenters concerns.

IV.J: Comments on the authority and responsibilities of Regional Administrators (RAs)

(1) ***Comment:*** Several commenters expressed support for requiring RAs be in "close consultation with the [appropriate] state agency" when determining when to require additional SO_2 monitors (North Carolina, Louisiana Chemical, South Carolina, and AirQuality). Similarly, AirQuality recommended EPA include provisions requiring RAs to provide a public comment period for proposed additional SO_2 monitors before a final decision is made. Finally, Louisiana Chemical suggested EPA require RAs to "consider certain objective factors when determining whether to require any additional ambient SO_2 monitors to the network."

Response: EPA agrees with the commenters' suggestions, and expects that Regional Administrators would work with state and local air agencies when evaluating and possibly requiring additional monitors above the minimum requirements. Regarding public input, any additional monitoring that a Regional Administrator might require of a state would be included in that state's annual monitoring plan. States must develop annual monitoring network plans as required by 40 CFR 58.10, those plans must be available to the public prior to submission to EPA.

(2) ***Comment:*** Several organizations recommended that an RA's authority to require additional SO_2 monitors be contingent upon the RA/EPA providing all the additional funding necessary to deploy and operate the additional monitoring stations (NYSDEC, Delaware, North Carolina, South Carolina, and AirQuality). recommended that additional SO_2 monitors required by the RA but dispute by state, local, or tribal monitoring authorities should be funded by the federal government "for three years or until enough data is collected to reach an attainment designation and address the concern." (.0843)

Response: In the event that an RA does require additional monitors above the minimum required, EPA will work with the monitoring agencies to develop a plan on how funds might be allocated for any new monitoring.

(3) ***Comment:*** ALA/EDF/NRDC/SC recommended EPA consider the likelihood of RAs requiring additional SO_2 monitors when creating the federal budget for the monitoring program.

Response: EPA always tries to create as accurate a budget as possible, and if any information regarding RA required monitoring is available as budgets are being developed, such information would be considered in the budget creation process.

(4) ***Comment:*** Florida recommended EPA grant RAs the authority to approve reductions in the number of required SO_2 monitors if it can be shown that marginal SO_2 monitors will not significantly benefit the public health.

Response: EPA disagrees with the concept that allows "RAs…to approve reductions in the number of required SO_2 monitors if it can be shown that marginal SO_2 monitors will not significantly benefit the public health." EPA notes that this comment was directed at the proposed monitoring network design which required a greater number of monitors compared to the final network design which is part of a hybrid analytical approach (introduced in section III of the preamble of the final rule). The minimum monitoring requirements are a 'minimum' to ensure that a network of sufficient size and focus is maintained to support the NAAQS.

(5) ***Comment:*** Florida recommended EPA "allow for the regional administrator to approve adjustment of the monitoring requirements to provide for flexibility for monitors to address multiple purposes."

Response: Under a hybrid analytical approach, as introduced in section III of the preamble to the final rule, the required monitoring network no longer must be wholly source-oriented in nature, and now can serve multiple monitoring objectives, as discussed in section IV.B.3, while the modeling of sources would be more efficient and effective in providing source-oriented SO2 concentration data. Due to the flexibility in the monitoring network design EPA believes the commenter's concerns are alleviated.

(6) ***Comment:*** AirQuality recommended "EPA should consider adding guidance to its monitoring network proposal that focuses on school-oriented sites in section d. 'Monitoring required by the regional administrator' [64854] to clarify if schools may be an example of 'a case where a source having modest emissions still has high potential to cause a violation of the NAAQS in a community or neighborhood.'"

Response: Under the final rule, Regional Administrators may consider requiring monitoring wherever monitoring objectives are not being met. EPA anticipates that in situations such as the example given by the commenter, the Regional Administrators would consider on a case-by-case basis the need for additional monitors in such situations.

VI. Air Quality Index

(1) ***Comment:*** Pennsylvania commented that EPA must provide timely implementation rules and guidance for issues such as SHLs, emergency action levels, and the updated AQI in order to adequately protect public health and the environment.

Response: EPA agrees with this comment which is why we have revised the Air Quality Index (AQI). EPA did not propose to change breakpoints at the higher end of the AQI scale (from 200 to 500), which would apply to state contingency plans or the Significant Harm Level (40 CFR 51.16), because the information from this review does not inform decisions about breakpoints at those higher levels.

(2) ***Comment:*** NESCAUM commended EPA's proposal to revise the AQI concurrently with the NAAQS. In a February 8, 2007, letter to EPA, NESCAUM indicated that the current AQI is not well designed for its current uses (e.g., addressing real-time exposures with additional messaging at lower levels approaching the standard). They stated that EPA should revisit and overhaul the AQI to address the multiple purposes it now serves and better serve public health protection (e.g., adjust the AQI to reflect shorter averaging times, account for multi-pollutant cumulative impacts, and consider additional contaminants).

Response: Structural changes to the AQI, called an overhaul by this commenter, would have to be made through a separate rulemaking.

(3) ***Comment:*** Letters from a mass comment campaign sponsored by the Sierra Club, and comments from NACAA, South Carolina, and Vermont support revisions to the AQI to conform with the new SO_2 primary standard, if it is promulgated.

Response: EPA agrees with these commenters.

(4) ***Comment:*** North Carolina strongly recommended that EPA establish the AQI breakpoints for SO_2 when they propose the final SO_2 NAAQS rule. North Carolina recommended that a 100 AQI correspond with the short-term SO_2 NAAQS, consistent with other NAAQS pollutants. The 50 and 150 AQI breakpoints should also be consistent with the other NAAQS pollutants. North

Carolina is concerned that failing to adequately define the AQI breakpoints might lead to problems such as those with the $PM_{2.5}$ AQI.

Response: EPA has identified all of the changed breakpoints in the AQI, and has made revisions to the 50 and 150 AQI breakpoints that are consistent with recent decisions made for other NAAQS.

(5) ***Comment:*** Air quality commented that the range for the AQI 50 breakpoint is acceptable because the approach EPA used to arrive at it is consistent with that of previous standards.

Response: EPA agrees with this commenter.

(6) ***Comment:*** NYSDEC recommended that the requirement for hourly AQI forecasts be delayed at least one year so that the data being collected and forecasted is shown to be reliable. In the meantime, EPA may want to make the SO_2 AQI based on a longer interval (e.g., 24-hour) that can be more accurately forecasted (NYSDEC) EPA should provide guidance for forecasting 1-hour SO_2 data and for communicating these forecasts to the public in a timely manner.

Response: EPA recommends and encourages air quality forecasting but it is not required (64 FR 42548, August 4, 1999). We agree that there will be new challenges associated with creating and communicating an SO_2 forecast. We will work with State agencies that want to develop an SO_2 forecasting program on issues including, but not limited to, forecasting for short term periods.

(7) ***Comment:*** While Wisconsin supports changing the AQI concurrent with the new NAAQS, they believe it is impractical to incorporate SO_2 into its forecasting and public health notification program because SO_2 does not behave like a regional pollutant. Exceedances may occur with little or no warning and for two hours or less. They requested EPA consider the resources necessary for public communications at the state and local levels, particularly in areas where other air quality exceedances are relatively rare.

Response: EPA recommends and encourages air quality forecasting but it is not required (64 FR 42548, August 4, 1999). We agree that there will be new challenges associated with creating and communicating an SO_2 forecast. We will work with State agencies that want to develop an SO_2 forecasting program on issues including, but not limited to, forecasting for short term periods.

(8) ***Comment:*** NESCAUM commends EPA on its proposal to revise the Air Quality Index (AQI) concurrently with the SO_2 NAAQS. NESCAUM has some questions regarding how EPA envisions reporting and forecasting SO_2 concentrations for the AQI using source-oriented monitors. For example, how does EPA expect geographic regions to be delineated, given the more localized nature of a source-oriented network?

Response: This final rule departs from the proposed rule in that it allows for a combined monitoring and modeling approach. Because of this, the monitoring network is not required to be wholly source-oriented in nature. States have flexibility to allow required monitoring sites to serve multiple monitoring objectives including characterizing source impacts, highest concentrations, population exposure, background, and regional transport. Further, EPA expects that much of the existing network will be retained by states to satisfy the minimum monitoring requirements. This means that it is unlikely that AQI reporting and forecasting will be heavily driven by source-oriented monitors. Rather, many of the existing monitors (a majority of which are community-wide monitors) will remain in place, which prevents the need for new geographic regions to be delineated.

(9) ***Comment:*** Additionally, NACAA requests that EPA work with state and local agencies to develop a forecast model and appropriate guidance for incorporating SO_2 into their daily air quality forecasts.

Response: We agree that there will be new challenges associated with creating and communicating an SO_2 forecast. We will work with State agencies that want to develop an SO_2 forecasting program on issues including, but not limited to, forecasting for short term periods.

(10) ***Comment:*** The State of Vermont APCD supports the EPA proposal to revise the SO_2 AQI concurrently with the primary SO_2 NAAQS.

> The ability to provide timely and geographically relevant air quality reporting, alerts and forecasts are important components of public health protection. However, we have some questions regarding how the EPA envisions reporting and forecasting SO_2 concentrations for the AQI using source oriented monitors. For example, how does EPA expect geographic regions to be delineated, given the more localized nature of a source-oriented network? Additionally, we also urge the EPA to work with the states to revisit and overhaul the AQI in light of the multiple purposes it now serves, including: adjusting the AQI to reflect shorter averaging times; accounting for multi-pollutant (i.e., cumulative) impacts; and considering additional contaminants. By so doing, public health protection would be better served.

Response: This final rule departs from the proposed rule in that it allows for a combined monitoring and modeling approach. Because of this, the monitoring network is not required to be wholly source-oriented in nature. States have flexibility to allow required monitoring sites to serve multiple monitoring objectives including characterizing source impacts, highest concentrations, population exposure, background, and regional transport. Further, EPA expects

that much of the existing network will be retained by states to satisfy the minimum monitoring requirements. This means that it is unlikely that AQI reporting and forecasting will be heavily driven by source-oriented monitors. Rather, many of the existing monitors (a majority of which are community-wide monitors) will remain in place, which prevents the need for new geographic regions to be delineated.

VII. Comments on the Process for Reviewing the SO_2 Primary NAAQS

(1) ***Comment:*** SAP generally commented that there was insufficient monitoring data for establishing a new 1-hour SO_2 standard. This commenter contends that EPA should propose to place additional monitors by 2013 and then review whether a new 1-hour standard is required.

Response: EPA disagrees with the commenter. Using the existing monitoring network numerous epidemiologic studies have reported positive associations between mostly 24-hour average and 1-hour daily maximum SO_2 concentrations and serious health outcomes such as hospital admissions. We further note that CASAC has approved: 1) the science underlying the determination in the ISA that there is a causal relationship between respiratory morbidity and short-term (5-minutes to 24-hour) exposure to SO_2; and 2) analyses in the REA estimating the extent to which a 1-hour standard will protect asthmatics from 5-minute SO_2 concentrations of concern identified from controlled human exposure studies. Finally, we note EPA is legally obligated to make a decision by June 2, 2010.

VIII. Interpretation of the Clean Air Act

(1) ***Comment:*** EPA cannot take into account costs of compliance on industries and state governments in establishing NAAQS; however it can and should take into account the effects of its policies on the economic health of the people affected, and particularly on economically February 8, 2010 Page 9 disadvantaged groups who appear to experience asthma disproportionately. It should not fail to consider the effects of that economic health and of economic stress (and distress) on the people's health in the affected areas. Put another way, the transfer of production jobs available to less educated persons from the US to China, from non-attainment areas to non-classified areas, and from less educated US laborers and craftsmen to well-paid engineers may be good for world productivity or good for a working man in China or in another less regulated area – outside the non-attainment area, but the economic stress is not without stress or health impact on the persons displaced or left behind or their children.

Response: However deeply felt the commenter's argument is, it has no legal merit and in fact has been rejected repeatedly. In Whitman v.American Trucking Associations. 531 U.S. 457, 466 (2001), the United States Supreme Court considered the argument that "the economic cost of implementing a very stringent standard might produce health losses sufficient to offset the health gains achieved in cleaning the air -- for example, by closing down whole industries and thereby impoverishing the workers and consumers dependent upon those industries." The Court continued, "That is unquestionably true, and Congress was unquestionably aware of it." The Court went on the reject the argument based on the statutory text: "requisite to protect the public health with an adequate margin of safety" makes no mention of cost, unlike the plethora of other CAA provisions which do.

The Circuit Court of Appeals for the District of Columbia Circuit has likewise rejected the argument. "AISI next contends that EPA erred in refusing to consider the health consequences of unemployment in determining the primary standards for particulate matter. This claim is entirely without merit. In three previous cases this court has emphatically stated that section 109 does not permit EPA to consider such costs in promulgating national ambient air quality standards. It is only health effects relating to pollutants in the air that EPA may consider. See [section 108 (a) (2) ("Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities.") Consideration of costs associated with alleged health risks from unemployment would be flatly inconsistent with the statute, legislative history and case law on this point." NRDC v. EPA, 902 F. 2d 962, 972-73 (D.C. Cir. 1990).

(2) ***Comment:*** The Clean Air Act requires that health effects be projected with a reasonable degree of scientific certainty. The commenter believes that setting a 1-hour standard in the range of 50-100 ppb is not supported by the scientific evidence. The Agency's review and utilization of the information contained in the ISA and the REA do not meet the requirements of the CAA, and EPA's promulgation of a final standard within the range proposed would be more stringent than necessary. (Progress Energy)

Response: EPA firmly believes that the standards adopted in the final rule are well supported by the air quality criteria as set out in the ISA and REA, and has explained why in the preambles to the proposed and final rules, as well as this Response to Comment Document. Nor are the standards more stringent than necessary, given that they are established at a level slightly below the 99^{th} percentile 1-hour daily maximum SO_2 concentrations in the epidemiologic studies EPA reasonably considered to be especially probative.

The commenter's statement that "health effects must be projected with a reasonable degree of scientific certainty" under the CAA (unsupported by legal citation), is also misleading. For example, the requirement in the Act that primary

NAAQS provide an "adequate margin of safety" specifically directs EPA to act even if a risk is uncertain in nature or degree, or not even identified. See S. Rep. No. 91-1196, at 10 (1970); see also American Farm Bureau et al. v. EPA, 559 F. 3d 512, 532-33 (D.C. Cir. 2009) ("Although the evidence of danger from coarse PM is, as the EPA recognizes, 'inconclusive', the agency need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health….'The Clean Air Act requires EPA to promulgate protective primary NAAQS even where, as here, the pollutant's risks cannot be quantified or precisely identified as to nature or degree'" (internal citations omitted)). In the situation here, where the ISA finds a causal relationship between respiratory morbidity and short-term exposure to SO2, and support in the epidemiologic evidence and risk analysis for all of EPA's decisions as to the elements of a revised standard, there is certainly sufficient certainty for EPA to revise the standard.

(3) ***Comment:*** UARG commented that when reviewing an existing NAAQS (which previously was determined to be at the level requisite to protect human health according to the CAA), the Administrator must provide a reasoned explanation for any conclusion that the existing NAAQS is no longer at the level requisite to protect public health with an adequate margin of safety. The commenter cites in support *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29,42 (1983) ("an agency changing course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance"); *Atchison, Topeka and Santa Fe Ry. Co. v. Wichita Bd. of Trade*, 412 U.S. 800, 808 (1973) (an agency must "explain its departure from prior norms"); and *AT&T Corp. v. FCC*, 263 F.3d 729, 736 (D.C. Cir. 2001) (reasoned decision making standard requires explanation of departure from prior decision). The commenter continues, "Rather, the changed conclusions are the result of changes in EPA's interpretation of the evidence. Only if she can supply a "reasoned analysis" for these changes can the Administrator rely on them for a change to the 1996 conclusion that effects of public health significance begin at 600 ppb, or for a reversal of the 1996 decision that no new short-term NAAQS was needed to protect public health with an adequate margin of safety. She has failed to present such an analysis."

Response: EPA must fully explain the basis for its decision in this NAAQS review (including explanation of policies and judgments involved in those decisions, and explanations of how any changes in the science since the last review were evaluated in making a decision. CAA section 307 (d) (3), (d) (6) (A) and (B). EPA has done so here. EPA, however, is not bound by previous NAAQS determinations, and carries no special burden of explanation (beyond providing a reasoned explanation) if it deviates from prior determinations. The cases the commenter cites are inapposite. The plurality opinion in Atchison, Topeka & Santa Fe Ry. Co. involved a situation where the Interstate Commerce Commission, in an adjudicative proceeding, issued a rate order which deviated from prior settled adjudicative precedent of the Commission (412 U.S. at 805-06).

The Commission had a settle principle (referred to in the opinion as "settled rule") addressing the general issue involved in the case, and attempted to distinguish the pending rate determination from that principle. The adequacy of the Commission's explanation for a departure from the settled principle was the basic issue on judicial review.

The Court addressed this issue with an overall focus on the need for an agency to explain its decision, as the fundamental precondition for adequate judicial review. An agency needs to explain its reasoning in order for a court to determine if the decision was with Congress' delegation of statutory authority. In that context, an adjudicatory agency could, through a course of agency action, establish a settled rule or principle that embodies the agency's informed judgment on the appropriate way to carry out the policies committed to it by Congress. In those circumstances a court reviewing an agency decision should properly presume that the agency's settled principle embodies the agency's view on what will best carry out the policies of Congress, calling for an adequate explanation by the agency if it departs from its own norm. The basic purpose of both the presumption and the need to explain a deviation from the settle norm derives from the obligation that an agency explain how its decision conforms to the policies committed to it by Congress. An agency may establish such a settled norm, and if it does then that norm provides an explanation for agency action in future cases. Once such a norm has been established, however, an agency must explain a deviation from it so the reviewing court can determine whether the agency's decision is still consistent with the policies committed to it by Congress.

EPA does not see that this situation has any relevance to the periodic NAAQS review process, or that EPA established any settled rule for interpretation of SO_2 clinical studies in the last review (much less establish one through a trial-type adjudicatory process) as in Atchison, Topeka & Santa Fe Ry. Co.

To the contrary, section 109 mandates a periodic review based on an updated review of the science. Prior NAAQS determinations, based on the then current science, do not have status as adjudicative precedent, "settled rule", or settled interpretation. The required review of the air quality criteria is to ensure that NAAQS decision are based on "the latest scientific knowledge" regarding effects of the pollutant in question, and this on-going dynamic process extends to interpretations of scientific evidence.

Nor does the statement from State Farm that agencies changing an existing rule are "obligated to supply a reasoned analysis beyond that which may be required when an agency does not act in the first instance" (463 U.S. at 42) support the proposition that there is some special burden over and beyond the requirements of section 109 (b) and (d) necessary to justify a change. The action reviewed in that case was a rescission of an existing rule adopted pursuant to a statutory scheme which required that standards be practicable. That is unlike the statutory scheme of the NAAQS, which not only requires periodic review, but requires that those

reviews be based on air quality criteria reflecting "the latest scientific knowledge" regarding the effects of the pollutant in question.

(4) ***Comment:*** API commented that although the Proposed Rule acknowledges that the SO_2 REA estimated "short-term exposures and potential human health risks" associated with recent ambient SO_2 levels, 74 Fed. Reg. at 64,821, the Administrator completely ignores those estimates in considering whether a new 1-hour NAAQS is necessary for public health protection. Those analyses, however, are very relevant for addressing the risks in a real world context. See Whitman, 531 U.S. at 494-95 (Breyer, J., concurring in part and concurring judgment). They indicate that exposures and risks associated with just attaining the 1-hour NAAQS that the Administrator has proposed (and therefore apparently deems "tolerable") 22 are comparable to those associated with recent air quality.

Response: The issue here is whether, in determining for purposes of section 109 (d) (1) whether it is appropriate to revise the current primary NAAQS for SO_2, EPA should consider the air quality allowed by that current standard or existing air quality. First, it is apparent that the provision requires review of the current standard, not current air quality. Second, EPA is to consider the test in section 109 (b) (1) in determining if it is "appropriate" for EPA to revise the standard (see section 109 (d)(1)). Section 109 (b) (1) requires that a primary NAAQS – not air quality at the time of a NAAQS – be requisite to protect the public health with an adequate margin of safety. Again, it is the standard itself which is at issue. Third, section 109 (d) (1) requires EPA to consider any revised air quality criteria in determining if it is appropriate to revise the NAAQS. Those criteria require consideration of "the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health … which may be expected from the presence of such pollutant in the ambient air, in varying quantities" and thus certainly authorize consideration of the effects the pollutant has at quantities allowed by the current standard. Consequently, EPA is at the least allowed to consider conditions allowed by the current standard in determining if it is appropriate to revise it.

The commenters cite part of Justice Breyer's concurring opinion in American Trucking Assn's, but that opinion is not applicable here. It does not discuss the question of whether EPA may consider actual or allowable air quality in deciding whether or not to revise a primary NAAQS.

(5) ***Comment:*** NPRA, which supports comments submitted by API, said that the CAA neither requires nor supports the proposed 1-hour SO_2 NAAQS because the proposed standard is four times lower than the lowest tested concentration in human exposure clinical trials and is eight times lower than the level at which statistically significant human exposure results occur. Without further substantial evidence from clinical human exposure trials, the proposed and alternative SO_2 NAAQS are "arbitrary and capricious."

Response: This comment ignores the difference in averaging times, so that the commenter's comparison is apples to oranges. Moreover, it is entirely permissible for EPA to base determinations as to a standard's level on epidemiologic studies, and indeed is required to consider such studies in developing standards since they "reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health … which may be expected from the presence of [SO_2} in the ambient air", i.e. part of the air quality criteria. CAA section 108 (a) (2).

(6) ***Comment:*** LEC, API, and RREIE commented that the definition of ambient air quality is interpreted too broadly to include areas that are hypothetically but not practically (or legally or safely) accessible to the public and that dispersion modeling is often applied to these areas. (LEC, API, RRI, RRI)

Response: EPA is now contemplating a hybrid approach to implementation which includes increased utilization of dispersion modeling. See sections III-VI of the preamble to the final rule.

(7) ***Comment:*** PE, supporting the comments of UARG and EEI, commented that EPA review and utilization of the information in the ISA and the REA do not meet the requirements of the CAA. EPA's promulgation of a final standard within the proposed range would be more stringent than necessary.

Response: EPA disagrees. The primary standard adopted in this rule is requisite to protect public health with an adequate margin of safety for the reasons given in section II.F of the preamble to the final rule.

IX. Comments on Implementation, Designations, and Exceptional Events

(1) ***Comment:*** Missouri believes that the Reasonable Future Progress requirement under CAA Section 171 should not be interpreted to mean a generally linear progression towards attainment. Missouri's previous analyses showed that many of the SO_2 sources are coal combustion and other large single-point emitters, and EPA acknowledges that these types of sources will likely be responsible for most of the impact in non-attainment areas. Step-down functions are not possible with these types of sources, Missouri claims. Missouri suggested EPA consider an all-in-one approach that would allow for a single control process (e.g., scrubber) on a large source to bring an area into attainment and meet the requirements of Reasonable Future Progress, reasonable available control technology, reasonable available control measures, and contingency measures for this type of non-attainment area. Such an approach would only be allowed with EPA Regional Office approval upon verification that it meets statutory requirements.

Response: This final rule is not taking final action regarding any implementation issues that may become the subject of future SIP rulemaking actions. Missouri's

comments would be more appropriately raised in the context of a specific SIP action, and are beyond the scope of today's final rule. Therefore, EPA is not taking a position here regarding whether it agrees with the approach stated by the commenter above.

(2) ***Comment:*** A commenter stated that the annual SO_2 standard should not be revoked until EPA approves SIPs in attainment areas under the future SO_2 secondary standard, which may also be based on an annual averaging time.

Response: EPA disagrees with the comment. This rulemaking concerns only the primary standards for SO_2. 74 Fed. Reg. at 64812 n. 2. The annual SO_2 standard is a primary standard, not a secondary standard. See 40 CFR section 50.4 (a). The exclusive secondary standard for SO_2 is the 3-hour standard codified in 40 CFR section 50.5. EPA is not determining the adequacy of this secondary standard in this review or this rulemaking, as just noted. The commenter's request to retain the annual primary standard until SIPs reflecting a new secondary standard are approved is effectively a request to amend the present secondary standard, and is therefore inappropriate given the scope of this review. In any case, in the event that any substantive responsive to this comment is required, air quality information indicates that a 1-hour standard of 75 ppb is estimated to generally keep annual SO_2 concentrations well below the level of the current annual standard. 74 FR at 64845. Thus, there would be no loss of protection to public welfare due to revocation of the annual primary standard.

A. Comments on designations of non-attainment

General comments on designations of non-attainment

(1) ***Comment:*** NESCAUM, NACAA, and ALA/EDF/NRDC/SC support EPA's proposal to keep non-attainment designations and subsequent requirements under the current SO_2 NAAQS in effect until the non-attainment area submits, and EPA approves, a SIP for the new SO_2 NAAQS. The commenters believe this is needed to maintain the needed public health protection and regulatory coverage until a new and workable SO_2 reduction plan is in place. ALA/EDF/NRDC/SC suggested keeping the current standards in place for at least a year during the transition to the new standards in order to comply with CAA provisions and to avoid arbitrarily and unjustifiably relaxing the health protections. (NESCAUM

Response: EPA appreciates the support of the commenters on the transition strategy for SO2.

(2) ***Comment:*** Pennsylvania commented that EPA must provide timely implementation rules and guidance for issues such as SILs, emergency action levels, and the updated AQI in order to adequately protect public health and the environment.

Response: See preamble section V.D.2. related to NSR and PSD requirements and section VII related to the AQI which addresses this comment.

(3) ***Comment:*** Sulfuric Acid Producers commented that EPA should examine if the proper regulatory infrastructure at the state and local levels is ready to address an increase in SO_2 non-attainment. EPA should also provide guidance for LAER and RACT for SO_2. EPA should also address if these programs will have a material effect on reducing the negative health impacts that are claimed in the REA.

Response: As stated in the implementation section of the preamble to the final NAAQS review notice, EPA believes that generally there are appropriate guidance and regulations currently in place to address the revised SO_2 NAAQS. However, EPA agrees that providing additional guidance on modeling for the new 1-hour standard is needed, and will be providing that guidance in time to help states and sources implement the new NAAQS. EPA also believes that the anticipated approach discussed in the preamble for designating areas for SO_2 also would provide states with sufficient time to address any control plans necessary to address areas that may be violating the revised NAAQS and to provide public health protection by helping areas that are violating the NAAQS attain the standard as expeditiously as practicable.

(4) ***Comment:*** Though EPA does not specifically indicate an approach for setting non-attainment area boundaries for the new SO_2 NAAQS, MIDNRE is concerned that EPA is considering using CBSAs, since EPA repeatedly mentions using CBSAs in determining PWEI and since EPA has often designated large, multi-county areas as non-attainment for other pollutants. MIDNRE believes CBSAs may be too large for SO_2 designations, since EPA is treating SO_2 as source-specific and heterogeneous in a given area. MIDNRE strongly recommends flexibility in setting non-attainment area boundaries, many of which should be smaller than CBSAs and maybe even smaller than counties.

Response: As stated in the designations section of the final SO_2 NAAQS preamble, the EPA intends to initially consider the county line as the presumptive nonattainment boundary for SO_2 unless the State provides justification in its recommendation as to why a different boundary would be more appropriate. Today's final rule does not bind states or EPA to treating the county line as the nonattainment boundary, but only explains the starting point for area-specific analyses. This approach would provide States with a clear starting point yet would allow the flexibility to show that a smaller or larger boundary is more appropriate. It is also consistent with the approach that EPA has taken for other NAAQS.

(5) ***Comment:*** ALA/EDF/NRDC/SC commented that EPA has historically and incorrectly made designations only when new standards are adopted. The new monitoring network is likely to identify many areas with high SO_2 levels. As

such, in the final rule, ALA/EDF/NRDC/SC urged EPA to include a timetable for the post-2012 evaluation of the attainment status of all monitored counties.

Response: The commenters essentially claim that SO_2 areas initially designated as "unclassifiable" and which subsequently violate the revised SO_2 NAAQS need to be redesignated to "nonattainment" to ensure that such areas take action to bring them into attainment. Section 107(d)(3) of the CAA provides EPA with discretion to redesignate areas at any time following initial designations. As discussed in the preamble to the final rule, we believe our expected approach to implementation of the new 1-hour SO_2 NAAQS would fully address the commenters' concern. Under CAA section 110(a)(1) all areas designated as "unclassifiable" would need to submit a SIP revision that demonstrates attainment with both monitoring and modeling data, as well as include measures to attain the SO_2 revised NAAQS if necessary. Under the CAA, that SIP revision will be due three years after promulgation of the NAAQS or, June 2013. By utilizing section 110(a)(1) of the CAA, the EPA's expected approach would result in States with unclassifiable areas implementing the revised SO_2 NAAQS sooner than if EPA were to rely exclusively upon redesignation under section 107(d)(3) to trigger a SIP demonstrating attainment. In any event, if States are unable to submit SIPs showing attainment by 2013, EPA has the authority to redesignate the area as "nonattainment," in addition to disapproving the SIP and promulgating a FIP.

We anticipate that under the expected approach discussed in the final rule, the delay in implementation reflected in the commenters' concerns should not occur, and that many areas in the country would be able to demonstrate attainment in their section 110(a)(1) SIPs--the effect of which would be more areas attaining the revised NAAQS as expeditiously as practicable.

B. Comments on date

(1) ***Comment:*** UARG is concerned that the following proposal is an error, with regards to how 2011 data is to be included for SO_2 designations: "2011 data must be flagged and detailed event documentation submitted 60 days after the end of a calendar quarter in which the event occurred or by March 31, 2011." According to UARG, this March, 2011 deadline seems odd for a number of reasons: (a) it seems arbitrary, and (b) it would not allow for consideration of a full calendar year of 2011 data (74 FR 64873/1 defines a year as a calendar year, so considering any 2011 data requires that all 2011 data be considered). UARG recommended the deadline for detailed 2011 documentation submittal be March 31, 2012, or as an alternative, 60 days after the end of each calendar quarter; the deadline should be March 31, 2013, if necessary to qualify FRMs and FEMs under new specifications.

Response: The commenter notes that the incorrect March 31, 2011 date as shown in the proposal for flagging and documenting 2011 data should be corrected to March 31, 2012, and will be corrected in the Final Rule Preamble, Regulatory

Text and Tables. Noting this date correction, the Agency stated in the proposal, "If a state intends 2011 data to be considered in SO2 designations, 2011 data must be flagged and detailed event documentation submitted 60 days after the end of the calendar quarter in which the event occurred or by March 31, 2012, whichever date occurs first. Again, EPA believes these deadlines will be feasible because experience suggest that exceptional events affecting SO2 data are few in number and easily assessed, so no state is likely to have a large workload." A deadline of March 31, 2012 is the midpoint of the first 6 months of 2012, and provides equally 3 months for states and 3 months for EPA to process exceptional events claims associated with the last quarter of calendar year 2011. The Agency continues to believe that three months is adequate time for a state to review and document any SO2-related exceptional event that may occur in the last three months of 2011. Since the initial area designations must be finalized by EPA by July 2012, the Agency does not believe it is reasonable to establish a deadline later than March 31, 2012. EPA needs sufficient time to review any state-submitted documentation during April through June of 2012 and make final decisions regarding exceptional events claims from 2011 prior to finalizing the designations in July 2012.

(2) ***Comment:*** ALA/EDF/NRDC/SC commented that this proposal suggests that SO_2 Part D SIPs be due 18 months from the effective date of an area's non-attainment designation, and that the attainment date will be determined from the non-attainment effective date. CAA Section 191 requires submission of the Part D SIP within 18 months "of the designation," and Section 192 requires attainment as quickly as possible but no later than 5 years from the non-attainment designation date. ALA/EDF/NRDC/SC stated that in neither of these cases does the statue allow measurement of the relevant time from the effective date of designation. Section 107 requires promulgation of designations within specified timeframes, and it does not provide for delayed effective dates.

Response: The statute uses different language to establish deadlines for issuing designations under section 107 and submitting SIPs under section 192. Under section 107(d)(1)(A), states must submit designations recommendations no later than 1 year "after promulgation of a new or revised" NAAQS, and under section 107(d)(1)(B)(i) EPA must promulgate designations no later than 2 years "from the date of promulgation of the new or revised" NAAQS. The courts have interpreted "promulgation" as meaning the date of signature of a final rule and its broad dissemination, so the time period under which states are to recommend designation and EPA is to issue designations does not need to await the effective date of the rule, which is later than its promulgation. In contrast, under sections 191 and 192, the dates for starting the requirements for nonattainment area SIP submittal and attainment are the dates "of the designation" and "of the nonattainment designation," respectively. These provisions do not refer to the date of "promulgation," as under section 107, but rather to the action taken, which EPA believes is reasonable to interpret as meaning the date that the state or area

actually becomes a nonattainment area (i.e., the effective date of EPA's designation action).

C. Comments on data to be used

(1) ***Comment:*** NPRA, supporting API comments, noted that EPA is proposing to conclusively designate an area with a violating monitor as being in non-attainment, while exercising undefined discretion when the opposite occurs. NPRA thinks it is unjustified to treat data differently when the information is valid and comes from the same type of monitors that are sited according to existing EPA regulations and guidance.

Response: First, in this rulemaking, EPA is not taking conclusive action on any area's designation, nor did EPA propose to take such conclusive action. Second, as we explain in sections III, IV, V and VI of the final rule preamble, for SO_2 EPA has long taken the position that the use of monitoring alone cannot always be relied upon to identify sources that cause or contribute to NAAQS violations.

Sulfur dioxide is emitted from sources which vary in size and stack height, causing a "patchwork" of violations--not all of which can be measured by a single, or even several, monitors. Therefore, in order to get a true picture of ambient air conditions in an area, EPA has traditionally depended upon both monitoring and modeling data, as appropriate, to accurately confirm that an area is in compliance with the NAAQS. This approach to SO_2 designations is consistent with that taken in previous actions, including those referred to in the final rule preamble. In addition, the CAA itself does not prescribe the type of data by which EPA's designation decisions may be informed, or what relative weight to give different types of data when they lead to different conclusions. For example, CAA section 107(d)(3)(A) refers to "air quality data, planning and control considerations, or any other air quality-related considerations the Administrator deems appropriate" as forming the basis for a redesignation decision. This certainly will allow EPA to take reasonable action in response to situations where, for example, modeling data indicate an area is not attaining the standard, while monitoring data might not reveal a violation.

(2) ***Comment:*** In order to obviate the need for states to install monitors at great cost where concentrations of SO_2 are a small fraction of the NAAQS, and to ensure that areas lacking robust monitoring data can be designated as non-attainment, NESCAUM and VTPAC recommended that EPA allow modeling be used in conjunction with monitoring data to better determine non-attainment areas.

Response: See sections III and IV of the preamble for the discussion on EPA's anticipated approach to the use of monitoring and modeling for the revised SO_2 standard.

(3) ***Comment:*** In modeling compliance with a statistically-based standard, API recommended that EPA consider applying realistic emissions profiles that are based on the expected frequency distribution of emissions.

Response: EPA currently plans to develop further guidance regarding modeling demonstrations of compliance with the NAAQS. EPA is taking API's recommendation under advisement, but today's final rule is not taking final action in response to API's request.

(4) ***Comment:*** RRI and API recommend that EPA develop refined modeling tools and guidance that will not penalize sources by being overly conservative, especially when considering combined impacts of the primary sources and background sources. It would be burdensome to states if highly conservative modeling results created false new non-attainment designations.

Response: EPA understands the importance of appropriately characterizing contributions from background sources, whether through representative monitoring data or through explicit modeling of background source emissions, as part of dispersion modeling analyses for compliance demonstrations recognizing the new form of the NAAQS. EPA expects to provide guidance on procedures for determining background concentrations, combining monitored background concentrations and modeled impacts to estimate the total air quality concentration to support the implementation phase of the NAAQS.

(5) ***Comment:*** By the 2012 deadline for determining attainment/non-attainment for the new SO_2 NAAQS, PCA is concerned that less than three years of short-term data will be available from the existing monitoring network, and even less data will be available from the proposed new monitoring network. PCA stated that it seems premature to determine attainment/non-attainment based on the existing monitoring network (which EPA admits is not representative of areas of maximum impact) and to then require states to prepare and submit SIPs to address non-attainment designations. It seems imprudent to go through this burdensome process while knowing that different, deeper, and more widespread emissions cuts will be needed to address non-attainment identified by the proposed new monitoring network.

Response: As we explain in sections III, IV, V and VI of the preamble to the final rule, we expect to follow an approach that would designate most areas in the country as "unclassifiable" in June 2012, pending receipt of additional data from SO_2 monitors and modeling conducted following our development of further modeling guidance under the 1-hour SO_2 standard. Areas that present both modeling and monitoring data that support a designation of "attainment" by June 2012 and that EPA finds demonstrate attainment would be designated as such. Areas for which monitoring or refined modeling data show sources cause or contribute to NAAQS violations would be designated as "nonattainment." We believe following such an approach would avoid the problem identified by the

commenter, as it would be far less dependent upon receipt of monitoring data under the new network.

(6) ***Comment:*** UARG commented that non-attainment decisions should be based on monitors that qualify as federal reference monitors under EPA's new specifications.

Response: EPA is not taking final action on any designation in this rulemaking. We expect, based on our discussed anticipated approach, to initially designate most areas in the country as "unclassifiable" in June 2012, pending receipt of additional data. Under section 110(a)(1) SIPs we expect states to rely upon appropriate modeling and monitoring data to support demonstrations of attainment and maintenance of the revised SO_2 NAAQS--demonstrations that will be assisted greatly by new rules that will reduce SO_2 levels nationwide.

(7) ***Comment:*** UARG, CE (supporting comments by UARG and EE), and NRECA commented that EPA has two options for making initial attainment/non-attainment designations with regard to whatever 1-hour NAAQS it adopts. These commenters believe that first, EPA could designate all areas as unclassifiable until adequate data have been collected with the new FRM. Second, if EPA believes that many existing monitors might qualify as new FRMs or FEMs, EPA could extend the deadline for attainment/non-attainment designations by a year. These commenters argued that EPA recently used CAA § 107(d)(1)(B) to defer designations for the 2008 ozone NAAQS by a year while it reconsiders that rule (75 FR 2936, Jan. 19, 2010), and UARG, CE, and NRECA believe it would be just as appropriate to use CAA § 107(d)(1)(B) to extend the SO_2 designation owing to an absence of FRM or FEM data. EPA could use that year to determine which monitors would qualify under the new FRM and FEM definitions. For those monitors that qualify, EPA could then appropriately rely on existing data to make designations.

Response: As the commenters suggest, under the anticipated approach discussed in sections III, IV, V and VI of the preamble the EPA expects to designate most areas as "unclassifiable" pending receipt of additional air quality data and refined SO_2 modeling from the states confirming their status as either meeting or not meeting the new SO_2 NAAQS. The commenters are correct that under section 107(d)(1)(B)(i), the CAA provides the EPA an additional third year to complete initial designations in the event that there is insufficient data on which to base designations. EPA considered this option, but expects that it would not be necessary to resolve the timing problem the commenters raised. Instead, we believe that an approach like that discussed in the preamble would allow States to develop the necessary data to support section 110(a)(1) SIP demonstrations of attainment and maintenance of the new 1-hour SO_2 NAAQS that rely upon expected SO_2 reductions to be achieved by the attainment date.

Furthermore, by designating most areas as "unclassifiable" pending receipt of additional data under the new SO_2 monitoring rules and refined modeling, we would be enabling states to account for new national and regional rules that we anticipate will have significant SO_2 benefits.

Regarding monitoring methods, as discussed in section IV.A of the preamble to the final rule, there may be more than one FRM and associated FEMs that may provide data for comparison to the NAAQS. As a result, the current FEMs in use in the SO2 network are appropriate for continued use to provide SO2 concentrations for comparison to the NAAQS.

(8) ***Comment:*** ACC recommended that EPA make attainment/non-attainment designations in 2012 based on current monitoring data, not as unclassified in certain cases as proposed.

Response: For most areas, EPA does not expect to receive either monitoring or refined modeling data in order to issue attainment or nonattainment designations by 2012. In such situations where areas cannot be classified on the basis of available information as meeting or not meeting the NAAQS, CAA section 107(d)(1)(A)(iii) requires that EPA issue an "unclassifiable" designation. We expect initial designations in June 2012 would be based on monitoring data plus refined modeling data that States choose to include to demonstrate that an area is or is not meeting the new SO2 NAAQS. Absent definitive data from necessary monitoring and refined modeling, the EPA expects to designate most areas as "unclassifiable." This approach would still allow States to request an initial designation of "attainment," provided that in their recommendations to EPA due June 2011, they included necessary clean monitoring data, as well as refined modeling data to support a designation of "attainment."

(9) ***Comment:*** MSCC commented that if one three-year period at one monitor is good enough for non-attainment designation, it should also be good enough for attainment designation, rebuttable by further failure in the future.

Response: This comment essentially makes the same claim as NPRA's comment below. As we explained above, due to the unique characteristics of SO_2, EPA has not traditionally relied exclusively upon monitoring to support designations and attainment determinations for the SO_2 NAAQS. While this final rulemaking is not taking final action on any specific area's designation, and while all future designation actions under the new 1-hour SO_2 NAAQS will be based on their own facts, as we explained in sections III, IV, V and VI of the preamble, we anticipate using a hybrid approach in issuing designations that would continue to rely upon appropriate modeling and monitoring data to ensure that our conclusions regarding specific areas are accurate.

Furthermore, by designating most areas as "unclassifiable" pending receipt of additional data under the new SO_2 monitoring rules and refined modeling, we

would be enabling States to account for new and regional national rules that we anticipate will have significant SO_2 benefits.

(10) ***Comment:*** NPRA, which supports comments by API, said that EPA's proposal to discriminate against monitors demonstrating attainment is contrary to the CAA and cannot be finalized. NPRA states that the CAA requires EPA to utilize the monitoring information that is available within the statutory period for designations, and that, following the promulgation of a new or revised NAAQS, the governor of each state must submit to EPA a list of all areas of attainment, non-attainment, and unclassifiable in the state, and EPA can modify the submission so long as the state is notified and has an opportunity to demonstrate that the modification is inappropriate.

Response: First, in this final rulemaking promulgating the new 1-hour SO_2 NAAQS and associated monitoring requirements, EPA is not taking final action on any approach toward issuing designations. EPA will issue future designations under CAA section 107 based on the information that is before the agency at that time. We therefore disagree with the commenter's assertion that the proposed NAAQS represented a "proposal to discriminate against monitors demonstrating attainment," as the NAAQS proposal did not in itself propose to either accept or reject any such monitoring data for any specific area. While we explain in today's notice that we expect to follow EPA's longstanding approach of relying upon both monitoring and modeling to inform future designations actions, only in such future actions will the agency's approach to this issue become final.

Second, we note that the Clean Air Act does not specify the kind of data upon which a future designation action must be based. Regarding initial designations, section 107(d)(1) makes no reference to the type of information that may inform a designation. Rather, section 107(d)(1) repeatedly states that EPA may issue a designation that the agency "deems appropriate," indicating that EPA has substantial discretion in issuing designations. *See*, *e.g.*, *NACAA v. EPA*, 489 F.3d 1221, 1229 (D.C. Cir. 2007) (characterizing EPA's authority to promulgate aircraft engine emission standards under CAA section 231(a)(3) "*as [it] deems appropriate*" as "both explicit and extraordinarily broad" and as leaving "a gap for the agency to fill" (emphasis in original)). In fact, in its only reference to the type of data that may inform initial designations, section 107(d)(1)(A)(iii) uses the phrase "on the basis of available information," without restriction. Moreover, CAA section 107(d)(3)(A) provides that EPA may issue re-designations "on the basis of air quality data, planning and control considerations, or any other air quality -related considerations the Administrator deems appropriate," without narrowing the type of information EPA may consider or specifying in what way EPA must treat any information. Thus, we do not agree that the Act supports the commenter's objection.

(11) ***Comment:*** ASC requested a detailed analysis of how predictive air dispersion modeling results will be used for attainment/non-attainment designations under the new proposed NAAQS. For example, "how will modeling be used to

determine impacts to at-risk people? The proposed rule needs to include a discussion of the accuracy and precision of the predicted modeling results compared to actual ambient monitored concentrations."

Response: AERMOD, EPA's preferred model for NSR/PSD permitting under Appendix W, 40 CFR Part 51, has been extensively evaluated based on 17 field study databases, several of which included hourly SO_2 monitored concentrations from operating facilities. Although AERMOD results were not meant to be compared against monitors on a "paired in time and space" basis, past AERMOD simulations, including those used for SO_2 Risk and Exposure Assessment, have shown good agreement with monitoring data. EPA feels that with proper emissions data, source characterization, and meteorological data, AERMOD results will generally compare well against ambient measurements.

(12) ***Comment:*** One commenter stated that the proposed NAAQS presents a host of complications related to nonattainment area attainment demonstrations that will need to be fully addressed in the "Guideline on Air Quality Modeling" (Appendix W, 40 CFR part 51) before implementation.

Response: EPA expects to provide technical guidance on modeling and analyses as part of SIP demonstrations. We expect that the models currently required for NSR/PSD permitting under our *Guideline on Air Quality Modeling* (40 CFR Part 51, Appendix W) will be suitable for demonstrating compliance with the revised SO_2 NAAQS.

(13) ***Comment:*** The commenter states that the proposed rule states that AERMOD, CALPUFF, and all other guideline models, such as Offshore and Coastal Dispersion Model (OCD) will need to be modified to provide for the 99th percentile (4th highest), or possibly the 98th percentile (8th highest) daily 1-hour concentration per year at each model receptor.

Response: At this time, EPA plans to issue further guidance on use of the AERMOD dispersion model to accommodate the new 1-hour standard. EPA is also developing a generic AERMOD post-processor to aid in calculating the design values for criteria pollutants for new and proposed NAAQS, including SO_2. As with the recently published NO2 NAAQS, EPA will publish a notice on the SCRAM website regarding modeling for the new 1-hour SO2 NAAQS.

(14) ***Comment:*** The commenter further states that the proposed SO_2 standard will present much greater compliance hurdles in comparison to the present standard. The commenter states that the manner that background concentrations are incorporated into the modeling results will be critical for realistic and not overly conservative compliance demonstrations. (RRI Energy)

Response: EPA understands the importance of background concentrations and combining them with modeling results for compliance demonstrations

recognizing the new form of the NAAQS. EPA expects to provide guidance on procedures for determining background concentrations, and combining background concentrations and modeled impacts to estimate the total air quality concentration to support the implementation phase of the NAAQS.

(15) ***Comment:*** One commenter states that the existing EPA models which are used for the implementation of the permitting program are not reliable for a short term 1-hr standard for SO_2. The commenter further states that the current models are not capable of predicting 1-hr SO_2 impacts. (South Dakota)

Response: EPA's regulatory model for NSR/PSD permitting under Appendix W, 40 CFR Part 51 has been extensively evaluated based on 17 field study databases, several of which included hourly SO_2 monitored concentrations from operating facilities. Since all applications of the model are based on hourly predictions, there is no information to support the commenter's claims and no basis to expect that model performance of AERMOD will not be appropriate for this 1-hour standard.

D. Future permitting

(1) ***Comment:*** CIBO commented on the nexus between the proposed rule and the NSR and PSD permitting programs. "A new SO_2 1-hour standard of 50-100 ppb would make it nearly impossible for industries to obtain permits for any changes that involve increased use of sulfur-bearing fuels or raw materials. Industries require workable permitting systems in order to expand, modernize equipment, and meet future energy demands." CIBO is disappointed that the regulatory impact analysis does not realistically assess this economic impact on the nation's manufacturing base and jobs, and believes non-EGU point sources will bear the brunt of the proposed rule. "Overall, the new hourly SO_2 standard will be impractical when applied to the major New Source Review program.

Response: The commenter states that a new 1-hour SO_2 standard of 50-100 ppb would make it nearly impossible for industries to obtain permits for increased use of sulfur bearing fuels and therefore non-EGUs will bear the brunt of the revised standard. The commenter did not provide any specific examples or analysis to support these claims. Furthermore, EPA does not construe the CAA to allow the Agency to take such implementation considerations into account when establishing NAAQS to protect public health with an adequate margin of safety. The CAA and EPA's implementing rules generally require compliance with or minimal impact on the NAAQS as a condition of PSD permitting. For nonattainment NSR permitting the CAA provides that, as a prerequisite to being permitted to construct and operate a new or modified stationary source, increased emissions from such source be offset by reductions in existing emissions so as to ensure reasonable progress toward attainment of the NAAQS.

(2) ***Comment:*** ASARCO, supporting comments by API, UARG, and NMA, commented that three years of on-site meteorological data would be required to demonstrate compliance with the three-year average NAAQS, which, in their opinion, is unreasonable for typical industrial projects that are time sensitive.

Response: The definition of the form of the 1-hour SO_2 NAAQS, based on a three-year average, is in relation to ambient monitoring data, and has no implication with regard to the length of meteorological data period required for dispersion modeling. The recommendations in Section 8.3.1.2 of EPA's Guideline on Air Quality Models (40 CFR Part 51, Appendix W) regarding the length of meteorological data record for dispersion modeling would apply for the new 1-hour SO_2 NAAQS. That provision states that "[t]he use of 5 years of NWS meteorological data or at least l year of site specific data is required."

(3) ***Comment:*** ASARCO, supporting comments by API, UARG, and NMA, commented that in order to implement the PSD program, EPA should adopt SILs such that facilities can determine if a project is "significant" from an air quality perspective. "The development of SILs and other appropriate thresholds has often lagged far behind the implementation of the new NAAQS, resulting in significant implementation difficulties in obtaining PSD permits."

Response: EPA agrees that the SIL is an useful screening tool for implementing the PSD requirements for SO_2 and all other regulated NSR pollutants. EPA plans to undertake rulemaking to establish a 1-hour SO2 SIL as a screening tool to facilitate implementing the 1-hour SO_2 NAAQS in the PSD permitting program. In addition, we are considering providing guidance which could include an interim SIL value for SO_2 that could be used by state permitting authorities while the final rule for a SIL is being completed, provided that the states establish an appropriate record for individual permitting actions based on the supporting technical information provided by EPA showing that a particular screening value reflects a de minimis impact level.

(4) ***Comment:*** ASARCO, supporting comments by API, UARG, and NMA, commented that if the 1-hour NAAQS is less than the 3-hour or 24-hour NAAQS, these increment values will potentially exceed the 1-hour NAAQS. This contradicts CAA Section 163(b)(2) as it relates to PSD increments – that section lists allowable increases in SO_2 concentrations above the baseline concentration.

Response: EPA acknowledges that, because of the stringency of the new one-hour SO_2 NAAQS, the 3-hour and 24-hour SO_2 increments allow greater increases in ambient concentrations of SO_2 than does the new 1-hour SO_2 NAAQS level. The CAA clearly provides that the amount of deterioration allowed by any increment cannot cause the NAAQS to be exceeded. Therefore, the new 1-hour SO_2 NAAQS would govern the amount of air quality deterioration that would be allowed in an area over the 3-hour and 24-hour averaging periods.

It should also be pointed out that because the existing 3-hour and 24-hour increments for SO_2 are defined by the CAA at section 163(b), EPA cannot alter those increments without prior congressional action authorizing EPA to make any necessary changes. EPA does not interpret section 163(b) as establishing a right to degrade air quality to the level of the increments that would preclude EPA from establishing the 1-hour SO2 NAAQS level established in this action. See, *National Corn Growers Ass'n v. EPA*, 291 F.3d 1, 12 (D.C. Cir. 2002).

(5) ***Comment:*** CRA commented that a stringent short-term SO_2 standard greatly increases the difficulty of modeling to demonstrate compliance, since the standard that these plants are held to may not necessarily reflect the annual or daily average emission rates of affected facilities.) CRA said that the current SO_2 increment standards are appropriate for dispersion modeling requirements under the new source review program, and that it would be unnecessary to promulgate a 1-hour PSD increment for SO_2.

Response: Section 166(a) of the CAA authorizes EPA to promulgate "regulations for the prevention of significant deterioration" for pollutants for which NAAQS are promulgated after 1977. Thus, we believe that it would be appropriate to consider the need for a short-term increment for SO_2 consistent with the 1-hour averaging period for the new SO_2 NAAQS. Historically, EPA has developed increments for each applicable averaging period for which a NAAQS has been promulgated. However, the court determined in earlier NO_2 increment litigation that increments for a particular pollutant do not necessarily need to match the averaging periods that have been established for NAAQS for the same pollutant. Environmental Defense Fund, Inc. v. EPA, 898 F.2d 183, 189-190 (D.C. Cir. 1990)("… the 'goals and purposes' of the PSD program, set forth in § 160, are not identical to the criteria on which the ambient standards are based.") We intend to evaluate the need for a 1-hour SO_2 increment in a subsequent rulemaking.

(6) ***Comment:*** DRSI, supporting the comments by UARG, commented that if EPA intends to specify new PSDs, SILs, SERs, and SMC requirements specific to a new 1-hour standard, then it should conduct a separate notice-and-comment rulemaking to allow adequate opportunity for public review and input.

Response: EPA does intend to use a separate rulemaking to propose screening tools for the new 1-hour SO_2 NAAQS that would be established in regulations. As described in our response to an earlier comment, we are also considering the development of guidance that suggests an interim SIL for SO_2 that state permitting authorities may use implement the new 1-hour SO_2 NAAQS if they establish an appropriate record. We recognize the importance of public participation in the ultimate development of any SIL that is used in permitting. An interim SIL reflected in any EPA guidance should be subject to public comment whenever it is applied by a permitting authority in permitting action. The public would also have an opportunity to comment on any permanent SIL EPA proposed to establish by rulemaking.

(7) ***Comment:*** Alexandria commented that it is false to say that the SIP and NSR programs are effective means of addressing the public health impacts of existing large stationary sources that violate the NAAQS. First, many of the "oldest, dirtiest pollution sources" are essentially perpetually grandfathered from the requirement to operate with the controls required to ensure compliance with the NAAQS (while new sources must adhere to strict procedures and controls). Second, recent changes in the federal NSR program have allowed large stationary sources significant flexibility in determining what time periods constitute their baseline. The result of the above two points is that the reliance on the SIP-based monitoring method of NAAQS implementation practically guarantees that many thousands to millions of people throughout the country will continue for many years to suffer the health effects of frequent and chronic exposures in excess of the short-term NAAQS. This may follow many years, possibly decades of exposure from the emissions of proximate single sources at levels exceeding those corresponding to adverse health effects. Third, when emissions from existing major sources are shown by themselves to violate health standards, vast resources must be committed. For example, the NSR program (both major and minor, and its requisite ambient air quality standards compliance demonstration) is triggered only when a physical modification at a source leads to annual emission increases. However, many large electricity-generating units and other stationary sources use physical modifications to modify their operating conditions, often to improve financial performance. These physical modifications can increase plant output, though annual emissions decrease or do not change from historical baseline.

Response: EPA generally agrees with the comment that the NSR program applies to existing sources when they modify the existing source (e.g, modify existing units or add additional units) and that the NSR program does not specifically address existing violations of the NAAQS by un-modified existing sources. However, another provision of the CAA, section 110(a)(1) and (a)(2)(A) requires that the state implementation plans demonstrate compliance (including schedules and timetables) with the NAAQS for existing sources. Such provisions are not limited to the regulation of only new sources or sources that propose to modify their existing facilities. In addition, areas that are found to be in violation of the NAAQS may be required to control those sources that are determined to be contributing to violations of the NAAQS through designation of the area as nonattainment, or through the implementation of a SIP call for the affected area. In these cases, states are required to adopt appropriate controls, or emissions limits, on the affected sources in order to bring about attainment in the area.

(8) ***Comment:*** Alexandria commented that EPA should not rely solely on any number of locally-cited monitors. This is because (a) the SIP process, and its categorical source control measures, is designed for assuring that regional pollutant levels comply with NAAQS, and (b) monitoring methods cannot fully and comprehensively identify all areas of non-compliance caused by a single source's maximum potential emissions for all possible local meteorological

conditions. A SIP remedy to a NAAQS contravention by a single source may take at least eight years, given the following timeline for an area for which conditions indicate a potential violation of the new NAAQS by a particular source: (1) regulators might assign a monitor(s) to the area, (2) public money would need to be expended for an air quality monitoring analysis, ensuring that those monitors be correctly located at the discrete points where emissions and meteorology together produce impacts exceeding the NAAQS, (3) after three years of modeling, a non-attainment area is defined, and (4) after another year, control measures commensurate with the NAAQS would be stipulated through the SIP (Alexandria) Instead, Alexandria requests that EPA propose and implement a streamlined procedure by which local air quality agencies can petition a single major source to demonstrate NAAQS compliance using standardized modeling techniques prescribed by the "Guideline." These results would then be used to determine an emissions control regime for a source that is NAAQS compliant. Alexandria stated that EPA has invested significant resources in developing standard modeling tools, preprocessors, and guidelines, such that an existing major source should now readily be able to calculate how their maximum potential emissions affect nearby ambient pollutant levels.

Response: In sections III, IV V and VI of the preamble to the final rule, we discuss our anticipated approach to implementing the new 1-hour NAAQS. We expect that many, if not all of Alexandria's concerns, would be satisfactorily addressed by such an approach.

(9) ***Comment:*** ALA/EDF/NRDC/SC commented that it is unlawful to use SILs and/or SMCs to waive or limit the CAA requirements for air quality impact analyses. For SILs: The CAA unequivocally mandates that a proposed PSD source or modification must demonstrate that its emissions "will not cause or contribute" to a violation of increments or of any NAAQS. "No major emitting facility" may be constructed unless it meets this requirement, and the emissions from a facility may not cause or contribute to an exceedance of "any" increment "for any pollutant in any area" or to an exceedance of "any" NAAQS. The statute requires that each permit applicant must conduct an air quality analysis, including obtaining continuous air quality monitoring data, which is "gathered for the purposes of determining whether emissions from such facility will exceed the maximum allowable increases or the maximum allowable concentration permitted under this part." For SMCs: Section 165(e)(2) mandates a full year of continuous air quality monitoring for each major source subject to the PSD program, without exception, other than a limited provision that allows for less than a year's worth of monitoring based on a determination "that a complete analysis for such purposes may be accomplished in a shorter period." ALA stated that exception "hardly amounts to the authority to waive monitoring entirely," which, in their opinion, is what SMCs do.

Response: The EPA disagrees with this commenter's claim that it is unlawful to use SILs and SMC as screening tools to provide a reasonable implementation

approach for PSD/NSR purposes. We believe that the concept of a SIL, or SMC, is grounded on the de minimis principles described by the court in Alabama Power v. Costle, 636 F.2d 323, 362 (D.C. Cir. 1979) (Alabama Power). In that case reviewing EPA's 1978 PSD regulations, the court recognized that "there is likely a basis for an implication of de minimis authority to provide exemption when the burdens of regulation yield a gain of trivial or no value." Alabama Power at 360. Additional discussion of EPA's legal authority to promulgate SILs and SMCs are provided in 72 Fed. Reg. 54112, 54139-41 (Sept. 21, 2007).

(10) ***Comment:*** Missouri commented that the revised 3-hour, 24-hour, and annual SO_2 increment standards could be addressed in a way similar to how Congress resolved the PM_{10} issue, though the issue is not quite the same since the PM_{10} issue involved a new size distinction. Based on the PM_{10} issue, though, Congress' intent is clearly only to require increment standards for pollutants and averaging times where the public or environment needs protection. It does not make sense to continue to include an increment evaluation for an averaging time that does not exist. It is very difficult to believe that a standard that is proposed to be tightened to this extent could be allowed to determine the issuing of permits to sources using the same principles that were adopted under the current standard. The more difficult question is, according to Missouri, "What is the correct course of action for areas that have already triggered a minor source baseline and have violated one of the existing increment standards or are near an increment violation?" Another critical issue, in their opinion, is the implementation of new significant impact levels, significant monitoring concentrations, and significant emission rates for the new standard.

Response: As described in an earlier response, the CAA explicitly defines increments for SO_2 that EPA cannot alter without prior authorization from Congress. EPA recognizes that there may be little need for annual and 24-hour SO_2 increments following the revocation of the annual and 24-hour NAAQS. Nevertheless, these increments must remain intact until and unless Congress decides to amend the CAA to itself make, or authorize EPA to make, any necessary changes.

(11) ***Comment:*** Dow, supporting ACC and API comments, recommended that EPA clarify that compliance with the new standard should be determined only by the ambient monitoring network. Dow clarified that state permitting agencies do not have to require regulated entities to conduct air dispersion modeling unless required by a review of the PSD air permit application.

Response: Under the anticipated implementation approach discussed in sections III, IV, V and VI of the preamble to the final rule, EPA expects to rely upon both monitoring and refined dispersion modeling to inform designations and determinations of whether implementation plans show attainment of the new 1-hour NAAQS. We note that section 110(a)(2)(K) of the CAA provides that the

Administrator may prescribe the use of ambient modeling for the purpose of predicting the effect on ambient air quality of any (emphasis added) emissions for which there is a NAAQS. Therefore, the use of ambient modeling need not be limited to only sources that must meet the PSD requirements. A prerequisite to the issuance of any construction permit for a stationary source is that it demonstrates that its emissions do not cause or contribute to a violation of any NAAQS. See, e.g., 40 CFR 51.160(a), (b), (f). Meeting this requirement may not in all cases require a modeling demonstration; however, we have in the past concluded that modeling is sometimes necessary to demonstrate NAAQS compliance as part of the issuance of even minor source permits, and we expect this to continue to be true. EPA's implementing rules for applying ambient modeling [see 40 CFR part 51, Appendix W, Guideline on Air Quality Models] contain the specific modeling requirements for existing and new sources. States are authorized under the SIP to use ambient modeling for these purposes. Nothing in the CAA suggests that only ambient monitoring, instead of modeling, must be used to determine source impacts and compliance with the NAAQS. The rules at 40 CFR 51.160 (f) requiring state plans to contain legally enforceable procedures also specify that the modeling meet the requirements of Appendix W. See 51.160 (f).

X. Responses to Significant Comments on Appendix T (Interpretation of Primary NAAQS and Exceptional Events Rules)

A. Comments on data completeness and data substitutions

(1) ***Comment*:** Iowa commented that they would prefer to couple a lower NAAQS level with simple design value calculations that are transparent to the public, rather than couple a higher NAAQS level with a complicated design value. As EPA moves towards one-hour standards for many gaseous pollutants, it is desirable to standardize the design value calculations across the pollutants. Iowa recommended using a quarterly data capture of at least 75% to produce a valid annual 98^{th} or 99^{th} percentile for design value calculations. The final form of the standard must be robust so as to more effectively control air pollution. According to Iowa, regulating the tails of the SO_2 distribution will cause great year-to-year variability in attainment, and the modeling hot spots that dictate monitor placement may also be diffuse and poorly defined when regulating the SO_2 distribution tails.

Response: EPA agrees with the comment on data completeness. The final rule incorporates this completeness requirement, but also provides for two diagnostic data substitution tests for use with data sets that do not meet the 75% requirement. These tests are complicated and may not be perceived as transparent to all the public, but EPA believes that this complexity is necessary and appropriate given

the usefulness of the tests in allowing at least some areas to be clearly determined to be meeting or not meeting the NAAQS despite the data incompleteness.

(2) ***Comment:*** NYSDEC does not believe that data substitution should be employed to make attainment/non-attainment designations.

Response: This issue is discussed in the NFR Preamble text, Section VII, Appendix T--Interpretation of the Primary NAAQS for Oxides of Sulfur and Revisions to the Exceptional Events Rule, *Interpretation of the NAAQS for Oxides of Sulfur* (Section VII.A). See also the response to the above comment.

(3) ***Comment*:** UARG and DSRI agreed that there should be completeness criteria for compliance data, but disagree with EPA's suggested approach. UARG and DSRI argued that the data completeness rule should include a system for determining when incomplete data should be used, rather than giving discretion to the Administrator (such discretion is in conflict with the current data completeness rule and opens the possibility of seemingly arbitrary decisions). Since only 75% of the expected data are required for completeness, when hypothetical data are substituted for missing data, enough substituted data should be used to bring the expected data to 75% rather than including enough substituted data to bring the expected data to 100%. The goal of the monitoring program should be a high degree of accuracy in ambient SO_2 measurements, and this accuracy will increase not just with an increasing percentage of expected data but also with an increasing percentage of actual monitoring data.

Response: The issue of substituting data up to 75% versus 100% completeness as part of the diagnostic data substitution tests is discussed in the NFR Preamble text, Section VII, Appendix T--Interpretation of the Primary NAAQS for Oxides of Sulfur and Revisions to the Exceptional Events Rule. The commenter also disagrees with a proposed provision allowing the Administrator to use incomplete data even in a situation in which the data substitution test does not produce a validated design value. The final rule retains this provision, which also is a feature of the data interpretation appendices for the $PM_{2.5}$ and the 1-hour NO_2 NAAQS. EPA believes that situations may arise in which using incomplete data is appropriate but which cannot be anticipated at this time. EPA notes that the public will have opportunity to comment on any such use of incomplete data that has regulatory consequences for a state, because EPA provides public notice prior to any final designation, clean data determination, or SIP approval/disapproval action.

(4) ***Comment:*** Wisconsin commented that EPA should consider allowing data to be qualified rather than invalidated for certain quality control failures like baseline drift and some calibration verification failures. Wisconsin agreed that some situations may call for using data substitution, but there may be many situations where the data gatherer/analyst notices a data bias that can be adjusted for, leading to a better estimate of actual concentrations versus using a data

substitution procedure. For example, a verification standard may exceed limits by a couple percent when the sample concentrations are near baseline–that is, the magnitude seems reliable but the absolute concentration is questionable. In this case, under the current data handling procedures, this important qualifying information would be lost. Wisconsin proposed that the data analyst be allowed to build in any necessary margin of error to the data.

Response: Section 2.a of Appendix T says that all data required to be submitted to AQS meeting requirements of part 58 shall be used in design value calculations. The situations and alternative courses of action described in the comment arise prior to submission of data to AQS, and are not addressed in Appendix T. Such issues are addressed by EPA monitoring guidance, which is outside the scope of this rulemaking.

(5) ***Comment:*** Several commenters expressed support for EPA's proposed 75% completeness requirement for daily and quarterly data.

Response: EPA agrees with the comment on data completeness. The NFR does what the comment suggests.

(6) ***Comment:*** North Carolina and AirQuality expressed support for EPA's proposed substitution criteria, although AirQuality only explicitly approves of the criteria if the form of the standard is the 4th highest concentration.

Response: This issue is discussed in the NFR Preamble text, Section VII, Appendix T--Interpretation of the Primary NAAQS for Oxides of Sulfur and Revisions to the Exceptional Events Rule.

(7) ***Comment:*** Iowa "do not favor the provisions in the proposed rule that disallow substitution of secondary monitor data for primary monitor data except in cases when the primary monitor is permanently removed from the site" because it will decrease data quality and consequently recommended that the "provision be removed from the final rule."

Response: This issue is discussed in the NFR Preamble text, Section VII, Appendix T--Interpretation of the Primary NAAQS for Oxides of Sulfur and Revisions to the Exceptional Events Rule.

(8) ***Comment:*** Iowa recommended EPA allow "states to upload hourly data from multiple monitors to the AQS database" in order to "construct a composite data set in AQS for which each hourly value represents the average of the valid hourly data collected for each instrument at the monitoring site. The data from the composite data set could then be used for computation of design values."

Response: This issue is discussed in the NFR Preamble text, Section VII, Appendix T--Interpretation of the Primary NAAQS for Oxides of Sulfur and Revisions to the Exceptional Events Rule.

(9) ***Comment:*** MIDNRE, concerned about the inherent instability of a short-term SO_2 standard (1, 3, or 8-hour), provided comments recommending EPA modify the methodology for siting SO_2 monitors so that state agencies can "average monitors within a specified area and compare the averaged level to the standard for attainment purposes or to classify a subset of data as not applicable for comparison of the NAAQS, in the same way that the original fine particulate network was set up." MIDNRE also expressed concern that "both the PWEI and contribution to national SO_2 emissions are emission based, and thus, redundant. The redundancy creates an added, unnecessary financial burden by requiring additional monitors. For states with a high contribution to the national inventory as well as many large urban areas, the number of monitoring sites and the short implementation time line would create an excessive burden."

Response: The commenter makes two suggestions said to be tied to a concern that the form and level of the proposed standard may cause some sites to flip in and out of attainment. The commenter provided a graph showing the variation of the three-year averages of various 1-hour SO_2 metrics from 1993 to 2007 for a monitoring site in Detroit, MI. It is not clear whether the "1st high" and other metrics shown in the graph are based on all hours of the year, or on daily maximum 1-hour values.

EPA's first response is that the graph provided by the commenter does not show a great deal of instability of the 4th high metric, which (assuming the graph is presenting the 4th high daily maximum value) is essentially the same as the proposed 99th percentile form of the standard. The value of this metric ranged between 40 and 80 ppb during this time period, and was appreciably outside the 40 to 60 ppb range only in the three 3-year periods that included data from 1999. EPA recognizes that while using a 3-year average reduces the instances of areas flipping in and out of attainment, there likely will always be some such cases in areas whose long term average air quality is close to the standard such that a single particularly bad year causes the design value to exceed the standard for three successive years.

The commenter's first suggestion is that states be allowed to "average monitors" within a specified area and compare the averaged levels to the standard for attainment purposes. It is not clear whether the suggestion envisions averaging same-hour concentrations across sites before identifying the 99th percentile (for example) value of the daily maximum 1-hour concentration, or averaging the three-year average of annual 99th percentile values across sites. The first approach has the potential to greatly reduce the level of protection afforded by a NAAQS set at a given level, because in any single hour the extent of the area of high SO_2 concentration may be quite limited such that averaging across sites

(even sites not widely separated in monitoring network terms) could result in an average value substantially below the actual concentration to which some individuals may be exposed. The second approach could have a lesser tendency to reduce the level of protection, if the sites being averaged have similar transport/dilution relationships to the same dominant SO_2 emission source(s) so that they experience a similar distribution of 1-hour concentrations during the year although not matched across sites hour-by-hour. However, the second approach could still tend to result in a reported concentration below the highest concentration to which some people may be exposed. EPA sees no advantage to such an approach. EPA notes that if spatial averaging were applied to monitoring data, the Administrator would have to consider this feature when selecting the level of the NAAQS. EPA also notes that in any case a spatial averaging approach could only be appropriate and relevant if multiple monitors are used near single sources, which EPA in general believes would often be a poor use of monitoring resources given the number of sources with potential to cause violations of the NAAQS.

The second suggestion is that a subset of monitors be classified as not applicable for comparison to the NAAQS, and the commenter makes reference to the fine PM network. The 1997 final rule for the $PM_{2.5}$ NAAQS established two new standards: an annual standard based on $PM_{2.5}$ concentrations from single or multiple community-oriented monitors; and a 24-hour standard based on 24-hour PM2.5 concentrations at population-oriented monitors within an area. 71 FR 61144, 61146, 61164-65 (October 17, 2006). Also see 40 CFR 58.30. This form of the annual standard was intended to characterize area-wide PM2.5 concentrations, in conjunction with a 24-hour standard designed to provide adequate protection against localized peak or seasonal $PM_{2.5}$ levels. The 24-hr standard was deigned to provide protection for people residing in or near localized areas of elevated concentrations. Id. These provisions were based largely on the specific evidence before EPA in that NAAQS review, which was focused largely on epidemiologic evidence with only limited evidence from clinical studies. EPA made various public health policy judgments concerning the appropriate level, averaging time, and form of the $PM_{2.5}$ standards in light of that evidence.

The body of evidence in this SO_2 review is quite different, including important clinical evidence as well as epidemiologic evidence. This body of evidence did not lead EPA to propose provisions concerning community-oriented monitors or population oriented monitors as a way to provide appropriate public health protection from short-term exposure to SO_2. The commenter raises concerns over the stability of a 1-hour SO_2 standard; however the monitoring provisions for the $PM_{2.5}$ NAAQS described above were not based on concerns over the stability of the standard. The issue of the stability of the standard is important, and it is addressed in this review through the use of a percentile form and a 3 year average. Commenter presents no evidence or argument supporting use of a different approach to address the issue of stability of the standard.

XI. Responses to Significant Comments on the Regulatory Impact Analysis

(1) ***Comment*:** Benefits from direct exposure to SO_2 are small; most of the benefits comes from emissions of particulate matter. (CIBO, AECT, South Carolina Chamber of Commerce, PE, EEI, UARG).

Response: EPA concurs that the monetized benefits of reduced SO_2 exposure appear small when compared to the monetized benefits of reduced $PM_{2.5}$ exposure. This result is consistent with other recent RIAs, where the $PM_{2.5}$ co-benefits represent a large proportion of total monetized benefits. This result is amplified in this RIA by the decision not to quantify SO_2-related premature mortality and other morbidity endpoints due to the uncertainties associated with estimating those endpoints. Studies have shown that there is a relationship between SO_2 exposure and premature mortality, but that relationship is limited by potential confounding. Because premature mortality generally comprises over 90% of the total monetized benefits, this decision may substantially underestimate the monetized health benefits of reduced SO_2 exposure.

EPA does not concur with the characterization of the benefits being restricted to only the monetized SO_2-related health benefits. As there are several other categories of benefits associated with the SO_2 reductions, EPA believes it is appropriate to compare the total monetized benefits with the costs. It is inappropriate to consider only one category of monetized benefits in isolation of the other benefits anticipated from the rule.

(2) ***Comment:*** At the low levels of exposure being studied, co-pollutant impact may be improperly attributed to SO_2. (AEPSC, UARG)

Response: EPA concurs that co-pollutants present in the ambient air may contribute to the health effects attributed to SO_2 in single pollutant models, which could lead to overestimating the SO_2 risks if those co-pollutants are highly correlated with SO_2. Where available, we have selected multipollutant effect estimates to control for the potential confounding effects of co-pollutants; these include NYDOH (2006), Schwartz et al. (1994) and O'Conner et al. (2007). Because the majority of the monetized benefits are from $PM_{2.5}$-related premature mortality and we did not estimate SO_2-related mortality, it is unlikely that potential confounding would have a substantial effect on the total monetized benefits.

(3) ***Comment***: Very few benefits come from reducing exposure to SO_2; virtually all of the benefits come from reduced exposure to particulate matter. PM co-benefits

should not be addressed in this RIA. (CIBO, PE, South Carolina Chamber of Commerce, EEI. UARG).

Response: EPA does not concur that the $PM_{2.5}$ co-benefits should excluded from the total monetized benefits. Because SO_2 is a precursor to $PM_{2.5,}$ reducing SO_2 emissions in the projected non-attainment areas will also reduce $PM_{2.5}$ formation, human exposure and the incidence of $PM_{2.5}$-related health effects. The PM co-benefits are directly related to the reduction of SO_2 emissions, not ancillary controls installed to reduce PM.

Reducing SO_2 emissions is associated with a variety of benefit categories, only some of which we were able to quantify and monetize in this analysis. In this analysis, we monetized the benefits associated with some SO_2-related morbidity endpoints and PM-related mortality and morbidity endpoints, but we did not monetize the benefits associated with SO_2-related mortality, acid deposition, mercury methylation from sulfate, or visibility.

The goal of an RIA is to provide a comprehensive estimate of all the anticipated costs and benefits associated with a regulatory action, regardless of the underlying justification for the action. Co-benefits that occur as a result of a regulatory action are appropriate to include in the RIA, and it is appropriate to compare the all of the monetized benefits with the costs. It is inappropriate to consider only one category of monetized benefits in isolation of the other benefits anticipated from the rule.

(4) ***Comment***: Health benefits from PM controls are "double-counted" with the PM NAAQS and other rules. (UARG, Pepper Hamilton, AA).

Response: EPA does not concur that the PM co-benefits estimated for this rule are "double-counted" with the PM NAAQS. The emission reductions estimated for NAAQS analyses are incremental to those estimated for previous NAAQS analyses. Reducing SO_2 also reduces $PM_{2.5}$ formation, human exposure and the incidence of $PM_{2.5}$-related health effects, regardless of the rule that requires the reduction. Because the control strategies to attain the NAAQS are illustrative, there may be unavoidable degree of overlap with rules that will be promulgated subsequent to this rulemaking. However, both the costs and benefits would be double-counted in that scenario.

Note also that EPA models $PM_{2.5}$-related premature mortality using a no-threshold, log-linear model, which is consistent with the conclusion in the Integrated Science Assessment for Particulate Matter (EPA, 2009c). The emission reductions from this rule occur in areas with varied concentrations of $PM_{2.5}$, including both regions that are in attainment with fine particle standard and would not be required to develop control strategies for the fine particulates, and those that would not be in attainment.

(5) ***Comment***: There is a NAAQS underway for fine particulates; if virtually all the benefits are from PM, then control PM and not SO_2. Claiming PM mortality as a benefit in the SO_2 NAAQS is misleading and misplaced. (RMA, PCA).

Response: The level of the SO_2 NAAQS is determined on the basis of the health effects associated with SO_2 exposure. Emission reductions from other rules such as the PM NAAQS may help an area achieve attainment, but those emission reductions do not affect the health basis for the SO_2 NAAQS.

(6) ***Comment***: Consideration of PM co-benefits may be appropriate for longer-term standards with longer averaging periods; it is inappropriate to consider those benefits in a short-term standard based on short-term effects. (CRA)

Response: EPA does not concur that it is inappropriate to consider PM co-benefits for a short-term SO_2 standard. Although the averaging period of the standard could affect the emission reductions needed to meet the standard, the averaging period of the standard is irrelevant to $PM_{2.5}$ formation from those SO_2 emissions.

(7) ***Comment***: EPA's assertion that there would be high PM mortality is among the least justified of all EPA's impact assumptions. (PCA).

Response: EPA does not concur with the characterization of PM-related premature mortality as the "least justified" assumption. After evaluating the body of scientific literature, the Integrated Science Assessment for Particulate Matter concluded that the relationship between both short-term and long-term exposure to $PM_{2.5}$ is causally associated with premature morality (EPA, 2009c).

(8) ***Comment***: The total monetized costs exceed the benefits from reducing SO_2 emissions by a significant amount. (*Pepper Hamilton, NPRA, AECT,* TAB, EEI, UARG)

Response: Total monetized benefits of the SO_2 standard exceed the costs by a substantial margin. EPA believes it is inappropriate to consider only one category of monetized benefits (direct SO_2 health impacts) in isolation of the other benefits (particulate matter health impacts) anticipated from compliance with the standard.

(9) ***Comment***: The RIA may substantially underestimate the health benefits of reducing exposure to SO_2 in cities like New York by relying on national data to estimate base incidence rates**.** (City of New York)

Response: EPA concurs that the $PM_{2.5}$ co-benefits are based on national averages, and thus do not reflect local variability in population density, meteorology, exposure, baseline health incidence rates, or other local factors. This methodology might lead to underestimates in some locations such as New York City and overestimates in other locations, but EPA believes that the overall

national estimate is not biased. (Based on projections, EPA estimates that New York City would attain the alternate standards without additional controls.)

(10) ***Comment***: Any revision to the SO_2 NAAQS that makes those standards more stringent will result in increased cost of electricity to cooperative consumer-owners. Because cooperatives have a disproportionate amount of fossil-fuel fired generation when compared to the electric utility industry as a whole, these negative impacts could be disproportionately higher for electric co-ops and their consumer owners – particularly in rural areas. (NRECA).

Response: In the RIA for the proposal, EPA included an economic impact analysis of the impact of the illustrative control strategies for areas to meet the 50 ppb alternative standard. That economic impact analysis shows that the electric power industry will only experience annualized costs of less than 0.4 percent of total industry revenues in 2020. While we do not provide impacts for individual power plants and their owners, the impact estimates do suggest that, at a broad scale, the electric power industry, as affected by illustrative control strategies such as those included in this RIA, will not experience substantial impacts from compliance with this NAAQS.

(11) ***Comment***: This RIA does not realistically assess the economic impact on the nation's manufacturing base and jobs. Non-EGU point sources will bear the brunt of the proposed rule and the economic impact on existing industrial facilities, including potential job losses, has not been accounted for in the RIA. (CIBO).

Response: In the RIA for the proposal, EPA included an economic impact analysis of the impact of the illustrative control strategies for areas to meet the 50 ppb alternative standard. That economic impact analysis shows that industries with non-EGU point sources affected by the illustrative control strategies will only experience annualized costs of less than 0.01 percent of total industry revenues in 2020. While we do not provide impacts for individual facilities and firms, the impact estimates do suggest that, at a broad scale, industries potentially affected by illustrative control strategies such as those included in this RIA will not experience substantial impacts from compliance with this NAAQS.

(12) ***Comment***: Neither the Proposed Rule nor its accompanying Regulatory Impact Analysis (RIA) discuss the Proposed Rule's potentially significant economic impacts on sulfuric acid plants. Neither document attempts to compare those economic impacts to the relatively small contribution of the sulfuric acid manufacturing industry to ambient SO_2. (Ad Hoc Committee of Sulfuric Acid Producers*).*

Response: In the RIA for the proposal, EPA included an economic impact analysis of the impact of the illustrative control strategies for areas to meet the 50 ppb alternative standard. That economic impact analysis shows that industries with non-EGU point sources such as the chemical manufacturing industry (which

includes sulfuric acid plants) that may be affected by this NAAQS will only experience annualized costs of less than 0.01 percent of total industry revenues in 2020. While we do not provide impacts for individual facilities and firms, the impact estimates do suggest that, at a broad scale, sulfuric acid plants that may be potentially affected by illustrative control strategies such as those included in this RIA will not experience substantial impacts from compliance with this NAAQS.

(13) ***Comment***: The RIA states that EPA was unable to identify SO_2 emissions control measures that would be capable of bringing some counties into attainment of such a SO_2 standard. (Ad Hoc Committee of Sulfuric Acid Producers).

Response: In this analysis we were not able to find controls that would bring all areas into attainment with the alternative standards in all areas. It is uncertain what controls States would put in place to attain a tighter standard. We should also note that because of data and resource limitations for this broad national analysis, we are not able to adequately represent in this analysis the impacts of some local emission control programs.

(14) ***Comment***: The RIA also does not make clear how or if retrofits and replacements of boilers burning residual oil and switching to natural gas or distillate heating oil is accounted for in the estimated costs of reducing SO_2 emissions. (City of New York)

Response: The RIA does not include any retrofits or replacements of boilers burning residual oil and switching to natural gas. The control measure considered for these sources was flue gas desulfurization. We should also note that because of data and resource limitations for this broad national analysis, we are not able to adequately represent in this analysis the impacts of some local emission control programs, or specific strategies that may be available to some sources in some areas.

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