



# Federal Register

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**Tuesday,  
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**Part II**

## **Environmental Protection Agency**

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**40 CFR Parts 50, 53, and 58  
Primary National Ambient Air Quality  
Standard for Sulfur Dioxide; Proposed  
Rule**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 50, 53, and 58

[EPA-HQ-OAR-2007-0352; FRL-8984-3]

RIN 2060-A048

### Primary National Ambient Air Quality Standard for Sulfur Dioxide

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

**ACTION:** Proposed rule.

**SUMMARY:** Based on its review of the air quality criteria for oxides of sulfur and the primary national ambient air quality standard (NAAQS) for oxides of sulfur as measured by sulfur dioxide (SO<sub>2</sub>), EPA is proposing to revise the primary SO<sub>2</sub> NAAQS to provide requisite protection of public health with an adequate margin of safety. Specifically, EPA proposes to establish a new 1-hour SO<sub>2</sub> standard within the range of 50–100 parts per billion (ppb), based on the 3-year average of the annual 99th percentile (or 4th highest) of 1-hour daily maximum concentrations. The EPA also proposes to revoke both the existing 24-hour and annual primary SO<sub>2</sub> standards.

**DATES:** Comments must be received on or before February 8, 2010. Under the Paperwork Reduction Act, comments on the information collection provisions must be received by OMB on or before January 7, 2010.

**Public Hearings:** A public hearing is scheduled for this proposed rule. The public hearing will be held on January 5, 2010 in Atlanta, Georgia.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2007-0352 by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

- *E-mail:* [a-and-r-Docket@epa.gov](mailto:a-and-r-Docket@epa.gov).

- *Fax:* 202-566-9744.

- *Mail:* Docket No. EPA-HQ-OAR-2007-0352, Environmental Protection Agency, Mail Code 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of two copies.

- *Hand Delivery:* Docket No. EPA-HQ-OAR-2007-0352, Environmental Protection Agency, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

**Public Hearings:** A public hearing is scheduled for this proposed rule. The

public hearing will be held on January 5, 2010 in Atlanta, Georgia. The hearing will be held at the following location: Sam Nunn Atlanta Federal Center, Conference Rooms B and C, 61 Forsyth Street, SW., Atlanta, GA 30303, Telephone: (404) 562-9077.

**Note:** All persons entering the Atlanta Federal Center must have a valid picture ID such as a Driver's License and go through Federal security procedures. All persons must go through a magnetometer and all personal items must go through x-ray equipment, similar to airport security procedures. After passing through the equipment, all persons must sign in at the guard station and show their picture ID.

See the **SUPPLEMENTARY INFORMATION** under "Public Hearing" for further information.

**Instructions:** Direct your comments to Docket ID No. EPA-HQ-OAR-2007-0352. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov) your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

**Docket:** All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute.

Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566-1742.

**FOR FURTHER INFORMATION CONTACT:** Dr. Michael J. Stewart, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C504-06, Research Triangle Park, NC 27711; telephone: 919-541-7524; fax: 919-541-0237; e-mail: [stewart.michael@epa.gov](mailto:stewart.michael@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### General Information

*What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through [www.regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

- Follow directions—the agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.

- Describe any assumptions and provide any technical information and/or data that you used.

- Provide specific examples to illustrate your concerns, and suggest alternatives.

- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

- Make sure to submit your comments by the comment period deadline identified.

#### Availability of Related Information

A number of the documents that are relevant to this rulemaking are available through EPA's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) Web site at [http://www.epa.gov/ttn/naaqs/standards/so2/s\\_so2\\_index.html](http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_index.html). These documents include the Integrated Review Plan and the Health Assessment Plan, available at, the Integrated Science Assessment (ISA), available at [http://www.epa.gov/ttn/naaqs/standards/so2/s\\_so2\\_cr\\_isa.html](http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_cr_isa.html), and the Risk and Exposure Assessment (REA), available at [http://www.epa.gov/ttn/naaqs/standards/so2/s\\_so2\\_cr\\_rea.html](http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_cr_rea.html). These and other related documents are also available for inspection and copying in the EPA docket identified above.

#### Public Hearing

The public hearing on January 5, 2010 will provide interested parties the opportunity to present data, views, or arguments concerning the proposed rule. The EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearing. Written comments must be received by the last day of the comment period, as specified in this proposed rulemaking.

The public hearing will begin at 10 a.m. and continue until 7 p.m. (local time) or later, if necessary, depending on the number of speakers wishing to participate. The EPA will make every effort to accommodate all speakers that arrive and register before 7 p.m. A lunch break is scheduled from 12:30 p.m. until 2 p.m.

If you would like to present oral testimony at the hearing, please notify Ms. Tricia Crabtree (C504-02), U.S. EPA, Research Triangle Park, NC 27711. The preferred method for registering is by e-mail ([crabtree.tricia@epa.gov](mailto:crabtree.tricia@epa.gov)). Ms. Crabtree may be reached by telephone at (919) 541-5688. She will arrange a

general time slot for you to speak. The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing.

Oral testimony will be limited to five (5) minutes for each commenter to address the proposal. We will not be providing equipment for commenters to show overhead slides or make computerized slide presentations unless we receive special requests in advance. Commenters should notify Ms. Crabtree if they will need specific audiovisual (AV) equipment. Commenters should also notify Ms. Crabtree if they need specific translation services for non-English speaking commenters. The EPA encourages commenters to provide written versions of their oral testimonies either electronically on computer disk, CD-ROM, or in paper copy.

The hearing schedule, including lists of speakers, will be posted on EPA's Web site for the proposal at [http://www.epa.gov/ttn/naaqs/standards/so2/s\\_so2\\_index.html](http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_index.html) prior to the hearing. Verbatim transcripts of the hearing and written statements will be included in the rulemaking docket.

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## I. Background

### A. Legislative requirements

Two sections of the Clean Air Act (Act or CAA) govern the establishment and revision of National Ambient Air Quality Standards NAAQS. Section 108 of the Act directs the Administrator to identify and list air pollutants that meet certain criteria, including that the air pollutant “in his judgment, cause[s] or contribute[s] to air pollution which may reasonably be anticipated to endanger public health and welfare” and “the presence of which in the ambient air results from numerous or diverse mobile or stationary sources.” CAA section 108 (a)(1)(A) & (B). For those air pollutants listed, section 108 requires the Administrator to issue air quality

criteria that “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air \* \* \*” Section 108 (a) (2).

Section 109(a) of the Act directs the Administrator to promulgate “primary” and “secondary” NAAQS for pollutants for which air quality criteria have been issued. 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.”<sup>1</sup> Section 109(b)(1). A secondary standard, in turn, 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.”<sup>2</sup> Section 109(b)(2) This proposal concerns exclusively the primary NAAQS for oxides of sulfur.

The requirement that primary standards include an adequate margin of safety is intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It is also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (DC Cir 1980), *cert. denied*, 449 U.S. 1042 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (DC Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower

<sup>1</sup> The legislative history of section 109 indicates that a primary standard is to be set at “the maximum permissible ambient air level \* \* \* which will protect the health of any [sensitive] group of the population,” and that for this purpose “reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.” S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

<sup>2</sup> EPA is currently conducting a separate review of the secondary SO<sub>2</sub> NAAQS jointly with a review of the secondary NO<sub>2</sub> NAAQS (see <http://www.epa.gov/ttn/naaqs/standards/no2so2sec/index.html> for more information).

pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In addressing the requirement for a margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of the at-risk population(s), and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator’s judgment. *Lead Industries Association v. EPA*, 647 F.2d at 1161–62.

In setting standards that are “requisite” to protect public health and welfare, as provided in section 109(b), EPA’s task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, EPA may not consider the costs of implementing the standards. *Whitman v. American Trucking Associations*, 531 U.S. 457, 471, 475–76 (2001).

Section 109(d)(1) of the Act requires the Administrator to periodically undertake a thorough review of the air quality criteria published under section 108 and the NAAQS and to revise the criteria and standards as may be appropriate. The Act also requires the Administrator to appoint an independent scientific review committee composed of seven members, including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies, to review the air quality criteria and NAAQS and to “recommend to the Administrator any new \* \* \* standards and revisions of existing criteria and standards as may be appropriate under section 108 and subsection (b) of this section.” CAA section 109 (d)(2). This independent review function is performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA’s Science Advisory Board.

### B. Related SO<sub>2</sub> control programs

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the Act, and related provisions, States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration program that covers these

pollutants. See CAA sections 160–169. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants through the Federal motor vehicle and motor vehicle fuel control program under title II of the Act, (CAA sections 202–250) which involves controls for emissions from all moving sources and controls for the fuels used by these sources; new source performance standards under section 111; and title IV of the Act (CAA sections 402–416), which specifically provides for major reductions in SO<sub>2</sub> emissions. EPA has also promulgated the Clean Air Interstate Rule (CAIR) to define additional SO<sub>2</sub> emission reductions needed in the Eastern United States to address the interstate impact provisions of CAA section 110(a)(2)(D), a rule which EPA is reevaluating pursuant to court remand.

Currently, there are several areas designated as being in nonattainment of the primary SO<sub>2</sub> NAAQS (see section VI). If the SO<sub>2</sub> NAAQS is revised as a result of this review; however, some additional areas could be classified as non-attainment. Certain States would then be required to develop SIPs that identify and implement specific air pollution control measures to reduce ambient SO<sub>2</sub> concentrations to attain and maintain the revised SO<sub>2</sub> NAAQS, most likely by requiring air pollution controls on sources that emit oxides of sulfur (SO<sub>x</sub>).

### C. History of reviews of the primary NAAQS for sulfur oxides

On April 30, 1971, the EPA promulgated primary SO<sub>2</sub> NAAQS (36 FR 8187). These primary standards, which were based on the findings outlined in the original 1969 Air Quality Criteria for Sulfur Oxides, were set at 0.14 parts per million averaged over a 24-hour period, not to be exceeded more than once per year, and 0.030 ppm annual arithmetic mean. In 1982, EPA published the Air Quality Criteria for Particulate Matter and Sulfur Oxides (EPA, 1982) along with an addendum of newly published controlled human exposure studies, which updated the scientific criteria upon which the initial standards were based (EPA, 1982). In 1986, EPA published a second addendum presenting newly available evidence from epidemiologic and controlled human exposure studies (EPA, 1986). In 1988, EPA published a proposed decision not to revise the existing standards (53 FR 14926) (April 26, 1988). However, EPA specifically requested public comment on the alternative of revising the current standards and adding a new 1-hour primary standard of 0.4 ppm (400 ppb)

to protect against 5–10 minute peak SO<sub>2</sub> concentrations.

As a result of public comments on the 1988 proposal and other post-proposal developments, EPA published a second proposal on November 15, 1994 (59 FR 58958). The 1994 re-proposal was based in part on a supplement to the second addendum of the criteria document, which evaluated new findings on 5–10 minute SO<sub>2</sub> exposures in asthmatics (EPA, 1994a). As in the 1988 proposal, EPA proposed to retain the existing 24-hour and annual standards. EPA also solicited comment on three regulatory alternatives to further reduce the health risk posed by exposure to high 5-minute peaks of SO<sub>2</sub> if additional protection were judged to be necessary. The three alternatives were: (1) Revising the existing primary SO<sub>2</sub> NAAQS by adding a new 5-minute standard of 0.6 ppm (600 ppb) SO<sub>2</sub>; (2) establishing a new regulatory program under section 303 of the Act to supplement protection provided by the existing NAAQS, with a trigger level of 0.6 ppm (600 ppb) SO<sub>2</sub>, one expected exceedance; and (3) augmenting implementation of existing standards by focusing on those sources or source types likely to produce high 5-minute peak concentrations of SO<sub>2</sub>.

On May 22, 1996, EPA announced its final decision not to revise the NAAQS for SO<sub>x</sub> (61 FR 25566). EPA found that asthmatics (a susceptible population group) could be exposed to such short-term SO<sub>2</sub> bursts resulting in repeated ‘exposure events’ such that tens or hundreds of thousands of asthmatics could be exposed annually to lung function effects “distinctly exceeding \* \* \* [the] typical daily variation in lung function” that asthmatics routinely experience, and found further that repeated occurrences should be regarded as significant from a public health standpoint. 61 FR at 25572, 25573. Nonetheless, the agency concluded that “the likelihood that asthmatic individuals will be exposed \* \* \* is very low when viewed from a national perspective”, that “5-minute peak SO<sub>2</sub> levels do not pose a broad public health problem when viewed from a national perspective”, and that “short-term peak concentrations of SO<sub>2</sub> do not constitute the type of ubiquitous public health problem for which establishing a NAAQS would be appropriate.” Id. at 25575. EPA concluded, therefore, that it would not revise the existing standards or add a standard to specifically address 5-minute exposures. EPA also announced an intention to propose guidance, under section 303 of the Act, to assist states in responding to short-term peak of SO<sub>2</sub>

and later initiated a rulemaking to do so (62 FR 210 (Jan. 2, 1997)).

The American Lung Association and the Environmental Defense Fund challenged EPA’s decision not to establish a 5-minute standard. On January 30, 1998, the Court of Appeals for the District of Columbia found that EPA had failed to adequately explain its determination that no revision to the SO<sub>2</sub> NAAQS was appropriate and remanded the determination back to EPA for further explanation. *American Lung Ass’n v. EPA*, 134 F. 3d 388 (DC Cir. 1998). Specifically, the court held that EPA had failed to adequately explain the basis for its conclusion that short-term SO<sub>2</sub> exposures to asthmatics do not constitute a public health problem, noting that the agency had failed to explain the link between its finding that repeated short-term exposures were significant, and that there would be tens to hundreds of thousands of such exposures annually to a susceptible subpopulation, but that a NAAQS was found not be appropriate. 134 F. 3d at 392. The court also rejected the explanation that short-term SO<sub>2</sub> bursts were “localized, infrequent, and site-specific” as a rational basis for the conclusion that no public health problem existed: “[N]othing in the Final Decision explains why ‘localized’, ‘site-specific’, or even ‘infrequent’ events might nevertheless create a public health problem, particularly since, in some sense, all pollution is local and site-specific \* \* \*”. *Id.* The court accordingly remanded the case to EPA to adequately explain its determination or otherwise take action in accordance with the opinion. In response, EPA has collected and analyzed additional air quality data focused on 5-minute concentrations of SO<sub>2</sub>. These air quality analyses conducted since the last review will help inform the current review, which will address the issues raised in the court’s remand of the Agency’s last decision.

EPA formally initiated the current review of the air quality criteria for oxides of sulfur and the SO<sub>2</sub> primary NAAQS on May 15, 2006 (71 FR 28023) with a general call for information. EPA’s draft Integrated Review Plan for the Primary National Ambient Air Quality Standards for Sulfur Dioxide (EPA, 2007a) was made available in April 2007 for public comment and was discussed by the CASAC via a publicly accessible teleconference on May 11, 2007. As noted in that plan, SO<sub>x</sub> includes multiple gaseous (*e.g.*, SO<sub>3</sub>) and particulate (*e.g.*, sulfate) species. Because the health effects associated with particulate species of SO<sub>x</sub> have been considered within the context of

the health effects of ambient particles in the Agency's review of the NAAQS for particulate matter (PM), the current review of the primary SO<sub>2</sub> NAAQS is focused on the gaseous species of SO<sub>x</sub> and does not consider health effects directly associated with particulate species.

The first draft of the Integrated Science Assessment for Oxides of Sulfur-Health Criteria (ISA) and the Sulfur Dioxide Health Assessment Plan: Scope and Methods for Exposure and Risk Assessment (EPA, 2007b) were reviewed by CASAC at a public meeting held on December 5–6, 2007. Based on comments received from CASAC and the public, EPA developed the second draft of the ISA and the first draft of the Risk and Exposure Assessment to Support the Review of the SO<sub>2</sub> Primary National Ambient Air Quality Standard (Risk and Exposure Assessment (REA)). These documents were reviewed by CASAC at a public meeting held on July 30–31, 2008. Based on comments received from CASAC and the public at this meeting, EPA released the final ISA in September of 2008 (EPA, 2008a; henceforth referred to as ISA). In addition, comments received were considered in developing the second draft of the REA. Importantly, the second draft of the REA contained a draft staff policy assessment that considered the evidence presented in the final ISA and the air quality, exposure, and risk characterization results presented in the second draft REA, as they related to the adequacy of the current SO<sub>2</sub> NAAQS and potential alternative primary SO<sub>2</sub> standards. This document was reviewed by CASAC at a public meeting held on April 16–17, 2009. In preparing the final REA report, which included the final staff policy assessment, EPA considered comments received from CASAC and the public at and subsequent to that meeting. The final REA containing the final staff policy assessment was completed in August 2009 (EPA 2009a; henceforth referred to as REA).

The schedule for completion of this review is governed by a judicial order resolving a lawsuit filed in September 2005, concerning the timing of the current review. *Center for Biologic Diversity v. Johnson* (Civ. No. 05–1814) (D.D.C. 2007). The order that now governs this review, entered by the court in August 2007 and amended in December 2008, provides that the Administrator will sign, for publication, notices of proposed and final rulemaking concerning the review of the primary SO<sub>2</sub> NAAQS no later than November 16, 2009 and June 2, 2010, respectively.

This action presents the Administrator's proposed decisions on the current primary SO<sub>2</sub> standards. Throughout this preamble a number of conclusions, findings, and determinations proposed by the Administrator are noted. Although they identify the reasoning that supports this proposal, they are not intended to be final or conclusive. EPA invites general, specific, and/or technical comments on all issues involved with this proposal, including all such proposed judgments, conclusions, findings, and determinations. In addition to requesting comment on the overall approach, EPA invites specific comment on the level, or range of levels, appropriate for such a standard, as well as on the rationale that would support that level or range of levels.

## II. Rationale for proposed decisions on the primary standards

This section presents the rationale for the Administrator's proposed decision to revise the existing SO<sub>2</sub> primary standards by replacing the current 24-hour and annual standards with a 1-hour standard and to specify this 1-hour standard to the nearest parts per billion (ppb). As discussed more fully below, this rationale takes into account: (1) Judgments and conclusions presented in the ISA and the REA; (2) CASAC advice and recommendations, as reflected in the CASAC panel's discussions of drafts of the ISA and REA at public meetings, in separate written comments, and in CASAC letters to the Administrator (Henderson 2008; Samet, 2009); and (3) public comments received at CASAC meetings during the development of the ISA and the REA.

In developing this rationale, EPA has drawn upon an integrative synthesis of the entire body of evidence on human health effects associated with the presence of SO<sub>2</sub> 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<sub>2</sub> in the ambient air. In considering this entire body of evidence, EPA chose to focus in particular on those health endpoints for which the ISA finds associations with SO<sub>2</sub> to be causal or likely causal (see section II.B below). Thus, the focus of this proposal will be on respiratory morbidity following short-term (5 minutes to 24 hours) exposure to SO<sub>2</sub>, for which the ISA found a causal relationship.

As discussed below, a substantial amount of new research has been conducted since EPA's last review of the

SO<sub>2</sub> NAAQS, with important new information coming from epidemiologic studies in particular. The newly available research studies evaluated in the ISA have undergone intensive scrutiny through multiple layers of peer review and opportunities for public review and comment. Although important uncertainties remain in the qualitative and quantitative characterizations of health effects attributable to exposure to ambient SO<sub>2</sub>, the review of this information has been extensive and deliberate.

The remainder of this section discusses the Administrator's rationale for the proposed decisions on the primary standard. Section II.A presents a discussion of the principal emitting sources and current patterns of SO<sub>2</sub> air quality, as well as the current SO<sub>2</sub> monitoring network from which those air quality patterns are obtained. Section II.B includes an overview of the scientific evidence related to the respiratory effects associated with ambient SO<sub>2</sub> exposure. This overview includes a discussion of the at-risk populations considered in the ISA. Section II.C discusses the approaches taken by EPA to assess exposures and health risks associated with exposure to ambient SO<sub>2</sub>, including a discussion of key uncertainties associated with the analyses. Section II.D presents the approach that is being used in the current review of the SO<sub>2</sub> NAAQS with regard to consideration of the scientific evidence and the air quality, exposure, and risk-based results related to the adequacy of the current standards and potential alternative standards. Sections II.E and II.F discuss the scientific evidence and the air quality, exposure, and risk-based results specifically as they relate to the current and potential alternative standards, including discussion of the Administrator's proposed decisions on the standards. Section II.G summarizes the Administrator's proposed decisions with regard to the SO<sub>2</sub> primary NAAQS.

### A. Characterization of SO<sub>2</sub> air quality

#### 1. Anthropogenic sources and current patterns of SO<sub>2</sub> Air Quality

Anthropogenic SO<sub>2</sub> emissions originate chiefly from point sources, with fossil fuel combustion at electric utilities (~66%) and other industrial facilities (~29%) accounting for the majority of total emissions (ISA, section 2.1). Other anthropogenic sources of SO<sub>2</sub> include both the extraction of metal from ore as well as the burning of high sulfur-containing fuels by locomotives, large ships, and equipment utilizing diesel engines. SO<sub>2</sub> emissions and

ambient concentrations follow a strong east to west gradient due to the large numbers of coal-fired electric generating units in the Ohio River Valley and upper Southeast regions. In the 12 Consolidated Metropolitan Statistical Areas (CMSAs) that had at least four SO<sub>2</sub> regulatory monitors from 2003–2005, 24-hour average concentrations in the continental U.S. ranged from a reported low of ~1 ppb in Riverside, CA and San Francisco, CA to a high of ~12 ppb in Pittsburgh, PA and Steubenville, OH (ISA, section 2.5.1). In addition, outside or inside all CMSAs from 2003–2005, the annual average SO<sub>2</sub> concentration was 4 ppb (ISA, Table 2–8). However, spikes in hourly concentrations occurred; the mean 1-hour maximum concentration outside or inside CMSAs was 13 ppb, with a maximum value of greater than 600 ppb outside CMSAs and greater than 700 ppb inside CMSAs (ISA, Table 2–8).

Temporal and spatial patterns of 5-minute peaks of SO<sub>2</sub> are also important given that human clinical studies have demonstrated that exposure to these peaks can result in adverse respiratory effects in exercising asthmatics (see section II.B). For those monitors which voluntarily reported 5-minute block average data,<sup>3</sup> when maximum 5-minute concentrations were reported, the absolute highest concentration over the ten-year period exceeded 4000 ppb, but for all individual monitors, the 99th percentile was below 200 ppb (ISA, section 2.5.2 Table 2–10). Median concentrations from these monitors reporting 5-minute data ranged from 1 ppb to 8 ppb, and the average for each maximum 5-minute level ranged from 3 ppb to 17 ppb. Delaware, Pennsylvania, Louisiana, and West Virginia had mean values for maximum 5-minute data exceeding 10 ppb. Among aggregated within-state data for the 16 monitors from which all 5-minute average intervals were reported, the median values ranged from 1 ppb to 5 ppb, and the means ranged from 3 ppb to 11 ppb (ISA, section 2.5.2). The highest reported concentration was 921 ppb, but the 99th percentile values for aggregated within-state data were all below 90 ppb (ISA, section 2.5.2).

## 2. SO<sub>2</sub> monitoring

Although the SO<sub>2</sub> standard was established in 1971, uniform minimum

monitoring requirements for SO<sub>2</sub> monitoring did not appear until May 1979. From the time of the implementation of the 1979 monitoring rule through 2008, the SO<sub>2</sub> network has steadily decreased in size from approximately 1496 sites in 1980 to the approximately 488 sites operating in 2008. At present, except for SO<sub>2</sub> monitoring required at National Core Monitoring Stations (NCore stations), there are no minimum monitoring requirements for SO<sub>2</sub> in 40 CFR part 58 Appendix D, other than a requirement for EPA Regional Administrator approval before removing any existing monitors and that any ongoing SO<sub>2</sub> monitoring must have at least one monitor sited to measure the maximum concentration of SO<sub>2</sub> in that area. EPA removed the specific minimum monitoring requirements for SO<sub>2</sub> in the 2006 monitoring rule revisions, based on the fact that there were no SO<sub>2</sub> nonattainment areas at that time, coupled with trends evidence showing an increasing gap between national average SO<sub>2</sub> concentrations and the current 24-hour and annual standards. Additionally, the minimum requirements were removed to provide State, local, and tribal air monitoring agencies flexibility in meeting higher priority monitoring needs for pollutants such as ozone and PM<sub>2.5</sub>, or implementing the new multi-pollutant sites (NCore network) required by the 2006 rule revisions, by allowing them to discontinue lower priority monitoring. More information on SO<sub>2</sub> monitoring can be found in section III.

### B. Health effects information

During the last review, EPA retained the current 24-hour and annual averaging times for the primary SO<sub>2</sub> NAAQS. The 24-hour NAAQS was largely based on epidemiologic studies that observed associations between 24-hour average SO<sub>2</sub> levels and adverse respiratory effects and daily mortality (EPA 1982, 1994a, 1994b). The annual standard was supported by a few epidemiologic studies that found an association between adverse respiratory effects and annual average SO<sub>2</sub> concentrations (EPA 1982, 1994a, 1994b). However, it was noted that in the locations where these epidemiologic studies were conducted, high SO<sub>2</sub> levels were usually accompanied by high levels of PM, thus making it difficult to disentangle the individual contribution each pollutant had on these health outcomes. Moreover, EPA noted that rather than 24-hour or annual average SO<sub>2</sub> levels, the health effects observed in these studies may have been related, at least in part, to the occurrence of

shorter-term peaks of SO<sub>2</sub> within a 24-hour period (53 FR 14930; April 26, 1988).

In the current review, the ISA along with its associated annexes, provided a comprehensive review and assessment of the scientific evidence related to the health effects associated with SO<sub>2</sub> exposures. For these health effects, the ISA characterized judgments about causality with a hierarchy that contains five levels (ISA, section 1–3): sufficient to infer a causal relationship, sufficient to infer a likely causal relationship (*i.e.*, more likely than not), suggestive but not sufficient to infer a causal relationship, inadequate to infer the presence or absence of a causal relationship, and suggestive of no causal relationship. Judgments about causality were informed by a series of aspects that are based on those set forth by Sir Austin Bradford Hill in 1965 (ISA, Table 1–1). These aspects include strength of the observed association, availability of experimental evidence, consistency of the observed association, biological plausibility, coherence of the evidence, temporal relationship of the observed association, and the presence of an exposure-response relationship.

Judgments made in the ISA about the extent to which relationships between various health endpoints and exposure to SO<sub>2</sub> are likely causal have been informed by several factors. As discussed in the ISA in section 1.3, these factors include the nature of the evidence (*i.e.*, controlled human exposure, epidemiologic, and/or toxicological studies) and the weight of evidence. The weight of evidence takes into account such considerations as biological plausibility, coherence of the evidence, strength of associations, and consistency of the evidence. Controlled human exposure studies provide directly applicable information for determining causality because these studies are not limited by differences in dosimetry and species sensitivity, which would need to be addressed in extrapolating animal toxicology data to human health effects, and because they provide data relating health effects specifically to SO<sub>2</sub> exposures, in the absence of the co-occurring pollutants present in ambient air. Epidemiologic studies provide evidence of associations between SO<sub>2</sub> concentrations and more serious health endpoints (*e.g.*, hospital admissions and emergency department visits) that cannot be assessed in controlled human exposure studies. For these 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

<sup>3</sup> A small number of sites, 98 total from 1997 to 2007 of the approximately 500 SO<sub>2</sub> monitors, and not the same sites in all years, voluntarily reported 5-minute block average data to AQS (ISA, section 2.5.2). Of these, 16 reported all twelve 5-minute averages in each hour for at least part of the time between 1997 and 2007. The remainder reported only the maximum 5-minute average in each hour.

SO<sub>2</sub> exposures alone and/or in combination with co-occurring pollutants.

In using a weight of evidence approach to inform judgments about the degree of confidence that various health effects are likely to be caused by exposure to SO<sub>2</sub>, confidence increases with the number of studies consistently reporting a particular health endpoint, with increasing support for the biological plausibility of the health effects, and with the strength and coherence of the evidence. Conclusions regarding biological plausibility, consistency, and coherence of evidence of SO<sub>2</sub>-related health effects are drawn from the integration of epidemiologic studies with controlled human exposure studies and with mechanistic information from animal toxicological studies. As discussed below, the weight of evidence is strongest for respiratory morbidity endpoints (e.g., lung function decrements, respiratory symptoms, hospital admissions, and emergency department visits) associated with short-term (5-minutes to 24-hours) exposure to ambient SO<sub>2</sub>.

For epidemiologic studies, strength of association refers to the magnitude of the association and its statistical strength, which includes assessment of both effect estimate size and precision. In general, when associations yield large relative risk estimates, it is less likely that the association could be completely accounted for by a potential confounder or some other bias. Consistency refers to the persistent finding of an association between exposure and outcome in multiple studies of adequate power in different persons, places, circumstances and times.

Being mindful of the considerations discussed above, the ISA concluded that there was sufficient evidence to infer a causal relationship between respiratory morbidity and short-term (5-minutes to 24-hours) exposure to SO<sub>2</sub> (ISA, section 5.2). The ISA based this conclusion 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<sub>2</sub> concentrations, and animal toxicological studies using exposures of minutes to hours (ISA, section 5.2). The ISA judged evidence of an association between SO<sub>2</sub> exposure and other health categories to be less convincing; other associations were judged to be suggestive but not sufficient to infer a causal relationship (i.e., short-term exposure to SO<sub>2</sub> and mortality) or inadequate to infer the presence or absence of a causal relationship (i.e., short-term exposure to

SO<sub>2</sub> and cardiovascular morbidity, and long-term exposure to SO<sub>2</sub> and respiratory morbidity, other morbidity, and mortality). Key conclusions from the ISA are described in greater detail in Table 5–3 of the ISA.

As summarized above, the ISA found a “causal” association between short-term (5 minutes to 24 hour) exposure to SO<sub>2</sub> and respiratory morbidity. The evidence leading to this conclusion will be discussed throughout this section as well as in the context of the adequacy of the current and proposed alternative standards (see section II.E and II.F) The ISA also found “suggestive but not sufficient” evidence to infer a causal relationship between short-term SO<sub>2</sub> exposure and mortality. EPA considered this suggestive evidence within the context of proposing a new 1-hour averaging time (see section II.F.2). The association between short- and long-term SO<sub>2</sub> exposure and other health categories was found to be inadequate to infer the presence or absence of a causal relationship and thus, will not be discussed in detail in this notice.

Section II.B.1 discusses the results of controlled human exposure studies demonstrating respiratory effects in exercising asthmatics following 5–10 minute exposures to SO<sub>2</sub>, and conclusions in the REA regarding the adversity of such effects. Section II.B.2 discusses the respiratory effects reported in U.S. epidemiologic studies of respiratory symptoms, as well as emergency department visits and hospital admissions for all respiratory causes and asthma. Section II.B.3 discusses ISA conclusions regarding short-term (5 minutes to 24-hours) exposure to SO<sub>2</sub> and respiratory effects, and section II.B.4 discusses long-term SO<sub>2</sub> exposure and potentially adverse health effects. Finally, section II.B.5 discusses SO<sub>2</sub>-related impacts on public health.

#### 1. Respiratory effects and 5–10 minute exposure to SO<sub>2</sub>

As noted above, the ISA concluded that there was sufficient evidence to infer a causal relationship between respiratory morbidity and short-term (5-minutes to 24-hours) exposure to SO<sub>2</sub> (ISA, section 5.2). This determination was primarily based on controlled human exposure studies demonstrating a relationship between 5–10 minute peak SO<sub>2</sub> exposures and adverse effects on the respiratory system in exercising asthmatics. The ISA described the controlled human exposure results as being the “definitive evidence” for its causal finding (ISA, section 5.2; p. 5–2).

Since the last review, several additional controlled human exposure

studies have been published that provide supportive evidence of SO<sub>2</sub>-induced decrements in lung function and increases in respiratory symptoms among exercising asthmatics (see ISA, Annex Table D–2). However, based in part on recent guidance from the American Thoracic Society (ATS) regarding what constitutes an adverse health effect of air pollution (ATS, 2000), a much larger body of key older studies described in the prior review were analyzed in the ISA along with studies published since the last review. 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) should be considered adverse, even if this shift does not result in the immediate occurrence of illness in any one individual in the population (ATS 2000). The ATS also recommended that transient loss in lung function with accompanying respiratory symptoms attributable to air pollution should be considered adverse. However, it was noted in the ISA that symptom perception is highly variable among asthmatics even during severe episodes of asthmatic bronchoconstriction, and that 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). Therefore, whereas the conclusions in the prior review of the SO<sub>2</sub> NAAQS were based on SO<sub>2</sub> exposure concentrations which resulted in large decrements in lung function and moderate to severe respiratory symptoms, the ISA’s current review of data from controlled human exposure studies focused on moderate to large SO<sub>2</sub>-induced 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). See also section II.B.1.c below discussing adversity of effects. Key controlled human exposure studies of respiratory symptoms and lung function are described briefly below and in more detail in section 3.1.3 of the ISA.

#### a. Respiratory symptoms

Numerous free-breathing controlled human exposure studies have evaluated respiratory symptoms (e.g. cough, wheeze, or chest tightness) in exercising asthmatic following 5–10 minute SO<sub>2</sub> exposures. Linn *et al.* (1983) reported that 5-minute exposures to SO<sub>2</sub> levels as low as 400 ppb resulted in exercising asthmatics experiencing statistically significant increases in respiratory symptoms (e.g., wheeze, chest tightness,

cough, substernal irritation). In a separate study, exercising asthmatics exhibited respiratory symptoms following a 10-minute exposure to 400–600 ppb SO<sub>2</sub> (Linn *et al.*, (1987); Smith (1993)). Gong *et al.*, (1995) exposed SO<sub>2</sub>-sensitive asthmatics to 0, 500 and 1000 ppb SO<sub>2</sub> for 10 minutes while performing different levels of exercise (light, medium, or heavy) and reported that respiratory symptoms increased with increasing SO<sub>2</sub> concentrations. The authors further reported that exposure to 500 ppb SO<sub>2</sub> during light exercise evoked a more severe symptomatic response than heavy exercise in clean air.

In addition to these free breathing chamber results described above, studies using mouthpiece exposure systems have reported respiratory symptoms within minutes of SO<sub>2</sub> exposure.<sup>4</sup> Balmes *et al.* (1987) reported that 7 out of 8 exercising asthmatics developed respiratory symptoms following a 500 ppb 3-minute exposure to SO<sub>2</sub> via mouthpiece (ISA section 3.1.3.1). In an additional study, Trenga *et al.* (1999) reported increases in respiratory symptoms in exercising asthmatics following 10-minute exposures to 500 ppb SO<sub>2</sub>. Although not directly comparable to the free-breathing chamber results described above, these mouthpiece exposure results nonetheless support an association between SO<sub>2</sub> exposure and respiratory symptoms.

#### b. Lung function decrements

The ISA found that in free-breathing chamber studies, asthmatic individuals exposed to SO<sub>2</sub> concentrations as low as 200–300 ppb for 5–10 minutes during exercise have been shown to experience moderate or greater bronchoconstriction, measured as a decrease in Forced Expiratory Volume in the first second (FEV<sub>1</sub>) of  $\geq 15\%$ , or an increase in specific airway resistance (sRaw) of  $\geq 100\%$  after correction for exercise-induced responses in clean air (Bethel *et al.*, 1985; Linn *et al.*, 1983, 1987; 1988; 1990; Roger *et al.*, 1985).<sup>5</sup> In addition, the ISA concluded that among asthmatics, both the percentage of individuals affected, and the severity of the response increases with increasing

SO<sub>2</sub> concentrations. That is, at concentrations ranging from 200–300 ppb, the lowest levels tested in free breathing chamber studies,<sup>6</sup> approximately 5–30% of exercising asthmatics experience moderate or greater decrements in lung function (ISA, Table 3–1). At concentrations of 400–600 ppb, moderate or greater decrements in lung function occur in approximately 20–60% of exercising asthmatics, and compared to exposures at 200–300 ppb, a larger percentage of asthmatics experience severe decrements in lung function (*i.e.*,  $\geq 200\%$  increase in sRaw, and/or a  $\geq 20\%$  decrease in FEV<sub>1</sub>) (ISA, Table 3–1). The ISA also noted that at SO<sub>2</sub> concentrations  $\geq 400$  ppb, moderate or greater decrements in lung function are frequently accompanied by respiratory symptoms (*e.g.*, cough, wheeze, chest tightness, shortness of breath) (ISA, Table 3–1). Further analysis and discussion of the individual studies presented above can be found in Sections 3.1.1 to 3.1.3.5 of the ISA.

In addition to the evidence from free-breathing chamber studies, the ISA notes very limited evidence of decrements in lung function in exercising asthmatics exposed to lower levels of SO<sub>2</sub> via mouthpiece. That is, the ISA cites two studies where some exercising asthmatics had small changes in FEV<sub>1</sub> or sRaw following exposure to 100 ppb SO<sub>2</sub> via mouthpiece (Koenig *et al.*, 1990 and Sheppard *et al.*, 1981).

#### c. Adversity of 5–10 minute respiratory effects

The ATS has previously defined adverse respiratory health effects as “medically significant physiologic changes generally evidenced by one or more of the following: (1) Interference with the normal activity of the affected person or persons, (2) episodic respiratory illness, (3) incapacitating illness, (4) permanent respiratory injury, and/or (5) progressive respiratory dysfunction” (ATS 1985). The ATS has also recommended that transient loss in lung function with accompanying respiratory symptoms, or detectable effects of air pollution on clinical measures (*e.g.*, medication use) be considered adverse (ATS 1985). In addition, the REA noted that during the last O<sub>3</sub> NAAQS review, the Criteria Document (CD) and Staff Paper

indicated that for many people with lung disease (*e.g.*, asthma), even moderate decrements in lung function (*e.g.*, FEV<sub>1</sub> decrements  $> 10\%$  but  $< 20\%$  and/or  $\geq 100\%$  increases in sRaw) or respiratory symptoms would likely interfere with normal activities and result in additional and more frequent use of medication (EPA 2006, EPA 2007d). The REA also noted that CASAC has previously indicated that in the context of standard setting, a focus on the lower end of the range of moderate functional responses is most appropriate for estimating potentially adverse lung function decrements in people with lung disease (73 FR16463). Finally, the REA noted that in the current SO<sub>2</sub> NAAQS review, clinicians on the CASAC Panel again advised that moderate or greater decrements in lung function can be clinically significant in some individuals with respiratory disease (hearing transcripts from USEPA Clean Air Scientific Advisory Committee (CASAC), July 30–31, 2008, Sulfur Oxides-Health Criteria (part 3 of 4) pages 211–213).<sup>7</sup>

As previously mentioned, the ATS published updated guidelines on what constitutes an adverse health effect of air pollution in 2000 (ATS, 2000). Among other considerations, the 2000 guidelines stated that measurable negative effects of air pollution on quality of life should be considered adverse (ATS 2000). These updated guidelines also indicated that exposure to air pollution that increases the risk of an adverse effect to the entire population is adverse, even though it may not increase the risk of any individual to an unacceptable level (ATS 2000). For example, a population of asthmatics could have a distribution of lung function such that no individual has a level associated with significant impairment. Exposure to air pollution could shift the distribution to lower levels that still do not bring any individual to a level that is associated with clinically relevant effects. However, this would be considered adverse because individuals within the population would have diminished reserve function, and therefore would be at increased risk if affected by another agent (ATS 2000).

At SO<sub>2</sub> concentrations  $\geq 400$  ppb, controlled human exposure studies have reported decrements in lung function that are often statistically significant at the group mean level, and that are frequently accompanied by respiratory symptoms. Being mindful that the ATS

<sup>4</sup> Studies utilizing a mouthpiece exposure system cannot be directly compared to studies involving freely breathing subjects, as nasal absorption of SO<sub>2</sub> is bypassed during oral breathing, thus allowing a greater fraction of inhaled SO<sub>2</sub> to reach the tracheobronchial airways. As a result, individuals exposed to SO<sub>2</sub> through a mouthpiece are likely to experience greater respiratory effects from a given SO<sub>2</sub> exposure.

<sup>5</sup> FEV<sub>1</sub> and sRaw are measures of bronchoconstriction. Decreases in FEV<sub>1</sub> or increases in sRaw can result in difficulty breathing.

<sup>6</sup> The ISA cites one chamber study with intermittent exercise where healthy and asthmatic children were exposed to 100 ppb SO<sub>2</sub> in a mixture with ozone and sulfuric acid. The ISA notes that compared to exposure to filtered air, exposure to the pollutant mix did not result in statistically significant changes in lung function or respiratory symptoms (ISA section 3.1.3.4)

<sup>7</sup> These transcripts can be found in Docket ID No. EPA-HQ-ORD-2006-0260. Available at [www.regulations.gov](http://www.regulations.gov).

guidelines described above specifically indicate decrements in lung function with accompanying respiratory symptoms as being adverse, exposure to 5–10 minute SO<sub>2</sub> concentrations ≥ 400 ppb are clearly adverse.

The ISA has also reported that exposure to SO<sub>2</sub> concentrations as low as 200–300 ppb for 5–10 minutes results in approximately 5–30% of exercising asthmatics experiencing moderate or greater decrements in lung function (defined in terms of a ≥ 15% decline in FEV<sub>1</sub> or 100% increase in sRaw; ISA, Table 3–1). Considering the 2000 ATS guidelines mentioned above, the REA found that these results could reasonably indicate an SO<sub>2</sub>-induced shift in these lung function measurements for this population. As a result, a significant percentage of exercising asthmatics exposed to SO<sub>2</sub> concentrations as low as 200 ppb would have diminished reserve lung function and would be at greater risk if affected by another respiratory agent (*e.g.*, viral infection). Importantly, diminished reserve lung function in a population that is attributable to air pollution is an adverse effect under ATS guidance. In addition to the 2000 ATS guidelines, the REA was also mindful of: (1) Previous CASAC recommendations (Henderson 2006) and NAAQS review conclusions (EPA 2006, EPA 2007d) indicating that moderate decrements in lung function can be clinically significant in some asthmatics; and (2) subjects participating in these controlled human exposure studies not likely including the most severe asthmatics. Taken together, the REA concluded that exposure to SO<sub>2</sub> concentrations at least as low as 200 ppb can result in adverse health effects in asthmatics.

Importantly, the final REA noted that this conclusion was in agreement with CASAC comments following the first draft SO<sub>2</sub> REA (REA section 4.3). The first draft SO<sub>2</sub> REA focused its analyses on exposures and risk associated with 5-minute SO<sub>2</sub> concentrations ≥ 400 ppb. However, CASAC strongly advised the Administrator that effects to exercising asthmatics at levels at least as low as 200 ppb can be adverse, and thus, should be considered in the second draft and final REAs (Henderson 2008).

## 2. Respiratory effects and 1- to 24-hour exposure to SO<sub>2</sub>

In addition to the controlled human exposure evidence described above, the ISA based its causal finding of an association between short-term (5-minutes to 24-hours) exposure to SO<sub>2</sub> and respiratory morbidity on results from epidemiologic studies of respiratory symptoms, as well as ED

visits and hospital admissions for all respiratory causes and asthma. More specifically, the ISA describes the results from these epidemiologic studies as providing “supporting evidence” for its determination of causality (ISA section 5.2). Key epidemiologic studies of respiratory symptoms, as well as ED visits and hospital admissions are discussed below.

### a. Respiratory symptoms

The ISA found that the strongest epidemiologic evidence of an association between short-term SO<sub>2</sub> concentrations and respiratory symptoms was in children. Studies conducted in North America and abroad generally reported positive associations between ambient SO<sub>2</sub> concentrations and respiratory symptoms in children. U.S. studies of respiratory symptoms in children (identified from Table 5–4 of the ISA), including three large multi-city studies, are described briefly below and in more detail in section 3.1.4.1 of the ISA.

The National Cooperative Inner-City Asthma Study (NCICAS, Mortimer *et al.* 2002) included asthmatic children (n = 846) from eight U.S. urban areas and examined the relationship between respiratory symptoms and summertime air pollution levels. The strongest associations were found between morning symptoms (*e.g.*, morning cough) and the median 3-hour average SO<sub>2</sub> concentrations during morning hours (8 a.m. to 11 a.m.)—following a 1- to 2-day lag (ISA, Figure 3–2). Three-hour average concentrations in the morning hours ranged from 17 ppb in Detroit to 37 ppb in East Harlem, NY. This relationship remained robust and statistically significant in multi-pollutant models with ozone (O<sub>3</sub>), and nitrogen dioxide (NO<sub>2</sub>). When PM<sub>10</sub> was also added to the model, the effect estimate remained relatively unchanged, although was no longer statistically significant (ISA, Figure 3–2). However, the ISA noted that the loss of statistical significance could have been the result of reduced statistical power since only three of the eight cities were included in the multi-pollutant analysis with PM (ISA, section 3.1.4.1).

The Childhood Asthma Management Program (CAMP, Schildcrout *et al.* 2006) examined the association between ambient air pollution and asthma exacerbations in children (n = 990) from eight North American cities. The median 24-hour average SO<sub>2</sub> concentrations (collected in seven of the eight study locations) ranged from 2.2 ppb in San Diego to 7.4 ppb in St. Louis. Positive associations with an increased risk of asthma symptoms were observed

at all lags, but only the association at the 3-day moving average was statistically significant (ISA, Figure 3–3). In joint-pollutant models with carbon monoxide (CO) and NO<sub>2</sub>, the 3-day moving average effect estimates remained robust and statistically significant. In a joint-pollutant model with PM<sub>10</sub>, the 3-day moving average effect estimate remained relatively unchanged, but was no longer statistically significant (ISA Figure 3–3).

A longitudinal study of schoolchildren (n = 1,844) during the summer months from the Harvard Six Cities Study suggested that the association between SO<sub>2</sub> and respiratory symptoms may potentially be confounded by PM<sub>10</sub> (Schwartz *et al.*, 1994). It should be noted that unlike the NCICAS and CAMP studies, this study was not limited to asthmatic children. The median 24-hour average SO<sub>2</sub> concentration during this period was 4.1 ppb. SO<sub>2</sub> concentrations were found to be statistically significantly associated with cough incidence and lower respiratory symptoms in single pollutant models. However, the effect of SO<sub>2</sub> was substantially reduced and no longer statistically significant after adjustment for PM<sub>10</sub> in a co-pollutant model. The ISA noted that because PM<sub>10</sub> concentrations were correlated strongly to SO<sub>2</sub>-derived sulfate particles (r = 0.80), the reduced SO<sub>2</sub> effect estimate may indicate that for PM<sub>10</sub> dominated by fine sulfate particles, PM<sub>10</sub> has a slightly stronger association than SO<sub>2</sub> to cough incidence and lower respiratory symptoms (ISA, section 3.1.4.1.1).

In addition to the three U.S. multi-city studies mentioned above, evidence of an association between ambient SO<sub>2</sub> and respiratory symptoms in children was found in two additional U.S. respiratory symptom studies. Delfino *et al.*, (2003) reported a statistically significant positive association between 1-hour daily maximum SO<sub>2</sub> concentrations in Los Angeles and respiratory symptoms in Hispanic children with asthma (n = 22). Similarly, Neas *et al.*, (1995) reported a positive association between 12-hour average SO<sub>2</sub> concentrations in Uniontown, PA and incidence of evening cough in 4th and 5th graders (n = 83; ISA section 3.1.4.1). Neither of these single city studies employed multi-pollutant models, but given the consistency of results with other epidemiologic evidence, they nonetheless support the association between ambient SO<sub>2</sub> concentrations and respiratory symptoms in children.

b. Emergency department visits and hospitalizations

Respiratory causes for ED and hospitalization visits typically include asthma, pneumonia, Chronic Obstructive Pulmonary Disorder (COPD), upper and lower respiratory infections, as well as other minor categories. Since the last review, there have been more than 50 peer reviewed epidemiologic studies published worldwide and overall, the ISA concluded that these studies provide evidence to support an association between ambient SO<sub>2</sub> concentrations and ED visits and hospitalizations for all respiratory causes and asthma (ISA, section 3.1.4.6). Notably, the ISA also found that when analyses of ED visit and hospitalizations for all respiratory causes were restricted by age, the results among children (0–14 years) and older adults (65+ years) were mainly positive, but not always statistically significant (ISA, section 3.1.4.6). In these same studies, when all age groups were combined, the ISA found that the results were mainly positive; however, the excess risk estimates were generally smaller compared to children and older adults (ISA, Figure 3–6). Results from key ED visit and hospital admission studies conducted in the U.S. are described in general below, and a more detailed discussion of both the U.S. and international literature can be found in the ISA (ISA, section 3.1.4.6).

Of the respiratory ED visit and hospital admission studies reviewed in the ISA, 10 key studies were conducted in the United States (ISA, Table 5–5). Of these 10 studies, three evaluated associations with SO<sub>2</sub> using multi-pollutant models (Schwartz *et al.*, (1995) in Tacoma, WA and New Haven CT; New York Department of Health (NYDOH), (2006) in Bronx and Manhattan, NY; and Ito *et al.*, (2007) in New York City), while seven studies evaluated the SO<sub>2</sub> effect using only single pollutant models (Wilson *et al.*, (2005) in Manchester, NH and Portland, ME; Peel *et al.*, (2005) in Atlanta, GA; Tolbert *et al.*, (2007) in Atlanta GA; Jaffe *et al.*, (2003) in Cleveland, Cincinnati and Columbus, OH; Schwartz *et al.*, (1996) in Cleveland OH; Sheppard *et al.*, (2003) in Seattle, WA; and Lin *et al.*, (2004) in Bronx, NY). Taken together, these studies generally reported positive, but frequently not statistically significant associations between ambient SO<sub>2</sub> and ED visits and hospital admissions for all respiratory causes and for asthma. With regard to U.S. studies employing multi-pollutant models, results reported in Bronx, NY (NYDOH 2006) and New York City, NY

(Ito *et al.*, 2007) remained robust and statistically significant in the presence of PM<sub>2.5</sub>, [10% (4, 16) and 29.6% (14.3, 46.8), respectively] while in New Haven, CT (Schwartz *et al.*, 1995) results remained robust and statistically significant in the presence of PM<sub>10</sub> [2% (1, 3)]. However, in Manhattan, NY (NYDOH 2006) results reported from single, and multi-pollutant models were negative (although not statistically significantly negative), and in Tacoma, WA (Schwartz *et al.*, 1995) the SO<sub>2</sub> effect estimate [3% (1.6)] was reduced and no longer statistically significant in a multi-pollutant model with PM<sub>10</sub> [–1% (–4, 3)]. In models including gaseous co-pollutants, the SO<sub>2</sub> effect estimate in the Bronx, NY (NYDOH 2006) remained statistically significant in the presence of NO<sub>2</sub> [10% (4.15)], while in NYC (Ito *et al.*, 2007) the SO<sub>2</sub> effect estimate remained statistically significant in the presence of O<sub>3</sub> [26.8% (13.7, 41.5)] and CO [31.1% (16.7, 47.2)], but not in the presence of NO<sub>2</sub> [–1.6% (–16.7, 16.1)].

3. ISA conclusions regarding short-term (5-minutes to 24-hours) SO<sub>2</sub> exposures

As noted above, the ISA found that moderate or greater decrements in lung function occur in some exercising asthmatics exposed to SO<sub>2</sub> concentrations as low as 200–300 ppb for 5–10 minutes. The ISA also found that among asthmatics, both the percentage of individuals affected, and the severity of the response increased with increasing SO<sub>2</sub> concentrations. That is, at 5–10 minute concentrations ranging from 200–300 ppb, the lowest levels tested in free breathing chamber studies, approximately 5–30% percent of exercising asthmatics experienced moderate or greater decrements in lung function (ISA, Table 3–1). At concentrations of 400–600 ppb, moderate or greater decrements in lung function occurred in approximately 20–60% of exercising asthmatics, and compared to exposures at 200–300 ppb, a larger percentage of asthmatics experienced severe decrements in lung function (*i.e.*, ≥200% increase in sRaw, and/or a ≥20% decrease in FEV<sub>1</sub>) (ISA, Table 3–1). Moreover, at SO<sub>2</sub> concentrations ≥400 ppb (5–10 minute exposures), moderate or greater decrements in lung function were frequently accompanied by respiratory symptoms.

In addition, the ISA concluded that epidemiologic studies of respiratory symptoms in children, as well as emergency department visits and hospitalizations for all respiratory causes and asthma 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). It was coherent in that respiratory symptom results from epidemiologic studies of short-term (predominantly 1-hour daily maximum or 24-hour average) SO<sub>2</sub> 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 ED visits and hospitalizations observed in epidemiologic studies (ISA, section 5.2). In addition, the ISA concluded that U.S. and international epidemiologic studies employing multi-pollutant models suggested that SO<sub>2</sub> had a generally independent effect on respiratory morbidity outcomes (ISA, section 5.2).

The ISA also found that the respiratory effects of SO<sub>2</sub> were consistent with the mode of action as it is currently understood from animal toxicological and human exposure studies (ISA, section 5.2). The immediate effect of SO<sub>2</sub> on the respiratory system is bronchoconstriction. This response is mediated by chemosensitive receptors in the tracheobronchial tree. Activation of these receptors triggers central nervous system reflexes that result in bronchoconstriction and respiratory symptoms that are often followed by rapid shallow breathing (ISA, section 5.2). The ISA noted that asthmatics are likely more sensitive to the respiratory effects of SO<sub>2</sub> due to pre-existing inflammation associated with the disease. For example, pre-existing inflammation may lead to enhanced release of inflammatory mediators, and/or enhanced sensitization of the chemosensitive receptors (ISA, section 5.2).

Taken together, the ISA concluded that the controlled human exposure, epidemiologic, and toxicological evidence supported its determination of a causal relationship between respiratory morbidity and short-term (5-minutes to 24-hours) exposure to SO<sub>2</sub>.

4. Health effects and long-term exposures to SO<sub>2</sub>

There were numerous studies published since the last review examining possible associations between long-term SO<sub>2</sub> exposure and mortality and morbidity (respiratory morbidity, carcinogenesis, adverse prenatal and neonatal outcomes)

endpoints. However, the ISA concluded that the evidence relating long-term (weeks to years) SO<sub>2</sub> exposure to adverse health effects was “inadequate to infer the presence or absence of a causal relationship” (ISA, Table 5–3). 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<sub>2</sub> was truly associated with these health outcomes (ISA, Table 1–2).

#### 5. SO<sub>2</sub>-related impacts on public health

Interindividual variation in human responses to air pollutants indicates that some subpopulations are at increased risk for the detrimental effects of ambient exposure to SO<sub>2</sub>. The NAAQS are intended to provide an adequate margin of safety for both general populations and sensitive subpopulations, or those subgroups potentially at increased risk for health effects in response to ambient air pollution. To facilitate the identification of subpopulations at the greatest risk for SO<sub>2</sub>-related health effects, studies have identified factors that contribute to the susceptibility and/or vulnerability of an individual to SO<sub>2</sub>. Susceptible individuals are broadly defined as those with a greater likelihood of an adverse outcome given a specific exposure in comparison with the general population (American Lung Association, 2001). The susceptibility of an individual to SO<sub>2</sub> can encompass a multitude of factors which represent normal developmental phases (*e.g.*, age) or biologic attributes (*e.g.*, gender); however, other factors (*e.g.*, socioeconomic status (SES)) may influence the manifestation of disease and also increase an individual's susceptibility (American Lung Association, 2001). In addition, subpopulations may be vulnerable to SO<sub>2</sub> in response to an increase in their exposure during certain windows of life (*e.g.*, childhood or old age) or as a result of external factors (*e.g.*, SES) that contribute to an individual being disproportionately exposed to higher concentrations than the general population. It should be noted that in some cases specific factors may affect both the susceptibility and vulnerability of a subpopulation to SO<sub>2</sub>. For example, a subpopulation that is characterized as having low SES may have less access to healthcare resulting in the manifestation of a disease, which increases their susceptibility to SO<sub>2</sub>, but they may also reside in a location that results in exposure to higher concentrations of SO<sub>2</sub>, increasing their vulnerability to SO<sub>2</sub>.

To examine whether SO<sub>2</sub> differentially affects certain subpopulations, stratified analyses are often conducted in epidemiologic investigations to identify the presence or absence of effect modification. A thorough evaluation of potential effect modifiers may help identify subpopulations that are more susceptible and/or vulnerable to SO<sub>2</sub>. These analyses require the proper identification of confounders and their subsequent adjustment in statistical models, which helps separate a spurious from a true causal association. Although the design of toxicological and human clinical studies does not allow for an extensive examination of effect modifiers, the use of animal models of disease and the study of individuals with underlying disease or genetic polymorphisms do allow for comparisons between subgroups. Therefore, the results from these studies, combined with those results obtained through stratified analyses in epidemiologic studies, contribute to the overall weight of evidence for the increased susceptibility and vulnerability of specific subpopulations to SO<sub>2</sub>. Those groups identified in the ISA to be potentially at greater risk of experiencing an adverse health effect from SO<sub>2</sub> exposure are described in more detail below.

##### a. Pre-existing respiratory disease

In human clinical studies, asthmatics have been shown to be more responsive to the respiratory effects of SO<sub>2</sub> exposure than healthy non-asthmatics. Although SO<sub>2</sub>-attributable decrements in lung function have generally not been demonstrated at concentrations ≤ 1000 ppb in non-asthmatics, statistically significant increases in respiratory symptoms and decreases in lung function have consistently been observed in exercising asthmatics following 5–10 minute SO<sub>2</sub> exposures at concentrations ranging from 400–600 ppb (ISA, section 4.2.1.1). Moderate or greater SO<sub>2</sub>-induced decrements in lung function have also consistently been observed at SO<sub>2</sub> concentrations ranging from 200–300 ppb in some asthmatics. The ISA also noted that a number of epidemiologic studies have reported respiratory morbidity in asthmatics associated with ambient SO<sub>2</sub> concentrations (ISA 4.2.1.1). For example, numerous epidemiologic studies have observed positive associations between ambient SO<sub>2</sub> concentrations and ED visits and hospitalizations for asthma (ISA section 4.2.1.1). Overall, the ISA concluded that epidemiologic and controlled human exposure studies indicated that

individuals with pre-existing respiratory diseases, particularly asthma, are at greater risk than the general population of experiencing SO<sub>2</sub>-associated health effects (ISA, section 4.2.1.1).

##### b. Genetics

The ISA noted that a consensus now exists among scientists that the potential for genetic factors to increase the risk of experiencing adverse health effects due to ambient air pollution merits serious consideration. Several criteria must be satisfied in selecting and establishing useful links between polymorphisms in candidate genes and adverse respiratory effects. First, the product of the candidate gene must be significantly involved in the pathogenesis of the effect of interest, which is often a complex trait with many determinants. Second, polymorphisms in the gene must produce a functional change in either the protein product or in the level of expression of the protein. Third, in epidemiologic studies, the issue of effect modification by other genes or environmental exposures must be carefully considered (ISA section 4.2.2).

Although many studies have examined the association between genetic polymorphisms and susceptibility to air pollution in general, only one study has specifically examined the effects of SO<sub>2</sub> exposure on genetically distinct subpopulations. Winterton *et al.* (2001) found a significant association between SO<sub>2</sub>-induced decrements in FEV<sub>1</sub> and the homozygous wild-type allele in the promoter region of Tumor Necrosis Factor- $\alpha$  (TNF- $\alpha$ ; AA, position-308). However, the ISA concluded that the overall body of evidence was too limited to reach a conclusion regarding the effects of SO<sub>2</sub> exposure on genetically distinct subpopulations at this time.

##### c. Age

The ISA identified children (*i.e.*, < 18 years of age) and older adults (*i.e.*, > 65 years of age) as groups that are potentially at greater risk of experiencing SO<sub>2</sub>-associated adverse health effects. In children, the developing lung is prone to damage from environmental toxicants as it continues to develop through adolescence. The biological basis for increased risk in the elderly is unknown, but one hypothesis is that it may be related to changes in antioxidant defenses in the fluid lining the respiratory tract. The ISA found a number of epidemiologic studies that observed increased respiratory symptoms in children associated with increasing SO<sub>2</sub> concentrations. In addition, several studies have reported

that the excess risk estimates for ED visits and hospitalizations for all respiratory causes, and to a lesser extent asthma, associated with a 10-ppb increase in 24-hour average SO<sub>2</sub> concentrations were higher for children and older adults than for all ages together (ISA, section 4.2.3). However, the ISA also noted that the evidence from controlled human exposure studies does not suggest that adolescents are either more or less at risk than adults to the respiratory effects of SO<sub>2</sub>, but rather adolescents may experience similar respiratory effects at a given exposure concentration (ISA, sections 3.1.3.5 and 4.2.3).<sup>8</sup> Overall, the ISA found that compared to the general population, there was limited evidence to suggest that children and older adults are at greater risk of experiencing SO<sub>2</sub>-associated health effects (ISA, section 4.2.3).

#### d. Time spent outdoors

Outdoor SO<sub>2</sub> concentrations are generally much higher than indoor concentrations. Thus, the ISA noted that individuals who spend a significant amount of time outdoors are likely at greater risk of experiencing SO<sub>2</sub>-associated health effects than those who spend most of their time indoors (ISA section 4.2.5).

#### e. Ventilation rate

Controlled human exposure studies have demonstrated that decrements in lung function and respiratory symptoms occur at significantly lower SO<sub>2</sub> exposure levels in exercising subjects compared to resting subjects. As ventilation rate increases, breathing shifts from nasal to oronasal, thus resulting in greater uptake of SO<sub>2</sub> in the tracheobronchial airways due to the diminished absorption of SO<sub>2</sub> in the nasal passages. Therefore, individuals who spend a significant amount of time at elevated ventilation rates (*e.g.* while playing, exercising, or working) are expected to be at greater risk of experiencing SO<sub>2</sub>-associated health effects (ISA section 4.2.5).

#### f. Socioeconomic status

There is limited evidence that increased risk to SO<sub>2</sub> exposure is associated with lower SES (ISA section 4.2.5). Finkelstein *et al.* (2003) found that among people with below-median income, the relative risk for above-median exposure to SO<sub>2</sub> was 1.18 (95% CI: 1.11, 1.26); the corresponding

relative risk among subjects with above-median income was 1.03 (95% CI: 0.83, 1.28). However, the ISA concluded that there was insufficient evidence to reach a conclusion regarding SES and exposure to SO<sub>2</sub> at this time (ISA section 4.2.5).

#### g. Size of at-risk populations

Considering the size of the groups mentioned above, large proportions of the U.S. population are likely to have a relatively high risk of experiencing SO<sub>2</sub>-related health effects. In the United States, approximately 7% of adults and 9% of children have been diagnosed with asthma. Notably, the prevalence and severity of asthma is higher among certain ethnic or racial groups such as Puerto Ricans, American Indians, Alaskan Natives, and African Americans (EPA 2008b). Furthermore, a higher prevalence of asthma among persons of lower SES and an excess burden of asthma hospitalizations and mortality in minority and inner-city communities have been observed. In addition, population groups based on age comprise substantial segments of individuals that may be potentially at risk for SO<sub>2</sub>-related health impacts. Based on U.S. census data from 2000, about 72.3 million (26%) of the U.S. population are under 18 years of age, 18.3 million (7.4%) are under 5 years of age, and 35 million (12%) are 65 years of age or older. There is also concern for the large segment of the population that is potentially at risk to SO<sub>2</sub>-related health effects because of increased time spent outdoors at elevated ventilation rates (those who work or play outdoors). Overall, the considerable size of the population groups at risk indicates that exposure to ambient SO<sub>2</sub> could have a significant impact on public health in the United States.

#### C. Human exposure and health risk characterization

To put judgments about SO<sub>2</sub>-associated health effects into a broader public health context, EPA has drawn upon the results of the quantitative exposure and risk assessments. Judgments reflecting the nature of the evidence and the overall weight of the evidence are taken into consideration in these quantitative exposure and risk assessments, discussed below. These assessments provide estimates of the likelihood that asthmatics at moderate or greater exertion (*e.g.* while exercising) would experience SO<sub>2</sub> exposures of potential concern as well as an estimate of the number and percent of exposed asthmatic individuals likely to experience SO<sub>2</sub>-induced lung function responses (*i.e.*,

moderate or greater decrements in lung function defined in terms of sRaw or FEV<sub>1</sub>) under varying air quality scenarios (*e.g.*, just meeting the current or alternative standards). These assessments also characterize the kind and degree of uncertainties inherent in such estimates.

This section describes the approach taken in the REA to characterize SO<sub>2</sub>-related exposures and health risks. Goals of the REA included estimating short-term exposures and potential human health risks associated with (1) recent levels of ambient SO<sub>2</sub>; (2) SO<sub>2</sub> levels adjusted to simulate just meeting the current standards; and (3) SO<sub>2</sub> levels adjusted to simulate just meeting potential alternative 1-hour standards. This section discusses the scientific evidence from the ISA that was used as the basis for the risk characterization (II.C.1), the approaches used in characterizing exposures and risks (II.C.2), and important uncertainties associated with these analyses (II.C.3). The results of the exposure and risk analyses, as they relate to the current and potential alternative standards, are discussed in subsequent sections of this proposal (sections II.E and II.F, respectively).

##### 1. Evidence base for the risk characterization

As previously mentioned, the ISA concluded that the evidence for an association between respiratory morbidity and SO<sub>2</sub> exposure was “sufficient to infer a causal relationship” (ISA, section 5.2) and that the “definitive evidence” for this conclusion was from the results of 5–10 minute controlled human exposure studies demonstrating decrements in lung function and/or respiratory symptoms in exercising asthmatics (ISA, section 5.2). Accordingly, the REA concluded that quantitative exposure and risk analyses should focus on 5-minute levels of SO<sub>2</sub> in excess of potential health effect benchmark values derived from the controlled human exposure literature (REA, section 6.2). These benchmark levels are not potential standards, but rather are concentrations which represent “exposures of potential concern” which are used in the analyses to estimate potential exposures and risks associated with 5-minute concentrations of SO<sub>2</sub>. In addition, although the REA concluded that the epidemiologic evidence was not appropriate for use in quantitative risk analyses (REA, section 6.3), these studies were considered in the selection of potential alternative standards for use in the air quality, exposure and risk analyses (REA, chapter 5), as well as in

<sup>8</sup> Very young children are not included in controlled human exposure studies and this absence of data on what is likely to be a sensitive life stage is a source of uncertainty for children's susceptibility.

the REA's assessment of the adequacy of the current and potential alternative primary standards (REA, sections 10.3; 10.4; and 10.5).

As mentioned above, the health effect benchmark values used in the REA were derived primarily from the ISA's evaluation of the 5–10 minute controlled human exposure literature. The ISA concluded that moderate or greater decrements in lung function occurred in approximately 5–30% of exercising asthmatics following exposure to 200–300 ppb SO<sub>2</sub> for 5–10 minutes. As explained in section II.B.1.b, the ISA concluded that moderate or greater decrements in lung function occurred in approximately 20–60% of exercising asthmatics following exposure to 400–600 ppb SO<sub>2</sub> for 5–10 minutes. The ISA also concluded that at SO<sub>2</sub> concentrations  $\geq$  400 ppb, statistically significant moderate or greater decrements in lung function at the group mean level have often been reported and are frequently accompanied by respiratory symptoms (ISA, section 3.1.3.5).

In addition to the health evidence from the ISA presented above, when considering potential health effect benchmark levels, the REA noted: (1) Subjects participating in human exposure studies typically do not include individuals who may be most susceptible to the respiratory effects of SO<sub>2</sub>, (e.g., the most severe asthmatics given the obvious ethical issues of subjecting such persons to the clinical tests) and (2) given that approximately 5–30% of exercising asthmatics experienced moderate or greater decrements in lung function following exposure to 200–300 ppb SO<sub>2</sub> (the lowest levels tested in free-breathing chamber studies), it is likely that a percentage of exercising asthmatics would also experience similar decrements in lung function following exposure to levels lower than 200 ppb (REA, section 6.2). That is, the REA concluded that there was no evidence to suggest that 200 ppb represented a threshold level below which no adverse respiratory effects would occur (REA, section 6.2). Moreover, the REA considered that small SO<sub>2</sub>-induced lung function decrements have been observed in exercising asthmatics at concentrations as low as 100 ppb when SO<sub>2</sub> is administered via mouthpiece (ISA, section 3.1.3).

Taken together, the REA concluded it appropriate to examine potential 5-minute benchmark values in the range of 100–400 ppb (REA, section 6.2). The lower end of the range considered the factors mentioned above, while the upper end of the range recognized that

400 ppb represents the lowest concentration at which moderate or greater decrements in lung function are frequently accompanied by respiratory symptoms (REA, section 6.2): a combination of effects which would clearly be considered adverse under ATS guidelines (ATS, 1985).

Although the analysis of exposures of potential concern were conducted using discrete benchmark levels (i.e., 100, 200, 300, 400 ppb), EPA recognizes that there is no sharp breakpoint within the continuum ranging from and above 400 ppb down to 100 ppb. In considering the concept of exposures of potential concern, it is important to balance concerns about the potential for health effects and their severity with the increasing uncertainty associated with our understanding of the likelihood of such effects at lower SO<sub>2</sub> levels. Within the context of this continuum, estimates of exposures of potential concern at discrete benchmark levels provide some perspective on the potential public health impacts of SO<sub>2</sub>-related health effects that have been demonstrated in controlled human exposure studies. They also help in understanding the extent to which such impacts could change by just meeting the current and potential alternative standards. However, estimates of the number of asthmatics likely to experience exposures of potential concern cannot be translated directly into quantitative estimates of the number of people likely to experience specific health effects. Due to individual variability in responsiveness, only a subset of asthmatics exposed at and above a specific benchmark level can be expected to experience health effects. The amount of weight to place on the estimates of exposures of potential concern at any of these benchmark levels depends in part on the weight of the scientific evidence concerning health effects associated with SO<sub>2</sub> exposures at and above that benchmark level. Such public health policy judgments are embodied in the NAAQS standard setting criteria (i.e., standards that, in the judgment of the Administrator, are requisite to protect public health with an adequate margin of safety).

Since exposures of potential concern cannot be directly translated into quantitative estimates of the number of individuals likely to experience specific health effects, the REA not only characterizes exposure and risks utilizing exposures of potential concern, but also uses information from the controlled human exposure literature to conduct a quantitative risk assessment. The quantitative risk assessment

estimated the number and percentage of exposed asthmatics at moderate or greater exertion expected to experience a moderate or greater lung function response (in terms of a  $\geq$  100% increase in sRaw and/or a  $\geq$  15% decline in FEV<sub>1</sub>; see section II.C.2).

## 2. Overview of approaches

As noted above, the purpose of the assessments described in the REA was to characterize air quality, exposures, and health risks associated with recent ambient levels of SO<sub>2</sub>, with SO<sub>2</sub> levels that could be associated with just meeting the current SO<sub>2</sub> NAAQS, and with SO<sub>2</sub> levels that could be associated with just meeting potential alternative standards. The REA utilizes three approaches to characterize health risks. In the first approach, for each air quality scenario, statistically estimated<sup>9</sup> and measured ambient 5-minute SO<sub>2</sub> concentrations were compared to the 5-minute potential health effect benchmark levels discussed above which (as noted) were derived from the controlled human exposure literature (REA, chapter 7). In the second approach, modeled estimates of 5-minute exposures in asthmatics at moderate or greater exertion (e.g. while exercising) were compared to these 5-minute potential health effect benchmark levels. In the third approach, exposure-response relationships from individual level data from controlled human exposure studies were used in conjunction with the outputs of the exposure analysis to estimate health impacts under the air quality scenarios mentioned above. A brief description of these approaches is provided below and each approach is described in detail in chapters 7 through 9 of the REA.

In the first approach, statistically estimated and actual measured 5-minute ambient SO<sub>2</sub> concentrations were compared to 5-minute potential health effect benchmark levels (REA, chapter 7). The results generated from the air quality analysis were considered a broad characterization of national air

<sup>9</sup>Benchmark values derived from the controlled human exposure literature were associated with a 5-minute averaging time. However, only 98 ambient monitors located in 13 states from 1997–2007 reported measured 5-minute SO<sub>2</sub> concentrations since such monitoring is not required (see section III). In contrast, 809 monitors in 48 states, DC, Puerto Rico, and the Virgin Islands reported 1-hour SO<sub>2</sub> concentrations over a similar time period. Therefore, to broaden analyses to areas where measured 5-minute SO<sub>2</sub> concentrations were not available, the REA utilized a statistical relationship to estimate the highest 5-minute level in an hour, given a reported 1-hour average SO<sub>2</sub> concentration (REA, section 6.4). Then, similar to measured 5-minute SO<sub>2</sub> levels, statistically estimated 5-minute SO<sub>2</sub> concentrations were compared to 5-minute potential health effect benchmark values.

quality and human exposures that might be associated with these 5-minute SO<sub>2</sub> concentrations. An advantage of the air quality analysis is its relative simplicity; however, there is uncertainty associated with the assumption that SO<sub>2</sub> air quality can serve as an adequate surrogate for total exposure to ambient SO<sub>2</sub>. Actual exposures might be influenced by factors not considered by this approach, including small scale spatial variability in ambient SO<sub>2</sub> concentrations (which might not be captured by the network of fixed-site ambient monitors) and spatial/temporal variability in human activity patterns.

In the second approach, an inhalation exposure model was used to generate more realistic estimates of personal exposures in asthmatics (REA, chapter 8). This analysis estimated temporally and spatially variable ambient 5-minute SO<sub>2</sub> concentrations and simulated asthmatics contact with these pollutant concentrations while at moderate or greater exertion (*i.e.*, while at elevated ventilation rates). The approach was designed to estimate exposures that are not necessarily represented by the existing ambient monitoring data. AERMOD, an EPA dispersion model, was used to estimate 1-hour ambient SO<sub>2</sub> concentrations using emissions estimates from stationary, non-point, and port sources. The Air Pollutants Exposure (APEX) model, an EPA human exposure model, was then used to estimate population exposures using the estimated hourly census block level SO<sub>2</sub> concentrations. From these 1-hour census block concentrations, 5-minute maximum SO<sub>2</sub> concentrations within each hour were estimated using the statistical relationship mentioned above. A probabilistic approach was then used to model asthmatics' exposures considering: (1) Time spent in different microenvironments; (2) time spent at moderate or greater exertion; and (3) the variable SO<sub>2</sub> concentrations that occur within these microenvironments across time, space, and microenvironment type. Estimates of personal exposure to 5-minute SO<sub>2</sub> levels were then compared to the 5-minute potential health benchmark levels (*i.e.*, 5-minute benchmark levels of 100, 200, 300, and 400 ppb). This approach to assessing exposures was more resource intensive than using ambient levels as an indicator of exposure; therefore, the final REA included the analysis of two locations: St Louis and Greene County, MO. Although the geographic scope of this analysis was limited, the approach provided estimates of SO<sub>2</sub> exposures in asthmatics and asthmatic children in St. Louis and Greene Counties and thus,

served to complement the broader air quality characterization.

For the characterization of risks in both the air quality analysis and the exposure modeling analysis described above, the REA used a range of 5-minute potential health effect benchmarks: 100, 200, 300, and 400 ppb. These benchmark values were compared to both SO<sub>2</sub> air quality levels and to estimates of SO<sub>2</sub> exposure in asthmatics. When SO<sub>2</sub> air quality was used as an indicator of exposure, a key output of the analysis was an estimate of the number of days per year specific locations experienced statistically estimated 5-minute daily maximum levels of SO<sub>2</sub> that exceeded one of these 5-minute potential health effect benchmarks. When personal exposures were simulated, the output of the analysis was an estimate of the number and percent of asthmatics and asthmatic children at risk for experiencing, at least once per year, a statistically estimated 5-minute daily maximum level of SO<sub>2</sub> of ambient origin in excess of one of these benchmarks. An advantage of using the benchmark approach to characterize health risks is that the effects observed in the controlled human exposure studies clearly result from SO<sub>2</sub> exposure, so the benchmarks are reliable levels at which effects to asthmatics from exposure to SO<sub>2</sub> can occur. A limitation of this approach is that the magnitude of the SO<sub>2</sub> effect on decrements in lung function and respiratory symptoms can vary considerably from individual to individual and thus, not all asthmatics would be expected to respond to the same levels of SO<sub>2</sub> exposure. Therefore, numbers of exposures can be quantified more readily than the number of individuals experiencing SO<sub>2</sub>-induced lung function decrements and/or respiratory symptoms.

The third approach was a quantitative risk assessment. This approach combined results from the exposure analysis (*i.e.*, the number of exposed total asthmatics or asthmatic children while at moderate or greater exertion) with exposure-response functions derived from individual level data from controlled human exposure studies (see ISA, Table 3-1 and Johns (2009)<sup>10</sup>) to estimate the percentage and number of exposed asthmatics and asthmatic children likely to experience a moderate or greater lung function response (*i.e.*, decrements in lung function defined in

terms of FEV<sub>1</sub> and sRaw) under the air quality scenarios mentioned above (REA, chapter 9). The advantage of this approach is that it recognizes that not all exposed asthmatics at moderate or greater exertion will have a lung function response. Moreover, it is advantageous in that rather than considering discrete potential health effect benchmark levels, it quantitatively estimates the number and percent of asthmatics and asthmatic children likely to experience a moderate or greater lung function response considering the entire distribution of personal exposures.

### 3. Key limitations and uncertainties

The way in which air quality, exposure, and risk results will inform ultimate decisions regarding the current and potential alternative SO<sub>2</sub> standards will depend upon the weight placed on each of the analyses when uncertainties associated with those analyses are taken into consideration. Sources of uncertainty associated with each of the analyses (air quality, exposure, and quantitative risk) are briefly presented below and are described in more detail in chapters 7-9 of the REA.

In the air quality analysis, the REA used ambient SO<sub>2</sub> data from both the limited number of monitors reporting 5-minute concentrations and the broader network of monitors reporting 1-hour concentrations of SO<sub>2</sub> to characterize U.S. air quality. There was general agreement in the monitor site attributes and emissions sources potentially influencing ambient monitoring concentrations for each set of data analyzed. However, the REA noted that the greatest relative uncertainty was in the spatial representativeness of both the overall monitoring network and the subsets of monitors chosen for detailed analyses (REA, section 7.4.2.4).

An additional source of uncertainty in the air quality analysis is associated with the statistical model used to estimate 5-minute maximum SO<sub>2</sub> concentrations at monitors that reported only 1-hour SO<sub>2</sub> concentrations (REA, section 7.4.2.6). Cross-validation of statistically estimated 5-minute concentrations with the limited number of reported 5-minute SO<sub>2</sub> measurements indicated that the greatest difference in the predicted versus observed numbers of benchmark exceedances occurred at the lower and upper tails of the distribution. However, the REA noted that overall, the results of the cross-validation analysis indicated reasonable model performance (REA, sections 10.3.3.1 and 10.5.2).

The air quality characterization assumes that the ambient monitoring

<sup>10</sup>EPA recently conducted a complete quality assurance review of all individual subject data. The results of this review did not substantively change any of the entries in ISA, Table 3-1, and did not in anyway affect the conclusions of the ISA (see Johns and Simmons, 2009).

data and the estimated days per year with exceedances of the specified benchmark levels can serve as an indicator of exposure. Longer-term personal SO<sub>2</sub> exposure (*i.e.*, days to weeks) concentrations are correlated with and are a fraction of ambient SO<sub>2</sub> concentrations. However, uncertainty remains in this relationship when considering short-term (*i.e.*, 5-minute) averaging times because of the lack of comparable measurement data (REA, section 7.4.2.7).

The St. Louis and Greene county exposure assessments were also associated with a number of key uncertainties that should be considered when interpreting the results with regard to decisions on the standard. Such uncertainties are highlighted below, and these, as well as other sources of uncertainty, are also discussed in greater depth in section 8.11 of the REA.

In the exposure analyses, it was necessary to derive an area source emission profile rather than use a default profile to improve the agreement between ambient measurements and model predicted 1-hour SO<sub>2</sub> concentrations. The improved model performance reduces uncertainty in the 1-hour SO<sub>2</sub> concentrations predictions, but nonetheless remains as an important uncertainty in the absence of actual local source emission profiles (REA, section 8.11.2).

The St. Louis and Greene county exposure assessments were performed to better reflect both the temporal and spatial representation of ambient concentrations and to estimate the rate of contact of asthmatic individuals with 5-minute SO<sub>2</sub> concentrations while engaged in moderate or greater exertion. Estimated annual average SO<sub>2</sub> exposures in the two exposure modeling domains are consistent with long-term personal exposures (*i.e.*, days to weeks) measured in other U.S. locations (REA, chapter 8). However, uncertainty remains in the estimated number of persons with 5-minute SO<sub>2</sub> concentrations above benchmark levels because of the lack of comparable measurement data, particularly considering both the short-term averaging time and geographic location (REA, section 8.11.2).

In addition, although all 5-minute ambient SO<sub>2</sub> concentrations in the exposure analyses were estimated by the exposure model, each hour was comprised of the maximum 5-minute SO<sub>2</sub> concentration and eleven other 5-minute SO<sub>2</sub> concentrations normalized to the 1-hour mean concentration. The REA assumed that this approach would reasonably estimate the number of individuals exposed to peak

concentrations. Sensitivity analyses revealed that both the number of persons exposed and where peak exposures occur can vary when considering an actual 5-minute temporal profile (REA, Section 8.11.2)

A number of key uncertainties should also be considered when interpreting the results of the St. Louis and Greene County risk assessment with regard to decisions on the standard. Such uncertainties associated with the St. Louis and Greene County risk assessment are discussed briefly below and in greater depth in section 9.4 of the REA.

In the quantitative risk assessment, it was necessary to estimate responses at SO<sub>2</sub> levels below the lowest exposure levels used in the free-breathing controlled human exposure studies (*i.e.*, below 200 ppb). Probabilistic exposure-response relationships were derived in the REA using two different functional forms (*i.e.*, probit and 2-parameter logistic), but nonetheless there remains greater uncertainty in responses below 200 ppb because of the lack of comparable experimental data. Moreover, because the controlled human exposure studies used in the risk assessment involved only SO<sub>2</sub> exposures, it was assumed in the REA that estimates of SO<sub>2</sub>-induced health responses are not affected by the presence of other pollutants (*e.g.*, PM<sub>2.5</sub>, O<sub>3</sub>, NO<sub>2</sub>; REA, section 9.4).

The risk assessment assumes that the SO<sub>2</sub>-induced responses for individuals are reproducible. The REA noted that this assumption had some support in that one study (Linn *et al.*, 1987) exposed the same subjects on two occasions to 600 ppb and the authors reported a high degree of correlation while observing a much lower correlation for the lung function response observed in the clean air with exercise exposure (REA, section 9.4).

Because the vast majority of controlled human exposure studies investigating lung function responses were conducted with adult subjects, the risk assessment relies on data from adult asthmatic subjects to estimate exposure-response relationships that have been applied to all asthmatic individuals, including children. The ISA (section 3.1.3.5) indicates that there is a strong body of evidence that suggests adolescents may experience many of the same respiratory effects at similar SO<sub>2</sub> levels, but recognizes that these studies administered SO<sub>2</sub> via inhalation through a mouthpiece (which can result in an increase in lung SO<sub>2</sub> uptake) rather than in an exposure chamber. Therefore, the uncertainty is greater in the risk

estimates for asthmatic children (REA, section 9.4)<sup>11</sup>.

#### *D. Considerations in review of the standards*

This section presents the integrative synthesis of the evidence and information contained in the ISA and the REA with regard to the current and potential alternative standards. EPA notes that the final decision on retaining or revising the current primary SO<sub>2</sub> standards is a public health policy judgment to be made by the Administrator. The Administrator's final decision will draw upon scientific information and analyses related to health effects, population exposures, and risks; as well as judgments about the appropriate response to the range of uncertainties that are inherent in the scientific evidence and analyses; and comments received in response to this proposal.

##### 1. Background on the current standards

There are currently two SO<sub>2</sub> primary standards. The 24-hour average standard is 0.14 ppm not to be exceeded more than once per year and the annual average standard is 0.03 ppm. In the last review of the SO<sub>2</sub> NAAQS, both the 24-hour and annual standards were retained. The rationale for the retention of these standards is discussed briefly below.

In the last review, retention of the 24-hour standard was based largely on epidemiologic studies conducted in London in the 1950s and 1960s. The results of those studies suggested an association between 24-hour average levels of SO<sub>2</sub> and increased daily mortality and aggravation of bronchitis when in the presence of elevated levels of PM (53 FR 14927). Additional epidemiologic evidence suggested that elevated SO<sub>2</sub> levels were associated with the possibility of small, reversible declines in children's lung function (53 FR 14927). However, it was noted that in the locations where these epidemiologic studies were conducted, high SO<sub>2</sub> levels were usually accompanied by high levels of PM, thus making it difficult to disentangle the individual contribution each pollutant had on these health outcomes. It was also noted that rather than 24-hour average SO<sub>2</sub> levels, the health effects observed in these studies may have been related, at least in part, to the

<sup>11</sup> Very young children were not included in the controlled human exposure data which served as the basis for the exposure-response relationships used in the risk assessment. This absence of data on what is likely to be a sensitive life stage is an additional source of uncertainty in the risk assessment.

occurrence of shorter-term peaks of SO<sub>2</sub> within a 24-hour period (53 FR 14927).

Retention of the annual standard in the last review was largely based on an assessment of qualitative evidence gathered from a limited number of epidemiologic studies. The strongest evidence for an association between annual SO<sub>2</sub> concentrations and adverse health effects in the 1982 AQCD was from a study conducted by Lunn et al (1967). The authors found that among children, a likely association existed between chronic upper and lower respiratory tract illnesses and annual SO<sub>2</sub> levels of 70–100 ppb in the presence of 230–301 µg/m<sup>3</sup> black smoke. Three additional studies described in the 1986 Second Addendum also suggested that long-term exposure to SO<sub>2</sub> was associated with adverse respiratory effects. Notably, studies conducted by Chapman *et al.* (1985) and Dodge *et al.* (1985) found associations between long-term SO<sub>2</sub> concentrations (with or without high particle concentrations) and cough in children and young adults. However, it was noted that there was considerable uncertainty associated with these studies because they were conducted in locations subject to high, short-term peak SO<sub>2</sub> concentrations (*i.e.*, locations near point sources); therefore it was difficult to discern whether this increase in cough was the result of long-term, low level SO<sub>2</sub> exposure, or repeated short-term peak SO<sub>2</sub> exposures.

It was concluded in the last review that there was no quantitative rationale to support a specific range for an annual standard (EPA, 1994b). However, it was also found that although no single epidemiologic study provided clear quantitative conclusions, there appeared to be some consistency across studies indicating the possibility of respiratory effects associated with long-term exposure to SO<sub>2</sub> just above the level of the existing annual standard (EPA, 1994b). In addition, air quality analyses conducted during the last review indicated that the short-term standards being considered (1-hour and/or 24-hour) could not by themselves prevent long-term concentrations of SO<sub>2</sub> from exceeding the level of the existing annual standard in several large urban areas. Ultimately, both the scientific evidence and the air quality analyses were used by the Administrator to conclude that retaining the existing annual standard was requisite to protect human health.<sup>12</sup>

<sup>12</sup> Section I.C above discusses potential standards considered but not adopted in the last review, notably some type of standard to deal with effects of 5 to 10 minute exposures.

2. Approach for reviewing the need to retain or revise the current standards

The decision in the present review on whether the current 24-hour and/or annual standards are requisite to protect public health with an adequate margin of safety will be informed by a number of scientific studies and analyses that were not available in the 1996 review. Specifically, as discussed above (section II.B), a large number of epidemiologic studies have been published since the 1996 review. Many of these studies evaluated associations between SO<sub>2</sub> and adverse respiratory endpoints (*e.g.*, respiratory symptoms, emergency department visits, hospital admissions) in locations where 24-hour and annual average SO<sub>2</sub> concentrations were below the levels allowed by the current standards. In addition, with respect to adverse health effects associated with 5-minute SO<sub>2</sub> concentrations, the REA described estimates of SO<sub>2</sub>-associated health risks that could be present in counties that just meet the current 24-hour or annual standards, whichever was controlling in a given county.<sup>13</sup> The approach for considering this scientific evidence and exposure/risk information is discussed below.

To evaluate whether the current primary SO<sub>2</sub> standards are adequate or whether consideration of revisions is appropriate, EPA is using an approach in this review described in chapter 10 of the REA which builds upon the approaches used in reviews of other criteria pollutants, including the most recent reviews of the NO<sub>2</sub>, Pb, O<sub>3</sub>, and PM NAAQS (EPA, 2008c; EPA, 2007c; EPA, 2007d; EPA, 2005), and reflects the body of evidence and information that is currently available. As in other recent reviews, EPA's considerations will include the implications of placing more or less weight or emphasis on different aspects of the scientific evidence and the exposure/risk-based information, recognizing that the weight to be given to various elements of the evidence and exposure/risk information is part of the public health policy judgments that the Administrator will

<sup>13</sup> As noted in the REA, the controlling standard by definition would be the standard that allows air quality to just meet either the annual concentration level of 30.4 ppb (*i.e.*, the annual standard is the controlling standard) or the 2nd highest 24-hour concentration level of 144 ppb (*i.e.*, the 24-hour standard is the controlling standard). The factor selected is derived from a single monitor within each county (even if there is more than one monitor in the county) for a given year. A different (or the same) monitor in each county could be used to derive the factor for other years; the only requirement for selection is that it be the lowest factor, whether derived from the annual or 24-hour standard level.

make in reaching decisions on the standard.

A series of general questions frames this approach to considering the scientific evidence and exposure-/risk-based information. First, EPA's consideration of the scientific evidence and exposure/risk information with regard to the adequacy of the current standards is framed by the following questions:

- To what extent does evidence that has become available since the last review reinforce or call into question evidence for SO<sub>2</sub>-associated effects that were identified in the last review?

- To what extent has evidence for different health effects and/or sensitive populations become available since the last review?

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

- To what extent does evidence and exposure-/risk-based information that has become available since the last review reinforce or call into question any of the basic elements of the current standard?

To the extent that the available evidence and exposure-/risk-based information suggests it may be appropriate to consider revision of the current standards, EPA considers that evidence and information with regard to its support for consideration of a standard that is either more or less stringent than the current standards. This evaluation is framed by the following questions:

- Is there evidence that associations, especially causal or likely causal associations, extend to ambient SO<sub>2</sub> concentrations as low as, or lower than, the concentrations that have previously been associated with health effects? If so, what are the important uncertainties associated with that evidence?

- Are exposures above benchmark levels and/or health risks estimated to occur in areas that meet the current standard? If so, are the estimated exposures and health risks important from a public health perspective? What are the important uncertainties associated with the estimated risks?

To the extent that there is support for consideration of a revised standard, EPA then considers the specific elements of the standard (indicator, averaging time, form, and level) within the context of the currently available information. In so doing, the Agency addresses the following questions regarding the elements of the standard:

- Does the evidence provide support for considering a different indicator for gaseous SO<sub>x</sub>?

- Does the evidence provide support for considering different, or additional averaging times?

- What ranges of levels and forms of alternative standards are supported by the evidence, and what are the associated uncertainties and limitations?

- To what extent do specific averaging times, levels, and forms of alternative standards reduce the estimated exposures above benchmark levels and risks attributable to exposure to ambient SO<sub>2</sub>, and what are the uncertainties associated with the estimated exposure and risk reductions?

The questions outlined above have been addressed in the REA. The following sections present considerations regarding the adequacy of the current standards and potential alternative standards, as discussed in chapter 10 of the REA, in terms of indicator, averaging time, form, and level.

#### E. Adequacy of the current standards

In considering the adequacy of the current standards, the policy assessment chapter of the REA considered the scientific evidence assessed in the ISA, as well as the air quality, exposure, and risk-based information presented in the REA. A summary of this evidence and information as well as CASAC recommendations and the Administrator's conclusions regarding the adequacy of the current standards are presented below. Section II.E.1 will discuss the adequacy of the current 24-hour standard and Section II.E.2 will then discuss adequacy of the current annual standard. Section II.E.3 will discuss CASAC views and finally, section II.E.4 discusses the Administrator's conclusions regarding the adequacy of the current 24-hour and annual standards.

##### 1. Adequacy of the current 24-hour standard

###### a. Evidence-based considerations

In considering the SO<sub>2</sub> epidemiologic studies as they relate to the adequacy of the current 24-hour standard, the REA noted that 24-hour average SO<sub>2</sub> concentrations were below the current 24-hour average SO<sub>2</sub> NAAQS in many locations where positive and sometimes statistically significant associations were observed (REA, section 10.3). As discussed previously (see section II.B.3), the ISA characterized the epidemiologic evidence for respiratory effects as being consistent and coherent (ISA, section 5.2). The evidence is consistent in that positive associations are reported in studies conducted in numerous

locations and with a variety of methodological approaches (ISA, section 5.2). It is coherent in the sense that respiratory symptom results from epidemiologic studies predominantly using 1-hour daily maximum or 24-hour average SO<sub>2</sub> concentrations are generally in agreement with the respiratory symptom results from controlled human exposure studies of 5–10 minutes. These results are also coherent in that the respiratory effects observed in controlled human exposure studies of 5–10 minutes provide a basis for a progression of respiratory morbidity that could lead to the ED visits and hospitalizations observed in epidemiologic studies (ISA, section 5.2). The ISA also noted that when the epidemiologic literature is considered as a whole, there are generally positive associations between SO<sub>2</sub> and respiratory symptoms in children, hospital admissions, and emergency department visits. Moreover, some of these associations were statistically significant, particularly the more precise effect estimates (ISA, section 5.2).

The interpretation of these SO<sub>2</sub> epidemiologic studies is complicated by the fact that SO<sub>2</sub> is but one component of a complex mixture of pollutants present in the ambient air. In order to provide some perspective on this uncertainty, the ISA evaluates epidemiologic studies that employ multi-pollutant models. Specifically, the ISA noted that a number of SO<sub>2</sub> epidemiologic studies have attempted to disentangle the effects of SO<sub>2</sub> from those of co-occurring pollutants by utilizing multi-pollutant models. When evaluated as a whole, SO<sub>2</sub> effect estimates in these models generally remained positive and relatively unchanged when co-pollutants were included. Therefore, although recognizing the uncertainties associated with separating the effects of SO<sub>2</sub> from those of co-occurring pollutants, the ISA concluded that the limited available evidence indicates that the effect of SO<sub>2</sub> on respiratory health outcomes appears to be generally robust and independent of the effects of gaseous co-pollutants, including NO<sub>2</sub> and O<sub>3</sub>, as well as particulate co-pollutants, particularly PM<sub>2.5</sub> (ISA, section 5.2; p. 5–9).

In drawing broad conclusions regarding the evidence, the ISA considered the epidemiologic and experimental evidence as well as the uncertainties associated with that evidence. When this evidence and its associated uncertainties were taken together, the ISA concluded that the results of epidemiologic and experimental studies form a plausible and coherent data set that supports a

relationship between SO<sub>2</sub> exposures and respiratory endpoints, including respiratory symptoms and ED visits, at ambient concentrations that are present in areas that meet the current 24-hour SO<sub>2</sub> NAAQS (ISA, section 5.5). Thus, taking into consideration the evidence discussed above, particularly the epidemiologic studies reporting SO<sub>2</sub>-associated health effects in locations that meet the current 24-hour standard, the REA concluded that the epidemiologic evidence calls into question the adequacy of the current 24-hour standard to protect public health (REA, section 10.3.4).

###### b. Air quality, exposure, and risk-based considerations

As previously mentioned, the ISA found the evidence for an association between respiratory morbidity and SO<sub>2</sub> exposure to be "sufficient to infer a causal relationship" (ISA, section 5.2) and that the "definitive evidence" for this conclusion comes from the results of controlled human exposure studies demonstrating decrements in lung function and/or respiratory symptoms in exercising asthmatics (ISA, section 5.2). Accordingly, the exposure and risk analyses presented in the REA focused on exposures and risks associated with 5-minute peaks of SO<sub>2</sub> in excess of the potential health effect benchmark values of 100, 200, 300, and 400 ppb SO<sub>2</sub>. In considering the results presented in these analyses, the REA particularly noted exceedances or exposures with respect to the 200 and 400 ppb 5-minute benchmark levels. These benchmark levels were highlighted in the REA because (1) 400 ppb represents the lowest concentration in controlled human exposure studies where moderate or greater lung function decrements which were often statistically significant at the group mean level, were frequently accompanied by respiratory symptoms; and (2) 200 ppb is the lowest level at which moderate or greater decrements in lung function in free-breathing human exposure studies have been observed (notably, 200 ppb is also the lowest level that has been tested). The REA also recognized that there was very limited evidence demonstrating small decrements in lung function at 100 ppb from two mouthpiece exposure studies. However, as previously noted (see section II.B.1.b), the results of these studies are not directly comparable to free-breathing chamber studies, and thus, the REA primarily considered exceedances of the 200 ppb and 400 ppb benchmark levels in its evaluation of the adequacy of the current 24-hour (as well

as the annual; see section II.E.2) standard.

A key output of the air quality analysis was the predicted number of statistically estimated 5-minute daily maximum SO<sub>2</sub> concentrations above benchmark levels given air quality simulated to just meet the level of the current 24-hour or annual SO<sub>2</sub> standard, whichever was controlling for a given county. Under this scenario, in 40 counties selected for detailed analysis, the REA found that the predicted yearly mean number of statistically estimated 5-minute daily maximum concentrations > 400 ppb ranges from 1–102 days per year,<sup>14</sup> with most counties in this analysis experiencing a mean of at least 20 days per year when statistically estimated 5-minute daily SO<sub>2</sub> concentrations exceed 400 ppb (REA, Table 7–14). In addition, the predicted yearly mean number of statistically estimated 5-minute daily maximum concentrations > 200 ppb ranged from 21–171 days per year, with about half of the counties in this analysis experiencing ≥ 70 days per year when 5-minute daily maximum SO<sub>2</sub> concentrations exceed 200 ppb (REA, Table 7–12).

The REA also generated exposure and risk estimates for two study areas in Missouri (*i.e.*, Greene County and several counties representing the St. Louis urban area) which had significant emission sources of SO<sub>2</sub>. As noted in REA 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. In addition, 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 differences in the number of asthmatics at elevated ventilation rates estimated to have a moderate or greater lung function response in Greene County when compared to St. Louis. The REA noted that the differences 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, the REA concluded that the St. Louis results were more informative in terms of ascertaining the extent to which the current standards protect against effects linked to the various benchmarks (linked in turn to 5-minute exposures). The results in fact suggested that the current standards may not adequately protect public health (REA, section 10.3.3). Moreover, the REA judged that the exposure and risk estimates for the St. Louis study area provided useful insights into exposures and risks for other urban areas in the U.S. with similar population and SO<sub>2</sub> emissions densities (REA, section 10.3.3).

When considering the St. Louis exposure results as they relate to the adequacy of the current standards, results discussed in the policy chapter of the REA included the percent of asthmatic children at moderate or greater exertion estimated to experience at least one exceedance of either the 200 or 400 ppb benchmark given air quality that was adjusted upward to simulate just meeting the current 24-hour standard (*i.e.*, the controlling standard in St. Louis).<sup>15</sup> Given this scenario, the REA found that approximately 24% of asthmatic children in that city would be estimated to experience at least one SO<sub>2</sub> exposure concentration greater than or equal to the 400 ppb benchmark level per year while at moderate or greater exertion (*e.g.*, while exercising; REA, Figure 8–19). Similarly, the REA found that approximately 73% of asthmatic children would be expected to experience at least one SO<sub>2</sub> exposure greater than or equal to a 200 ppb benchmark level while at moderate or greater exertion (REA, Figure 8–19).

When considering the St. Louis risk results as they relate to the adequacy of the current 24-hour standard, the policy assessment chapter of the REA included the percent of asthmatic children at elevated ventilation rates likely to experience at least one lung function response given air quality that is adjusted upward to simulate just meeting the current standards. Under this scenario, 19.1% to 19.2% of exposed asthmatic children at elevated

ventilation rates were estimated to experience at least one moderate lung function response per year (defined as an increase in sRaw ≥ 100% (REA, Table 9–8)).<sup>16</sup> Furthermore, 7.9% to 8.1% of exposed asthmatic children at moderate or greater exertion were estimated to experience at least one large lung function response per year (defined as an increase in sRaw ≥ 200% (REA, Table 9–8)).

c. Summary of considerations from the REA regarding the 24-hour standard

As noted above, the policy chapter of the REA considered several lines of scientific evidence when evaluating the adequacy of the current 24-hour standard to protect the public health. These included causality judgments made in the ISA, as well as the human exposure and epidemiologic evidence supporting those judgments. In particular, the REA concluded that numerous epidemiologic studies reporting positive associations between ambient SO<sub>2</sub> and respiratory morbidity endpoints were conducted in locations that met, or were below the current 24-hour standard (REA, section 10.3.4). The REA concluded that to the extent that these considerations are emphasized, the adequacy of the current 24-hour standard to protect the public health would clearly be called into question (REA, section 10.3.4). The REA found this suggested consideration of a revised 24-hour standard and/or that an additional shorter-averaging time standard may be needed to provide additional health protection for sensitive groups, including asthmatics and individuals who spend time outdoors at elevated ventilation rates (REA, section 10.3.4). This also suggested that an alternative SO<sub>2</sub> standard(s) should protect against health effects ranging from lung function responses and increased respiratory symptoms following 5–10 minute peak SO<sub>2</sub> exposures, to increased respiratory symptoms and respiratory-related ED visits and hospital admissions associated with 1-hour daily maximum or 24-hour average

<sup>16</sup> The risk results presented represent the median estimate of exposed asthmatics expected to experience moderate or greater lung function decrements. Results are presented for both the probit and 2-parameter logistic functional forms. The full range of estimates can be found in chapter 9 of the REA, and in all instances the smaller estimate is a result of using the probit function to estimate the exposure-response relationship.

<sup>17</sup> In this notice, risk results with respect to moderate or greater lung function responses are presented in terms of sRaw (*i.e.*, ≥ 100% increases in sRaw). Risk results with respect to decrements in lung function defined in terms of FEV<sub>1</sub> can be found in chapter 9 of the REA.

<sup>14</sup> Air quality estimates presented in this section represent the mean number of days per year when 5-minute daily maximum SO<sub>2</sub> concentrations exceed a particular benchmark level given 2001–2006 air quality adjusted to just meet the current standards (see REA, Tables 7–11 to 7–14).

<sup>15</sup> Exposure and risk results presented in this notice are with respect to asthmatic children, results for all asthmatics are presented in REA chapters, 8, 9, and 10.

SO<sub>2</sub> concentrations (REA, section 10.3.4).

In examining the air quality, exposure, and risk-based information with regard to the adequacy of the current 24-hour SO<sub>2</sub> standard to protect the public health, the REA found that the results described above (and in more detail in chapters 7–9 of the REA) indicated that 5-minute exposures that could reasonably be judged important from a public health perspective (see section II.B.1.c) were associated with air quality adjusted upward to simulate just meeting the current 24-hour standard. These exposures were judged in the REA to be significant from a public health perspective due to their frequency: approximately 24% of child asthmatics at moderate or greater exertion in St. Louis are estimated to be exposed at least once per year to air quality exceeding the 5-minute 400 ppb benchmark, a level associated with lung function decrements in the presence of respiratory symptoms. Additionally, approximately 73% of child asthmatics in St. Louis would be expected to be exposed at least once per year to air quality exceeding the 5-minute 200 ppb benchmark. Moreover, slightly over 19% of exposed child asthmatics in St. Louis would be expected to experience at least one adverse lung function response (defined in terms of a  $\geq 100\%$  increase in sRaw) each year. Therefore, the REA concluded that the air quality, exposure, and risk-based considerations reinforced the epidemiologic evidence in supporting the conclusion that consideration should be given to revising the current 24-hour standard and/or setting a new shorter averaging time standard (*e.g.*, 1-hour or less) to provide increased public health protection, especially for sensitive groups (*e.g.*, asthmatics), from SO<sub>2</sub>-related adverse health effects (REA, section 10.3.4).

## 2. Adequacy of the current annual standard

In considering the adequacy of the current annual standard, the policy assessment chapter of the REA considered the scientific evidence assessed in the ISA and the air quality, exposure, and risk-based information presented in the REA. A summary of this evidence and information is presented below.

### a. Evidence-based considerations

As an initial consideration with regard to the adequacy of the current annual standard, the REA noted that evidence relating long-term (weeks to years) SO<sub>2</sub> exposure to adverse health effects (respiratory morbidity,

carcinogenesis, adverse prenatal and neonatal outcomes, and mortality) was judged by the ISA to be “inadequate to infer the presence or absence of a causal relationship” (ISA, Table 5–3). That is, the ISA found the health evidence to be of insufficient quantity, quality, consistency, or statistical power to make a determination as to whether SO<sub>2</sub> is truly associated with these health endpoints (ISA, Table 1–2). With respect specifically to respiratory morbidity in children (in part, the basis for the current annual standard; see section II.D.1), the ISA presented recent epidemiologic evidence of an association with long-term exposure to SO<sub>2</sub> (ISA, section 3.4.2). However, the ISA found the strength of these epidemiologic studies to be limited because of (1) variability in results across studies with respect to specific respiratory morbidity endpoints; (2) high correlations between long-term average SO<sub>2</sub> and co-pollutant concentrations, particularly PM; and (3) a lack of evaluation of potential confounding (ISA, section 3.4.2.1).

The REA also noted that many epidemiologic studies demonstrating positive associations between 1-hour daily maximum or 24-hour average SO<sub>2</sub> concentrations and respiratory symptoms, ED visits, and hospitalizations were conducted in areas where ambient SO<sub>2</sub> concentrations were well below the level of the current annual NAAQS (REA, section 10.4.2). The REA noted that this evidence suggested that the current annual standard was not providing adequate protection against health effects associated with shorter-term SO<sub>2</sub> concentrations found in epidemiologic studies (REA, section 10.4.2).

### b. Air quality, exposure, and risk-based considerations

Results of the risk characterization based on the air quality assessment provided additional insight into whether there is a need to revise the current annual standard, focusing again on the extent to which the annual standard may be providing protection against effects associated with short-term exposures. In general, analyses presented in the REA described the extent to which the current annual standard provided protection against 5-minute peaks of SO<sub>2</sub> in excess of potential health effect benchmark levels (REA, chapter 7). The REA found that many of the monitors where frequent 5-minute exceedances were reported had annual average SO<sub>2</sub> concentrations well below the level of the current annual standard. Moreover, the REA found that there was little to no correlation

between the annual average SO<sub>2</sub> concentration and the number of 5-minute daily maximum concentrations above potential health effect benchmark levels at these monitors (REA section 7.3.1). Thus, the REA concluded that the annual standard adds little in the way of protection against 5-minute peaks of SO<sub>2</sub> (REA, section 10.4.4).

### c. Summary of considerations from the REA regarding the annual standard

As noted above, the ISA concluded that the evidence relating long-term (weeks to years) SO<sub>2</sub> exposure to adverse health effects (respiratory morbidity, carcinogenesis, adverse prenatal and neonatal outcomes, and mortality) was “inadequate to infer the presence or absence of a causal relationship” (ISA, Table 5–3). The ISA also reported that many epidemiologic studies demonstrating positive associations between short-term (*e.g.*, 1-hour daily maximum, 24-hour average) SO<sub>2</sub> concentrations and respiratory symptoms, as well as ED visits and hospitalizations, were conducted in areas where annual ambient SO<sub>2</sub> concentrations were well below the level of the current annual NAAQS. In addition, analyses conducted in the REA suggested that the current annual standard is not providing protection against 5–10 minute peaks of SO<sub>2</sub>. Thus, the scientific evidence and the risk and exposure information suggest that the current annual SO<sub>2</sub> standard: (1) Is likely not needed to protect against health risks associated with long term exposure to SO<sub>2</sub>; and 2) does not provide adequate protection from the health effects associated with shorter-term (*i.e.*  $\leq 24$ -hours) SO<sub>2</sub> exposures. Thus, the policy chapter of the REA accordingly concluded that consideration should be given to either revoking the annual standard or retaining it without revision, in conjunction with setting an appropriate short-term standard(s) (REA, section 10.4.4).

## 3. CASAC views regarding the adequacy of the current 24-hour and annual standards

With regard to the adequacy of the current standards, CASAC conclusions were consistent with the views expressed in the policy assessment chapter of the REA.<sup>18</sup> CASAC agreed

<sup>18</sup>CASAC views with respect to the current 24-hour and annual standards, as well as with respect to potential alternative standards are those following their review of the second draft SO<sub>2</sub> REA, which contained a staff policy assessment chapter. EPA did not solicit, nor did it receive CASAC comments on the final policy assessment chapter contained in the final REA.

that the primary concern in this review is to protect against health effects that have been associated with short-term SO<sub>2</sub> exposures, particularly those of 5–10 minutes (Samet 2009). CASAC also agreed that the current 24-hour and annual standards are not sufficient to protect public health against the types of exposures that could lead to these health effects. Given these considerations, and as noted in their letter to the EPA Administrator, CASAC agreed “that the current 24-hour and annual standards are not adequate to protect public health, especially in relation to short term exposures to SO<sub>2</sub> (5–10 minutes) by exercising asthmatics” (Samet, 2009, p. 15). CASAC also noted: “assuming that EPA adopts a one hour standard in the range suggested, and if there is evidence showing that the short-term standard provides equivalent protection of public health in the long-term as the annual standard, the panel is supportive of the REA discussion of discontinuing the annual standard” (Samet 2009, p. 15). With regard to the current 24-hour standard, CASAC was generally supportive of using the air quality analyses in the REA as a means of determining whether the current 24-hour standard was needed in addition to a new 1-hour standard to protect public health. CASAC stated: “the evidence presented [in REA Table 10–3] was convincing that some of the alternative one-hour standards could also adequately protect against exceedences of the current 24-hour standard” (Samet 2009, p. 15) Discussion regarding CASAC’s views on how the standard should be revised is provided below within the context of discussions on the elements (*i.e.*, indicator, averaging time, form, level) of a new short-term standard.

#### 4. The Administrator’s conclusions regarding adequacy of the current 24-hour and annual standards

Based on the epidemiologic evidence, the risk and exposure data set out in this section, as well as CASAC’s advice and recommendations, the Administrator concludes (subject to consideration of public comment) that the current standards are not adequate to protect public health with an adequate margin of safety. The basis for this conclusion is as follows. First, the Administrator accepts and agrees with the ISA’s conclusion that the results of controlled human exposure and epidemiologic studies form a plausible and coherent data set that supports a causal relationship between short-term (5–minutes to 24-hours) SO<sub>2</sub> exposures and adverse respiratory effects. The

Administrator further agrees that the epidemiologic evidence (buttressed by the clinical evidence) indicates that the effects seen in the epidemiologic studies are attributable to exposure to SO<sub>2</sub>. She also accepts and agrees with the conclusion of the ISA that “[i]n the epidemiologic studies, respiratory effects were observed in areas where the maximum ambient 24-h avg SO<sub>2</sub> concentration was below the current 24-h avg NAAQS level \* \* \*” (ISA, section 5.2, p. 5–2.) and so would occur at ambient SO<sub>2</sub> concentrations that are present in locations meeting the current 24-hour NAAQS. The Administrator also notes that these effects occurred in areas with annual air quality levels considerably lower than those allowed by the current annual standard, indicating that the annual standard also is not providing protection against such effects. Existence of epidemiologic studies showing adverse effects occurring at levels allowed by the current standards is an accepted justification for finding that it is appropriate to revise the existing standards. See, *e.g. American Trucking Ass’n v. EPA*, 283 F. 3d 355, 370 (DC Cir. 2002).

With regard to the exposure and risk results, the Administrator notes and agrees with the analyses in the REA supporting that 5-minute exposures, reasonably judged important from a public health perspective, were associated with air quality adjusted upward to simulate just meeting the current standards. The Administrator especially notes the results of the St. Louis exposure analysis which, as summarized above, indicates that substantial percentages of asthmatic children at moderate or greater exertion would be exposed, at least once annually, to air quality exceeding the 400 and 200 ppb benchmarks. Moreover, in addition to the health evidence and risk-based information, the Administrator agrees with CASAC’s conclusion that the current SO<sub>2</sub> standards do not adequately protect the public’s health.

In considering approaches to revising the current standards, the Administrator is proposing that it is appropriate to consider setting a new short-term standard. The Administrator initially notes that a 1-hour standard could provide increased public health protection, especially for members of at-risk groups, from health effects described in both controlled human exposure and epidemiologic studies, and hence, health effects associated with 5-minute to 24-hour exposures to SO<sub>2</sub>. As discussed in section II.F.5 below, depending on the degree of

protection afforded by such a standard, it may be appropriate to replace, and not retain, the current 24-hour and annual standards in conjunction with setting a new short-term standard.

#### F. Conclusions on the elements of a proposed new short-term standard

In considering alternative SO<sub>2</sub> primary NAAQS, the Administrator notes the need to protect at-risk populations from: (1) 1-hour daily maximum and 24-hour average exposures to SO<sub>2</sub> that could cause the types of respiratory morbidity effects reported in epidemiologic studies; and (2) 5–10 minute SO<sub>2</sub> exposure concentrations reported in controlled human exposure studies to result in moderate or greater lung function responses and/or respiratory symptoms. Considerations with regard to potential alternative standards and the specific options being proposed are discussed in the following sections in terms of indicator, averaging time, form, and level (sections II.F.1 to II.F.4).

##### 1. Indicator

In the last review, EPA focused on SO<sub>2</sub> as the most appropriate indicator for ambient SO<sub>x</sub>. In making a decision in the current review on the most appropriate indicator, the Administrator has considered the conclusions of the ISA and REA as well as the views expressed by CASAC. The REA noted that, although the presence of gaseous SO<sub>x</sub> species other than SO<sub>2</sub> has been recognized, no alternative to SO<sub>2</sub> has been advanced as being a more appropriate surrogate for ambient gaseous SO<sub>x</sub>. Controlled human exposure studies and animal toxicology studies provide specific evidence for health effects following exposure to SO<sub>2</sub>. Epidemiologic studies also typically report levels of SO<sub>2</sub>, as opposed to other gaseous SO<sub>x</sub>. Because emissions that lead to the formation of SO<sub>2</sub> generally also lead to the formation of other SO<sub>x</sub> oxidation products, measures leading to reductions in population exposures to SO<sub>2</sub> can generally be expected to lead to reductions in population exposures to other gaseous SO<sub>x</sub>. Therefore, meeting an SO<sub>2</sub> standard that protects the public health can also be expected to provide protection against potential health effects that may be independently associated with other gaseous SO<sub>x</sub> even though such effects are not discernable from currently available studies indexed by SO<sub>2</sub> alone. See *American Petroleum Institute v. EPA*, 665 F. 2d 1176, 1186 (DC Cir. 1981) (reasonable for EPA to use ozone as the indicator for all photochemical oxidants even though

health information on the other photochemical oxidants is unknown; regulating ozone alone is reasonable since it presents a “predictable danger” and in doing so EPA did not abandon its responsibility to regulate other photochemical oxidants encompassed by the determination that photochemical oxidants as a class may be reasonably anticipated to endanger public health or welfare). Given these key points, the REA concluded that the available evidence supports the retention of SO<sub>2</sub> as the indicator in the current review (REA, section 10.5.1). Consistent with this conclusion, CASAC stated in a letter to the EPA Administrator that “for indicator, SO<sub>2</sub> is clearly the preferred choice” (Samet 2009, p. 14). The Administrator agrees with this consensus, and therefore proposes to retain SO<sub>2</sub> as the indicator for oxides of sulfur in the current review.

## 2. Averaging time

In considering whether it is appropriate to revise the averaging times of the current standards, the first consideration is what health effects the standard is addressing, and specifically whether those effects are associated with short-term (*i.e.*, 5-minutes to 24-hours), and/or long-term (*i.e.* weeks to years) exposure to SO<sub>2</sub>. There are distinct differences in the causality judgments in the ISA as to short-term versus long-term health effects of SO<sub>2</sub>. The ISA found evidence relating long-term (weeks to years) SO<sub>2</sub> exposures to adverse health effects to be “inadequate to infer the presence or absence of a causal relationship” (ISA, Table 5–3). In contrast, the ISA judged evidence relating short-term (5-minutes to 24-hours) SO<sub>2</sub> exposure to respiratory morbidity to be “sufficient to infer a causal relationship” (the strongest possible conclusion as to causality) and short-term exposure to SO<sub>2</sub> and mortality to be “suggestive of a causal relationship” (ISA, Table 5–3). Taken together, the REA concluded that these judgments most directly supported standard averaging time(s) that focus protection on SO<sub>2</sub> exposures from 5-minutes to 24-hours (REA, section, 10.5.2).

### a. Evidence and air quality, exposure, and risk-based considerations

In considering the level of support available for specific short-term averaging times, the REA noted the strength of evidence from human exposure and epidemiologic studies evaluated in the ISA. As previously mentioned, controlled human exposure studies exposed exercising asthmatics to

5–10 minute peak concentrations of SO<sub>2</sub> and consistently found decrements in lung function and/or respiratory symptoms. Importantly, the ISA described the controlled human exposure studies as being the “definitive evidence” for its conclusion that there exists a causal association between short-term (5-minutes to 24-hours) SO<sub>2</sub> exposure and respiratory morbidity (ISA, section 5.2). In addition to the controlled human exposure evidence, there is a relatively small body of epidemiologic studies describing positive associations between 1-hour daily maximum SO<sub>2</sub> levels and respiratory symptoms as well as hospital admissions and ED visits for all respiratory causes and asthma (ISA Tables 5.4 and 5.5). In addition to the evidence from these 1-hour daily maximum epidemiologic studies, there is a considerably larger body of epidemiologic studies reporting positive associations between 24-hour average SO<sub>2</sub> levels and respiratory symptoms, as well as hospitalizations and ED visits for all respiratory causes and asthma. Moreover, with respect to these epidemiologic studies, there is support that adverse respiratory effects are more likely to occur at the upper end of the distribution of ambient SO<sub>2</sub> concentrations (see section II.F.3 on Form). In addition, when describing epidemiologic studies observing positive associations between ambient SO<sub>2</sub> 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). Similarly, the ISA stated that: “the effects of SO<sub>2</sub> on respiratory symptoms, lung function, and airway inflammation observed in the human clinical studies using peak exposures further provides a basis for a progression of respiratory morbidity resulting in increased ED visits and hospital admissions” and makes the associations observed in the epidemiologic studies “biologica[lly] plausible” (ISA, section 5.2 at p. 5–5).

The controlled human exposure evidence described above provided support for an averaging time that protects against 5–10 minute peak SO<sub>2</sub> exposures (REA, section 10.5.2). In addition, the REA found that results from epidemiologic studies provided support for both 1-hour and 24-hour averaging times (REA, section 10.5.2). In addition, both the epidemiologic and controlled human exposure evidence suggests that a new short-term standard should be focused on limiting peak SO<sub>2</sub> exposures. Thus, it can reasonably be concluded from the ISA and REA that

it would be appropriate to consider the degree of protection potential alternative standards with averaging times under consideration provide against peak 5-minute to 24-hour SO<sub>2</sub> exposures. Moreover, as fully discussed in section II.F.3, this same information makes it reasonable that the form of a new short-term standard reflect a strategy to limit peak SO<sub>2</sub> exposures. Thus, with respect to the analyses presented below regarding averaging time, a 99th percentile form will be considered. See *American Petroleum Institute*, 665 F. 2d at 1186 (selection of highest average ozone level in one hour to determine compliance with ozone NAAQS is reasonable “because it is calculated to measure the maximum exposure, which has been found to be a relevant factor in determining the likely consequences of ozone exposure”).

In considering the level of support available for specific short-term averaging times, the policy assessment chapter of the REA also took into account air quality considerations. More specifically, since the shortest averaging time for the current primary SO<sub>2</sub> standard is 24-hours, the REA evaluated the potential for a standard based on 24-hour average SO<sub>2</sub> concentrations to limit 5-minute peak SO<sub>2</sub> exposures (REA, section 10.5.2). The REA evaluated ratios between 99th percentile 5-minute daily maximum and 99th percentile 24-hour average SO<sub>2</sub> concentrations for 42 monitors reporting measured 5-minute data for any year between 2004–2006 (REA, Table 10–1). Across this set of monitors, ratios of 99th percentile 5-minute daily maximum to 99th percentile 24-hour average SO<sub>2</sub> concentrations spanned a range of 2.0 to 14.1 (REA, Table 10–1). These results suggested a standard based on 24-hour average SO<sub>2</sub> concentrations would not likely be an effective or efficient approach for addressing 5-minute peak SO<sub>2</sub> concentrations. That is, the REA concluded using a 24-hour average standard to address 5-minute peaks would likely result in over-controlling in some areas, while under-controlling in others (REA, section 10.5.2). This analysis also suggested that a 5-minute standard would not likely be an effective or efficient means for controlling 24-hour average SO<sub>2</sub> concentrations (REA, section 10.5.2).

The REA also reported ratios between 99th percentile 5-minute daily maximum and 99th percentile 1-hour daily maximum SO<sub>2</sub> levels from this set of monitors. Compared to the ratios discussed above (5-minute daily maximum to 24-hour average), there was far less variability between 5-

minute daily maximum and 1-hour daily maximum ratios. More specifically, 39 of the 42 monitors had 99th percentile 5-minute daily maximum to 99th percentile 1-hour daily maximum ratios in the range of 1.2 to 2.5 (REA, Table 10–1). The remaining three monitors had ratios of 3.6, 4.2 and 4.6 respectively. Overall, the REA found that this relatively narrow range of ratios (compared to the range of ratios presented above with respect to 5-minute daily maximum to 24-hour average) suggested that a standard with a 1-hour averaging time would be more efficient and effective at limiting 5-minute peaks of SO<sub>2</sub> than a standard with a 24-hour averaging time (REA, section 10.5.2.2). This analysis also suggested that a 5-minute standard could be a relatively effective means of controlling 1-hour daily maximum SO<sub>2</sub> concentrations.<sup>19</sup>

The REA further evaluated the potential of the 1-hour daily maximum

standards analyzed in the air quality, exposure, and risk analyses to limit peak 24-hour average SO<sub>2</sub> exposures (REA, section 10.5.2) since there is epidemiologic evidence to suggest that adverse respiratory effects are more likely to occur at the upper end of the distribution of ambient SO<sub>2</sub> concentrations. The 99th percentile 24-hour average SO<sub>2</sub> concentrations in cities where U.S. ED visit and hospitalization studies (for all respiratory causes and asthma; identified from Table 5–5 of the ISA) were conducted ranged from 16 ppb to 115 ppb (Thompson and Stewart, 2009). Moreover, effect estimates that remained statistically significant in multi-pollutant models with PM were found in cities with 99th percentile 24-hour average SO<sub>2</sub> concentrations ranging from approximately 36 ppb to 64 ppb. The REA found that a 99th percentile 1-hour daily maximum standard set at a level of 50–100 ppb would generally

limit 99th percentile 24-hour average SO<sub>2</sub> concentrations in locations where epidemiologic studies reported statistically significant results in multi-pollutant models with PM (Table 1). That is, for 2004, given air quality adjusted to just meet a 50 ppb 99th percentile 1-hour daily maximum standard, the REA found that no county included in this analysis was estimated to have 24-hour average SO<sub>2</sub> concentrations ≥ 36 ppb (Table 1). In addition, given air quality adjusted to just meet a 100 ppb 99th percentile 1-hour daily maximum standard, only 6 of the 39 counties (Linn, Union, Bronx, Fairfax, Hudson, and Wayne) included in this 2004 analysis were estimated to have 99th percentile 24-hour average SO<sub>2</sub> concentrations ≥ 36 ppb (Table 1). The REA repeated this analysis for the years 2005 and 2006 and found similar results (REA, Appendix Tables D1 and D2).<sup>20</sup>

TABLE 1—99TH PERCENTILE 24-HOUR AVERAGE SO<sub>2</sub> CONCENTRATIONS FOR 2004 GIVEN JUST MEETING THE ALTERNATIVE 1-HOUR DAILY MAXIMUM 99TH AND 98TH PERCENTILE POTENTIAL STANDARDS ANALYZED IN THE AIR QUALITY ASSESSMENT

[Source: REA, Table 10–2].<sup>21</sup>

State	County	1-hour daily maximum standards						
		99th percentile					98th percentile	
		50	100	150	200	250	100	200
AZ	Gila	6	12	18	25	31	16	32
DE	New Castle	12	23	35	47	59	28	56
FL	Hillsborough	10	20	30	40	50	28	55
IL	Madison	12	24	36	48	60	28	56
IL	Wabash	7	13	20	27	33	19	38
IN	Floyd	8	15	23	31	39	20	41
IN	Gibson	9	18	27	36	45	20	41
IN	Lake	12	24	36	48	60	31	62
IN	Vigo	10	19	29	39	48	24	48
IA	Linn	21	42	64	85	106	49	98
IA	Muscatine	17	34	51	68	85	38	76
MI	Wayne	17	33	50	66	83	37	74
MO	Greene	12	24	36	48	60	31	62
MO	Jefferson	9	18	27	36	45	25	51
NH	Merrimack	17	33	50	66	83	39	79
NJ	Hudson	19	38	57	76	95	48	96
NJ	Union	18	36	54	72	90	44	89
NY	Bronx	23	47	70	93	117	54	107
NY	Chautauqua	13	27	40	54	67	32	65
NY	Erie	14	27	41	54	68	30	61
OH	Cuyahoga	17	34	51	67	84	40	80
OH	Lake	10	19	29	39	48	23	47
OH	Summit	12	24	36	48	61	27	55
OK	Tulsa	16	32	47	63	79	36	72
PA	Allegheny	12	23	35	47	59	30	60
PA	Beaver	10	20	30	40	51	25	49
PA	Northampton	11	23	34	45	56	36	72
PA	Warren	11	22	33	44	56	28	56
PA	Washington	15	31	46	62	77	36	71
TN	Blount	15	31	46	61	77	35	71

<sup>19</sup> 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<sub>2</sub>. 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.

<sup>20</sup> In 2005, given a 99th percentile 1-hour daily maximum standard at 50 ppb, Wayne County, West

Virginia would have an estimated 99th percentile 24-hour average SO<sub>2</sub> concentration > 36 ppb (43 ppb; REA Appendix Table D–1).

TABLE 1—99TH PERCENTILE 24-HOUR AVERAGE SO<sub>2</sub> CONCENTRATIONS FOR 2004 GIVEN JUST MEETING THE ALTERNATIVE 1-HOUR DAILY MAXIMUM 99TH AND 98TH PERCENTILE POTENTIAL STANDARDS ANALYZED IN THE AIR QUALITY ASSESSMENT—Continued

[Source: REA, Table 10–2].<sup>21</sup>

State	County	1-hour daily maximum standards						
		99th percentile					98th percentile	
		50	100	150	200	250	100	200
TN .....	Shelby .....	17	34	51	68	85	41	81
TN .....	Sullivan .....	8	16	24	32	39	23	46
TX .....	Jefferson .....	9	17	26	35	44	21	41
VA .....	Fairfax .....	23	46	69	92	116	52	103
WV .....	Brooke .....	12	24	37	49	61	31	62
WV .....	Hancock .....	15	29	44	58	73	35	69
WV .....	Monongalia .....	10	20	30	40	50	25	51
WV .....	Wayne .....	30	59	89	119	149	67	133
VI .....	St Croix .....	14	27	41	54	68	51	101

The air quality information presented above strongly support the likelihood that an alternative 99th percentile (see discussion of form below in II.F.3) 1-hour daily maximum standard set at an appropriate level (see discussion of level in II.F.4) can substantially reduce the upper end of the distribution of SO<sub>2</sub> levels more likely to be associated with adverse respiratory effects; that is: (1) 99th percentile 1-hour daily maximum air quality concentrations in cities observing positive effect estimates in epidemiologic studies of hospital admissions and ED visits for all respiratory causes and asthma; and (2) 99th percentile 24-hour average air quality concentrations found in U.S. cities where ED visit and hospitalization studies (for all respiratory causes and asthma) observed statistically significant associations in multi-pollutant models with PM (*i.e.*, 99th percentile 24-hour average SO<sub>2</sub> concentration ≥ 36 ppb). In addition, based on the air quality and exposure analyses presented in chapters 7 and 8 of the REA, there is also a strong likelihood that a 99th percentile 1-hour daily maximum standard will limit 5–10 minute peaks of SO<sub>2</sub> shown in human exposure studies to result in decrements in lung function and/or respiratory symptoms in exercising asthmatics (see especially: REA Tables 7–11 to 7–14 and Figure 8–19). Such analyses are also summarized in section II.F.4 of this

notice. Taken together, these results support that a 1-hour daily maximum standard, with an appropriate form and level, can provide adequate protection against the range of health outcomes associated with averaging times from 5-minutes to 24-hours (REA, section 10.5.2.3).

The REA also considered the possibility of a 5-minute averaging time based solely on the controlled human exposure evidence. However, the REA did not favor such an approach (REA 10.5.2.3). As in past NAAQS reviews, the stability of the design of pollution control programs in considering the elements of a NAAQS was considered, since more stable programs are more effective, and hence result in enhanced public safety. *American Trucking Associations v. EPA*, 283 F. 3d 355, 375 (DC Cir. 2002) (choice of 98th percentile form for 24-hour PM NAAQS, which allows a number of high exposure days per year to escape regulation under the NAAQS, justifiable as “promot[ing] development of more ‘effective [pollution] control programs’”, since such programs would otherwise be “less ‘stable’—and hence \* \* \* less effective—than programs designed to address longer-term average conditions”, and there are other means (*viz.* emergency episode plans) to control those high exposure days). In this review, there were concerns about the stability of a standard using a 5-minute averaging time. Specifically, there was concern that compared to longer averaging times (*e.g.*, 1-hour, 24-hour), year-to-year variation in 5-minute SO<sub>2</sub> concentrations were likely to be substantially more temporally and spatially diverse. Thus, it is likely that locations would frequently shift in and out of attainment thereby reducing public health protection by disrupting

an area’s ongoing implementation plans and associated control programs. Consequently, the REA concluded that a 5-minute averaging time would not provide a stable regulatory target and therefore would not be the preferred approach to provide adequate public health protection. However, as noted above, analyses in the REA support that a 1-hour averaging time, given an appropriate form and level (discussed below in sections II.F.3 and II.F.4, respectively) can adequately limit 5-minute SO<sub>2</sub> exposures and provide a more stable regulatory target than setting a 5-minute standard.

#### b. CASAC views

CASAC agreed with the conclusions of the policy assessment chapter of the REA that a primary consideration of the SO<sub>2</sub> NAAQS should be the protection provided against health effects associated with short-term exposures. In their letter to the EPA Administrator, CASAC stated that they were “in agreement with having a short-term standard and finds that the REA supports a one-hour standard as protective of public health” (Samet 2009, p. 1). Furthermore, CASAC agreed with the REA that a “one-hour standard is the preferred averaging time” (Samet 2009, p.15).”

#### c. Administrator’s conclusions on averaging time

In considering the most appropriate averaging time(s) for the SO<sub>2</sub> primary NAAQS, the Administrator notes the conclusions and judgments made in the ISA about the available scientific evidence, conclusions from the REA, and CASAC recommendations discussed above. Based on these considerations, the Administrator proposes to set a new standard based on 1-hour daily maximum SO<sub>2</sub>

<sup>21</sup> 99th or 98th percentile 1-hour daily maximum concentrations were determined for each monitor in a given county for the years complete data were available from 2004–2006. These concentrations were averaged, and the monitor with the highest average in a given county was determined. Based on this highest average, all monitors in a given county were adjusted to just meet the potential alternative standards defined above, and for each of the years, the 99th percentile 24-hour average SO<sub>2</sub> concentration was identified. Results for the years 2005 and 2006 are presented in the REA, Appendix D.

concentrations to provide increased protection against effects associated with short-term (5-minutes to 24-hours) exposures. First, the Administrator agrees with the REA's conclusion that the standard should focus protection on short-term SO<sub>2</sub> exposures from 5-minutes to 24-hours. As noted above, CASAC's strong recommendation supports this approach as well. Second, the Administrator agrees that the standard must provide requisite protection from 5–10 minute exposure events (the critical issue in the previous review), but believes (subject to consideration of public comment) that this can be done without having a standard with a 5-minute averaging time. The Administrator agrees with the REA conclusion that it is likely a 1-hour standard—with the appropriate form and level—can substantially reduce 5–10 minute peaks of SO<sub>2</sub> shown in controlled human exposure studies to result in respiratory symptoms and/or decrements in lung function in exercising asthmatics. The Administrator further believes that a 5-minute averaging time would result in significant and unnecessary instability and is undesirable for that reason. The Administrator also notes the statements from CASAC addressing whether a one-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” for a one-hour standard, and that “a 1-hour standard is the preferred averaging time” (Samet 2009, p. 16).

Third, the Administrator agrees that a one-hour averaging time (again, with the appropriate form and level) would provide protection against the range of health outcomes associated with averaging times of one hour to 24 hours. Specifically, the Administrator finds that a 1-hour standard can substantially reduce the upper end of the distribution of SO<sub>2</sub> levels more likely to be associated with adverse respiratory effects; that is: (1) 99th percentile 1-hour daily maximum air quality concentrations in U.S. cities where positive effect estimates in epidemiologic studies of hospital admissions and ED visits for all respiratory causes and asthma were observed; and (2) 99th percentile 24-hour average air quality concentrations found in U.S. cities where ED visit and hospitalization studies (for all respiratory causes and asthma) observed statistically significant associations in multi-pollutant models with PM. Finally, the Administrator notes that the proposal to establish a new 1-hour

averaging time is in agreement with CASAC recommendations. As noted above, CASAC stated that they were “in agreement with having a short-term standard and finds that the REA supports a one-hour standard as protective of public health” (Samet, 2009, p. 1).

### 3. Form

When evaluating alternative forms in conjunction with specific levels, the REA considered the adequacy of the public health protection provided by the combination of level and form to be the foremost consideration. In addition, the REA recognized that it is important that the standard have a form that is reasonably stable. As just explained in the context of a five-minute averaging time, a standard set with a high degree of instability could have the effect of reducing public health protection because shifting in and out of attainment could disrupt an area's ongoing implementation plans and associated control programs.

#### a. Evidence, air quality, and risk-based considerations

As previously mentioned, the policy chapter of the REA (chapter 10) recognized that the adequacy of the public health protection provided by a 1-hour daily maximum potential alternative standard will be dependent on the combination of form and level. It is therefore important that the particular form selected for a 1-hour daily maximum potential alternative standard reflect the nature of the health risks posed by increasing SO<sub>2</sub> concentrations. That is, the REA noted that the form of the standard should reflect results from controlled human exposure studies demonstrating that the percentage of asthmatics affected, and the severity of the respiratory response (*i.e.* decrements in lung function, respiratory symptoms) increases as SO<sub>2</sub> concentrations increase. Taking this into consideration, the REA concluded that a concentration-based form, averaged over three years, is more appropriate than an exceedance-based form (REA, section 10.5.3). This is because a concentration-based form averaged over three years would give proportionally greater weight to years when 1-hour daily maximum SO<sub>2</sub> concentrations are well above the level of the standard, than to years when 1-hour daily maximum SO<sub>2</sub> concentrations are just above the level of the standard. In contrast, an expected exceedance form would give the same weight to years when 1-hour daily maximum SO<sub>2</sub> concentrations are just above the level of the standard, as to years when 1-hour

daily maximum SO<sub>2</sub> concentrations are well above the level of the standard. Therefore, the REA concluded that a concentration-based form, averaged over three years (which also increases the stability of the standard) better reflects the continuum of health risks posed by increasing SO<sub>2</sub> concentrations (*i.e.* the percentage of asthmatics affected and the severity of the response increases with increasing SO<sub>2</sub> concentrations; REA, section 10.5.3).

The form of the standard should also reflect health information in the ISA that suggests that adverse respiratory effects are more likely to occur at the upper end of the distribution of ambient SO<sub>2</sub> concentrations. Specifically, a few studies found that the increase in SO<sub>2</sub>-related respiratory health effects was observed at the upper end of the distribution of SO<sub>2</sub> concentrations (ISA, section 5.3, p. 5–9). For example, an epidemiologic study conducted in Bronx, NY suggested an increased risk of asthma hospitalizations on the days with the highest SO<sub>2</sub> concentrations (Lin *et al.*, 2004). More specifically, the authors observed an increasing linear trend with respect to asthma hospitalizations across the range of SO<sub>2</sub> concentrations, with more marked effects observed at SO<sub>2</sub> concentrations somewhere between the 90th and 95th percentiles (ISA, section 4.1.2 and ISA, Figure 4–4).

The epidemiologic evidence is consistent with the large body of controlled human exposure studies of exercising asthmatics exposed to short-term peak concentrations of SO<sub>2</sub>; these controlled human exposure studies provide the “definitive evidence” that short term peak SO<sub>2</sub> exposure is associated with respiratory morbidity (SO<sub>x</sub> ISA, Section 5.3, page 5–2). These studies consistently found moderate or greater decrements in lung function (*i.e.* ≥ 100% increase in sRaw and/or ≥ 15% decline in FEV<sub>1</sub>)<sup>22</sup> and/or respiratory symptoms in exercising asthmatics following 5–10 minute peak exposures to SO<sub>2</sub>. Moreover, as noted in the discussion on averaging time (section II.F.2), when discussing the possible relationship between effects observed in controlled human exposure studies and associations reported in epidemiologic analyses, the ISA stated with respect to epidemiologic studies of respiratory symptoms: “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). Similarly, the ISA stated that: “the effects of SO<sub>2</sub> on respiratory symptoms,

<sup>22</sup> See section II.B.1.b above explaining sRaw and FEV<sub>1</sub>.

lung function, and airway inflammation observed in the human clinical studies using peak exposures further provides a basis for a progression of respiratory morbidity resulting in increased ED visits and hospital admissions” and makes the associations observed in the epidemiologic studies “biologica[lly] plausible” (ISA, section 5.2 at p. 5–5). Thus, both the epidemiologic and controlled human exposure evidence suggests that the form of the standard should be focused on limiting peak SO<sub>2</sub> exposures.

In considering specific concentration-based forms, the REA recognized the importance of: (1) Minimizing the number of days per year that an area could exceed the level of the standard and still attain the standard and thus, limiting the upper end of the distribution of SO<sub>2</sub> levels most likely associated with adverse respiratory effects (2) limiting the prevalence of 5-minute peaks of SO<sub>2</sub>; and (3) providing a stable regulatory target to prevent areas from frequently shifting in and out of attainment. The REA focused on 98th and 99th percentile forms averaged over 3 years. The REA first noted that in most locations analyzed, the 99th percentile form of a 1-hour daily maximum standard would correspond to the 4th highest daily maximum concentration in a year, while a 98th percentile form would correspond approximately to the 7th to 8th highest daily maximum concentration in a year (REA, Table 10–5 and Thompson, 2009). In addition, results from the REA air quality analysis suggested that at a given SO<sub>2</sub> standard level, a 99th percentile form is appreciably more effective at limiting 5-minute peak SO<sub>2</sub> concentrations than a 98th percentile form (REA, section 10.5.3 and REA, Figures 7–27 and 7–28). For example, the REA reported that compared to the same standard with a 99th percentile form, a 98th percentile 1-hour daily maximum standard set at a level of 100 ppb allows for on average, an estimated 90 and 74% more days per year when SO<sub>2</sub> concentrations would likely exceed the 200 and 400 ppb benchmark values respectively (REA, section 10.5.3 and REA, Figure 7–28). Moreover, in the counties selected for analysis in the REA air quality assessment, the estimated number of benchmark exceedances using a 98th percentile 1-hour daily maximum standard set at a level of 200 ppb was similar to the corresponding 99th percentile standard set at a level of 250 ppb (REA, section 10.5.3 and REA, Tables 7–11 through 7–14). Similarly, the estimated number of

benchmark exceedances considering a 98th percentile standard set at a level of 100 ppb fell within the range of benchmark exceedances estimated for 99th percentile standards set at levels of 100 and 150 ppb (*id.*).

As an additional matter, the REA compared trends in 98th and 99th percentile design values, as well as design values based on the 4th highest daily maximum from 54 sites located in the 40 counties selected for the detailed air quality analysis (REA section 10.5.3 and Thompson, 2009). These results suggested that at the vast majority of sites, there would have been similar changes in 98th and 99th percentile design values over the last ten years (*i.e.* based evaluating overlapping three year intervals over the last ten years; see REA, Figure 10–1 and Thompson, 2009). These results also demonstrated that design values based on the 4th highest daily maximum are virtually indistinguishable from design values based on the 99th percentile (REA, Figure 10–1 and Thompson, 2009). As part of this analysis, all of the design values over this ten year period for all 54 sites were aggregated and the standard deviation calculated (REA, Figure 10–2 and Thompson, 2009). Results demonstrated similar standard deviations—*i.e.* similar stability—based on aggregated 98th or aggregated 99th percentile design values over the ten year period (see REA, Figure 10–2 and Thompson 2009).

Considering the evidence and air quality analyses presented above, the REA concluded that a concentration-based form provides the best protection against the health risks posed by increasing SO<sub>2</sub> concentrations (REA, section 10.5.3). Moreover, the REA found that at a given standard level, a 99th percentile or 4th highest daily maximum form provides appreciably more public health protection against 5-minute peaks than a 98th percentile or 7th–8th highest daily maximum form (REA, section 10.5.3). In addition, over the last 10 years and for the vast majority of the sites examined, there appears to be little difference in 98th and 99th percentile design value stability (REA, section 10.5.3). Thus, the REA ultimately concluded that consideration should be given primarily to a 1-hour daily maximum standard with a 99th percentile or 4th highest daily maximum form (REA, section 10.5.3.3).

#### b. CASAC views

CASAC agreed with the importance of considering the public health protection provided by the combination of form and level. Moreover, CASAC was in

general agreement with the forms being considered. In a letter to the Administrator, CASAC stated: “there is adequate information to justify the use of a concentration-based form averaged over 3 years” (Samet 2009, p. 16). Moreover, when considering 98th vs. 99th percentile forms, CASAC encouraged EPA to consider analyses in the REA (and perhaps additional analyses) with respect to the number of days per year 98th vs. 99th percentile forms would allow SO<sub>2</sub> concentrations to exceed the selected level. CASAC also encouraged EPA to consider analyses such as those presented above with respect to the number exceedences of 5-minute benchmarks given 98th vs. 99th percentile forms at a given standard level (Samet 2009).

#### c. Administrator’s conclusions on form

When considering alternative forms, the Administrator notes and agrees with the views expressed in the REA and the recommendations from CASAC, as described above. In particular, she agrees that the standard should use a concentration-based form averaged over three years in order to give due weight to years when 1-hour SO<sub>2</sub> concentrations are well above the level of the standard, than to years when 1-hour SO<sub>2</sub> concentrations are just above the level of the standard. The Administrator agrees further, for the reasons given above, that a 99th percentile (or 4th highest) form could be appreciably more protective than a 98th (or 7th or 8th highest) form, and thus, should be utilized. Given these considerations, and in light of the specific range proposed for level below, the Administrator proposes to adopt either a 99th percentile or a 4th highest form, averaged over 3 years.

#### 4. Level

In assessing the level of a one-hour standard with either a 99th percentile or 4th highest average form (averaged over three years in either case) to propose, the Administrator has considered the broad range of scientific evidence assessed in the ISA, including the epidemiologic studies and controlled human exposure studies, as well as the results of air quality, exposure, and risk analyses presented in the REA. In light of this body of evidence and analyses, the Administrator reiterates that it is necessary to provide increased public health protection for at-risk populations against an array of adverse respiratory health effects related to short-term (*i.e.*, 5 minutes to 24 hours) exposures to ambient SO<sub>2</sub>. In considering the most appropriate way to provide this protection, the Administrator is mindful

of the extent to which the available evidence and analyses can inform a decision on the level of a standard. Specifically, the range of proposed standard levels discussed below is informed by epidemiologic and controlled human exposure studies.

#### a. Evidence-based considerations

Evidence-based considerations take into account the full body of scientific evidence assessed in the ISA. When considering the extent to which this scientific evidence can inform a decision on the level of a 1-hour standard, it is important to note that SO<sub>2</sub> concentrations represent different measures of exposure when drawn from experimental versus epidemiologic studies. Concentrations of SO<sub>2</sub> tested in experimental studies, such as controlled human exposure studies, represent exposure concentrations in the breathing zone of the individual test subjects. In cases where controlled human exposure studies report effects, those effects are caused directly by exposure to a specified concentration of SO<sub>2</sub>. In contrast, concentrations of SO<sub>2</sub> drawn from epidemiologic studies are often based on ambient monitoring data. SO<sub>2</sub> concentrations recorded at these ambient monitors are used as surrogates for the distribution of SO<sub>2</sub> exposures across the study area and over the time period of the study.

Since the last review, there have been more than 50 peer reviewed epidemiologic studies published worldwide dealing with SO<sub>2</sub> exposure and effects (see ISA Tables 5–4 and 5–5). Overall, the ISA concluded that these studies provide evidence of an association between ambient SO<sub>2</sub> concentrations and respiratory symptoms, as well as ED visits and hospitalizations for all respiratory causes and asthma (ISA, section 3.1.4). Moreover, the ISA indicates that many of these epidemiologic studies have reported that children and older adults may be at increased risk for SO<sub>2</sub>-associated adverse respiratory effects (ISA, section 5.2). In assessing the extent to which these studies and their associated air quality information can inform the level of a new 99th percentile (see sections II.F.2 and II.F.3) 1-hour daily maximum standard for the U.S., the REA considered U.S. and Canadian air quality information to be most relevant. EPA sent a request to the authors of U.S. and Canadian epidemiologic studies (studies were identified from Tables 5–4 and 5–5 of the ISA) for 99th (and 98th) percentile 1-hour daily maximum SO<sub>2</sub> concentrations from the monitor recording the highest SO<sub>2</sub> level in the

location and time period corresponding to their studies (see Thompson and Stewart (2009)). Air quality information was received from authors of both U.S. and Canadian studies; however, as noted in the REA (REA, section 5.5), SO<sub>2</sub> concentrations reported for Canadian studies are not directly comparable to those reported for studies in the U.S. because SO<sub>2</sub> levels reported for Canadian analyses represent the average 1-hour daily maximum level across multiple monitors in a given city (see REA Figure 5–5), rather than the concentration from the single monitor that recorded the highest SO<sub>2</sub> concentration (see Thompson and Stewart, 2009). Thus, the REA noted that SO<sub>2</sub> concentrations associated with Canadian studies would be relatively lower (potentially significantly lower) than those levels presented for U.S. epidemiologic studies, and therefore the REA focused on 99th percentile air quality information from U.S. studies for informing potential 1-hour standard levels.

Figures 1 to 4 present 99th (and 98th) percentile 1-hour daily maximum SO<sub>2</sub> concentrations from ten U.S. epidemiologic studies (some of which were conducted in multiple cities) of ED visits and hospital admissions<sup>23</sup> (Figures 5–1 to 5–4 in the REA). The REA noted that this information provides evidence for effects in cities with particular 99th percentile 1-hour SO<sub>2</sub> levels, and hence, was of particular relevance for identifying standard levels that could protect against the SO<sub>2</sub> concentrations observed in these studies. The air quality information presented in these figures generally shows that positive associations between ambient SO<sub>2</sub> concentrations and ED visit and hospitalizations have been reported in cities where 99th percentile 1-hour daily maximum SO<sub>2</sub> concentrations ranged from approximately 50–460 ppb. More specifically, seven of these studies were in cities where 99th percentile 1-hour daily maximum SO<sub>2</sub> concentrations ranged from approximately 75–150 ppb. Among these epidemiologic studies in the range of 75–150 ppb, there is a cluster of three studies reporting statistically significant results in multi-pollutant models with PM. Specifically,

<sup>23</sup> In some cases, U.S. authors provided the AQS monitor IDs used in their studies and the statistics from the highest reporting monitor were calculated by EPA. In cases where U.S. authors were unable to provide the requested data (Schwartz 1995, Schwartz 1996, and Jaffe 2003), EPA identified the maximum reporting monitor from all monitors located in the study area and calculated the 98th and 99th percentile statistics (see Thompson and Stewart 2009). Results presented from study locations for which effect estimates were reported.

in epidemiologic studies conducted in the Bronx, NY (NYDOH 2006), and in NYC, NY (Ito *et al.*, 2007), the SO<sub>2</sub> effect estimate remained positive and statistically significant in multi-pollutant models with PM<sub>2.5</sub> in these locations when 99th percentile 1-hour daily maximum SO<sub>2</sub> levels were 78 and 82 ppb respectively. (ISA, Table 5–5). Moreover, in an epidemiologic study conducted in New Haven, CT (Schwartz *et al.*, 1995), the SO<sub>2</sub> effect estimate remained positive and statistically significant in a multi-pollutant model with PM<sub>10</sub> in this location when the 99th percentile 1-hour daily maximum SO<sub>2</sub> concentration was 150 ppb. The REA noted that although statistical significance in co-pollutant models is an important consideration, it is not necessary for appropriate consideration of and reliance on such epidemiologic evidence.<sup>24</sup> However, as noted earlier, there is special sensitivity in this review in disentangling PM-related effects (especially sulfate PM) from SO<sub>2</sub>-related effects in interpreting the epidemiologic studies; thus, these studies are of particular relevance here, lending strong support both to the conclusion that SO<sub>2</sub> effects are generally independent of PM (ISA, section 5.2) and that these independent adverse effects of SO<sub>2</sub> have occurred in cities with 1-hour daily maximum, 99th percentile concentrations in the range of 78–150 ppb.

In addition to the study locations where SO<sub>2</sub> concentrations ranged from 75–150 ppb, the REA noted that two epidemiologic studies included cities reporting positive associations between ambient SO<sub>2</sub> levels and ED visits when 99th percentile 1-hour daily maximum SO<sub>2</sub> concentrations were approximately 50 ppb (Wilson *et al.*, (2005) in Portland, ME and Jaffe *et al.*, (2003) in Columbus, OH). These studies reported generally positive and sometimes statistically significant results using single pollutant models (Figures 1 and 2), and did not evaluate potential confounding through the use of multi-pollutant models. Nonetheless, these studies provide limited evidence of an association between ED visits and 99th percentile 1-hour daily maximum SO<sub>2</sub> concentrations in locations where SO<sub>2</sub> levels were approximately 50 ppb. Finally, the REA noted that studies

<sup>24</sup> For example, evidence of a pattern of results from a group of studies that find effect estimates similar in direction and magnitude would warrant consideration of and reliance on such studies even if the studies did not all report statistically significant associations in single- or multi-pollutant models. The SO<sub>2</sub> epidemiologic studies fit this pattern, and are buttressed further by the results of the clinical studies. ISA, section 5.2.

conducted in Cleveland and Cincinnati, OH (Schwartz *et al.* 1996 and Jaffe *et al.* 2003) reported positive associations between ambient SO<sub>2</sub> levels and ED visits and hospital admissions when 99th percentile 1-hour daily maximum SO<sub>2</sub> concentrations in these cities ranged from 170–457 ppb (REA, section 5.5). The REA found the SO<sub>2</sub> level in Cincinnati (Jaffe *et al.*, 2003; REA section 5.5) to be of particular concern. The 99th percentile 1-hour daily maximum SO<sub>2</sub> level in Cincinnati was > 400 ppb (Figure 2), which in 5–10 minute controlled human exposure studies, was an SO<sub>2</sub> concentration range consistently shown

to result in clearly adverse health effects in exercising asthmatics (*i.e.*, decrements in lung function accompanied by respiratory symptoms).

Taken together, the epidemiologic evidence described above suggests that standard levels at and below 75 ppb should be considered to limit SO<sub>2</sub> concentrations such that the upper end of the distribution of daily maximum hourly concentrations would likely be below that observed in most of these U.S. studies. Notably, a standard at or below 75 ppb would be lower than the SO<sub>2</sub> air quality levels found in the cluster of three epidemiologic studies finding statistically significant effects in multi-pollutant models with PM (*i.e.*,

99th percentile 1-hour daily maximum SO<sub>2</sub> concentrations ≥ 78 ppb). Moreover, standard levels at or below 75 ppb recognize the limited evidence from two epidemiologic studies reporting mostly positive and sometimes statistically significant associations in single pollutant models when 99th percentile 1-hour daily maximum SO<sub>2</sub> concentrations were approximately 50 ppb (Wilson *et al.*, (2005) in Portland, ME and Jaffe *et al.*, (2003) in Columbus, OH; see Figures 1 and 2). Judgments about the weight to place on uncertainties inherent in such studies should also inform selection of a specific standard level.

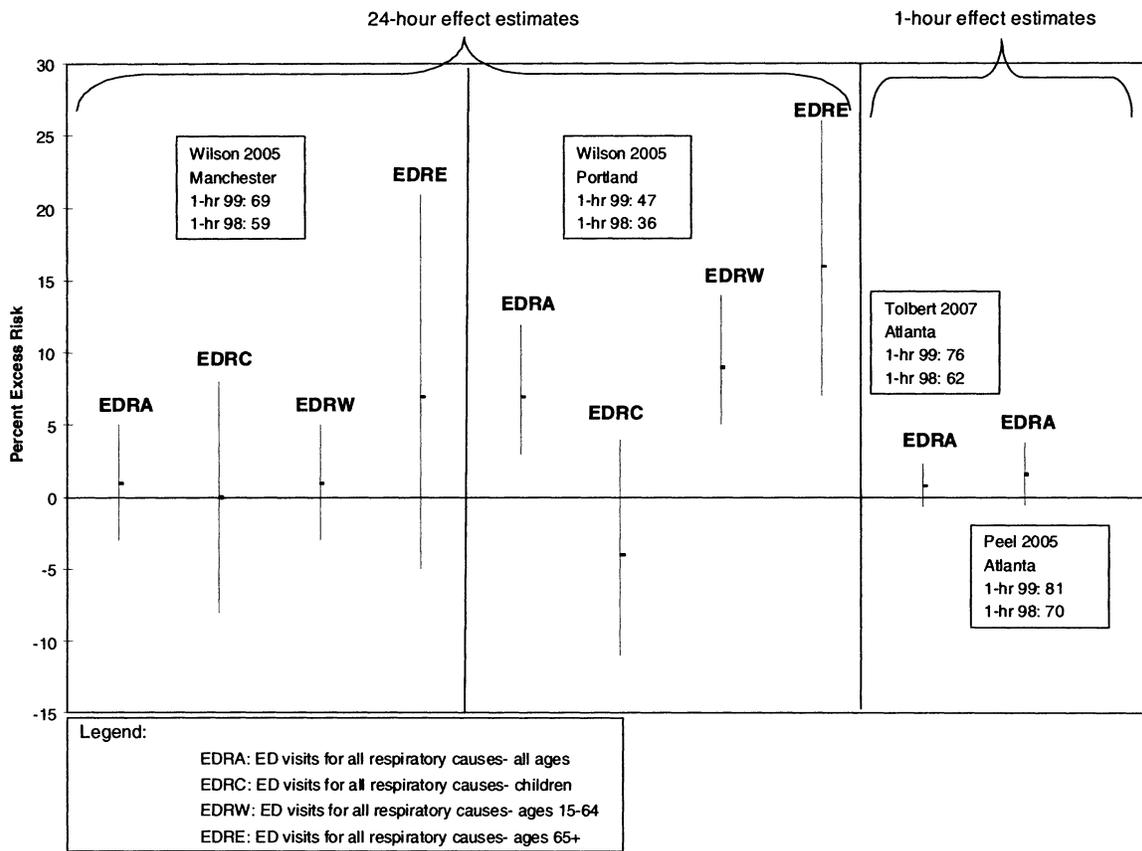


Figure 1. Effect estimates for U.S. all respiratory ED visit studies and associated 98<sup>th</sup> and 99<sup>th</sup> percentile 1-hour daily maximum SO<sub>2</sub> levels.

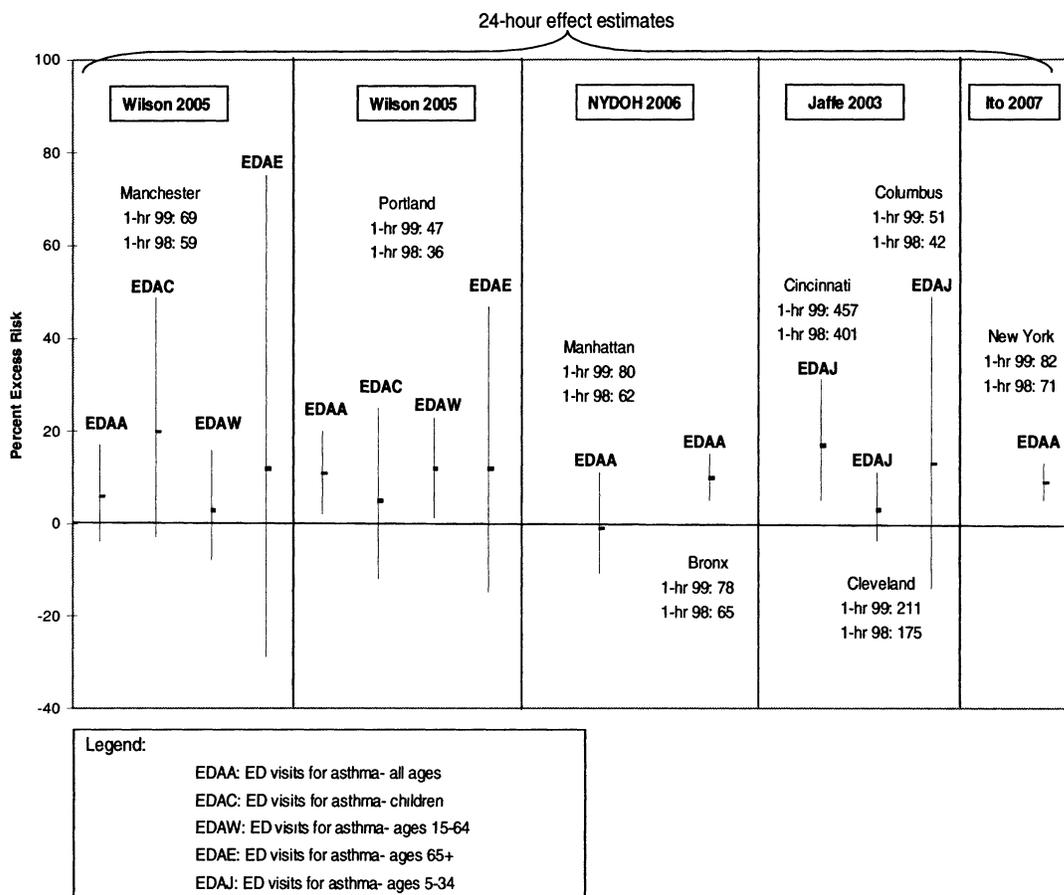


Figure 2. 24-hour effect estimates for U.S. asthma ED visit studies and associated 98<sup>th</sup> and 99<sup>th</sup> percentile 1-hour daily maximum SO<sub>2</sub> levels.

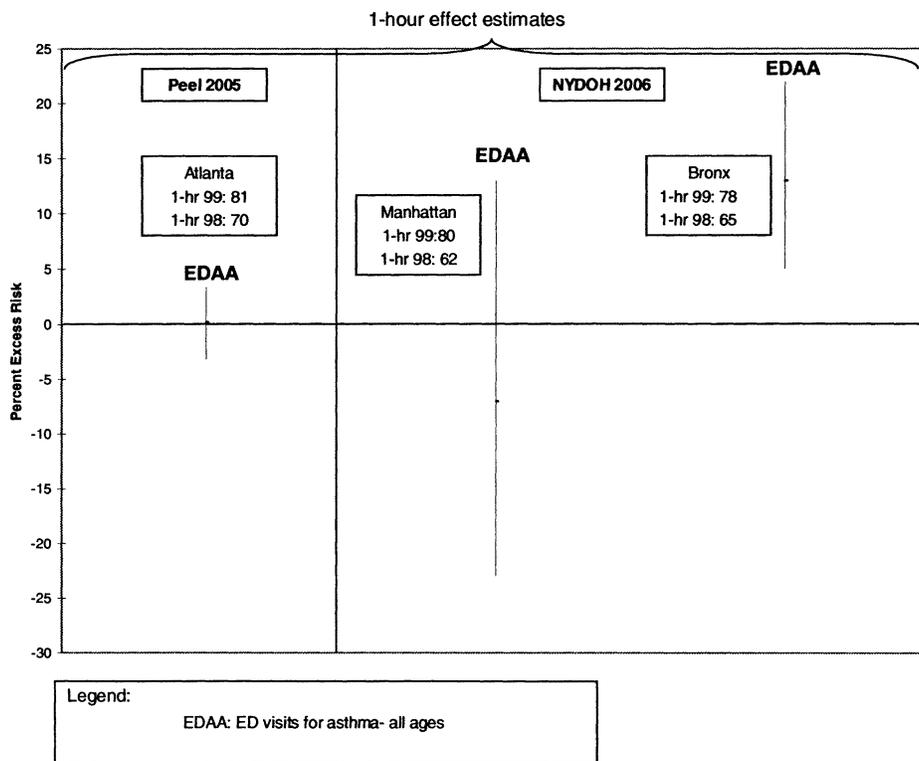


Figure 3. 1-hour effect estimates for U.S. asthma ED visit studies and associated 98<sup>th</sup> and 99<sup>th</sup> percentile 1-hour daily maximum SO<sub>2</sub> levels.

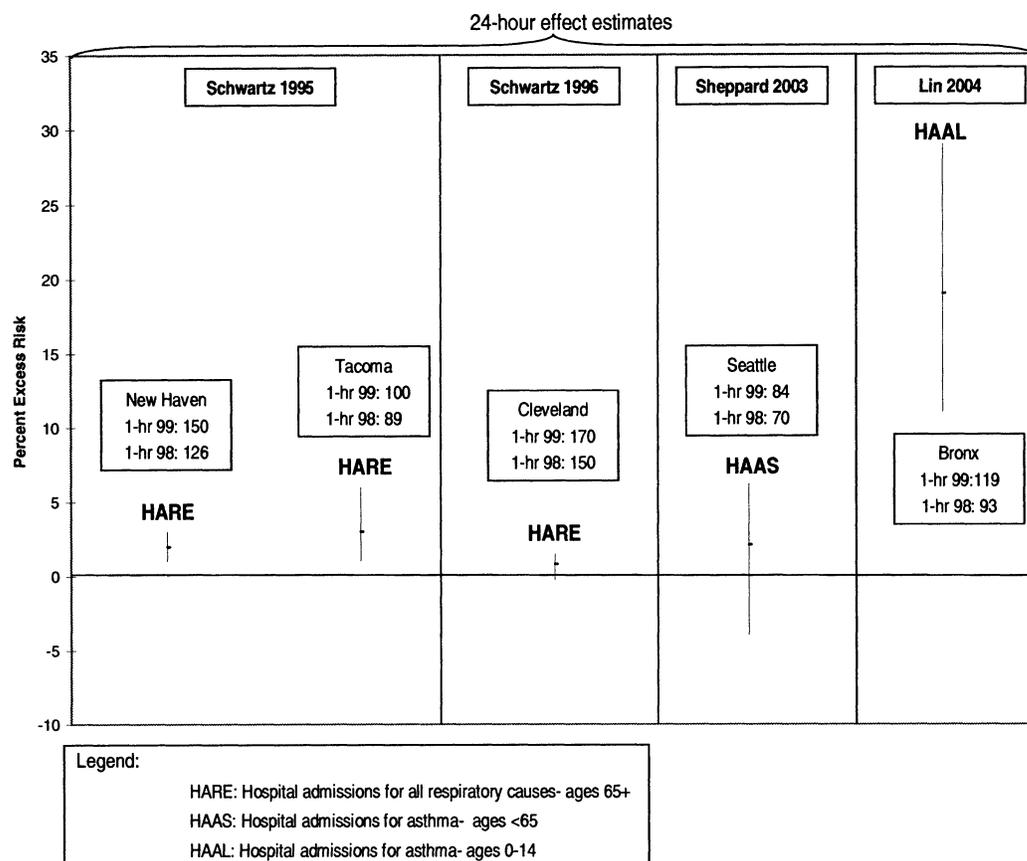


Figure 4. 24-hour effect estimates for U.S. hospitalization studies and associated 98<sup>th</sup> and 99<sup>th</sup> percentile 1-hour daily maximum SO<sub>2</sub> levels.<sup>25</sup>

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The REA also considered findings from controlled human exposure studies when evaluating potential alternative standard levels. The ISA found that the most consistent evidence of decrements in lung function and/or respiratory symptoms was from controlled human exposure studies exposing exercising asthmatics to SO<sub>2</sub> concentrations  $\geq$  400 ppb for 5–10 minute durations (ISA, section 3.1.3.5). As previously mentioned, at SO<sub>2</sub> concentrations ranging from 400–600 ppb, moderate or greater decrements in lung function occur in approximately 20–60% of exercising asthmatics, and compared to exposures at 200–300 ppb, a larger percentage of subjects experience severe decrements in lung function. Moreover, at concentrations  $\geq$  400 ppb, decrements in lung function are often statistically significant at the group mean level, and are frequently accompanied by respiratory symptoms (ISA, Table 5–1).

Controlled human exposure studies have also demonstrated decrements in lung function in exercising asthmatics

following 5–10 minute SO<sub>2</sub> exposures starting as low as 200–300 ppb in free-breathing chamber studies. At concentrations ranging from 200–300 ppb, the lowest levels tested in free breathing chamber studies, approximately 5–30% percent of exercising asthmatics are likely to experience moderate or greater decrements in lung function in these studies. Moreover, although these individuals experienced lung function decrements, they were not frequently accompanied by respiratory symptoms and at these SO<sub>2</sub> concentrations, group mean changes in lung function have not been shown to be statistically significant. However, the ISA and REA noted that for evident ethical reasons, the subjects participating in the controlled human exposure studies described above do not include the most severe asthmatics. Thus, the REA found it is reasonable to anticipate that individuals who are more sensitive to SO<sub>2</sub> would have a greater response at 200–300 ppb SO<sub>2</sub>, and/or would respond to SO<sub>2</sub> concentrations even lower than 200 ppb (REA, section 10.5.4). Similarly, the REA noted that there is no evidence to suggest that 200

ppb represents a threshold below which no adverse respiratory effects occur (REA, section 10.5.4). In fact, limited evidence from two mouthpiece exposure studies suggests that exposure to 100 ppb SO<sub>2</sub> can result in small decrements in lung function.<sup>26</sup>

Considering the controlled human exposure evidence presented above, the ISA concluded that as SO<sub>2</sub> concentrations increase the percentage of asthmatics affected increases as does the severity of the response. Moreover, as previously noted, effects associated with SO<sub>2</sub> concentrations  $\geq$  400 ppb are clearly considered adverse effects of air pollution under ATS guidelines, while effects at 200–300 ppb were considered adverse in the REA based on interpretation of ATS guidelines, CASAC recommendations, and previous conclusions from comparable situations in other NAAQS reviews (see section II.B.1.c). Taken together, the REA concluded that the level of a new 99<sup>th</sup> percentile 1-hour daily maximum

<sup>26</sup> Although not directly comparable to free-breathing chamber studies, findings from these mouthpiece studies may be particularly relevant to those asthmatics who breathe oronasally even at rest (EPA, 1994b).

<sup>25</sup> There were no U.S. hospitalization studies with 1-hour effect estimates identified in Table 5–5 of the ISA.

standard should provide substantial protection against SO<sub>2</sub> concentrations ≥ 400 ppb, and appreciable protection against 5-minute SO<sub>2</sub> concentrations ≥ 200 ppb (REA, section 10.5.4).

b. Air quality, exposure and risk-based considerations

In evaluating the extent to which 99th percentile 1-hour daily maximum alternative standard levels limit 5-minute SO<sub>2</sub> concentrations ≥ 400 and ≥ 200 ppb, the REA first considered key results of the air quality analysis. As previously noted, the results generated from the air quality analysis were from 40 counties and considered a broad characterization of national air quality and human exposures that might be associated with these 5-minute SO<sub>2</sub> concentrations (see section II.C). However, there is uncertainty associated with the assumption that SO<sub>2</sub> air quality measured at fixed site monitors can serve as an adequate surrogate for total exposure to ambient SO<sub>2</sub>. Actual

exposures might be influenced by factors not considered in this analysis including small scale spatial variability in ambient SO<sub>2</sub> concentrations (which might not be captured by the network of fixed-site ambient monitors) and spatial/temporal variability in human activity patterns.

Table 2 reports the maximum mean number of days per year 5-minute daily maximum SO<sub>2</sub> levels would be expected to exceed a given 5-minute potential health effect benchmark level in any of the 40 counties included in the air quality analysis, given air quality simulated to just meet the current, and potential alternative 99th percentile 1-hour daily maximum standards analyzed in the REA. In addition, although not directly analyzed in the REA, these tables include air quality results given a 99th percentile 1-hour daily maximum standard at 75 ppb; this concentration was included in these tables because as mentioned above, the epidemiologic evidence suggested

consideration of a standard level at or below 75 ppb.<sup>27</sup> Table 2 shows that at standard levels ranging from 50–100 ppb, there would be at most two days per year when statistically estimated 5-minute SO<sub>2</sub> concentrations in these counties exceed the 400 ppb benchmark, while at standard levels of 150 ppb and above there is a marked increase in the maximum number of days per year the 400 ppb benchmark is exceeded. Similar trends are seen with respect to the 300 ppb benchmark level. With respect to the 200 and 100 ppb benchmarks, the 50 ppb standard is clearly the most effective at limiting these 5-minute SO<sub>2</sub> concentrations. However, compared to standards at 150 ppb and above, standards in the range of 75–100 ppb would allow considerably less exceedence of the 200 and 100 ppb benchmarks. Additional and more detailed results from the air quality analysis can be found in chapter 7 of the REA.

TABLE 2—MAXIMUM MEAN NUMBER OF DAYS PER YEAR IN ANY OF THE COUNTIES INCLUDED IN THE AIR QUALITY ANALYSIS WHEN 5-MINUTE DAILY MAXIMUM SO<sub>2</sub> CONCENTRATIONS EXCEED THE 100, 200, 300, AND 400 PPB POTENTIAL HEALTH EFFECT BENCHMARK VALUES GIVEN AIR QUALITY ADJUSTED TO JUST MEET THE CURRENT STANDARDS, OR ALTERNATIVE 99TH PERCENTILE 1-HOUR DAILY MAXIMUM STANDARDS

Exposure benchmarks (5-minute exposures)	Air quality scenarios						
	Just meeting current standards	99th percentile 1-hour daily maximum standards					
		50 ppb	75 ppb	100 ppb	150 ppb	200 ppb	250 ppb
400 ppb .....	102	0	(0–2)	2	7	13	18
300 ppb .....	130	0	(0–5)	5	13	20	27
200 ppb .....	171	2	(2–13)	13	24	42	69
100 ppb .....	234	13	(13–43)	43	93	133	180

While the air quality analysis results presented in Table 2 used estimated 5-minute SO<sub>2</sub> concentrations as a surrogate for exposure, the results from the exposure analysis considered the likelihood that an asthmatic at elevated ventilation rate would come into contact with a 5-minute SO<sub>2</sub> concentration at or above a given benchmark level one or more times per year. As previously noted, this resource intensive analysis was performed for St. Louis and Greene County, MO, but results from the St. Louis analysis were found to be more informative with respect to informing standard levels given that the St. Louis results: (1) Suggested that the current standards were not adequate to protect public health; and (2) likely provide useful insights into exposures and risk

for other urban areas in the U.S. with similar population and SO<sub>2</sub> emissions density (*i.e.*, areas where SO<sub>2</sub> exposures are more likely).

Table 3 reports the estimated percent of asthmatic children at moderate or greater exertion in St. Louis, that would be expected to experience at least one SO<sub>2</sub> exposure per year, at or above a health effect benchmark level in scenarios in which air quality was adjusted to meet the current, and alternative 99th percentile 1-hour daily maximum standards. This analysis estimates that standard levels ranging from 50–100 ppb would protect > 99% of asthmatic children, at moderate or greater exertion, from experiencing at least one SO<sub>2</sub> exposure ≥ 400 ppb per year.<sup>28</sup> Similarly, a standard at 150 ppb

is estimated to protect ~ 99% of asthmatic children at moderate or greater exertion from experiencing at least one SO<sub>2</sub> exposure ≥ 400 ppb. Compared to standards ranging from 50–150 ppb, standards at 200 and 250 ppb are estimated to allow appreciably more exposures ≥ 400 ppb (Table 3). With respect to the 300 ppb benchmark, standards at 50, 75, and 100 ppb provide similar protection, while there is a marked increase in exposures of asthmatic children at moderate or greater exertion at standard levels ≥ 150 ppb (Table 3). Considering the 200 ppb benchmark level, it is estimated that 1-hour standard levels ranging from 50–100 ppb limit 5-minute SO<sub>2</sub> exposures ≥ 200 ppb considerably more than 1-hour standard levels ≥ 150 ppb. More

<sup>27</sup> Air quality, exposure, and risk numbers reported in Chapter 10 of the REA for a 75 ppb standard were bound by the estimates from air quality adjusted to just meet 99th percentile 1-hour daily maximum standards at 50 and 100 ppb.

<sup>28</sup> Table 3 reports that given a 99th percentile 1-hour daily maximum standard in the range of 50–100 ppb, < 1% of asthmatic children at moderate or greater exertion would be estimated to experience an SO<sub>2</sub> exposure ≥ 400 ppb, hence it can be stated

that this range of levels would protect >99% of asthmatic children at moderate or greater exertion from experiencing at least one SO<sub>2</sub> exposure ≥ 400 ppb per year.

specifically, standards in the range of 50–100 ppb are estimated to protect approximately 97 to > 99% of asthmatic children at moderate or greater exertion from experiencing at least one 5-minute exposure ≥ 200 ppb per year, while

standards ranging from 150–250 ppb are estimated to protect approximately 60 to 88% of these children from experiencing at least one 5-minute SO<sub>2</sub> exposure ≥ 200 ppb per year. Finally, similar to the air quality analysis, a

standard at 50 ppb is clearly most effective at limiting 5-minute SO<sub>2</sub> exposures ≥ 100 ppb. Additional and more detailed results from the exposure assessment can be found in chapter 8 of the REA.

**TABLE 3—ESTIMATED PERCENT OF ASTHMATIC CHILDREN IN ST. LOUIS AT MODERATE OR GREATER EXERTION EXPECTED TO EXPERIENCE AT LEAST ONE 5-MINUTE EXPOSURE ABOVE THE 100, 200, 300, AND 400 PPB POTENTIAL HEALTH EFFECT BENCHMARK LEVELS GIVEN AIR QUALITY ADJUSTED TO JUST MEET THE CURRENT STANDARDS, OR ALTERNATIVE 99TH PERCENTILE 1-HOUR DAILY MAXIMUM STANDARDS**

Exposure benchmarks (5-minute exposures)	Air quality scenarios						
	Just meet- ing current standards	99th Percentile 1-hour daily maximum standards					
		50 ppb	75 ppb	100 ppb	150 ppb	200 ppb	250 ppb
400 ppb .....	24%	< 1%	< 1% .....	< 1%	~1%	2.7%	6.3%
300 ppb .....	43.8%	< 1%	< 1% .....	< 1%	2.7%	8%	16%
200 ppb .....	73.1%	< 1%	(~1 to 2.7%) .....	2.7%	11.6%	24.5%	40%
100 ppb .....	96.7%	2.7%	(2.7 to 24.5%) .....	24.5%	54.5%	73.6%	84.8%

In evaluating the extent to which alternative standard levels provide protection against the health effects associated with 5-minute SO<sub>2</sub> exposures, the REA also considered key results from the quantitative risk assessment (REA, chapter 9). Table 4 presents the percent of exposed asthmatic children at moderate or greater exertion in St. Louis expected to

experience at least one moderate or greater lung function response per year, in terms of sRaw, given the 99th percentile 1-hour daily maximum standards analyzed in the REA. Results presented in Table 4 show that standard levels in the range of 100 to 150 ppb would generally be expected to protect approximately 95 to 98% of exposed asthmatic children at moderate or

greater exertion from experiencing at least one ≥ 100% increase in sRaw per year, while standards around and below 75 ppb would be estimated to provide exposed asthmatic children with protection approaching 99% or greater. Additional and more detailed risk analyses can be found in chapter 9 of the REA.

**TABLE 4—ESTIMATED PERCENT OF ASTHMATIC CHILDREN IN ST. LOUIS AT MODERATE OR GREATER EXERTION EXPECTED TO EXPERIENCE A ≥ 100% INCREASE IN SRAW GIVEN AIR QUALITY ADJUSTED TO JUST MEET EITHER THE CURRENT STANDARDS, OR ALTERNATIVE 99TH PERCENTILE 1-HOUR DAILY MAXIMUM STANDARDS**

Just meeting current standards	Air quality scenarios					
	99th Percentile 1-hour daily maximum standards					
	50 ppb	75 ppb	100 ppb	150 ppb	200 ppb	250 ppb
19.1–19.2% .....	0.4–0.9%	(0.4–2.9%)	2.1–2.9%	4.6–5.4%	7.4–8.1%	10.4–10.9%

**c. Observations based on evidence and risk-based considerations**

The policy assessment chapter of the REA considered the scientific evidence and the air quality, exposure, and risk information as they relate to considering alternative 1-hour SO<sub>2</sub> standards that could be judged to be requisite to protect public health with an adequate margin of safety. This evidence and information supports the following conclusions:

- Given the U.S. epidemiologic evidence and their associated air quality levels (see Figures 1–4), 99th percentile 1-hour standard levels at and below 75 ppb should be considered to limit SO<sub>2</sub> concentrations such that the upper end of the distribution of daily maximum hourly concentrations would likely be below that observed in most of the U.S. studies. Judgments about the weight to

place on uncertainties inherent in such studies should also inform selection of a specific standard level.

- Based on the air quality and exposure results, 1-hour standard levels in the range of 50–100 ppb should be considered to substantially limit 5-minute SO<sub>2</sub> concentrations ≥ 400 ppb and appreciably limit 5-minute SO<sub>2</sub> concentrations ≥ 200 ppb.
- Based on the air quality and exposure results, compared to a 1-hour standard in the range of 50–100 ppb, a 1-hour standard level at 150 ppb would be expected to similarly limit 5-minute SO<sub>2</sub> concentrations ≥ 400 ppb, but would limit 5-minute SO<sub>2</sub> concentrations ≥ 200 ppb considerably less.
- If relatively more weight is placed on certain types of uncertainties in the epidemiologic and controlled human

exposure evidence, levels up to 150 ppb could be considered, recognizing the questions as to the adequacy of protection that would be raised by levels at the higher end of this range.

- Placing relatively more weight on the consideration that participants in controlled human exposure studies do not include the most severe asthmatics would add support to considering standard levels down to 50 ppb.

**d. CASAC views**

CASAC expressed their views on potential levels for a standard in a letter to the EPA Administrator (Samet, 2009) within the context of their review of the 2nd draft REA, which also contained the draft policy assessment chapter. In drawing conclusions regarding the level of a short-term standard, CASAC considered the scientific evidence

evaluated in the ISA, the air quality, exposure, and risk results presented in the 2nd draft REA, and the evidence- and risk-based considerations presented in the policy assessment chapter of the 2nd draft REA. CASAC concurred with the conclusion from the policy assessment chapter for a range of standard levels beginning at 50 ppb: “[that chapter 10] clearly provides sufficient rationale for the range of levels beginning at a lower limit of 50 ppb” (Samet 2009, p. 16). For instance, CASAC has previously indicated that EPA should consider in its analyses the uncertainty that asthmatics participating in controlled human exposure studies do not represent the most SO<sub>2</sub> sensitive asthmatics (Henderson 2008 p. 6). With respect to the upper end of the range, CASAC stated, “an upper limit of 150 ppb posited in Chapter 10 could be justified under some interpretations of weight of evidence, uncertainties, and policy choices regarding margin of safety,” (Samet 2009, p. 16) although the letter did not provide any indication of what interpretations, uncertainties, or policy choices might support selection of a level as high as 150 ppb. Further, CASAC stated that “the draft REA appropriately implies that levels greater than 150 ppb are not adequately supported” (id). Moreover, CASAC stated that: “the panel agrees that the posited range of 50 to 150 ppb and the exposition of factors to consider when comparing values within the range are appropriately conveyed (Samet 2009, p. 16).”

e. Administrator’s conclusions on level for a 1-hour standard

As discussed above, in sections II.F.2 and II.F.3, the Administrator has proposed setting a 1-hour standard with a 99th percentile form. For the reasons discussed below, the Administrator proposes to set a level for a new 99th percentile 1-hour daily maximum primary SO<sub>2</sub> standard within the range from 50 to 100 ppb. In reaching this proposed decision, the Administrator has considered: (1) The evidence-based considerations from the final ISA and the final REA; (2) the results of the air quality, exposure, and risk assessments discussed above and in the final REA; (3) CASAC advice and recommendations on both the ISA and REA discussed above and provided in CASAC’s letters to the Administrator; and (4) public comments received on the first and second drafts of the ISA and REA. In considering what level of a 1-hour SO<sub>2</sub> standard is requisite to protect public health with an adequate margin of safety, the Administrator is mindful that this choice requires

judgments based on an interpretation of the evidence and other information that neither overstates nor understates the strength and limitations of that evidence and information.

The Administrator notes that the most direct evidence of respiratory effects from exposure to SO<sub>2</sub> comes from the controlled human exposure studies. These studies exposed groups of exercising asthmatics to defined concentrations of SO<sub>2</sub> for 5–10 minutes and found adverse respiratory effects. As discussed above, SO<sub>2</sub> exposure levels which resulted in respiratory effects in controlled human exposure studies were used in the REA as 5-minute benchmark exposures of potential concern. With respect to these 5-minute benchmarks, the Administrator focused on exceedences of the 400 and 200 ppb benchmarks. She notes that under ATS guidelines (ATS 1985, 2000) exposure to 5–10 minute SO<sub>2</sub> concentrations  $\geq$  400 ppb results in health effects which are clearly adverse: moderate or greater decrements in lung function (in terms of FEV<sub>1</sub> or sRaw<sup>29</sup>) that are frequently accompanied by respiratory symptoms.<sup>30</sup>

The Administrator also focused on exceedences of the 200 ppb benchmark, the lowest SO<sub>2</sub> concentration tested in free-breathing chamber studies. In these studies, moderate or greater decrements in lung function occurred in approximately 5 to 30% of exercising asthmatics, depending on the study. The Administrator further notes that while concentrations as low as 200 ppb have not been frequently accompanied by respiratory symptoms, she considers these effects to be adverse in light of CASAC advice and ATS guidelines. The REA concluded that these controlled human exposure studies could reasonably be interpreted to indicate an SO<sub>2</sub>-induced shift in lung function for this population of asthmatics (REA, section 4.3), such that asthmatics would have diminished reserve lung function and would be at greater risk if affected by another respiratory agent (e.g., viral infection). Importantly, diminished reserve lung function in a population

that is attributable to air pollution is an adverse effect under ATS guidelines as discussed in section II.B.1.c.

As discussed below, the Administrator also considered the results of the air quality, exposure, and risk analyses, as they serve to estimate the extent to which a given 1-hour standard limits peaks of SO<sub>2</sub> above the 5-minute benchmark concentrations derived from controlled human exposure studies. In considering these results as they relate to limiting 5-minute SO<sub>2</sub> concentrations  $\geq$  400 ppb and  $\geq$  200 ppb, and being mindful that more severe effects occur following 5-minute SO<sub>2</sub> exposures  $\geq$  400 ppb, the Administrator finds the most support for 99th percentile 1-hour daily maximum standard levels up to 100 ppb to protect against 5-minute SO<sub>2</sub> exposures  $\geq$  200 ppb. She notes that the 40-county air quality analysis estimates that a 100 ppb 1-hour standard would allow at most 2 days per year on average when estimated 5-minute daily maximum SO<sub>2</sub> concentrations exceed the 400 ppb benchmark, and at most 13 days per year on average when 5-minute SO<sub>2</sub> concentrations exceed the 200 ppb benchmark (Table 2). Furthermore, given a simulated 1-hour 100 ppb standard level, most counties in the air quality analysis were estimated to experience 0 days per year on average when 5-minute SO<sub>2</sub> concentrations exceed the 400 ppb benchmark and  $\leq$  3 days per year on average when 5-minute SO<sub>2</sub> concentrations were estimated to exceed the 200 ppb benchmark (see REA, Tables 7–14 and 7–12).

In addition, the St. Louis exposure analysis estimates that a 99th percentile 1-hour standard at a level of 100 ppb would likely protect > 99% of asthmatic children at moderate or greater exertion from experiencing at least one 5-minute exposure  $\geq$  400 ppb per year, and approximately 97% of asthmatic children at moderate or greater exertion from experiencing at least one exposure  $\geq$  200 ppb per year. In contrast, the Administrator notes that the St. Louis exposure analysis estimates a 99th percentile 1-hour daily maximum standard at a level of 150 ppb would likely protect only about 88% of asthmatic children at moderate or greater exertion from experiencing at least one 5-minute exposure  $\geq$  200 ppb per year. Finally, the Administrator notes that the St. Louis risk assessment estimates that a 99th percentile 1-hour standard level at 100 ppb would likely protect about 97–98% of exposed asthmatic children from experiencing at least one moderate or greater lung function response (defined as a  $\geq$  100% increase in sRaw). Based on these

<sup>29</sup> Decreases of 10–20% in FEV<sub>1</sub> (forced expiratory volume) and/or 100–200% increases in sRaw (specific airway resistance) are defined as moderate decrements in lung function.

<sup>30</sup> The ISA concluded that collective evidence from controlled human exposure studies considered in the previous review, along with a limited number of new controlled human exposure studies, consistently indicates that with elevated ventilation rates a large percentage of asthmatic individuals tested in a given chamber study (up to 60%, depending on the study) experience moderate or greater decrements in lung function, frequently accompanied by respiratory symptoms, following peak exposures to SO<sub>2</sub> at concentrations of 0.4–0.6 ppm. (ISA, p 3–9).

considerations, she concludes that there is support for a 99th percentile 1-hour daily maximum standard level at or below 100 ppb to appreciably limit 5-minute exposures to SO<sub>2</sub> above the 200 ppb benchmark level.

Turning to the epidemiologic evidence, the Administrator notes that epidemiologic studies have reported associations between more serious health outcomes (*i.e.* respiratory-related ED visits and hospitalizations) and ambient SO<sub>2</sub> concentrations. Unlike the controlled human exposure studies however, results from epidemiologic studies can be complicated by the fact that SO<sub>2</sub> is but one component of a complex mixture of pollutants in the ambient air. This uncertainty is addressed by the ISA which concluded that the limited available evidence indicates that the effect of SO<sub>2</sub> on respiratory health outcomes appears to be generally robust and independent of the effects of gaseous co-pollutants, including NO<sub>2</sub> and O<sub>3</sub>, as well as particulate co-pollutants, particularly PM<sub>2.5</sub> (ISA, section 5.2; p. 5–9).

The Administrator also notes that in general, associations reported in epidemiologic analyses are not associated with a defined exposure level of a pollutant (unlike the controlled human exposure studies), but represent concentrations of a pollutant taken from ambient monitoring data during the study period. These concentrations are used as surrogates for the distribution of pollutant exposures across the study area over the time period of the study. This introduces a degree of uncertainty in the interpretation of epidemiologic results in that it can be difficult to discern what part of the distribution of pollutant levels are likely most linked to the associations reported in epidemiologic analyses.

With respect to SO<sub>2</sub> specifically, the Administrator notes that adverse respiratory effects in epidemiologic studies are especially likely to occur at the upper end of the distribution of ambient SO<sub>2</sub> concentrations. Although some epidemiologic studies reported a linear relationship across the entire range of SO<sub>2</sub> concentrations, a few other studies found that the increase in SO<sub>2</sub>-related respiratory health effects was observed at the upper end of the distribution of SO<sub>2</sub> concentrations (ISA, section 5.3, p. 5–9). For example, an epidemiologic study conducted in Bronx, NY suggested an increased risk of asthma hospitalizations on the days with the highest SO<sub>2</sub> concentrations (Lin *et al.*, 2004). More specifically, these authors observed increased risk of asthma hospitalizations at SO<sub>2</sub> concentrations somewhere between the

90th and 95th percentiles (ISA, section 4.1.2 and ISA, Figure 4–4).

This epidemiologic evidence, though not independently sufficient to draw conclusions regarding causation, is consistent with, and informed by, the large body of controlled human exposure studies of exercising asthmatics exposed to short-term peak concentrations of SO<sub>2</sub>; these controlled human exposure studies provide the “definitive evidence” that short-term peak SO<sub>2</sub> exposure is associated with respiratory morbidity (ISA, Section 5.3, page 5–8). These studies consistently found moderate or greater decrements in lung function (*i.e.*  $\geq 100\%$  increase in sRaw and/or  $\geq 15\%$  decline in FEV<sub>1</sub>) and/or respiratory symptoms in exercising asthmatics following 5–10 minute peak exposures to SO<sub>2</sub>. Discussing the possible relationship between effects observed in these controlled human exposure studies and the associations reported in the epidemiologic studies, the ISA stated: “it is possible that these associations [in the epidemiologic studies] are determined in large part by peak exposures within a 24-hour period” (ISA, section 5.2 at p. 5–5). Similarly, the ISA stated that: “the effects of SO<sub>2</sub> on respiratory symptoms, lung function, and airway inflammation observed in the human clinical studies using peak exposures further provides a basis for a progression of respiratory morbidity resulting in increased ED visits and hospital admissions” and makes the associations observed in the epidemiologic studies “biologica[lly] plausible” (ISA, section 5.2 at p. 5–5). Thus, considered together, the epidemiologic and controlled human exposure evidence suggest that it is a reasonable approach to move the air quality distribution lower in a manner that targets control of both hourly and 5–10 minute peak SO<sub>2</sub> exposures.

For the reasons discussed above in section II.F.3, the Administrator has proposed a 99th percentile of the 1-hour daily maximum concentration as an appropriate form.<sup>31</sup> Moreover, as just discussed, there is support for the Agency’s view that adverse respiratory effects in epidemiologic studies are especially likely to occur at the upper end of the distribution of ambient SO<sub>2</sub> concentrations. Therefore, the Administrator finds it reasonable to

<sup>31</sup> As previously discussed in section II.F.3, a 99th percentile form was proposed to: (1) Minimize the number of days per year that an area could exceed the level of the standard and still attain the standard; (2) limit the prevalence of 5-minute peaks of SO<sub>2</sub>; and (3) provide a stable regulatory target to prevent areas from frequently shifting in and out of attainment.

focus on limiting the 99th percentile SO<sub>2</sub> levels reported in locations where positive associations were found in key epidemiologic studies. Adjusting the distribution of SO<sub>2</sub> levels in this manner will target control of those hourly and 5–10 minute peak SO<sub>2</sub> concentrations that are of most concern.

In considering the epidemiologic evidence with regard to level, the Administrator notes that there have been more than 50 peer reviewed epidemiologic studies evaluating SO<sub>2</sub> published worldwide (ISA, Tables 5–4 and 5–5). The Administrator finds that in assessing the extent to which these studies and their associated air quality information can inform the level of a new 99th percentile 1-hour daily maximum standard, U.S. and Canadian air quality information is most relevant. As described in section II.F.4.a, SO<sub>2</sub> concentrations reported for Canadian studies are not directly comparable to those reported for U.S. studies. That is, concentrations reported for Canadian analyses represent the average 99th percentile 1-hour daily maximum level across multiple monitors in a given city (REA Figure 5–5), rather than the concentration from the single monitor that recorded the highest SO<sub>2</sub> level (see Thompson and Stewart, 2009). Thus, the Administrator focused on 99th percentile air quality information from U.S. studies for informing potential 1-hour standard levels.

The Administrator notes that Figures 1 to 4 include 99th percentile 1-hour daily maximum SO<sub>2</sub> concentrations from ten U.S. epidemiologic studies of ED visits and hospital admissions (Figures 5–1 to 5–4 in the REA). The Administrator agrees with the REA finding that this information provides evidence of associations between ambient SO<sub>2</sub> and ED visits and hospital admissions in cities with particular 99th percentile 1-hour SO<sub>2</sub> levels. This information is relevant for identifying standard levels that could significantly limit SO<sub>2</sub> concentrations so that the upper end of the distribution of daily maximum hourly concentrations would likely be below that observed in most of these studies. These figures report mostly positive, and sometimes statistically significant, associations between ambient SO<sub>2</sub> concentrations and ED visit and hospital admissions in locations where 99th percentile 1-hour daily maximum SO<sub>2</sub> levels ranged from 50–460 ppb. Moreover, within this broader range of SO<sub>2</sub> concentrations, seven of these studies were in locations where the 99th percentile of the 1-hour daily maximum SO<sub>2</sub> concentrations were in the range of 75–150 ppb. The Administrator particularly notes the

cluster of three epidemiologic studies between 78–150 ppb (for the 99th percentile of the 1-hour SO<sub>2</sub> concentrations) where the SO<sub>2</sub> effect estimate remained positive and statistically significant in multi-pollutant models with PM (NYDOH (2006), Ito *et al.*, (2007), and Schwartz *et al.*, (1995)). The Administrator also notes the limited evidence from two epidemiologic studies employing single pollutant models that found mostly positive, and sometimes statistically significant, associations between ambient SO<sub>2</sub> and ED visits in locations where 1-hour SO<sub>2</sub> concentrations were approximately 50 ppb (Figures 1 and 2). Based on the interpretation of the epidemiologic evidence discussed above, the Administrator concludes that this evidence provides support for consideration of a 99th percentile 1-hour daily maximum standard level at or below 75 ppb to limit SO<sub>2</sub> concentrations such that the upper end of the distribution of daily maximum hourly concentrations would likely be below that observed in most of the U.S. studies. The Administrator also recognizes that judgments about the weight to place on uncertainties inherent in such studies should inform selection of a specific standard level.

Based on the epidemiologic and controlled human exposure information presented above, the Administrator considered what range of standard levels would be requisite to protect public health, including the health of at-risk groups, with an adequate margin of safety that is sufficient but not more than necessary to achieve that result. The assessment of a standard level calls for consideration of both the degree of risk to public health at alternative levels of the standard as well as the certainty that such risk will occur at any specific level. Based on the information available in the ISA, there is no evidence-based bright line that indicates a single appropriate level. Moreover, given that a 1-hour averaging time is being used to control 5-minute peaks of SO<sub>2</sub>, the Administrator also recognizes that the results of the air quality, exposure, and risk analyses will have to be considered given that these analyses indicate the extent to which a particular 99th percentile 1-hour daily maximum standard will likely limit 5-minute SO<sub>2</sub> peaks of a given concentration. Thus, the combination of scientific evidence and air quality, exposure, and risk-based information needs to be considered as a whole in making this public health policy judgment.

In selecting a level that would serve as an appropriate upper end for a range of levels to propose, the Administrator

has considered a cautious approach to interpreting the available evidence and exposure/risk-based information—that is, an approach that places relatively more weight on those types of uncertainties and limitations in the information that would lead to placing less reliance on the results of the epidemiologic studies. This approach would tend to avoid potentially overestimating public health risks and the degree of protection likely to be associated with just meeting a particular standard level. This approach would place more weight in particular on uncertainties in epidemiologic evidence such as concerns related to exposure measurement error, the possible role of co-pollutants and effects modifiers, and interindividual differences in susceptibility to SO<sub>2</sub>-related effects.

In applying this approach, the Administrator has selected an upper end of a range of levels to propose at 100 ppb. The selection of this level focuses on the results of the controlled human exposure studies and is primarily based on the results of the air quality and exposure analyses which suggest that a 1-hour standard should be at or below 100 ppb to appreciably limit 5-minute SO<sub>2</sub> benchmark concentrations  $\geq 200$  ppb. That is, as mentioned above, the St. Louis exposure analysis indicates that a 1-hour standard at 100 ppb would still be estimated to protect about 97% of asthmatic children at moderate or greater exertion from experiencing at least one 5-minute SO<sub>2</sub> exposure  $\geq 200$  ppb. In contrast, the St. Louis exposure analysis estimates that a 1-hour standard at 150 ppb would likely only protect about 88% of asthmatic children at moderate or greater exertion from experiencing at least one 5-minute SO<sub>2</sub> exposure  $\geq 200$  ppb.

In selecting a level that would serve as an appropriate lower end for a range of levels to propose, the Administrator has considered a precautionary approach to interpreting the available evidence and exposure/risk-based information—that is, an approach that places relatively more weight on the results of the epidemiological studies, as well as more weight on those types of uncertainties that may be associated with potentially underestimating health effects in the most sensitive populations. This approach would tend to avoid potentially underestimating public health risks and the degree of protection likely to be associated with just meeting a particular standard level. This approach would place more weight on the consideration that the participants in controlled human exposure studies did not include individuals with severe asthma.

In applying this approach, she has selected 50 ppb as the lower end of a range of levels to propose, which is consistent with CASAC's advice. The selection of this level focuses in part on the epidemiologic evidence. With respect to the epidemiologic studies, seven of ten U.S. ED visit and hospital admission studies reporting generally positive associations with ambient SO<sub>2</sub> were conducted in locations where 99th percentile 1-hour daily maximum SO<sub>2</sub> levels were about 75–150 ppb, and three of these studies observed statistically significant positive associations between ambient SO<sub>2</sub> and respiratory-related ED visits and hospitalizations in multi-pollutant models with PM (NYDOH (2006), Ito *et al.*, (2007), and Schwartz *et al.*, (1995)). Further, the Administrator notes that a 99th percentile 1-hour daily maximum standard set at a level of 50 ppb is well below the 99th percentile 1-hour daily maximum SO<sub>2</sub> concentrations reported in locations where these studies were conducted (*i.e.* well below 99th percentile 1-hour daily maximum SO<sub>2</sub> levels of 78–150 ppb). Finally, the Administrator notes that two epidemiologic studies reported generally positive associations between ambient SO<sub>2</sub> and ED visits in cities when 99th percentile 1-hour daily maximum SO<sub>2</sub> concentrations were approximately 50 ppb, but does not consider that evidence strong enough to set a lower standard level.

In considering the results of the air quality and exposure analyses, the Administrator also notes that the 40-county air quality analysis estimates that a 99th percentile 1-hour daily maximum standard set at a level of 50 ppb would result in zero days per year when estimated 5-minute SO<sub>2</sub> concentrations exceed the 400 ppb 5-minute benchmark level and at most 2 days per year when modeled 5-minute SO<sub>2</sub> concentrations exceed the 200 ppb 5-minute benchmark level. In addition, the St. Louis exposure analysis estimates that a 99th percentile 1-hour daily maximum standard set at a level of 50 ppb would likely protect > 99% of asthmatic children at moderate or greater exertion from experiencing at least one 5-minute exposure both  $\geq 400$  and  $\geq 200$  ppb per year.

The Administrator thus proposes to set the level of a new 1-hour standard that would protect public health with an adequate margin of safety between 50 ppb and 100 ppb. In so doing, the Administrator is relying on reported findings from both epidemiologic and controlled human exposure studies, as well as the results of air quality and exposure analyses. The Administrator

solicits comment on this proposed range of standard levels as well as on the approach she has used to identify the range. Specifically, the Administrator solicits comment on the following:

- The weight she has placed on the epidemiologic evidence, the controlled human exposure evidence, and the air quality, exposure, and risk information, the benchmark used to select the proposed range, and the uncertainties associated with each of these.

- The most appropriate level within this proposed range given the available scientific evidence, and air quality, exposure, and risk information, and the uncertainties associated with each.

With regard to the proposed range of standard levels, the Administrator notes that the lower end of the proposed range is consistent with CASAC advice that there is clearly sufficient evidence for consideration of standard levels starting at 50 ppb (Samet 2009). With respect to the upper end of the proposed range, the Administrator notes that CASAC concluded that standards up to 150 ppb “could be justified under some interpretations of weight of evidence, uncertainties, and policy choices regarding margin of safety” (Samet 2009, p. 16), although the letter did not provide any indication of what interpretations, uncertainties, or policy choices might support selection of a level as high as 150 ppb.

In light of the range of levels included in CASAC’s advice, the Administrator solicits comment on setting a standard level above 100 ppb and up to 150 ppb. In so doing, the Administrator again recognizes that there are uncertainties with the scientific evidence, such as attributing effects reported in epidemiologic studies specifically to SO<sub>2</sub> given the presence of co-occurring pollutants, especially PM, and the uncertainties associated with using ambient SO<sub>2</sub> concentrations as a surrogate for exposure. Any comments should specifically address the cluster of epidemiologic studies that remained statistically significant in co-pollutant models with PM, two of which had 99th percentile levels appreciably lower than 150 ppb. Commenters should also address the conclusion in the ISA that the respiratory effects seen in the epidemiologic studies are generally robust and independent of co-pollutants. In addition, the Administrator notes that compared to the proposed range of 50–100 ppb, a standard level as high as 150 ppb would not comparably limit 5-minute SO<sub>2</sub> exposures  $\geq$  200 ppb. She notes that the St. Louis exposure analysis estimates that a 150 ppb standard would protect approximately 88% of asthmatic

children at moderate or greater exertion from experiencing at least one SO<sub>2</sub> exposure  $\geq$  200 ppb per year (compared to  $>$  99% and approximately 97% given standards at 50 and 100 ppb respectively; see Table 3). There are also questions as to whether a standard set at this level would provide an adequate margin of safety. Thus, with respect to considering whether it would be appropriate to set a standard level as high as 150 ppb, the Administrator invites comment on the extent to which it is appropriate to emphasize uncertainties with respect to the epidemiologic evidence. She also invites comment on the implications such considerations would have on limiting 5-minute SO<sub>2</sub> exposures  $\geq$  200 ppb.

#### 5. Implications for retaining or revoking current standards

The REA recognized that the particular level selected for a new 1-hour daily maximum standard would have implications for reaching decisions on whether to retain or revoke the current 24-hour and annual standards. That is, with respect to SO<sub>2</sub>-induced respiratory morbidity, the lower the level selected for a 99th percentile 1-hour daily maximum standard, the less additional public health protection the current standards would be expected to provide. As previously mentioned (see section I.E.3), CASAC expressed a similar view following their review of the 2nd draft REA: “assuming that EPA adopts a one hour standard in the range suggested, and if there is evidence showing that the short-term standard provides equivalent protection of public health in the long-term as the annual standard, the panel is supportive of the REA discussion of discontinuing the annual standard” (Samet 2009, p. 15). With regard to the current 24-hour standard, CASAC was generally supportive of using the air quality analyses in the REA as a means of determining whether the current 24-hour standard was needed in addition to a new 1-hour standard to protect public health. CASAC stated: “the evidence presented [in REA Table 10–3] was convincing that some of the alternative one-hour standards could also adequately protect against exceedances of the current 24-hour standard” (Samet 2009, p. 15).

In accordance with the REA findings and CASAC recommendations mentioned above, the Administrator notes that the 1-hour standards being proposed (*i.e.*, 99th percentile 1-hour daily maximum SO<sub>2</sub> standards at 50–100 ppb) would have the effect of maintaining 24-hour and annual SO<sub>2</sub>

concentrations generally well below the levels of the current 24-hour and annual NAAQS (see REA Tables 10–3 and 10–4 and REA Appendix Tables D–3 to D–6). Thus, if a new 99th percentile 1-hour daily maximum standard is set in the proposed range of 50–100 ppb, than the Administrator proposes to revoke the current 24-hour and annual standards. However, if a standard is set at a level  $>$ 100 ppb and up to 150 ppb, then the Administrator proposes to retain the existing 24-hour standard, recognizing that a 99th percentile 1-hour daily maximum standard at 150 ppb would not have the effect of maintaining 24-hour average SO<sub>2</sub> concentrations below the level of the current 24-hour standard in all locations analyzed (see REA Appendix Table D–4). However, the Administrator would revoke the current annual standard recognizing: (1) 99th percentile 1-hour daily maximum standards in the range of 50–150 ppb would maintain annual average SO<sub>2</sub> concentrations below the level of the current annual standard (see REA Table 10–4 and REA Appendix tables D–5 and D–6); and (2) the lack of sufficient evidence linking long-term SO<sub>2</sub> exposure to adverse health effects.

#### G. Summary of proposed decisions on the primary standard

For the reasons discussed above, and taking into account information and assessments presented in the ISA and REA as well as the advice and recommendations of CASAC, the Administrator proposes that the current 24-hour and annual standards are not requisite to protect public health with an adequate margin of safety. The Administrator proposes to establish a new 1-hour standard that will afford increased protection for asthmatics and other at-risk populations against an array of adverse respiratory health effects related to short-term (5-minutes to 24-hours) SO<sub>2</sub> exposure. These effects include increased decrements in lung function (defined in terms of sRaw and FEV<sub>1</sub>), increases in respiratory symptoms, and related serious indicators of respiratory morbidity including emergency department visits and hospital admissions for respiratory causes.

Specifically, the Administrator proposes to set a new short-term primary SO<sub>2</sub> standard with a 1-hour (daily maximum) averaging time and a form defined as the 3-year average of the 99th percentile or the 4th highest daily maximum concentration. The level for the new standard is proposed to be within the range of 50–100 ppb. The Administrator also solicits comment on levels as high as 150 ppb. In addition to

setting a new 1-hour standard in the proposed range of 50–100 ppb, the Administrator proposes to revoke the current 24-hour and annual standards recognizing that a 1-hour standard set in the proposed range of 50–100 ppb will have the effect of generally maintaining 24-hour and annual SO<sub>2</sub> concentrations well below the levels of the current 24-hour and annual standards. Moreover, the Administrator notes that there is little health evidence to support an annual standard for the purpose of protecting against health effects associated with long-term SO<sub>2</sub> exposures.

### III. Proposed Amendments to Ambient Monitoring and Reporting Requirements

EPA is proposing changes to the ambient air monitoring, reporting, and network design requirements for the SO<sub>2</sub> NAAQS. This section discusses the changes we are proposing that are intended to support the proposed 1-hour NAAQS, and the possible retention of the existing 24-hour NAAQS depending on the selected level of the 1-hour NAAQS, as described in Section II above. Ambient SO<sub>2</sub> monitoring data are used to determine whether an area is in violation of the SO<sub>2</sub> NAAQS. Ambient SO<sub>2</sub> monitoring data are collected by state, local, and tribal monitoring agencies (“monitoring agencies”) in accordance with the monitoring requirements contained in 40 CFR parts 50, 53, and 58.

#### A. Monitoring methods

To be used in a determination of compliance with the SO<sub>2</sub> NAAQS, SO<sub>2</sub> data must be collected using either a Federal Reference Method (FRM) or a Federal Equivalent Method (FEM) as defined in 40 CFR Parts 50 and 53. The current monitoring methods in use by most State and local monitoring agencies are FEM analyzers based on the ultraviolet fluorescence (UVF) measurement principle. These continuous analyzers were implemented into the SO<sub>2</sub> monitoring networks in the early 1980s, and the current manual FRM for SO<sub>2</sub> is no longer used for field monitoring. The current list of all approved FRMs and FEMs capable of providing ambient SO<sub>2</sub> data for use in attainment designations may be found on the EPA Web site <http://www.epa.gov/ttn/amtic/files/ambient/criteria/reference-equivalent-methods-list.pdf>.

For reasons explained subsequently, EPA proposes to establish a new FRM for measuring SO<sub>2</sub> in the ambient air. This proposed new FRM for SO<sub>2</sub> would be an automated method based on UVF

(the same type of analyzers now in widespread use), and it would be specified in the form of a reference measurement principle and a calibration procedure. It would be in a new Appendix A–1 to 40 CFR Part 50. Analyzers approved as FRMs for SO<sub>2</sub> after the effective date of the final rule would be subject to performance specifications and other requirements set forth in 40 CFR Part 53, under associated amendments proposed for Part 53. The existing FRM for SO<sub>2</sub> (a wet-chemical, manual method) would be retained for some period of time, thereby permitting continued use of currently designated FEMs to avoid any disruption to existing SO<sub>2</sub> monitoring networks.

#### 1. Background

FRMs, as set forth in several appendices to 40 CFR Part 50, serve either or both of two primary purposes. The first is to provide a specified, definitive methodology for routinely measuring concentrations of various ambient air pollutants for comparison to the NAAQS in Part 50 and for other air monitoring objectives. The second is to provide a standard of comparison for determining equivalence to the specified reference method of alternative and perhaps more practical pollutant measurement methods (FEMs) that can be used in lieu of the FRM for routine monitoring.

Some of the FRMs contained in appendices to Part 50 (such as the current SO<sub>2</sub> FRM) are manual methods that are completely specified within their respective appendices. Others (such as the ozone FRM) are in the form of a measurement principle and associated calibration procedure that must be implemented in a commercial FRM analyzer model. Such FRM analyzers must be tested and shown to meet explicit performance and other requirements that are set forth in 40 CFR Part 53 (Ambient Air Monitoring Reference and Equivalent Methods). Each of these analyzer models is considered to be an FRM only upon specific designation as such by EPA under the provisions of Part 53.

From time to time, as pollutant measurement technology advances, the reference methods in these Part 50 appendices need to be assessed to determine if improved or more suitable measurement technology has become available to better meet current FRM needs as well as potential future FRM requirements. Such new technology can either be presented to EPA for evaluation by an FEM applicant under § 53.16, or (as in this case) EPA can originate the process itself as provided

in § 53.7. If, after reviewing a new methodology, the Administrator determines that the new methodology is substantially superior, § 53.16 of Part 53 provides for supersession of FRMs under these circumstances.

The FRM for measuring SO<sub>2</sub> in the ambient air was promulgated on April 30, 1971 (36 FR 8186), in conjunction with EPA's establishment (originally as 42 CFR Part 410) of the first national ambient air quality standards (NAAQS) for six pollutants (including sulfur dioxide) as now set forth in 40 CFR Part 50. This SO<sub>2</sub> FRM is specified in Appendix A of Part 50 and identified as the pararosaniline method. It is a manual, wet-chemical method requiring sample air to be bubbled through an absorbing reagent (tetrachloromercurate), which is then returned to a laboratory for chemical analysis. At the time of its promulgation, the method was considered the best available method and was in considerable use for monitoring SO<sub>2</sub> in the air. However, newly developed automated continuous analyzers approved as FEMs rapidly supplanted use of this manual method for air monitoring in the U.S. By the 1990's, the FRM was no longer used at all in domestic air monitoring (EPA, 2009b), and since then the method has been used mainly as a comparison reference method for the testing and designation of candidate FEMs for SO<sub>2</sub> in accordance with 40 CFR Part 53.

The pararosaniline manual FRM has served its role for many years, but now a better method is needed that more fully meets the needs of contemporary SO<sub>2</sub> monitoring. The existing FRM is primarily a 24-hour integrated method, whereas a 1-hour SO<sub>2</sub> FRM measurement capability would be needed to implement the proposed 1-hour SO<sub>2</sub> NAAQS. Existing FEM analyzers can and do provide 1-hour measurement capability, but EPA wishes to facilitate the approval of new monitoring technologies as well. While the existing manual reference method can produce 1-hour averages, it is clearly impractical for routine use in making 1-hour SO<sub>2</sub> measurements. Also, the 1-hour mode of the manual method is not a good standard for approving new FEMs with 1-hour measurement capability, because scores of 1-hour measurements would be needed during equivalency testing. Further, the existing FRM is cumbersome to use and requires a mercury-containing reagent that is potentially hazardous to operators or to the environment if it is mishandled.

These operational shortcomings suggest that the existing FRM should be replaced with a more suitable

methodology. Fortunately, the existing SO<sub>2</sub> instrumental measurement technique based on the UVF measurement principle offers superior performance and substantial operational advantages, as reported in an FRM evaluation for EPA produced by Research Triangle Institute (Rickman, 1987). Analyzers using this technique can well provide the needed detection limits, precision, and accuracy and fulfill other purposes of an FRM, including use as an appropriate standard of reference for testing and designation of new FEM analyzers. After reviewing these factors, EPA has determined that a new, automated FRM for SO<sub>2</sub> based on the UVF measurement principle should be adopted. EPA is proposing to add the new FRM in a new Appendix A-1 to Part 50.

In association with the proposed new FRM, EPA is also proposing to update the performance-based requirements for FEM SO<sub>2</sub> analyzers currently in 40 CFR Part 53. These requirements were established in the 1970's, based primarily on the wet-chemical measurement technology available at that time. Those initial requirements have become significantly outdated and should be modified to match current technology, particularly because they would apply to new FRM analyzers under the proposed new FRM. The better instrumental performance available with the proposed new UVF reference method technique allows the performance requirements for SO<sub>2</sub> in 40 CFR Part 53 to be made more stringent for both FRM and FEM analyzers (EPA, 2009c).

## 2. Proposed new FRM measurement technique

Since the 1970's, a variety of measurement principles have been successfully used to produce continuous analyzers for SO<sub>2</sub>, some of which have qualified for EPA designation as equivalent methods (found at <http://www.epa.gov/ttn/amtic/files/ambient/criteria/reference-equivalent-methods-list.pdf>). These include methods based on ultraviolet fluorescence, flame photometry, differential optical absorption spectroscopy, coulometric and conductometric techniques, and second derivative ultraviolet absorption spectrometry. Although some of these techniques saw considerable utilization in the 1970's, their use dwindled after the introduction of UVF analyzers because of various shortcomings such as non-specificity for SO<sub>2</sub>, susceptibility to interferences, marginal performance, or operational disadvantages (e.g. requiring hydrogen gas or wet-chemical reagents).

Consequently, the UVF technique has emerged as the clearly dominant measurement technique for SO<sub>2</sub>, providing a majority of the domestic air monitoring data obtained over the last three decades, and virtually 100% of the current monitoring data (EPA, 2009b). As the proposed new reference method, the UVF technique would be specified in performance-based form, with a generic reference measurement principle and associated calibration procedure in a new Appendix A-1 to 40 CFR Part 50. Associated performance requirements applicable to candidate UVF FRM analyzers would be specified in 40 CFR Part 53. This form of the FRM is consistent with that specified for FRMs for CO, O<sub>3</sub>, and NO<sub>2</sub> in Appendices C, D, and F (respectively) to 40 CFR Part 50.

Reasonable commercial availability of high quality analyzers utilizing the reference measurement principle that can be offered by multiple manufacturers, ideally over many years, is an important aspect of any new reference measurement principle. EPA has designated more than a dozen UVF analyzers as equivalent to the current reference method over the last 30 years. Although most of the early model UVF analyzers are no longer in production, many have been replaced by redesigned and improved models, and entirely new models continue to become designated as FEMs. Currently, more than a half-dozen designated FEM models offered by multiple manufacturers are commercially available. The widespread use of the method has three important technical advantages for an FRM: (1) A variety of analyzer models are available and will likely continue to be available from multiple manufacturers for many years to come, (2) analyzer manufacturers have had (and continue to have) a strong marketing incentive to improve, refine, perfect, and continue to market such analyzers, and (3) the number of accumulated UVF field monitoring datasets (including related QC data) provide an extensive, available performance track record that can be evaluated to assess the performance of the analyzers in actual monitoring use.

The only other equivalent method measurement technique that has even a small representation among currently available FEM analyzers is the differential optical absorption spectrometric method. The open-path nature of this method (measurement of pollutants in the open air without a closed measurement cell) is not suitable for many of the purposes of a reference method. Further, this method is only available as two product models from two manufacturers, and very few State

and local monitoring agencies are using such analyzers.

The UVF technique is not without some imperfections as a reference method. Analyzers utilizing the technique are, to a limited degree, susceptible to interference from aromatic hydrocarbon species and potentially other compounds at existing levels or levels that may occur at many monitoring sites. However, analyzer manufacturers have developed very effective ways to reduce these potential limitations, including careful selection of wavelengths, optimum optical design, and sample air scrubbers, such that typical interferences are minimal.

All UVF analyzers that have been designated as SO<sub>2</sub> FEMs have been tested and shown to meet the existing performance requirements of 40 CFR Part 53. These include required testing for both positive and negative potential interferences, minimum level of measurement, zero and span drift, and precision. The results of these tests have been submitted to EPA and are in the archived FEM applications for these analyzers. Many newer models substantially exceed those requirements, with sensitivities down to less than 1 ppb, and typically commensurate levels of signal noise, precision, and zero drift (EPA, 2009c). In addition, UVF analyzers can accommodate a wide range of concentration measurement ranges. They are quite well suited to measure high, short-term SO<sub>2</sub> concentrations near sources, and they can also be used to measure trace-level concentrations in clean areas.

For these reasons, EPA has decided to propose a new automated SO<sub>2</sub> FRM based on the UVF measurement technology. EPA is confident that commercially available UVF instrument models would provide capability to serve not only current monitoring and FRM applications but anticipated monitoring and FRM needs well into future years. EPA solicits comment on the proposal to promulgate an FRM for SO<sub>2</sub> that would be an automated method based on ultraviolet fluorescence, which would be specified in the form of a reference measurement principle and calibration procedure, as stated here, and contained in a new Appendix A-1 to 40 CFR Part 50.

## 3. Technical description of the proposed UVF FRM

The proposed new reference method is based on automated measurement of the intensity of the characteristic fluorescence released by SO<sub>2</sub> in an ambient air sample when irradiated by ultraviolet light. The SO<sub>2</sub> fluorescence produced is also in the ultraviolet range,

but is measured at a longer wavelength. An analyzer implementing this measurement principle would include a measurement cell, an ultraviolet light source of appropriate wavelength, an ultraviolet detector system with appropriate wavelength sensitivity, and a pump and flow control system for sampling the ambient air. Generally, the analyzer also requires a means to reduce concentrations of aromatic hydrocarbons and possibly other compounds (depending on target wavelengths and other parameters used) in the air sample to control for potential measurement interferences. The analyzer is calibrated by referencing the instrumental fluorescence measurements to SO<sub>2</sub> standard concentrations traceable to a NIST (National Institute of Standards and Technology) primary standard for SO<sub>2</sub>. This generic description of the FRM would be contained in Appendix A-1 to 40 CFR Part 50 and would be coupled with explicit analyzer performance requirements specified in Subpart B of 40 CFR Part 53. To qualify as an FRM, an analyzer model based on this principle would have to be tested in accordance with test procedures in Subpart B Part 53 and shown to meet the performance requirements specified in that Subpart. EPA could then designate the analyzer model as an FRM analyzer, as provided in Part 53.

#### 4. Implications to air monitoring networks

Under § 53.16, EPA must consider the benefits of a proposed supersession of an existing reference method, the potential economic consequences of such action for State and local monitoring agencies, and any disruption of State and local air quality monitoring programs that might result from such action. Supersession of an existing reference method, as described in § 53.16, presumes that the existing FRM would be deleted from Part 50 and replaced with a new FRM, and that all equivalent methods based on the old FRM would be cancelled. In the case of SO<sub>2</sub>, essentially all current domestic air monitoring activity is carried out using FEM UVF analyzers. Cancellation of the FEM designations of all these analyzers now would be potentially very disruptive to State, local, and other monitoring networks, even though § 53.16 alludes to a possible transition period to allow monitoring agencies some period of time to replace cancelled FEM analyzers.

EPA recognizes that these existing SO<sub>2</sub> FEMs are providing monitoring data that are adequate for the current and the proposed SO<sub>2</sub> NAAQS and for

many other purposes, and there appears to be no need or purpose served by their withdrawal. Therefore, in this case, EPA proposes instead to retain the existing manual FRM for SO<sub>2</sub> and to promulgate an entirely new automated FRM for SO<sub>2</sub>. The new FRM description would be contained in a new Appendix A-1 to 40 CFR Part 50, and the existing FRM would be re-codified as Appendix A-2 to 40 CFR Part 50, with both reference methods coexisting. Following adoption of the new Appendix A-1, new language proposed for § 53.2(a) and (b) would provide that new FRM and FEM analyzers for SO<sub>2</sub> be designated only with reference to the proposed new Appendix A-1. At the same time, retention of the existing SO<sub>2</sub> reference method will preclude the need to cancel the designations of all existing FEMs for SO<sub>2</sub>.

Under this proposal, no monitoring agencies would be required to change their SO<sub>2</sub> monitoring procedures as a result of the proposed changes, so it would have no economic costs for implementation and no disruptive effects on state, local, or tribal air quality monitoring programs. Further, since UVF FEM analyzers have been in dominant use for many years, no bias or discontinuity in any aspect of the monitoring data obtained subsequently would result from the proposed change in the SO<sub>2</sub> reference methodology.

In conjunction with the proposed new FRM, EPA is also proposing to adopt updated performance requirements in 40 CFR Part 53, applicable to both FRM and FEM analyzers, consistent with the automated methods and in anticipation of future NAAQS needs. This would ensure that, going forward, all new SO<sub>2</sub> monitors would have improved performance. EPA believes that the proposal to retain the existing FRM while adding the new FRM would provide for a smooth, evolutionary transition from the older, manual FRM to the new, modern, automated FRM and FEM technology and the associated better performance requirements, with no immediate impact to current monitoring activities. For purposes of comparing SO<sub>2</sub> monitoring data to the SO<sub>2</sub> NAAQS, the EPA believes that the UVF FEMs are appropriate for continued use under the current standards and under the option being considered for a new 1-hour averaged primary SO<sub>2</sub> NAAQS. After several years, at a time when either a new SO<sub>2</sub> NAAQS would require higher monitoring data quality or there would be no further potential for disruption to monitoring agencies, EPA would plan to withdraw the older reference method and its associated FEMs.

#### 5. Proposed revisions to 40 CFR Part 53

Several amendments associated with the proposed new SO<sub>2</sub> reference measurement principle are proposed to 40 CFR Part 53. The most significant of these would update the performance requirements for both new FRM and new FEM analyzers for SO<sub>2</sub>, as set forth in proposed revised Table B-1. Based on typical performance capabilities available for UVF analyzers, EPA is proposing to reduce the allowable noise from 5 ppb to 1 ppb, the lower detectable limit from 10 ppb to 2 ppb, and the allowable interference equivalent limits from  $\pm 20$  ppb to  $\pm 5$  ppb for each interferent and from 60 ppb to 20 ppb for the total of all interferents. Also, EPA proposes to change the allowable zero drift limits from  $\pm 20$  ppb to  $\pm 4$  ppb, and to delete the specified limits for span drift at 20% of the upper range limit (URL) for SO<sub>2</sub> analyzers. Review of FEM analyzer performance test results has shown that the 20% URL span limit requirements are unnecessary because drift performance requirements are adequately covered by the zero drift and 80% URL span drift limits. EPA proposes to change the lag time allowed from 20 to 2 minutes and change the rise and fall time limits from 15 to 2 minutes. For precision, EPA proposes to change the form of the precision limit specifications from ppm to percent (of the URL) for SO<sub>2</sub> analyzers and to set the limit at 2 percent for both 20% and 80% of the URL. Two percent is equivalent to 10 ppb for the standard (500 ppb) range, which is equivalent to the existing limit value for precision at 20% of the URL, but would be a reduction from 15 ppb to 10 ppb for the limit value at 80% of the URL. This change in units from ppm (or ppb as given here) to percent makes the requirement responsive to higher and lower measurement ranges. Also, a new footnote is proposed to be added to Table B-1 to clarify how noise tests are to be carried out for candidate analyzers having an adjustable or automatic time constant capability.

EPA recognizes that SO<sub>2</sub> monitoring needs can vary widely, from monitoring background levels in pristine areas to measuring short-term (1-hour) or even very short-term (less than 1-hour) high-level averages in the vicinity of substantial sources of SO<sub>2</sub>. To address the need for more sensitive, lower measurement ranges for SO<sub>2</sub> analyzers, EPA is proposing 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. These additional requirements are listed in the proposed revised Table B-1. A candidate analyzer that meets the Table B-1 requirements for the standard measurement range (0 to 0.5 ppm) could optionally have one or more narrower ranges included in its FRM or FEM designation by further testing to show that it meets these supplemental, narrower-range requirements.

At the other (high) end of the concentration measurement spectrum, another related change proposed for § 53.20 would allow optional designation of measurement ranges for SO<sub>2</sub> up to 2 ppm rather than 1 ppm as is now permitted, and designation of these higher ranges would be applicable to both FRM and FEM analyzers. Such higher ranges are often needed for measurement of short-interval SO<sub>2</sub> averages. Finally, EPA is proposing to clarify in § 53.20 that optional testing for auxiliary higher or lower measurement ranges (for all gaseous pollutants) may include tests for only some of the performance parameters, since the test results for the other performance parameters carried out for the standard measurement range would be technically applicable and adequate for the higher and/or lower ranges as well.

EPA believes that these changes in performance requirements are appropriate, based on analyzer performance data available from analyzer manuals and recent FEM applications. EPA solicits comments especially from UVF instrument users and manufacturers on these proposed changes, particularly in regard to whether they are reasonable, appropriate, of significant benefit, and achievable without undue cost. Comments are also requested on such issues as the trade off between a high measurement range and the need for adequate resolution at concentrations near the annual NAAQS, a similar trade off between noise level and response time (some analyzers allow these parameters to be adjusted by the operator or may adjust them automatically based on the rate of change of the concentration level), and whether such performance parameters should be addressed in more detail in 40 CFR Part 53. In particular, should SO<sub>2</sub> analyzer requirements address the potential need for faster measurement response time to permit more accurate monitoring of short-term intervals such as 5-minute or 10-minute averages, and are the special performance requirements EPA is proposing for measuring very low levels (trace levels) of SO<sub>2</sub> appropriate and effective?

Another significant change proposed to 40 CFR Part 53 would add some low and medium level 1-hour comparability tests to the Subpart C comparability test requirements, as specified in Table C-1. These would help to ensure that the 1-hour measurement performance of candidate FEMs are adequate, relative to the FRM. Also, EPA proposes to amend Table A-1 in Subpart A to reflect the new FRM description in proposed new Appendix A-1 of 40 CFR Part 50. This table would also be amended to correct some printing errors in the current table as well as to add new entries related to the new FRM for lead in PM<sub>10</sub> that was recently promulgated. Other minor changes would be necessary in the wording of a few sections of Subparts A and B due to the proposed change in the nature of the SO<sub>2</sub> FRM from a manual to an automated method or to update the language. These changes are reflected in the proposed regulatory text section of this notice.

EPA proposes additional minor revisions to Tables B-2 and B-3 of Subpart B. The changes proposed to Table B-2 would update some of the analytical methods for generation or verification of SO<sub>2</sub> and interferent test concentrations and their associated references. Similarly, Table B-3 would be updated to add a specific listing for ultraviolet fluorescent methods and to add a few additional interferent test species for some other measurement techniques that have been found from experience to be needed.

#### B. Network design

##### 1. Background

The basic objectives of an ambient monitoring network, as noted in 40 CFR Part 58 Appendix D, include (1) providing air pollution data to the general public in a timely manner, (2) supporting compliance with ambient air quality standards and emissions strategy development, and (3) providing support for air pollution research. The SO<sub>2</sub> network was originally deployed to support implementation of the SO<sub>2</sub> NAAQS established in 1971. Although the SO<sub>2</sub> standard was established in 1971, EPA did not establish uniform minimum monitoring requirements for SO<sub>2</sub> monitoring until May 1979. From the time of the implementation of the 1979 monitoring rule, through 2008, the SO<sub>2</sub> network has steadily decreased in size from approximately 1496 sites in 1980 to the approximately 488 sites operating in 2008 (Watkins and Thompson, 2009). The reduction in network size is due in part to the change in the source sector contributions to the overall SO<sub>2</sub> inventory and the general

decline of ambient SO<sub>2</sub> levels over time. In the early decades of the SO<sub>2</sub> network, particularly the 1970s, there was a wider variety of more ubiquitous SO<sub>2</sub> sources in urban areas, including residential coal and oil furnaces, when compared to the stationary source, electric generating unit (EGU)-dominated inventories of today (see below). The situation in the 1970s led to a network design keyed on population, an appropriate approach at the time considering the close proximity of sources and people, particularly in urban, residential settings (Watkins and Thompson, 2009).

An analysis of the approximately 488 monitoring sites comprising the current (2008) SO<sub>2</sub> monitoring network indicates that just under half (46%) of the sites in the current SO<sub>2</sub> network are reported to be for the assessment of concentrations for general population exposure. As for the present day inventory, the 2005 NEI (<http://www.epa.gov/ttn/chief/net/2005inventory.html>) indicates that SO<sub>2</sub> emissions from EGUs contribute approximately 70% of the anthropogenic SO<sub>2</sub> emissions in the U.S. However, only approximately one third (35%) of the network is reported to be addressing locations of maximum (highest) concentrations, likely linked to a specific source or group of sources such as EGUs.

The current network supports the reporting of 1-hour data to EPA's Air Quality System (AQS) database, as required in § 58.12 of 40 CFR Part 58, since the network utilizes the continuous UVF FEM, which can provide time-resolved data averaged over periods as short as several minutes. The routine submittal of hourly data by state, local, and tribal air monitoring agencies to AQS is suitable for use in comparison to both of the current primary 24-hour and annual NAAQS. There are a few monitoring agencies who also report 5-minute data voluntarily to AQS.

The current network is sited at a variety of spatial scales; however a majority of the network, just over sixty percent, is sited at the neighborhood spatial scale<sup>32</sup> (Watkins and Thompson,

<sup>32</sup> Spatial scales are defined in 40 CFR Part 58 Appendix D, Section 1.2, where the scales of representativeness include:

1. Microscale—Defines the concentration in air volumes associated with area dimensions ranging from several meters up to about 100 meters.

2. Middle scale—Defines the concentration typical of areas up to several city blocks in size, with dimensions ranging from about 100 meters to 0.5 kilometers.

3. Neighborhood scale—Defines concentrations within some extended area of the city that has

2009). Although there are 488 SO<sub>2</sub> monitors operating in the network, there are currently no minimum monitoring requirements for SO<sub>2</sub> in 40 CFR part 58 Appendix D, other than the following three: (1) SO<sub>2</sub> must be monitored at National Core (NCore) monitoring sites (discussed below), (2) the EPA Regional Administrator must approve the removal of any existing monitors, and (3) any ongoing SO<sub>2</sub> monitoring must have at least one monitor sited to measure the maximum concentration of SO<sub>2</sub> in that area.

The SO<sub>2</sub> monitors that are required as part of the National Core monitoring network (NCore) were not required solely for providing direct support of the SO<sub>2</sub> NAAQS. The monitoring rule promulgated in 2006 (71 FR 61236) and codified at 40 CFR Part 58 and its Appendices established the NCore multi-pollutant network requirement to support integrated air quality management data needs. Further, NCore is intended to establish long-term sites providing data for air quality trends analysis, model evaluation, and, for urban sites, tracking metropolitan air quality statistics. To do this, NCore sites are required to measure various pollutants, including SO<sub>2</sub>, but are not sited to monitor maximum concentrations of SO<sub>2</sub>. NCore sites provide data representing concentrations at the broader neighborhood and urban spatial scales. The data from the NCore sites will be compared to the NAAQS although, as noted earlier, NAAQS comparisons are not the primary objective of NCore. The NCore network, which will be fully implemented by January 1, 2011, will result in approximately 83 sites, each with an SO<sub>2</sub> monitor, with approximately 60 sites being located in urban areas.

As set out in detail in section II.B of this notice, there is a causal relationship between short-term SO<sub>2</sub> exposure and respiratory morbidity, with "short-term" meaning exposures from 5–10 minutes up to and including 24 hours. This finding is based primarily on results from controlled human exposure studies

relatively uniform land use with dimensions in the 0.5 to 4.0 kilometers range.

4. Urban scale—Defines concentrations within an area of city-like dimensions, on the order of 4 to 50 kilometers. Within a city, the geographic placement of sources may result in there being no single site that can be said to represent air quality on an urban scale. The neighborhood and urban scales have the potential to overlap in applications that concern secondarily formed or homogeneously distributed air pollutants.

5. Regional scale—Defines usually a rural area of reasonably homogeneous geography without large sources, and extends from tens to hundreds of kilometers.

of 5–10 minutes as well as epidemiologic studies using mostly 1-hour daily maximum and 24-hour average SO<sub>2</sub> concentrations. Importantly, the ISA described the controlled human exposure studies of 5–10 minutes as being the "definitive evidence" for this conclusion (ISA, section 5.2). In addition, when describing epidemiologic studies observing positive associations between ambient SO<sub>2</sub> 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). The ISA also stated that the respiratory effects following 5- to 10-minute SO<sub>2</sub> exposures in controlled human exposure studies provide a basis for a progression of respiratory morbidity that could result in increased ED visits and hospital admissions (ISA, section 5.2). Thus, the monitoring network to support the proposed NAAQS should be focused on identifying the expected maximum short-term concentrations in any particular area.

The ISA (Section 2.1) indicates that point (*i.e.*, stationary) sources account for approximately 95% of the total anthropogenic SO<sub>2</sub> emissions in the U.S. According to the 2005 National Emissions Inventory (<http://www.epa.gov/ttn/chief/net/2005inventory.html>), electrical generating units (EGUs) emit approximately 70% of the anthropogenic SO<sub>2</sub> emissions in the U.S. The 2005 NEI indicates that the total anthropogenic emission inventory of SO<sub>2</sub> is approximately 14,742 thousand tons per year. Of those 14,742 thousand tons per year of emitted SO<sub>2</sub>, approximately 85% were emitted by stationary sources that emit 100 or more tons per year (comprising approximately 1,928 of the 32,988 facilities listed in the 2005 NEI). This information indicates that a relatively small number (6%) of all SO<sub>2</sub> emitting stationary sources are responsible for a large majority of the total anthropogenic emissions inventory (85%) in the U.S. Therefore, monitors sited to reflect locations of expected maximum concentrations should be primarily oriented towards locations influenced by one or a cluster of high SO<sub>2</sub> emitting sources.

As noted in the key observations of the exposure analysis of the REA (REA, Section 8.12), there are a variety of factors that influence overall population exposure to ground-level concentrations in a given area, including population density and proximity to sources, emissions density in an area, and source

specific emission parameters such as stack height, among other factors. In general, however, it is expected that any short-term peaks that may occur in an area are more likely to occur nearer to a source or sources, or in an area where multiple sources are significantly contributing to increased ground level concentrations (an area with high emissions density).<sup>33</sup> Given that maximum ground-level concentrations of SO<sub>2</sub> are usually directly traceable to specific sources, or a cluster of sources, the network design should support implementation of the proposed 1-hour SO<sub>2</sub> NAAQS by targeting maximum ground-level concentrations in areas of both higher population and higher emissions.

## 2. Proposed changes

In conjunction with the proposed 1-hour primary NAAQS and (if EPA should adopt a standard at the upper end of the range of levels for which the Agency is soliciting comment) the potential retention of the current 24-hour NAAQS, we are proposing a number of changes to the SO<sub>2</sub> monitoring network. As just noted, there are currently minimum monitoring requirements for SO<sub>2</sub> only at NCore sites. The proposal for a new 1-hour NAAQS necessitates the re-introduction of minimum monitoring requirements. An analysis of the approximately 488 monitoring sites comprising the current (2008) SO<sub>2</sub> monitoring network indicates that just under half (~46%) of the sites in the current SO<sub>2</sub> network are reported to be for the assessment of concentrations for general population exposure. The current network was not originally deployed to address current short-term, peak concentrations, such as those locations nearer to stationary sources or in areas of higher emissions densities, where maximum hourly and 5- to 10-minute concentrations are likely to occur. The Agency has data indicating that only about one third of the existing SO<sub>2</sub> network may be source-oriented monitors and/or sited in locations of expected maximum concentrations (Watkins and Thompson, 2009).

To fully support the proposed SO<sub>2</sub> NAAQS, the monitoring network needs to identify where short-term, peak ground-level concentrations—*i.e.* concentrations from 5 minutes to one hour (or potentially up to 24 hours)—

<sup>33</sup> There is inherent variability in where peak ground level concentrations may occur in space and time from an individual source or group of sources, due to multiple factors including tons emitted, stack height, meteorology, among others. These factors are discussed further in the Monitor Placement and Siting section of this chapter.

may occur. Due to the multiple variables that affect ground level SO<sub>2</sub> concentrations caused by one or more stationary sources, it is difficult to specify a source specific threshold, algorithm, or metric by which to require monitoring in a rule such as this. To achieve this goal, therefore, EPA is proposing a two-pronged network design to ensure that States perform a sufficient amount of monitoring of ambient concentrations of SO<sub>2</sub> to determine attainment of the proposed SO<sub>2</sub> NAAQS that intends to prevent exposure to peak concentrations. EPA anticipates this two-pronged network would require approximately 345 monitors nationwide, providing data for comparison with both the proposed 1-hour and the 24-hour standard if retained. The network would be wholly comprised of monitors sited at locations of expected maximum hourly concentrations. EPA is proposing that the two prongs of this SO<sub>2</sub> network design would be distributed based on: (1) A Population Weighted Emissions Index (PWEI) and (2) the state-level contribution to the national, SO<sub>2</sub> emissions inventory. EPA notes that although we propose that the network include a minimum number of required monitors, State, local, and tribal agencies may conduct additional monitoring above the minimum requirements. If those additional monitors satisfy all applicable requirements in 40 CFR Part 58, the data from those monitors would be comparable to the NAAQS. EPA estimates that one-half to two-thirds of the monitors in the existing network (excluding any currently operating NCore sites) may have to be moved in order to be counted towards the requirement for monitors sited at locations of expected maximum short-term concentrations of SO<sub>2</sub>.

We solicit comment on whether the estimated 348 monitors required by this proposal, distributed based on the two network design components presented below, are too few, too many, or suitable to establish a minimum network sufficient to meet the monitoring objectives noted above, including supporting compliance with the proposed 1-hour SO<sub>2</sub> NAAQS.

We propose that state and, where appropriate, local air monitoring agencies submit a plan for deploying SO<sub>2</sub> monitors in accordance with the proposed requirements presented below by July 1, 2011. We also propose that the SO<sub>2</sub> network being proposed be physically established no later than January 1, 2013. Considering the proposed timeline and criteria presented in the network design, we

solicit comment on whether alternative dates would be more appropriate as deadlines for state and local monitoring agencies to submit a monitoring plan. We also solicit comments on whether alternative dates would be more appropriate as deadlines for state and local monitoring agencies to physically deploy monitors.

a. Population weighted emissions index (PWEI) triggered monitoring

The EPA proposes that the first prong of the ambient SO<sub>2</sub> monitoring network account for SO<sub>2</sub> exposure by requiring monitors in locations where population and emissions may lead to higher potential for population exposure to peak hourly SO<sub>2</sub> concentrations. In order to do this, EPA has developed a Population Weighted Emissions Index (PWEI) that uses population and emissions inventory data at the CBSA<sup>34</sup> level to assign required monitoring for a given CBSA (population and emissions being obvious relevant factors in prioritizing numbers of required monitors). The PWEI for a particular CBSA is calculated by multiplying the population (using the latest Census Bureau estimates) of a CBSA by the total amount of SO<sub>2</sub> emissions in that CBSA. The CBSA emission value is in tons per year, and is calculated by aggregating the county level emissions for each county in a CBSA. We then normalize by dividing the resulting product of CBSA population and CBSA SO<sub>2</sub> emissions by 1,000,000 to provide a PWEI value, the units of which are millions of people-tons per year. This calculation has been performed for each CBSA and has been posted in the docket as "CBSA PWEI Calculation, 2009". EPA believes that using this PWEI metric to inform where monitoring is required is more appropriate for the SO<sub>2</sub> network design than utilizing a population-only type of approach, so that we may focus monitoring resources in areas of the country where people and emission sources are in greater proximity. In addition, EPA's initial view is that this PWEI concept is appropriate for SO<sub>2</sub> but is not necessarily transferrable to the other criteria pollutants. From a very broad vantage point, SO<sub>2</sub> is exclusively a primarily emitted pollutant (*i.e.* unlike PM<sub>2.5</sub> and ozone there is no secondary formation of SO<sub>2</sub>), is almost exclusively emitted by stationary sources (unlike NO<sub>2</sub>, CO, PM<sub>2.5</sub>, thoracic coarse PM, and ozone), and is a gaseous pollutant which

is somewhat more subject to transport (unlike Pb in the Total Suspended Particulate (TSP) and PM<sub>10</sub> size fractions).

We propose that the first prong of the SO<sub>2</sub> network design require monitors in CBSAs, according to the following criteria. For any CBSA with a calculated PWEI value equal to or greater than 1,000,000, a minimum of three SO<sub>2</sub> monitors are required within that CBSA. For any CBSA with a calculated PWEI value equal to or greater than 10,000, but less than 1,000,000, a minimum of two SO<sub>2</sub> monitors are required within that CBSA. For any CBSA with a calculated PWEI value equal to or greater than 5,000, but less than 10,000, a minimum of one SO<sub>2</sub> monitor is required within that CBSA. EPA believes that the monitors required within these breakpoints provide a reasonable minimum number of monitors in a CBSA that considers the combination of population and emissions that exist in a given CBSA. This proposed requirement is based on factors that will ensure highly populated areas will receive monitoring even if the emissions in that area are moderate, which is appropriate given the fact that the greater population creates increased potential for exposure to those moderate sources. Additionally, this proposed requirement also ensures that those areas with higher emissions or emission densities, with moderate or modest populations will receive monitoring since those increased emissions are likely to have a significant impact on whatever population may exist nearby.

EPA estimates that these criteria will result in 231 required sites in 132 CBSAs. We propose that monitors triggered in this first prong of the network design must be sited in locations of expected maximum 1-hour concentrations, at the appropriate spatial scale<sup>35</sup>, within the boundaries of a given CBSA. EPA also proposes that when state or local agencies make selections for monitoring sites from a pool of similar candidate site locations, they shall prioritize monitoring where the maximum expected hourly concentrations occur in relative greater proximity to populations. EPA believes that states will likely need to use some form of quantitative analysis, such as

<sup>34</sup> CBSAs are defined by the U.S. Census Bureau, and are comprised of both Metropolitan Statistical Areas and Micropolitan Statistical Areas (<http://www.census.gov>).

<sup>35</sup> Due to the variability in where maximum ground-level concentrations may occur (discussed in the Monitor Siting and Placement section of this chapter), the appropriate spatial scales within which an SO<sub>2</sub> monitor might be placed include the microscale, middle, and neighborhood scales, which are defined in 40 CFR Part 58 Appendix D. [could also refer to the fn above where these are described]

modeling, data analysis, or saturation studies to aid in determining where ground-level SO<sub>2</sub> maxima may occur in a given CBSA. The selection of these sites shall be documented in the Annual Monitoring Network Plan per § 58.10, which includes a requirement for public inspection or comment, and approval by the EPA Regional Administrator.

EPA solicits comment on (1) the use of the Population Weighted Emissions Index (PWEI), (2) the PWEI calculation method, (3) the PWEI breakpoints that correlate to a number of required monitors, (4) the requirement that the monitors shall be sited in locations of expected maximum 1-hour concentration, and (5) that state or local agencies making selections for monitoring sites from a pool of similar candidate site locations shall prioritize monitoring where the maximum expected hourly concentrations occur in relative greater proximity to populations.

EPA recognizes that CBSA populations and emissions inventories change over time, suggesting a need for periodic review of the monitoring network. At the same time, EPA recognizes the advantages of a stable monitoring network. Therefore, while EPA currently provides for updates of the NEI every 3 years, EPA believes that the current network review requirements per § 58.10 which requires an annual network plan and recurring 5-year assessments provide a suitable

schedule for planning and assessing the monitoring network. Through the 5-year assessments, states will be in a position to review emissions distributions from updated NEIs to calculate PWEI values for each CBSA and subsequently assess whether the operational monitoring network remains appropriate. EPA proposes that the number of sites required to operate as a result of the PWEI values calculated for each CBSA be reviewed and revised for each CBSA through the 5-year network assessment cycle required in § 58.10. EPA solicits comment on whether such adjustments to the network should be required on a 5-year cycle that matches the general frequency of network assessments or some other frequency.

b. State-level emissions triggered monitoring

As the second prong of the SO<sub>2</sub> network, we are proposing to require a monitor or monitors in each state, allocated by state-level SO<sub>2</sub> emissions. In this prong, EPA proposes to distribute approximately 117 sites, based on the corresponding percent contribution of each individual state to the national anthropogenic SO<sub>2</sub> emission inventory. This prong of the network design is intended to allow a portion of the overall required monitors to be placed where needed, independent of the PWEI, inside or outside of CBSAs. EPA proposes to require monitors, using state boundaries as the geographic unit

for allocation purposes, in proportion to a state's SO<sub>2</sub> emissions, *i.e.*, a state with higher emissions will be required to have a proportionally higher number of monitors. The proposed percent contribution of individual states is based on the most recent NEI, with SO<sub>2</sub> emissions being aggregated by state. Each one percent (after rounding) would correspond to one required monitor. For example, according to the 2005 NEI, the State of Ohio contributes 8.66% of the total anthropogenic SO<sub>2</sub> inventory, which would correspond to requiring nine monitors to be distributed within Ohio. Further, EPA proposes that each state have at least one monitor required as part of this second prong, even if a particular state contributes less than 0.5% of the total anthropogenic national emissions inventory. As a result, approximately 117 monitoring sites would be required and distributed based on state-level SO<sub>2</sub> emissions in the most recent NEI, which in this case, is the 2005 NEI. EPA solicits comment on the use of state-level emission inventories based on the most recent NEI to proportionally distribute approximately one third (117 sites) of the required monitoring network.

According to the most recent NEI, for this proposed second prong, we estimate the state/percent contribution to the national inventory/required monitor distribution to be:

TABLE 5—STATE-LEVEL EMISSION TRIGGERED MONITORS—THIS TABLE SHOWS STATE AND TERRITORY LEVEL CONTRIBUTIONS TO THE NATIONAL SO<sub>2</sub> INVENTORY AND THE CORRESPONDING NUMBER OF MONITORS REQUIRED FOR EACH STATE AS PROPOSED IN PRONG 2 OF THE PROPOSED NETWORK DESIGN

State or Territory	Percent contribution to the national SO <sub>2</sub> inventory (percent)	Proposed number of required monitors
Alabama	4.02	4
Alaska	0.46	1
American Samoa	N/A	1
Arizona	0.60	1
Arkansas	0.77	1
California	1.48	1
Colorado	0.54	1
Connecticut	0.23	1
Delaware	0.58	1
District of Columbia	0.03	1
Florida	4.40	4
Georgia	5.07	5
Guam	N/A	1
Hawaii	0.08	1
Idaho	0.16	1
Illinois	3.51	4
Indiana	7.10	7
Iowa	1.50	2
Kansas	1.33	1
Kentucky	3.88	4
Louisiana	2.40	2
Maine	0.25	1
Maryland	2.58	3
Massachusetts	1.07	1

TABLE 5—STATE-LEVEL EMISSION TRIGGERED MONITORS—THIS TABLE SHOWS STATE AND TERRITORY LEVEL CONTRIBUTIONS TO THE NATIONAL SO<sub>2</sub> INVENTORY AND THE CORRESPONDING NUMBER OF MONITORS REQUIRED FOR EACH STATE AS PROPOSED IN PRONG 2 OF THE PROPOSED NETWORK DESIGN—Continued

State or Territory	Percent contribution to the national SO <sub>2</sub> inventory (percent)	Proposed number of required monitors
Michigan .....	3.32	3
Minnesota .....	1.05	1
Mississippi .....	0.81	1
Missouri .....	2.8	3
Montana .....	0.26	1
Nebraska .....	0.82	1
Nevada .....	0.49	1
New Hampshire .....	0.43	1
New Jersey .....	0.69	1
New Mexico .....	0.32	1
New York .....	2.65	3
North Carolina .....	4.40	4
North Dakota .....	1.08	1
Northern Mariana Islands .....	N/A	1
Ohio .....	8.66	9
Oklahoma .....	1.12	1
Oregon .....	0.32	1
Pennsylvania .....	7.96	8
Puerto Rico .....	N/A	1
Rhode Island .....	0.06	1
South Carolina .....	2.06	2
South Dakota .....	0.19	1
Tennessee .....	2.63	3
Texas .....	6.34	6
Utah .....	0.35	1
Vermont .....	0.05	1
Virgin Islands .....	N/A	1
Virginia .....	2.34	2
Washington .....	0.45	1
West Virginia .....	3.63	4
Wisconsin .....	1.79	2
Wyoming .....	0.83	1

EPA proposes siting requirements for this second prong of required monitors to be the same as those in the first prong: siting in locations of expected maximum 1-hour concentrations, at the appropriate spatial scale, within the boundaries of a given state, and prioritizing the selection of candidate sites where the maximum expected hourly concentrations occur in greater proximity to populations. This again would need to be determined case-by-case using quantitative analysis, such as modeling, data analysis, or saturation studies to aid in determining where ground-level SO<sub>2</sub> maxima may occur in a given state. We propose that these monitors can be located inside or outside of CBSA boundaries. However, if a monitor required by the second prong is placed inside a CBSA that already has a requirement for monitoring due to the first prong of this network design, that monitor would not be allowed to count towards satisfying the first prong requirements. As noted for the first prong of required monitors, the selection of these sites shall be

documented in the Annual Monitoring Network Plan per § 58.10, which includes a requirement for public inspection or comment, and approval by the EPA Regional Administrator.

The EPA solicits comment on (1) the use of state-level emission inventories to proportionally distribute required monitors, (2) requiring each state to have at least one monitor under this prong of the network design, and (3) requiring all monitors to be sited in locations of expected maximum 1-hour concentration inside or outside of CBSAs.

EPA recognizes that emissions inventories change over time, suggesting a need for periodic review of the monitoring network. At the same time, EPA recognizes the advantages of a stable monitoring network. Therefore, while EPA currently provides for updates of the NEI every 3 years, EPA believes that the current network review requirements per § 58.10 which requires an annual network plan and recurring 5-year assessments provide a suitable schedule for planning and assessing the monitoring network. Through the 5-year

assessments, states will be in a position to review emissions distributions from updated NEIs to assess whether the monitoring requirements remain appropriate. EPA proposes that the number of sites required to operate as a result of state-level emissions be reviewed and revised for each state through the 5-year network assessment cycle required § 58.10. EPA solicits comment on whether such adjustments to the network should be required on a 5-year cycle that matches the general frequency of network assessments or some other frequency.

#### c. Monitor placement and siting

Sites that are to be placed in locations of expected maximum 1-hour concentrations, will also likely discern 5-minute peaks as well. EPA expects that in general, these locations will be in proximity to larger emitting sources (in tons per year) and/or areas of relatively high emissions densities where multiple sources may be contributing to peak ground-level concentrations. The variability in where such locations exist relative to the

responsible emission source(s) depends on multiple factors including the tonnage emitted by a source (or group of sources), stack height, stack diameter, emission exit velocity, emission temperature, terrain, and meteorology. Depending on these variables, plumes may heavily fumigate areas immediately downwind of a source, or may never truly touch down at all, dispersing into ambient air where SO<sub>2</sub> concentrations continually decrease with increasing distance away from the source. This is illustrated in an example where a relatively large source with a tall stack height may not produce exceedingly high ground level concentrations anywhere along its plume trajectory while a smaller source with a relatively short stack may cause relatively higher ground level concentrations under the same meteorological conditions at the same location. The primary reason for this variability is because the peak impacts of sources with higher stacks will generally be farther downwind and may be more variably located than is the case for sources with shorter stacks. Further, depending on meteorology, an emission plume from an individual source may cause increased ground-level concentrations at any heading, relative to the parent source, corresponding to the prevailing winds.

When analyzing a particular source, a state may find multiple locations where peak ground-level concentrations may occur around an individual source. EPA does not intend for multiple monitors to be sited around or in proximity to one source. Not siting multiple monitors around, or in proximity, to one source ensures that more individual sources or groups of sources will receive attention by the monitoring network. States always have the discretion to perform additional monitoring above the minimum requirements to increase monitoring around a particular source or group of sources.

Due to the variability of how, when, where, and to what degree a source or group of sources can contribute to peak, ground-level SO<sub>2</sub> concentrations, EPA expects that State and local monitoring agencies will need to analyze all relevant information, including available ambient and emissions data, and potentially use air quality modeling or saturation studies to select appropriate monitoring site locations. Further, due to the variability in where maximum ground-level concentrations may occur, the appropriate spatial scales within which a monitor might be placed include the microscale, middle, and neighborhood scales, which are defined in 40 CFR Part 58 Appendix D. EPA believes that states, in evaluating a

source (or group of sources) that contribute to a peak ground-level SO<sub>2</sub> concentration that varies with space and time, should identify where the highest concentrations are expected to occur in developing candidate site locations. EPA proposes that when state and local agencies make selections for monitoring sites from candidate site locations, they shall prioritize monitoring where the maximum expected hourly concentrations occur in greater proximity to populations. EPA solicits comment on the role of population exposure in the site selection process.

d. Monitoring required by the regional administrator

In addition to the two prongs of the proposed SO<sub>2</sub> network design, we propose that the Regional Administrator will have discretion to require monitoring above these minimum requirements under prongs 1 and 2, as necessary to address situations where the minimum monitoring requirements are not sufficient to meet monitoring objectives noted above. EPA recognizes that the minimum required monitors in the proposed network design under the two prongs described above are based on indicators that may not provide for all the monitoring that may be necessary in an area. An example where EPA envisions requiring an additional monitor might be a case where a source having modest emissions still has high potential to cause a violation of the NAAQS in a community or neighborhood. This situation might occur where a modest SO<sub>2</sub> source has, for example, a low emission stack and/or is in an area where meteorological conditions cause situations, such as inversions or stagnation, that might lead to high ground-level concentrations of SO<sub>2</sub>. In this example, such a monitor might be needed even though a state is fulfilling its monitoring requirements under the first and second prongs of the proposed network design. The purpose of this provision is to monitor in and provide data for otherwise non-monitored locations that have the potential to exceed the level of the NAAQS or that are perceived to have higher exposure risks due to proximity to a source or sources. In such an example, the Regional Administrators may make use of any available data including existing model data, existing data analyses, or screening tools such as AERSCREEN or SCREEN3, to inform a decision of whether or not a monitor should be required for a given area or location. Any monitor required through the Regional Administrator and selected by the state or local agency would be included in the Annual Monitoring

Network Plan per § 58.10, which includes a requirement for public inspection or comment, and approval by the EPA Regional Administrator. In any case, EPA encourages state, local, and tribal monitoring agencies to provide input and information to the appropriate Regional Administrators in determining whether additional monitors are needed and the locations of such monitors. We solicit comment on the proposal to allow Regional Administrators the discretion to require monitoring above the requirements under prongs 1 and 2 for any area or location where those monitoring requirements are not sufficient to meet monitoring objectives.

EPA notes that existing requirements detailed in § 58.14(c) address certain conditions where existing monitors can be shut down, with EPA Regional Administrator approval. EPA is not reopening or otherwise reconsidering this provision. However, this requirement is noted here so that state or local agency requests to potentially relocate SO<sub>2</sub> monitors to meet the proposed requirements of prongs 1 or 2 will be considered with the specific provisions of § 58.14(c) in mind.

e. Alternative network design

EPA solicits comments on alternative network designs, including alternative methods to determine the minimum number of monitors per state. We are particularly interested in whether a screening approach for assessing the likelihood of a NAAQS exceedance could be developed and serve as a basis for determining the number and location of required monitors.

More specifically, EPA requests comment on whether it should utilize existing screening tools such as AERSCREEN or SCREEN3, which use parameters such as effective stack height and emissions levels to identify facilities with the potential to cause an exceedance of the proposed standard. For that set of sources, EPA could then require states to conduct more refined modeling (likely using the American Meteorological Society (AMS)/EPA Regulatory Model (AERMOD)) to determine locations where monitoring should be conducted. Any screening or modeling would likely be carried out by states by using EPA recommended models and techniques referenced by 40 CFR Part 51, Appendix W, which provides guidance on air quality modeling. Such screening or modeling uses facility emission tonnage, stack heights, stack diameters, emission temperatures, emission velocities, and accounts for local terrain and meteorology in determining where

expected maximum hourly concentrations may occur. In using this approach, EPA would then require states to locate monitors at the point of maximum concentration around sources identified as likely causing NAAQS exceedances.

This approach could lead to monitors being required at a significantly larger number of locations than under the proposed approach. For example, the NEI shows that 2,407 sources emit 50 tons per year or more of SO<sub>2</sub>, while 1,928 sources emit 100 tons per year or more of SO<sub>2</sub>. If, for example, the state screening approach found that a substantial fraction of those 50 or 100 ton per year sources had a significant probability of violating the NAAQS, states could be required to model, evaluate, and potentially monitor a corresponding number of sources. EPA also notes that this alternative approach would not distinctly use population as a factor for where monitors should be placed. EPA solicits comment on the resource implications for state and local agencies associated with this approach.

If EPA selects a standard level near the lower end of the proposed range, it is likely that a greater number of areas would exceed the NAAQS, leading to the need for additional monitors. A facility screening approach, as described above would explicitly account for the specific parameters of a facility, air quality information, and the stringency of the standard for determining the number of monitors, in contrast to the proposed approach. EPA solicits comment on how, in the absence of a facility screening approach, the number of monitors required nationwide could be adjusted if EPA finalizes a standard near the lower end of the proposed range.

### C. Data reporting

SO<sub>2</sub> UV fluorescence FEMs are continuous gas analyzers, producing updated data values on the order of every 20 seconds. Data values are typically aggregated into minute averages and then compiled into hourly averages for reporting purposes. EPA proposes to retain the existing requirement that State and local monitoring agencies report hourly SO<sub>2</sub> data to AQS within 90 days of the end of each calendar quarter. EPA encourages monitoring agencies to voluntarily report their pre-validated data on an hourly basis to EPA's real time AIRNow data system.

The definitive evidence for the ISA's conclusion of causal association between short-term SO<sub>2</sub> exposure and respiratory morbidity is from controlled human exposure studies of 5–10

minutes in exercising asthmatics (ISA, section 5.2). The REA therefore assessed exposure and risks associated with 5-minute SO<sub>2</sub> concentrations above 5-minute health effect benchmark levels derived from these controlled human exposure studies. In performing these analyses, the REA noted that: (1) The majority of the current SO<sub>2</sub> monitoring network reported 1-hour SO<sub>2</sub> concentrations (REA section 7.2.3); (2) very few state and local agencies in the U.S. voluntarily reported ambient 5-minute SO<sub>2</sub> concentrations, as such reporting is not required (REA, section 10.3.3.2); and (3) the lack of 5-minute monitoring data necessitated the use of statistically estimated 5-minute SO<sub>2</sub> concentrations derived from reported 1-hour SO<sub>2</sub> levels (see REA section 7.2.3) in order to expand the geographic scope of the exposure and risk analyses. Thus given the demonstrated importance of 5-minute SO<sub>2</sub> concentrations, EPA proposes that State and local agencies shall report to AQS the maximum 5-minute block average of the twelve 5-minute block averages of SO<sub>2</sub> for each hour, in addition to the existing requirement to report the 1-hour average.

EPA solicits comment on the proposed requirement for state and local monitoring agencies to report both hourly average and the maximum 5-minute block average out of the twelve 5-minute block averages of SO<sub>2</sub> for each hour. EPA also solicits comment on the advantages and disadvantages of alternatively requiring state and local agencies to report all twelve 5-minute SO<sub>2</sub> values for each hour. Having all twelve 5-minute SO<sub>2</sub> values for each hour would provide more detailed information for health research purposes and provide additional information to help inform the next review of the SO<sub>2</sub> standard. We also solicit comment on alternatively requiring state and local agencies to report the maximum 5-minute concentration in an hour based on a moving 5-minute averaging period rather than time block averaging.

EPA notes the potential resource burden with the proposed requirement to report 5-minute average values in addition to 1-hour average values, as is currently required. Accordingly, we solicit comment on the magnitude and importance of this resource burden, recognizing that monitoring agencies utilize a variety of automated data acquisition and management programs, and that the resulting burden of validating and reporting 5-minute data may vary from a relatively trivial matter to an issue of greater importance, depending on the procedures utilized

within each agency's data reporting process.

As a part of the larger data quality performance requirements of the ambient monitoring program, we are proposing data quality objectives (DQOs) for the proposed SO<sub>2</sub> network. The DQOs are meant to identify measurement uncertainty for a given pollutant method. We propose a goal for acceptable measurement uncertainty for SO<sub>2</sub> methods to be defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 15 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent. We solicit comment on the proposed DQOs and on what the acceptable measurement uncertainty should be.

### IV. Proposed Appendix T— Interpretation of the Primary NAAQS for Oxides of Sulfur and Proposed Revisions to the Exceptional Events Rule

The EPA is proposing to add Appendix T, Interpretation of the Primary National Ambient Air Quality Standards for Oxides of Sulfur, to 40 CFR Part 50 in order to provide data handling procedures for the proposed SO<sub>2</sub> 1-hour primary standard. The proposed § 50.11 which sets the averaging period, level, indicator and form of the NAAQS refers to this Appendix T. The proposed Appendix T would detail the computations necessary for determining when the proposed 1-hour primary SO<sub>2</sub> NAAQS is met. The proposed Appendix T also would address data reporting, data completeness considerations, and rounding conventions.

Two versions of the proposed Appendix T are printed at the end of this notice. The first applies to a 1-hour primary standard based on the annual 4th high value form, while the second applies to a 1-hour primary standard based on the 99th percentile daily value form. (As explained in section II.F. 3 above, EPA is proposing alternative forms here based on technical analysis that they are equally effective.) The discussion here addresses the first of these versions, followed by a brief description of the differences found in the second version.

For the proposed 1-hour primary standard, EPA is proposing data handling procedures, a proposed addition of a cross-reference to the Exceptional Events Rule, a proposed addition to allow the Administrator discretion to consider otherwise incomplete data to be complete, and a proposed provision addressing the

possibility of there being multiple SO<sub>2</sub> monitors at one site.

The EPA is also proposing SO<sub>2</sub>-specific changes to the deadlines in 40 CFR 50.14, by which states must flag ambient air data that they believe have been affected by exceptional events and submit initial descriptions of those events, and to the deadlines by which states must submit detailed justifications to support the exclusion of that data from EPA determinations of attainment or nonattainment with the NAAQS. The deadlines now contained in 40 CFR 50.14 are generic, and are not always appropriate for SO<sub>2</sub> given the anticipated schedule for the designations of areas under the proposed SO<sub>2</sub> NAAQS.

#### A. Background

The general purpose of a data interpretation appendix is to provide the practical details on how to make a comparison between multi-day and possibly multi-monitor ambient air concentration data and the level of the NAAQS, so that determinations of attainment and nonattainment are as objective as possible. Data interpretation guidelines also provide criteria for determining whether there are sufficient data to make a NAAQS level comparison at all.

The regulatory language for the current SO<sub>2</sub> NAAQS, originally adopted in 1977, contains data interpretation instructions only for the issue of data completeness. This situation contrasts with the situations for ozone, PM<sub>2.5</sub>, PM<sub>10</sub>, and most recently Pb for which there are detailed data interpretation appendices in 40 CFR Part 50 addressing issues that can arise in comparing monitoring data to the NAAQS. EPA has used its experience developing and applying these other data interpretation appendices to develop the proposed text for Appendix T.

An exceptional event is defined in 40 CFR 50.1 as an event that affects air quality, is not reasonably controllable or preventable, is an event caused by human activity that is unlikely to recur at a particular location or is a natural event, and is determined by the Administrator in accordance with 40 CFR 50.14 to be an exceptional event. Air quality data that is determined, under the procedural steps and substantive criteria specified in section 50.14, to have been affected by an exceptional event may be excluded from consideration when EPA makes a determination that an area is meeting or not meeting the associated NAAQS. The key procedural deadlines in section 50.14 are that a State must notify EPA

that data have been affected by an event, *i.e.*, "flag" the data in the Air Quality Systems (AQS) database, and provide an initial description of the event by July 1 of the year after the data are collected, and that the State must submit the full justification for exclusion within 3 years after the quarter in which the data were collected. However, if a regulatory decision based on the data, for example a designation action, is anticipated, the schedule is shortened and all information must be submitted to EPA no later than a year before the decision is to be made. This generic schedule presents problems when a NAAQS has been recently revised, as discussed below.

#### B. Interpretation of the primary NAAQS for oxides of sulfur

The purpose of a data interpretation rule for the SO<sub>2</sub> NAAQS is to give effect to the form, level, averaging time, and indicator specified in the proposed regulatory text at 40 CFR 50.11, anticipating and resolving in advance various future situations that could occur. The proposed Appendix T provides definitions and requirements that apply to the proposed 1-hour primary standard for SO<sub>2</sub>. The requirements concern how ambient data are to be reported, what ambient data are to be considered (including the issue of which of multiple monitors' data sets will be used when more than one monitor has operated at a site), and the applicability of the Exceptional Events Rule to the primary SO<sub>2</sub> NAAQS.

##### 1. 1-hour primary standard based on the annual 4th high value form

With regard to data completeness for the proposed 1-hour primary standard, the proposed Appendix follows past EPA practice for other NAAQS pollutants by requiring that in general at least 75% of the monitoring data that should have resulted from following the planned monitoring schedule in a period must be available for the key air quality statistic from that period to be considered valid. For the proposed 1-hour primary SO<sub>2</sub> NAAQS, the key air quality statistics are the daily maximum 1-hour concentrations in three successive years. It is important that sampling within a day encompass the period when concentrations are likely to be highest and that all seasons of the year are well represented. Hence, the 75% requirement is proposed to be applied at the daily and quarterly levels. EPA invites comment on the proposed completeness requirements.

Recognizing that there may be years with incomplete data, the proposed text provides that a design value derived

from incomplete data will nevertheless be considered valid in either of two situations.

First, if the design value calculated from at least four days of monitoring observations in each of these years exceeds the level of the 1-hour primary standard, it would be valid. This situation could arise if monitoring was intermittent but high SO<sub>2</sub> levels were measured on enough hours and days for the mean of the three annual 4th highest values to exceed the standard. In this situation, more complete monitoring could not possibly have indicated that the standard was actually met.

Second, we are proposing a diagnostic data substitution test which is intended to identify those cases with incomplete data in which it nevertheless is very likely, if not virtually certain, that the daily 1-hour design value would have been observed to be below the level of the NAAQS if monitoring data had been minimally complete.

The diagnostic test would be applied only if there is at least 50% data capture in each quarter of each year and if the 3-year mean of the observed annual 4th highest maximum hourly values in the incomplete data is below the NAAQS level. The test would substitute a high hypothetical concentration for as much of the missing data as needed to meet the 100% requirement in each quarter. The value that is substituted for the missing values is the highest daily maximum 1-hour observed in the same quarter, looking across all three years under evaluation. If the resulting 3-year design value is below the NAAQS, it is highly likely that the design value calculated from complete data would also have been below the NAAQS, so the original design value indicating compliance would be considered valid.

It should be noted that one possible outcome of applying the proposed substitution test is that a year with incomplete data may nevertheless be determined to not have a valid design value and thus to be unusable in making 1-hour primary NAAQS compliance determinations for that 3-year period. EPA invites comment on incorporating the proposed substitution test into the final rule.

EPA is proposing that the Administrator have general discretion to use incomplete data to calculate design values that would be treated as valid for comparison to the NAAQS despite the incompleteness, either at the request of a state or at her own initiative. Similar provisions exist already for the PM<sub>2.5</sub> and lead NAAQS, and EPA has recently proposed such provisions to accompany the proposed 1-hour NO<sub>2</sub> and SO<sub>2</sub> NAAQS. The Administrator would

consider monitoring site closures/moves, monitoring diligence, and nearby concentrations in determining whether to use such data.

2. 1-hour primary standard based on the annual 99th percentile daily value form

The second version of the proposed Appendix T appearing at the end of this notice contains proposed interpretation procedures for a 1-hour primary standard based on the 99th percentile daily value form. The 4th high daily value form and the 99th percentile daily value form would yield the same design value in a situation in which every hour and day of the year has reported monitoring data, since the 99th percentile of 365 daily values is the 4th highest value. However, the two forms diverge if data completeness is 82% or less, because in that case the 99th percentile value is the 3rd highest (or higher) value, to compensate for the lack of monitoring data on days when concentrations could also have been high.

Logically, provisions to address possible data incompleteness under the 99th percentile daily value form should be somewhat different from those for the 4th highest form. With a 4th highest form, incompleteness should not invalidate a design value that exceeds the standard, for reasons explained above. With the 99th percentile form, however, a design value exceeding the standard stemming from incomplete data should not automatically be considered valid, because concentrations on the unmonitored days could have been relatively low, such that the actual 99th percentile value for the year could have been lower, and the design value could have been below the standard. The second proposed version of Appendix T accordingly has somewhat different provisions for dealing with data incompleteness. One difference is the addition of another diagnostic test based on data substitution, which in some cases can validate a design value based on incomplete data that exceeds the standard.

The second version of the proposed Appendix T provides a table for determining which day's maximum 1-hour concentration will be used as the 99th percentile concentration for the year. The proposed table is similar to one used now for the 24-hour PM<sub>2.5</sub> NAAQS, which is based on a 98th percentile form, but adjusted to reflect a 99th percentile form for the 1-hour primary SO<sub>2</sub> standard. The proposed Appendix T also provides instructions for rounding (not truncating) the average of three annual 99th percentile hourly

concentrations before comparison to the level of the primary NAAQS.

### *C. Exceptional events information submission schedule*

The Exceptional Events Rule at 40 CFR 50.14 contains generic deadlines for a state to submit to EPA specified information about exceptional events and associated air pollutant concentration data. A state must initially notify EPA that data have been affected by an event by July 1 of the calendar year following the year in which the event occurred; this is done by flagging the data in AQS and providing an initial event description. The state must also, after notice and opportunity for public comment, submit a demonstration to justify any claim within 3 years after the quarter in which the data were collected. However, if a regulatory decision based on the data (for example, a designation action) is anticipated, the schedule to flag data in AQS and submit complete documentation to EPA for review is shortened, and all information must be submitted to EPA no later than one year before the decision is to be made.

These generic deadlines are suitable for the period after initial designations have been made under a NAAQS, when the decision that may depend on data exclusion is a redesignation from attainment to nonattainment or from nonattainment to attainment. However, these deadlines present problems with respect to initial designations under a newly revised NAAQS. One problem is that some of the deadlines, especially the deadlines for flagging some relevant data, may have already passed by the time the revised NAAQS is promulgated. Until the level and form of the NAAQS have been promulgated a state does not know whether the criteria for excluding data (which are tied to the level and form of the NAAQS) were met on a given day. Another problem is that it may not be feasible for information on some exceptional events that may affect final designations to be collected and submitted to EPA at least one year in advance of the final designation decision. This could have the unintended consequence of EPA designating an area nonattainment because of uncontrollable natural or other qualified exceptional events.

The Exceptional Events Rule at § 50.14(c)(2)(v) indicates "when EPA sets a NAAQS for a new pollutant, or revises the NAAQS for an existing pollutant, it may revise or set a new schedule for flagging data for initial designation of areas for those NAAQS."

For the specific case of SO<sub>2</sub>, EPA anticipates that the signature date for

the revised SO<sub>2</sub> NAAQS will be June 2, 2010 (a date specified by Consent Decree), that state/tribal designations recommendations will be due by June 2, 2011, and that initial designations under the revised NAAQS will be made by June 1, 2012 (since June 2, 2012 would be on a Saturday) and will be based on air quality data from the years 2008–2010 or 2009–2011 if there is sufficient data for these data years. (See Section VI below for more detailed discussion of the designation schedule and what data EPA intends to use.) Under the current rule, because final designations would be made by June 1, 2012, all events to be considered during the designations process would have to be flagged and fully documented by states one year prior to designations, by June 1, 2011. A state would not be able to flag and submit documentation regarding events that occurred between June to December 2011 by one year before designations are made in June 2012.

EPA is proposing revisions to 40 CFR 50.14 only to change submission dates for information supporting claimed exceptional events affecting SO<sub>2</sub> data. The proposed rule text at the end of this notice shows the changes that would apply if a revised SO<sub>2</sub> NAAQS is promulgated by June 2, 2010, and designations are made two years after such promulgation. For air quality data collected in 2008, we propose to extend the generic July 1, 2009 deadline for flagging data (and providing a brief initial description of the event) to October 1, 2010. EPA believes this extension would provide adequate time for states to review the impact of exceptional events from 2008 on the revised standard and notify EPA by flagging the relevant data in AQS. EPA is not proposing to change the foreshortened deadline of June 1, 2011 for submitting documentation to justify an SO<sub>2</sub>-related exceptional event from 2008. We believe the generic deadline provides adequate time for states to develop and submit proper documentation.

For data collected in 2009, EPA proposes to extend generic deadline of July 1, 2010 for flagging data and providing initial event descriptions to October 1, 2010. EPA is retaining the deadline of June 1, 2011 for states to submit documentation to justify an SO<sub>2</sub>-related exceptional event from 2009. EPA plans to assist the states by providing at the time of signature our assessment of which monitoring sites and days have exceeded the NAAQS in 2008 and 2009. For data collected in 2010, EPA is proposing a deadline of June 1, 2011 for flagging data and providing initial event descriptions and

for submitting documentation to justify exclusion of the flagged data. EPA believes that this deadline provides states with adequate time to review and identify potential exceptional events that occur in calendar year 2010, even for those events that might occur late in the year. EPA believes these deadlines will be feasible because experience suggest that exceptional events affecting SO<sub>2</sub> data are few in number and easily assessed, so no state is likely to have a large workload.

If a state intends 2011 data to be considered in SO<sub>2</sub> 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, 2011, whichever date occurs first. Again, EPA believes these deadlines will be feasible because experience suggest that exceptional events affecting SO<sub>2</sub> data are few in number and easily assessed, so no state is likely to have a large workload.

Table 6 summarizes the proposed designation deadlines discussed in this section and provides designation schedule information from recent, pending or prior NAAQS revisions for other pollutants. If the promulgation date for a revised SO<sub>2</sub> NAAQS occurs on a different date than June 1, 2010 (*i.e.*

if the consent decree should be amended—which EPA does not presently anticipate), EPA will revise the final SO<sub>2</sub> exceptional event flagging and documentation submission deadlines accordingly, consistent with this proposal, to provide states with reasonably adequate opportunity to review, identify, and document exceptional events that may affect an area designation under a revised NAAQS. EPA invites comment on these proposed changes in the exceptional event flagging and documentation submission deadlines for the revised SO<sub>2</sub> NAAQS shown in Table 6.

TABLE 6—SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN DESIGNATIONS DECISIONS FOR NEW OR REVISED NAAQS

NAAQS pollutant/standard/(level)/promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
PM <sub>2.5</sub> /24-Hr Standard (35 µg/m <sup>3</sup> ) Promulgated October 17, 2006.	2004–2006	October 1, 2007 <sup>a</sup> .....	April 15, 2008 <sup>a</sup> .
	2005–2007	June 18, 2009 <sup>a</sup> .....	June 18, 2009 <sup>a</sup> .
Ozone/8-Hr Standard (0.075 ppm) Promulgated March 12, 2008.	2008	June 18, 2009 <sup>a</sup> .....	June 18, 2009 <sup>a</sup> .
	2009	60 Days after the end of the calendar quarter in which the event occurred or February 5, 2010, whichever date occurs first <sup>b</sup> .	60 Days after the end of the calendar quarter in which the event occurred or February 5, 2010, whichever date occurs first <sup>b</sup> .
NO <sub>2</sub> /1-Hour Standard (80–100 Ppb, Final Level Tbd).	2008	July 1, 2010 <sup>a</sup> .....	January 22, 2011 <sup>a</sup> .
	2009	July 1, 2010 <sup>a</sup> .....	January 22, 2011 <sup>a</sup> .
SO <sub>2</sub> /1-Hour Standard (50–100 PPB, Final Level Tbd).	2010	April 1, 2011 <sup>a</sup> .....	July 1, 2011 <sup>a</sup> .
	2008	October 1, 2010 <sup>b</sup> .....	June 1, 2011 <sup>b</sup> .
	2009	October 1, 2010 <sup>b</sup> .....	June 1, 2011 <sup>b</sup> .
	2010	June 1, 2011 <sup>b</sup> .....	June 1, 2011 <sup>b</sup> .
	2011	60 Days after the end of the calendar quarter in which the event occurred or March 31, 2011, whichever date occurs first <sup>b</sup> .	60 Days after the end of the calendar quarter in which the event occurred or March 31, 2011, whichever date occurs first <sup>b</sup> .

<sup>a</sup> These dates are unchanged from those published in the original rulemaking, or are being proposed elsewhere and are shown in this table for informational purposes—the agency is not opening these dates for comment under this rulemaking.

<sup>b</sup> Indicates change from general schedule in 40 CFR 50.14.

**Note:** EPA notes that the table of revised deadlines *only* applies to data EPA will use to establish the final initial designations for new or revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

**V. Designations for the SO<sub>2</sub> NAAQS**

After EPA establishes or revises a NAAQS, the CAA directs EPA and the states to begin taking steps to ensure that the new or revised NAAQS is met. The first step is to identify areas of the country that do not meet the new or revised NAAQS. This step is known as the initial area designations.

Section 107(d)(1)(A) of the CAA provides that, “By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised NAAQS for any pollutant under section 109, the Governor of each state shall \* \* \* submit to the Administrator a list of all areas (or portions thereof) in the

state” that designates those areas as nonattainment, attainment, or unclassifiable. The CAA section 107(d)(1)(A)(i) defines an area as nonattainment if it is violating the NAAQS or if it is contributing to a violation in a nearby area.

Section 107(d)(1)(B)(i) further provides, “Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) \* \* \* as expeditiously as practicable, but in no case later than 2 years from the date of promulgation. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations within 2 years. By no later

than 120 days prior to promulgating designations, EPA is required to notify states of any intended modifications to their boundaries as EPA may deem necessary. States then have an opportunity to comment on EPA’s intended decisions. (See section 107(d)(1)(B)(ii).) Whether or not a state provides a recommendation, EPA must promulgate the designation that the Agency deems appropriate.

Therefore, following promulgation of any revised SO<sub>2</sub> NAAQS in June 2010, EPA must promulgate initial designations by June 2012, or, by June 2013 in the event that the Administrator has insufficient information to promulgate initial designations within 2 years. Along with the proposal to set a

new 1-hour primary SO<sub>2</sub> NAAQS, elsewhere in this action, EPA is proposing new SO<sub>2</sub> ambient air monitoring network requirements. As proposed, any new monitors would be deployed no later than January 1, 2013. Compliance with the proposed 1-hour SO<sub>2</sub> NAAQS would be determined based on 3 years of complete, quality assured, certified monitoring data. We do not expect newly sited monitors for the proposed new network to generate sufficient monitoring data for EPA to use in determining whether areas are in compliance with the revised SO<sub>2</sub> NAAQS by the statutory deadline for EPA to complete initial designations, even if EPA were to take an additional third year. Therefore, EPA intends to complete the designations on a 2-year schedule, by June 2012, based on 3 years of complete, quality assured, certified air quality monitoring data from the current monitoring network.

EPA expects to base designations on air quality data from the years 2008–2010 or 2009–2011. Because the new monitoring network requirements would not apply until January 1, 2013, EPA expects that many SO<sub>2</sub> monitors now operating will continue in operation at their current locations at least through the end of 2011.<sup>36</sup> The SO<sub>2</sub> monitors in the current network were generally sited to measure the highest 24-hour and annual average SO<sub>2</sub> concentrations. However, all of the monitors report hourly data. EPA estimates that around 488 monitors operated in 2008. EPA believes at least one third of the monitors meet the proposed network design requirements and therefore would not need to be moved. Additional monitors may be retained in their current locations if they are measuring high levels of SO<sub>2</sub>. If a monitor in the existing network indicates a violation of the 1-hour SO<sub>2</sub> NAAQS, EPA intends to designate the area nonattainment, regardless of whether or not the monitor is located such that it could be counted towards meeting the proposed new network requirements. However, if the monitor indicates that the monitoring site meets the 1-hour SO<sub>2</sub> NAAQS, EPA's decision on the designation of the area would be made on a case-by-case basis. One possible outcome is that the area may be designated as unclassifiable because EPA would be unable to determine whether the area is violating the 1-hour

<sup>36</sup> EPA Regional Administrator approval will be required for any state to discontinue an existing monitoring site, and EPA does not expect that it will before 2011 approve discontinuation of monitoring at any site which appears to have a substantial likelihood of violating the 1-hour NAAQS.

SO<sub>2</sub> NAAQS, or contributing to a violation in a nearby area, because of a lack of a complete monitoring network meeting the new network requirements.

Accordingly, state Governors would need to submit their initial designation recommendations to EPA no later than June 2011. If the Administrator intends to modify any state recommendation, EPA would notify the state's Governor no later than February 2012, 120 days prior to promulgating the final designations. States would then have an opportunity to comment on EPA's tentative decisions before EPA promulgates the final designations in June 2012.

While CAA section 107 specifically addresses states, EPA intends to follow the same process for tribes to the extent practicable, pursuant to section 301(d) of the CAA regarding tribal authority, and the Tribal Authority Rule (63 FR 7254; February 12, 1998). Pursuant to the Tribal Authority Rule, Tribes are not subject to the schedule requirements that apply to states. However, EPA intends to promulgate designations for Tribal land as well as state land according to the schedule mandated for state land, so EPA encourages Tribes that wish to provide input on EPA's designations to provide this input on the schedule mandated for states.

## VI. Clean Air Act Implementation Requirements

This section of the preamble discusses the Clean Air Act (CAA) requirements that states and emissions sources would need to address when implementing new or revised SO<sub>2</sub> NAAQS based on the structure outlined in the CAA and existing rules.<sup>37</sup> The EPA believes that there are sufficient guidance documents and regulations currently in place to fully implement the proposed revision to the SO<sub>2</sub> NAAQS.<sup>38</sup> However, EPA may provide additional guidance in the future, as necessary, to assist states and emissions sources to comply with the CAA provisions for implementing a new or revised SO<sub>2</sub> NAAQS.

The CAA assigns important roles to EPA, states and tribal governments to achieve the NAAQS. States have the primary responsibility for developing and implementing state implementation plans (SIPs) that contain state measures

<sup>37</sup> Since EPA is proposing to take comments on retaining the current 24-hr standards without revision if the 1-hr standard is set at 100–150 ppb, the discussion in this section relates to implementation of the proposed 1-hour standard and the possible retention or revocation of the current 24-hr standard.

<sup>38</sup> See SO<sub>2</sub> Guideline Document, Office of Air Quality Planning and Standards, Research Triangle Park, NC 27711, EPA-452/R-94-008, February 1994.

necessary to achieve the air quality standards in each area once EPA has established the NAAQS. EPA provides assistance to states and tribes by providing technical tools, assistance, and guidance, including information on the potential control measures that may assist in helping areas attain the standards.

Under section 110 of the CAA, 42 U.S.C. 7410, and related provisions, states are directed to submit, for EPA approval, SIPs that provide for the attainment and maintenance of such standards through control programs directed at sources of SO<sub>2</sub> emissions. If a state fails to adopt and implement the required SIPs by the time periods provided in the CAA, EPA has the responsibility under the CAA to adopt a federal implementation plan (FIP) to assure that areas attain the NAAQS in an expeditious manner. The states, in conjunction with EPA, also administer the prevention of significant deterioration (PSD) program for SO<sub>2</sub>. See sections 160–169 of the CAA, 42 U.S.C. 7470–7479. In addition, federal programs provide for nationwide reductions in emissions of SO<sub>2</sub> and other air pollutants under Title II of the Act, 42 U.S.C. 7521–7574. These programs involve limits on the sulfur content of the fuel used by automobiles, trucks, buses, motorcycles, non-road engines and equipment, marine vessels and locomotives. EPA is also in the process of establishing limits on the sulfur content of the fuel used by ocean going vessels. Emissions reductions for SO<sub>2</sub> are also obtained from implementation of the new source performance standards (NSPS) for stationary sources under sections 111 and 129 of the CAA, 42 U.S.C. 7411 and 7429; and the national emission standards for hazardous air pollutants (NESHAP) for stationary sources under section 112 of the CAA, 42 U.S.C. 7412.

### A. How this rule applies to tribes

CAA section 301(d) authorizes EPA to treat eligible Indian tribes in the same manner as states (TAS) under the CAA and requires EPA to promulgate regulations specifying the provisions of the statute for which such treatment is appropriate. EPA has promulgated these regulations—known as the Tribal Authority Rule or TAR—at 40 CFR Part 49. See 63 FR 7254 (February 12, 1998). The TAR establishes the process for Indian tribes to seek TAS eligibility and sets forth the CAA functions for which TAS will be available. Under the TAR, eligible tribes may seek approval for all CAA and regulatory purposes other than a small number of functions enumerated at section 49.4. Implementation plans

under section 110 are included within the scope of CAA functions for which eligible tribes may obtain approval. Section 110(o) also specifically describes tribal roles in submitting implementation plans. Eligible Indian tribes may thus submit implementation plans covering their reservations and other areas under their jurisdiction.

The CAA and TAR do not, however, direct tribes to apply for TAS or implement any CAA program. In promulgating the TAR EPA explicitly determined that it was not appropriate to treat tribes similarly to states for purposes of, among other things, specific plan submittal and implementation deadlines for NAAQS-related requirements. 40 CFR 49.4(a). In addition, where tribes do seek approval of CAA programs, including section 110 implementation plans, the TAR provides flexibility and allows them to submit partial program elements, so long as such elements are reasonably severable—*i.e.*, “not integrally related to program elements that are not included in the plan submittal, and are consistent with applicable statutory and regulatory requirements”. 40 CFR 49.7.

To date, very few tribes have sought TAS for purposes of section 110 implementation plans. However, some tribes may be interested in pursuing such plans to implement today's proposed standard, once it is promulgated. In several sections of this preamble, EPA describes the various roles and requirements states will address in implementing today's proposed standard. Such references to states generally include eligible Indian tribes to the extent consistent with the flexibility provided to tribes under the TAR. Where tribes do not seek TAS for section 110 implementation plans, EPA under its discretionary authority will promulgate FIPs as “necessary or appropriate to protect air quality.” 40 CFR 49.11(a). EPA also notes that some tribes operate air quality monitoring networks in their areas. For such monitors to be used to measure attainment with the proposed revised primary NAAQS for SO<sub>2</sub>, the criteria and procedures identified in this proposed rule would apply.

#### B. Attainment dates

The latest date by which an area is required to attain the SO<sub>2</sub> NAAQS is determined from the effective date of the nonattainment designation for the affected area. For areas designated nonattainment for the revised SO<sub>2</sub> NAAQS, SIPs must provide for attainment of the NAAQS as expeditiously as practicable, but no later than 5 years from the effective date of

the nonattainment designation for the area. See section 192(a) of the CAA. The EPA will determine whether an area has demonstrated attainment of the SO<sub>2</sub> NAAQS by evaluating air quality monitoring data consistent with the form of the NAAQS for SO<sub>2</sub>, if revised, which will be codified at 40 CFR part 50, Appendix T.

#### 1. Attaining the NAAQS

In order for an area to be redesignated as attainment, it must meet five conditions provided under section 107(d)(3)(E) of the CAA. This section requires that:

- EPA must have determined that the area has met the SO<sub>2</sub> NAAQS;
- EPA has fully approved the state's implementation plan;
- The improvement in air quality in the affected area is due to permanent and enforceable reductions in emissions;
- EPA has fully approved a maintenance plan for the area; and
- The state(s) containing the area have met all applicable requirements under section 110 and part D.

#### 2. Consequences of failing to attain by the statutory attainment date

Any SO<sub>2</sub> nonattainment area that fails to attain by its statutory attainment date would be subject to the requirements of sections 179(c) and (d) of the CAA. EPA is required to make a finding of failure to attain no later than 6 months after the specified attainment date and publish a notice in the **Federal Register**. The state would then need to submit an implementation plan revision no later than one year following the effective date of the **Federal Register** notice making the determination of the area's failure to attain. This submission must demonstrate that the standard will be attained as expeditiously as practicable, but no later than 5 years from the effective date of EPA's finding that the area failed to attain. In addition, section 179(d)(2) provides that the SIP revision must include any specific additional measures as may be reasonably prescribed by EPA, including “all measures that can be feasibly implemented in the area in light of technological achievability, costs, and any nonair quality and other air quality-related health and environmental impacts.”

#### C. Section 110(a)(1) and (2) NAAQS infrastructure requirements

Section 110(a)(2) of the CAA directs all states to develop and maintain a solid air quality management infrastructure, including enforceable emission limitations, an ambient

monitoring program, an enforcement program, air quality modeling capabilities, and adequate personnel, resources, and legal authority. Section 110(a)(2)(D) also requires state plans to prohibit emissions from within the state which contribute significantly to nonattainment or maintenance areas in any other state, or which interfere with programs under part C of the CAA to prevent significant deterioration of air quality or to achieve reasonable progress toward the national visibility goal for Federal class I areas (national parks and wilderness areas).

Under sections 110(a)(1) and (2) of the CAA, all states are directed to submit SIPs to EPA which demonstrate that basic program elements have been addressed within 3 years of the promulgation of any new or revised NAAQS. Subsections (A) through (M) of section 110(a)(2) set forth the elements that a state's program must contain in the SIP.<sup>39</sup> The list of section 110(a)(2) NAAQS implementation requirements are the following:

- Ambient air quality monitoring/data system: Section 110(a)(2)(B) requires SIPs to provide for setting up and operating ambient air quality monitors, collecting and analyzing data and making these data available to EPA upon request.
- Program for enforcement of control measures: Section 110(a)(2)(C) requires SIPs to include a program providing for enforcement of SIP measures and the regulation and permitting of new/modified sources.
- Interstate transport: Section 110(a)(2)(D) requires SIPs to include provisions prohibiting any source or other type of emissions activity in the state from contributing significantly to nonattainment or interfering with maintenance of the NAAQS in another state, or from interfering with measures required to prevent significant deterioration of air quality or to protect visibility.
- Adequate resources: Section 110(a)(2)(E) directs states to provide assurances of adequate funding, personnel and legal authority to implement their SIPs.
- Stationary source monitoring system: Section 110(a)(2)(F) directs

<sup>39</sup> Two elements identified in section 110(a)(2) are not listed below because, as EPA interprets the CAA, SIPs incorporating any necessary local nonattainment area controls would not be due within 3 years, but rather are due at the time the nonattainment area planning requirements are due. These elements are: (1) Emission limits and other control measures, section 110(a)(2)(A), and (2) Provisions for meeting part D, section 110(a)(2)(I), which requires areas designated as nonattainment to meet the applicable nonattainment planning requirements of part D, title I of the CAA.

states to establish a system to monitor emissions from stationary sources and to submit periodic emissions reports to EPA.

- Emergency power: Section 110(a)(2)(G) directs states to include contingency plans, and adequate authority to implement them, for emergency episodes in their SIPs.
- Provisions for SIP revision due to NAAQS changes or findings of inadequacies: Section 110(a)(2)(H) directs states to provide for revisions of their SIPs in response to changes in the NAAQS, availability of improved methods for attaining the NAAQS, or in response to an EPA finding that the SIP is inadequate.
- Consultation with local and Federal government officials: Section 110(a)(2)(J) directs states to meet applicable local and Federal government consultation requirements when developing SIPs and reviewing preconstruction permits.
- Public notification of NAAQS exceedances: Section 110(a)(2)(J) directs states to adopt measures to notify the public of instances or areas in which a NAAQS is exceeded.
- PSD and visibility protection: Section 110(a)(2)(J) also directs states to adopt emissions limitations, and such other measures, as may be necessary to prevent significant deterioration of air quality in attainment areas and protect visibility in Federal Class I areas in accordance with the requirements of CAA Title I, part C.
- Air quality modeling/data: Section 110(a)(2)(K) requires that SIPs provide for performing air quality modeling for predicting effects on air quality of emissions of any NAAQS pollutant and submission of data to EPA upon request.
- Permitting fees: Section 110(a)(2)(L) requires the SIP to include requirements for each major stationary source to pay permitting fees to cover the cost of reviewing, approving, implementing and enforcing a permit.
- Consultation/participation by affected local government: Section 110(a)(2)(M) directs states to provide for consultation and participation by local political subdivisions affected by the SIP.

#### D. Attainment planning requirements

##### 1. SO<sub>2</sub> nonattainment area SIP requirements

Any state containing an area designated as nonattainment with respect to the SO<sub>2</sub> NAAQS would need to develop for submission to EPA a SIP meeting the requirements of part D, Title I, of the CAA, providing for attainment by the applicable statutory

attainment date. See sections 191(a) and 192(a) of the CAA. As indicated in section 191(a), all components of the SO<sub>2</sub> part D SIP must be submitted within 18 months of the effective date of an area's designation as nonattainment.

Section 172 of the CAA addresses the general requirements for areas designated as nonattainment. Section 172(c) directs states with nonattainment areas to submit a SIP which contains an attainment demonstration showing that the affected area will attain the standard by the applicable statutory attainment date. The SIP must show that the area will attain the standard as expeditiously as practicable, and must "provide for the implementation of all Reasonably Available Control Measures (RACM) as expeditiously as practicable (including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of Reasonably Available Control Technology (RACT))."

SIPs required under Part D of the CAA must also provide for reasonable further progress (RFP). See section 172(c)(2) of the CAA. The CAA defines RFP as "such annual incremental reductions in emissions of the relevant air pollution as are required by part D, or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable NAAQS by the applicable attainment date." See section 171 of the CAA. Historically, for some pollutants, RFP has been met by showing annual incremental emission reductions sufficient to maintain generally linear progress toward attainment by the applicable attainment date.

All SO<sub>2</sub> nonattainment area SIPs must include contingency measures which must be implemented in the event that an area fails to meet RFP or fails to attain the standards by its attainment date. See section 172(c)(9) of the CAA. These contingency measures must be fully adopted rules or control measures that take effect without further action by the state or the Administrator. The EPA interprets this requirement to mean that the contingency measures must be implemented with only minimal further action by the state or the affected sources with no additional rulemaking actions such as public hearings or legislative review.

Emission inventories are also critical for the efforts of state, local, and federal agencies to attain and maintain the NAAQS that EPA has established for criteria pollutants including SO<sub>2</sub>. Section 191(a) in conjunction with section 172(c) requires that areas designated as nonattainment for SO<sub>2</sub>

submit an emission inventory to EPA no later than 18 months after designation as nonattainment. In the case of SO<sub>2</sub>, sections 191(a) and 172(c) also direct states to submit periodic emission inventories for nonattainment areas. The periodic inventory must include emissions of SO<sub>2</sub> for point, nonpoint, mobile, and area sources.

##### 2. New source review and prevention of significant deterioration requirements

The Prevention of Significant Deterioration (PSD) and nonattainment New Source Review (NSR) programs contained in parts C and D of Title I of the CAA govern preconstruction review of any new or modified major stationary sources of air pollutants regulated under the CAA as well as any precursors to the formation of that pollutant when identified for regulation by the Administrator.<sup>40</sup> The EPA rules addressing these programs can be found at 40 CFR 51.165, 51.166, 52.21, 52.24, and Part 51, appendix S.

The PSD program applies when a major source located in an area that is designated as attainment or unclassifiable for any criteria pollutant is constructed or undergoes a major modification.<sup>41</sup> The nonattainment NSR program applies on a pollutant-specific basis when a major source constructs or modifies in an area that is designated as nonattainment for that pollutant. The minor NSR program addresses major and minor sources that undergo construction or modification activities that do not qualify as major, and it applies, as necessary to assure attainment, regardless of the designation of the area in which a source is located.

PSD permit requirements are effective on the promulgation date of a new or revised standard. SIPs that address the PSD requirements related to attainment areas are due no later than 3 years after the promulgation of a revised NAAQS for SO<sub>2</sub>. The PSD requirements include but are not limited to the following:

- Installation of Best Available Control Technology (BACT);
- Air quality monitoring and modeling analyses to ensure that a project's emissions will not cause or contribute to a violation of any NAAQS

<sup>40</sup> The terms "major" and "minor" define the size of a stationary source, for applicability purposes, in terms of an annual emissions rate (tons per year, tpy) for a pollutant. Generally, a minor source is any source that is not "major." "Major" is defined by the applicable regulations—PSD or nonattainment NSR.

<sup>41</sup> In addition, the PSD program applies to non-criteria pollutants subject to regulation under the Act, except those pollutants regulated under section 112 and pollutants subject to regulation only under section 211(o).

or maximum allowable pollutant increase (PSD increment);

- Notification of Federal Land Manager of nearby Class I areas; and public comment on the permit.

If EPA establishes a 1-hour NAAQS for SO<sub>2</sub>, the owner or operator of any major stationary source or major modification locating in an attainment or unclassifiable area for SO<sub>2</sub> will be required, as a prerequisite for a PSD permit, to demonstrate that the emissions increases from the new or modified source will not cause or contribute to a violation of the that new NAAQS. The EPA does not anticipate that this will pose a technical problem, since the modeling capability and SO<sub>2</sub> emissions input data already exist. Depending on the final form of the 1-hour NAAQS, it may be necessary to make adjustments to the AERMOD modeling system to accommodate the form of the standard; however, EPA anticipates that any such adjustments can be readily accomplished in coordination with the promulgation of any new NAAQS for SO<sub>2</sub> in time to enable states to implement such standard via the PSD program. The analyses for the 1-hour NAAQS will be in addition to the existing demonstration of compliance for the annual and 24-hour SO<sub>2</sub> NAAQS, which will continue to be required unless EPA revokes these standards in conjunction with its promulgation of a new 1-hour NAAQS for SO<sub>2</sub>.

The owner or operator of a new or modified source will still be required to demonstrate compliance with the annual and 24-hour SO<sub>2</sub> increments, even if their counterpart NAAQS are revoked. The annual and 24-hour increments are established in the CAA and will need to remain in the PSD regulations because EPA does not interpret the Clean Air Act to authorize EPA to remove them. It appears necessary for Congress to amend the Act to make appropriate changes to the statutory SO<sub>2</sub> increments, perhaps similar to the way the Act was amended to accommodate PM<sub>10</sub> increments in lieu of the statutory TSP increments. If we establish a new 1-hour SO<sub>2</sub> NAAQS, EPA will consider the need to adopt new 1-hour SO<sub>2</sub> increments.

In association with the requirement to demonstrate compliance with the NAAQS and increments, the owner or operator of a new or modified source must submit for review and approval a source impact analysis and an air quality analysis. The source impact analysis, primarily a modeling analysis, must demonstrate that allowable emissions increases from the proposed source or modification, in conjunction

with emissions from other existing sources will not cause or contribute to either a NAAQS or increment violation. The air quality analysis must assess the ambient air quality in the area that the proposed source or modification would affect.

For the air quality analysis, the owner or operator must submit in its permit application air quality monitoring data that shall have been gathered over a period of one year and is representative of air quality in the area of the proposed project. If existing data representative of the area of the proposed project is not available, new data may need to be collected by the owner or operator of the source or modification. Where data is already available, it might be necessary to evaluate the location of the monitoring sites from which the SO<sub>2</sub> data were collected in comparison to any new siting requirements associated with the 1-hour NAAQS. If existing sites are inappropriate for providing the necessary representative data, then new monitoring data will need to be collected by the owner or operator of the proposed project.

Historically, EPA has allowed the use of several screening tools to help facilitate the implementation of the new source review program by reducing the permit applicant's burden, and streamlining the permitting process for de minimis circumstances. These screening tools include a significant emissions rate (SER), significant impact levels (SILs), and a significant monitoring concentration (SMC). The SER, as defined in tons per year for each regulated pollutant, is used to determine whether any proposed source or modification will emit sufficient amounts of a particular pollutant to require the review of that pollutant under the NSR permit program. EPA will consider whether to evaluate the existing significant emissions rate (SER) for SO<sub>2</sub> to see if it would change substantially based on the NAAQS levels for the 1-hour averaging period. Historically, we have defined a de minimis pollutant impact as one that results in a modeled ambient impact of less than approximately 4% of the short-term NAAQS. The current SER for SO<sub>2</sub> (40 tpy) is based on the impact on the 24-hour SO<sub>2</sub> NAAQS. See, 45 FR 52676, 52707 (August 7, 1980). We have typically used the most sensitive averaging period to calculate the SER, and we may want to evaluate the new 1-hour period for SO<sub>2</sub> because it is likely to represent most sensitive averaging period for SO<sub>2</sub>.

The SIL, expressed as an ambient pollutant concentration (µg/m<sup>3</sup>), is used to determine whether the impact of a

particular pollutant is significant enough to warrant a complete air quality impact analysis for any applicable NAAQS and increments. EPA has promulgated regulations under 40 CFR 51.165(b) which include SILs for SO<sub>2</sub> to determine whether a source's impact would be considered to cause or contribute to a NAAQS violation for either the 3-hour, 24-hour or annual averaging periods. These SILs were originally developed in 1978 to limit the application of air quality dispersion models to a downwind distance of no more than 50 kilometers or to "insignificant levels." See, 43 FR 26398, June 19, 1978. Through guidance, EPA has also allowed the use of SILs to determine whether or not it is necessary for a source to carry out a comprehensive source impact analysis and to determine the extent of the impact area in which the analysis will be carried out. The existing SILs for SO<sub>2</sub> were not developed on the basis of specific SO<sub>2</sub> NAAQS levels, so if the existing NAAQS are not being revised, there is probably no need to revise the existing SILs. Even if we decide to revoke any of the existing NAAQS, the corresponding SIL should still be useful for increment assessment. A SIL for the 1-hour averaging period does not exist, and would need to be developed for use with modeling for 1-hour SO<sub>2</sub> NAAQS and increments (if and when developed).

Finally, the SMC, also measured as an ambient pollutant concentration (µg/m<sup>3</sup>), is used to determine whether it may be appropriate to exempt a proposed project from the requirement to collect ambient monitoring data for a particular pollutant as part of a complete permit application. EPA first defined SMCs for regulated pollutants under the PSD program in 1980. See, 45 FR 52676, 52709–10 (August 7, 1980). The existing SMC for SO<sub>2</sub>, based on a 24-hour averaging period, may need to be re-evaluated to consider the effect of basing the SMC on the 1-hour averaging period, especially in light of the fact that we may revoke the NAAQS for the 24-hour averaging period. Third, even if the 1-hour averaging period does not indicate the need for a revised SMC for SO<sub>2</sub>, the fact that the original SMC for SO<sub>2</sub> is based on 1980 monitoring data (Lowest Detectable Level, correction factor of "5"), could be a basis for revising the existing value. More up-to-date monitoring data and statistical analyses of monitoring accuracy may yield a different—possibly lower—correction factor today. A new 1-hour NAAQS would not necessarily cause this result, but may provide a "window

of opportunity” to re-evaluate the SMC for SO<sub>2</sub>. See sections II.E.2 and II.F.2 above.

As a means of reducing the permit applicant’s burden, and to streamline permitting, permit authorities use screening tools referred to as significant impact levels (SILs) and a significant monitoring concentration (SMC). EPA issued unofficial SO<sub>2</sub> SILs for the 3-hour (secondary standard), 24-hour and annual averaging periods. These SILs were developed in 1978 to limit the application of air quality dispersion models to a downwind distance of no more than 50 kilometers or to “insignificant levels.” See, 43 FR 263—, 26398, (June 19, 1978). These values were not developed on the basis of specific SO<sub>2</sub> NAAQS levels, so if the existing NAAQS are not being revised, there is probably no need to revise the existing SILs. Even if we decide to revoke any of the existing NAAQS, the corresponding SIL should still be useful for increment assessment. A SIL for the 1-hour averaging period does not exist, and would need to be developed for use with modeling for the 1-hour SO<sub>2</sub> NAAQS and increments (if and when developed).

States which have areas designated as nonattainment for the SO<sub>2</sub> NAAQS are directed to submit, as a part of the SIP due 18 months after an area is designated as nonattainment, provisions requiring permits for the construction and operation of new or modified stationary sources anywhere in the nonattainment area. Prior to adoption of the SIP revision addressing major source nonattainment NSR for SO<sub>2</sub> nonattainment areas, the requirements of 40 CFR part 51, appendix S will apply. Nonattainment NSR requirements include but are not limited to:

- Installation of Lowest Achievable Emissions Rate (LAER) control technology;
- Offsetting new emissions with creditable emissions reductions;
- A certification that all major sources owned and operated in the state by the same owner are in compliance with all applicable requirements under the CAA;
- An alternative siting analysis demonstrating that the benefits of a proposed source significantly outweigh the environmental and social costs imposed as a result of its location, construction, or modification; and
- Public comment on the permit.

Minor NSR programs must meet the statutory requirements in section 110(a)(2)(C) of the CAA which requires “\* \* \* regulation of the modification and construction of any stationary

source \* \* \* as necessary to assure that the [NAAQS] are achieved.” These programs must be established in each state within 3 years of the promulgation of a new or revised NAAQS.

### 3. General conformity

Section 176(c) of the CAA requires that all federal actions conform to an applicable implementation plan developed pursuant to section 110 and part D of the CAA. The EPA rules developed under section 176(c) prescribe the criteria and procedures for demonstrating and assuring conformity of federal actions to a SIP. Each federal agency must determine that any actions covered by the general conformity rule conform to the applicable SIP before the action is taken. The criteria and procedures for conformity apply only in nonattainment areas and those areas redesignated attainment since 1990 (“maintenance areas”) with respect to the criteria pollutants under the CAA<sup>42</sup>: carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO<sub>2</sub>), ozone (O<sub>3</sub>), particulate matter (PM<sub>2.5</sub> and PM<sub>10</sub>), and sulfur dioxide (SO<sub>2</sub>). The general conformity rules apply one year following the effective date of designations for any new or revised NAAQS.<sup>43</sup>

The general conformity determination examines the impacts of direct and indirect emissions related to federal actions. The general conformity rule provides several options to satisfy air quality criteria, such as modeling or offsets, and requires the federal action to also meet any applicable SIP requirements and emissions milestones. The general conformity rule also requires that notices of draft and final general conformity determinations be provided directly to air quality regulatory agencies and to the public by publication in a local newspaper.

#### *E. Transition from the existing SO<sub>2</sub> NAAQS to a revised SO<sub>2</sub> NAAQS*

As stated in section II.F.5 of this notice, in addition to proposing a short-term 1-hour SO<sub>2</sub> NAAQS, EPA is proposing to revoke the current annual

<sup>42</sup> Criteria pollutants are those pollutants for which EPA has established a NAAQS under section 109 of the CAA.

<sup>43</sup> Transportation conformity is required under CAA section 176(c) (42 U.S.C. 7506(c)) to ensure that federally supported highway and transit project activities are consistent with (“conform to”) the purpose of the SIP. Transportation conformity applies to areas that are designated nonattainment, and those areas redesignated to attainment after 1990 (“maintenance areas”) with plans developed under CAA section 175A) for transportation-related criteria pollutants. Due to the relatively small amounts of sulfur in gasoline and on-road diesel fuel, transportation conformity does not apply to the SO<sub>2</sub> NAAQS. 40 CFR 93.102(b)(1).

and 24-hour standards, (annual 0.03 ppm and 24-hour 0.14 ppm). Specifically, EPA is proposing that the level for the 1-hour standard for SO<sub>2</sub> be a range between 50–100 ppb, and is taking comment on setting the level of the standard up to 150 ppb. If the Administrator sets the 1-hour standard at 100 ppb or lower, EPA is proposing to revoke the current 24-hour standard. If the Administrator sets the level of the 1-hour standard between a range of 100–150 ppb, then EPA would retain the current 24-hour standard.

If EPA revises the SO<sub>2</sub> NAAQS and revokes either the current annual or 24-hour standard, EPA would need to promulgate adequate anti-backsliding provisions. The CAA establishes anti-backsliding requirements where EPA relaxes a NAAQS. Here, if EPA were to replace the annual and/or 24-hour standard with a short term 1-hour standard, EPA would need to address the section 172(e) anti-backsliding provision of the CAA and determine whether it applies on its face or by analogy, and what provisions would be appropriate to provide for transition to the new standard. States would need to insure that the health protection provided under the existing SO<sub>2</sub> NAAQS continues to be achieved as well as maintained as states begin to implement a revised NAAQS. This means that states would be directed to continue implementing attainment and maintenance SIPs associated with the existing SO<sub>2</sub> NAAQS until such time as they are subsumed by any new planning and control requirements associated with a revised NAAQS.

Whether or not section 172(e) directly applies to EPA’s final action on the SO<sub>2</sub> NAAQS, EPA has previously looked to other provisions of the CAA to determine how to address anti-backsliding. The CAA contains a number of provisions that indicate Congress’s intent to not allow provisions from implementation plans to be altered or removed if the plan revision would jeopardize the air quality protection being provided by the existing plan when EPA revises a NAAQS to make it more stringent. For example, section 110(l) provides that EPA may not approve a SIP revision if it interferes with any applicable requirement concerning attainment and RFP, or any other applicable requirement under the CAA. In addition, section 193 of the CAA prohibits the modification of a control, or a control requirement, in effect or required to be adopted as of November 15, 1990 (*i.e.*, prior to the promulgation of the Clean Air Act Amendments of 1990), unless such a modification would

ensure equivalent or greater emissions reductions. Further, section 172(e) of the CAA specifies that if EPA revises a NAAQS to make it less stringent than a previous NAAQS, control obligations that apply in nonattainment area SIPs may not be relaxed, and adopting those controls that have not yet been adopted as needed may not be avoided. The intent of Congress, concerning the aforementioned sections of the CAA, was confirmed in a recent DC Circuit Court opinion on the Phase I ozone implementation rule. See *South Coast Air Quality Management Dist. v. EPA*, 472 F.3d 882 (DC Cir. 2006).

To ensure that the antibacksliding provisions and principles of section 172(e) are met and applied if EPA revokes the current standards, EPA is proposing that the current SO<sub>2</sub> NAAQS would remain in effect for one year following the effective date of the initial designations under section 107(d)(1) for the revised SO<sub>2</sub> NAAQS before the current NAAQS are revoked in most attainment areas. However, any existing SIP provisions under CAA sections 110, 191 and 192 associated with the existing annual and 24-hour SO<sub>2</sub> NAAQS would remain in effect, including all currently implemented planning and emissions control obligations, including both those in the state's SIP and that have been promulgated by EPA in FIPs. This would ensure that both the new nonattainment NSR requirements and the general conformity requirements for a revised standard are in place so that there will be no gap in the public health protections provided by these two programs. It will also insure that all nonattainment areas under the current NAAQS and all areas for which SIP calls have been issued would continue to be protected by currently required control measures.

EPA is also proposing that the existing NAAQS remain in place for any current nonattainment area, or any area for which a state has not fulfilled the requirements of a SIP call, until the affected area submits, and EPA approves, a SIP with an attainment demonstration which fully addresses the attainment requirements of the revised SO<sub>2</sub> NAAQS. This, in combination with the CAA mechanisms provided in sections 110(l), 193, and 172(e) will help to ensure that continued progress is made toward timely attainment of the SO<sub>2</sub> NAAQS. Also, in light of the nature of the proposed revision of the SO<sub>2</sub> NAAQS, the lack of classifications (and mandatory controls associated with such classifications pursuant to the CAA), and the small number of current nonattainment areas, and areas subject

to SIP calls, EPA believes (subject to consideration of public comment) that retaining the current standard for a limited period of time until attainment SIPs are approved for the new standard in current nonattainment areas and SIP call areas, and one year after designations in other areas, will adequately serve the anti-backsliding requirements and goals of the CAA.<sup>44</sup>

## VII. Communication of Public Health Information

Information on the public health implications of ambient concentrations of criteria pollutants is currently made available primarily through EPA's Air Quality Index (AQI) program. The current Air Quality Index has been in use since its inception in 1999 (64 FR 42530). It provides accurate, timely, and easily understandable information about daily levels of pollution (40 CFR 58.50). The AQI establishes a nationally uniform system of indexing pollution levels for NO<sub>2</sub>, carbon monoxide, ozone, particulate matter and sulfur dioxide. The AQI converts pollutant concentrations in a community's air to a number on a scale from 0 to 500. Reported AQI values enable the public to know whether air pollution levels in a particular location are characterized as good (0–50), moderate (51–100), unhealthy for sensitive groups (101–150), unhealthy (151–200), very unhealthy (201–300), or hazardous (300–500). The AQI index value of 100 typically corresponds to the level of the short-term primary NAAQS for each pollutant. An AQI value greater than 100 means that a pollutant is in one of the unhealthy categories (*i.e.*, unhealthy for sensitive groups, unhealthy, very unhealthy, or hazardous) on a given day; an AQI value at or below 100 means that a pollutant concentration is in one of the satisfactory categories (*i.e.*, moderate or good). Decisions about the pollutant concentrations at which to set the various AQI breakpoints, that delineate the various AQI categories, draw directly from the underlying health information that supports the review of the primary NAAQS.

The Agency recognizes the importance of revising the AQI in a timely manner to be consistent with any revisions to the primary NAAQS. Therefore EPA proposes to finalize

conforming changes to the AQI, in connection with the Agency's final decision on the SO<sub>2</sub> NAAQS if revisions to the primary standard are promulgated. If EPA promulgates a short-term primary SO<sub>2</sub> NAAQS, conforming changes would include setting the 100 level of the AQI at the same level as the revised primary SO<sub>2</sub> NAAQS. Conforming changes also would include setting the other AQI breakpoints at the lower end of the AQI scale (*i.e.*, AQI values of 50 and 150). EPA does 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.

With regard to an AQI value of 50, the breakpoint between the good and moderate categories, historically this value is set at the level of the annual NAAQS, if there is one, or one-half the level of the short-term NAAQS in the absence of an annual NAAQS (63 FR 67823, Dec. 12, 1998). Taking into consideration this practice, EPA is proposing to set the AQI value of 50 to be between 25 and 50 ppb SO<sub>2</sub>, 1-hour average. EPA anticipates that figures towards the lower end of this range would be appropriate if the standard is set towards the lower end of the range for the proposed standard (*e.g.* 50 ppb), while figures towards the higher end of the range would be more appropriate for standards set at the higher end of the range (*e.g.*, 100 ppb). If the short-term standard is set at a level above 100 ppb, and (contrary to the proposal) the annual standard is not revoked, then consideration could be given to setting an AQI value of 50 at the level of the annual standard, or 30 ppb. EPA solicits comments on this range for an AQI of 50, and the appropriate basis for selecting an AQI of 50 both within this range and, in light of EPA's solicitation of comment on 1-hour standard levels above 100 ppb, above this range.

With regard to an AQI value of 150, the breakpoint between the unhealthy for sensitive groups and unhealthy categories, historically values between the short-term standard and an AQI value of 500 are set at levels that are approximately equidistant between the AQI values of 100 and 500 unless there is health evidence that suggests a specific level would be appropriate (63 FR 67829, Dec. 12, 1998). For an AQI value of 150, the range of 175 to 200 ppb SO<sub>2</sub>, 1-hour average, represents the midpoint between the proposed range for the short-term standard and the level

<sup>44</sup> The areas that are currently designated as nonattainment for the pre-existing SO<sub>2</sub> primary NAAQS are Hayden, AZ; Armstrong, PA; Laurel, MT; Piti, GU; and Tanguisson, GU. The areas that are designated nonattainment for both the primary and the secondary standards are East Helena, MT, Salt Lake Co, MT, Toole Co, UT, and Warren Co, NJ. (See <http://www.epa.gov/oar/oaqps/greenbk/Inc.html>). The Billings/Laurel, MT, area is the only area currently subject to a SIP call.

of an AQI value of 200 (300 ppb SO<sub>2</sub>, 1-hour average).

### VIII Statutory and Executive Order Reviews

#### A. Executive Order 12866: Regulatory Planning and Review

Under section 3(f)(1) of Executive Order 12866 (58 FR 51735, October 4, 1993), this action is an “economically significant regulatory action” because it is likely to have an annual effect on the economy of \$100 million or more. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action. In addition, EPA prepared a Regulatory Impact Analysis (RIA) of the potential costs and benefits associated with this action. However, the CAA and judicial decisions make clear that the economic and technical feasibility of attaining the national ambient standards cannot be considered in setting or revising NAAQS, although such factors may be considered in the development of State implementation plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered by EPA in developing this proposed rule.

#### B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA for these proposed revisions to part 58 has been assigned EPA ICR number 2370.01

The information collected under 40 CFR part 53 (*e.g.*, test results, monitoring records, instruction manual, and other associated information) is needed to determine whether a candidate method intended for use in determining attainment of the NAAQS in 40 CFR part 50 will meet the design, performance, and/or comparability requirements for designation as a Federal reference method (FRM) or Federal equivalent method (FEM). We do not expect the number of FRM or FEM determinations to increase over the number that is currently used to estimate burden associated with SO<sub>2</sub> FRM/FEM determinations provided in the current ICR for 40 CFR part 53 (EPA ICR numbers 2370.01). As such, no change in the burden estimate for 40

CFR part 53 has been made as part of this rulemaking.

The information collected and reported under 40 CFR part 58 is needed to determine compliance with the NAAQS, to characterize air quality and associated health impacts, to develop emissions control strategies, and to measure progress for the air pollution program. The proposed amendments would revise the technical requirements for SO<sub>2</sub> monitoring sites, require the siting and operation of additional SO<sub>2</sub> ambient air monitors, and the reporting of the collected ambient SO<sub>2</sub> monitoring data to EPA’s Air Quality System (AQS). The annual average reporting burden for the collection under 40 CFR part 58 (averaged over the first 3 years of this ICR) is \$13,863,950. Burden is defined at 5 CFR 1320.3(b). State, local, and tribal entities are eligible for State assistance grants provided by the Federal government under the CAA which can be used for monitors and related activities.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations in 40 CFR are listed in 40 CFR part 9.

To comment on the Agency’s need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a public docket for this rule, which includes this ICR, under Docket ID number EPA–HQ–OAR–2007–0352. Submit any comments related to the ICR to EPA and OMB. See **ADDRESSES** section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after December 8, 2009, a comment to OMB is best assured of having its full effect if OMB receives it by January 7, 2010. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

#### C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant

economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined by the Small Business Administration’s (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of SO<sub>2</sub> in ambient air as required by section 109 of the CAA. *American Trucking Ass’n v. EPA*, 175 F. 3d 1027, 1044–45 (DC Cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). Similarly, the proposed amendments to 40 CFR Part 58 address the requirements for States to collect information and report compliance with the NAAQS and will not impose any requirements on small entities. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

#### D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Unless otherwise prohibited by law, under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with “Federal mandates” that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is required under section 202, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of

regulatory alternatives and to adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This action is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has determined that this proposed rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. The revisions to the SO<sub>2</sub> NAAQS impose no enforceable duty on any State, local or Tribal governments or the private sector. The expected costs associated with the monitoring requirements are described in EPA's ICR document, but those costs are not expected to exceed \$100 million in the aggregate for any year. Furthermore, as indicated previously, in setting a NAAQS, EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards. Because the CAA prohibits EPA from considering the types of estimates and assessments described in section 202 when setting the NAAQS, the UMRA does not require EPA to prepare a written statement under section 202 for the revisions to the SO<sub>2</sub> NAAQS.

With regard to implementation guidance, the CAA imposes the obligation for States to submit SIPs to implement the SO<sub>2</sub> NAAQS. In this proposed rule, EPA is merely providing an interpretation of those requirements. However, even if this rule did establish an independent obligation for States to submit SIPs, it is questionable whether an obligation to submit a SIP revision would constitute a Federal mandate in any case. The obligation for a State to

submit a SIP that arises out of section 110 and section 191 of the CAA is not legally enforceable by a court of law, and at most is a condition for continued receipt of highway funds. Therefore, it is possible to view an action requiring such a submittal as not creating any enforceable duty within the meaning of U.S.C. 658 for purposes of the UMRA. Even if it did, the duty could be viewed as falling within the exception for a condition of Federal assistance under U.S.C. 658.

EPA has determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments because it imposes no enforceable duty on any small governments. Therefore, this rule is not subject to the requirements of section 203 of the UMRA.

#### *E. Executive Order 13132: Federalism*

Executive Order 13132, entitled "Federalism" (64 FR 43255; August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule does not alter the relationship between the Federal government and the States regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, CAA section 116 preserves the rights of States to establish more stringent requirements if deemed necessary by a State. Furthermore, this rule does not impact CAA section 107 which establishes that the States have primary responsibility for implementation of the NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on State, local, or tribal governments or the private sector. Thus,

Executive Order 13132 does not apply to this rule.

However, EPA recognizes that States will have a substantial interest in this rule and any corresponding revisions to associated air quality surveillance requirements, 40 CFR part 58. Therefore, in the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

#### *F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This proposed rule does not have tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and tribes. The rule does not alter the relationship between the Federal government and tribes as established in the CAA and the TAR. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, this rule does not infringe existing tribal authorities to regulate air quality under their own programs or under programs submitted to EPA for approval. Furthermore, this rule does not affect the flexibility afforded to tribes in seeking to implement CAA programs consistent with the TAR, nor does it impose any new obligation on tribes to adopt or implement any NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on tribal governments. Thus, Executive Order 13175 does not apply to this rule. However, EPA recognizes that tribes may be interested in this rule and any corresponding revisions to associated air quality surveillance requirements. Therefore, in the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and tribes, EPA specifically solicits additional comment on this proposed rule from tribal officials.

*G. Executive Order 13045: Protection of Children From Environmental Health & Safety Risks*

This action is subject to Executive Order (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by Executive Order 12866, and we believe that the environmental health risk addressed by this action has a disproportionate effect on children. The proposed rule will establish uniform national ambient air quality standards for SO<sub>2</sub>; these standards are designed to protect public health with an adequate margin of safety, as required by CAA section 109. The protection offered by these standards may be especially important for asthmatics, including asthmatic children, because respiratory effects in asthmatics are among the most sensitive health endpoints for SO<sub>2</sub> exposure. Because asthmatic children are considered a sensitive population, we have evaluated the potential health effects of exposure to SO<sub>2</sub> pollution among asthmatic children. These effects and the size of the population affected are discussed in chapters 3 and 4 of the ISA; chapters 3, 4, 7, 8, 9 of the REA, and sections II.A through II.E of this preamble.

*H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use*

This rule is not a “significant energy action” as defined in Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355; May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this rule is to establish revised NAAQS for SO<sub>2</sub>. The rule does not prescribe specific control strategies by which these ambient standards will be met. Such strategies will be developed by States on a case-by-case basis, and EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, EPA concludes that this rule is not likely to have any adverse energy effects.

*I. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 27) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise

impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking involves technical standards with regard to ambient monitoring of SO<sub>2</sub>. The use of this voluntary consensus standard would be impractical because the analysis method does not provide for the method detection limits necessary to adequately characterize ambient SO<sub>2</sub> concentrations for the purpose of determining compliance with the proposed revisions to the SO<sub>2</sub> NAAQS.

EPA welcomes comments on this aspect of the proposed rule, and specifically invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in the regulation.

*J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order 12898 (59 FR 7629; Feb. 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health effects on any population, including any minority or low-income population. The proposed rule will establish uniform national standards for SO<sub>2</sub> in ambient air. EPA solicits comment on environmental justice issues related to the proposed revision of the SO<sub>2</sub> NAAQS.

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**List of Subjects**

*40 CFR Part 50*

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

*40 CFR Part 53*

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

*40 CFR Part 58*

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: November 16, 2009.

**Lisa P. Jackson,**  
*Administrator.*

For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

**PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS**

1. The authority citation for part 50 continues to read as follows:

**Authority:** 42 U.S.C. 7401, *et seq.*

2. Section 50.4 is amended by adding paragraph (e) to read as follows:

**§ 50.4 National primary ambient air quality standards for sulfur oxides (sulfur dioxide).**

\* \* \* \* \*

(e) The standards set forth in this section will remain applicable to all areas notwithstanding the promulgation of SO<sub>2</sub> national ambient air quality standards (NAAQS) in § 50.17. The SO<sub>2</sub> NAAQS set forth in this section will no longer apply to an area one year after the effective date of the designation of that area, pursuant to section 107 of the Clean Air Act, for the SO<sub>2</sub> NAAQS set forth in § 50.17; except that for areas designated nonattainment for the SO<sub>2</sub> NAAQS set forth in this section as of the effective date of § 50.17, and areas not meeting the requirements of a SIP call with respect to requirements for the SO<sub>2</sub> NAAQS set forth in this section, the SO<sub>2</sub> NAAQS set forth in this section will apply until that area submits, pursuant to section 191 of the Clean Air Act, and EPA approves, an implementation plan providing for attainment of the SO<sub>2</sub> NAAQS set forth in § 50.17.

3. Section 50.14 is amended by revising paragraph (c)(2)(vi) to read as follows:

**§ 50.14 Treatment of air quality monitoring data influenced by exceptional events.**

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(vi) When EPA sets a NAAQS for a new pollutant or revises the NAAQS for an existing pollutant, it may revise or set a new schedule for flagging exceptional event data, providing initial data descriptions and providing detailed data documentation in AQS for the initial designations of areas for those NAAQS. Table 1 provides the schedule for submission of flags with initial descriptions in AQS and detailed documentation. These schedules shall apply for those data which will or may influence the initial designation of areas for those NAAQS. EPA anticipates revising Table 1 as necessary to accommodate revised data submission schedules for new or revised NAAQS.

**TABLE 1—SCHEDULE OR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN DESIGNATIONS DECISIONS FOR NEW OR REVISED NAAQS**

NAAQS pollutant/standard/(level)/promulgation date	Air quality data collected for calendar year	Event flagging and initial description deadline	Detailed documentation submission deadline
PM <sub>2.5</sub> /24-Hr Standard (35 µg/m <sup>3</sup> ) Promulgated October 17, 2006.	2004–2006	October 1, 2007 <sup>a</sup> .....	April 15, 2008 <sup>a</sup> .
Ozone/8-Hr Standard (0.075 ppm) Promulgated March 12, 2008.	2005–2007	June 18, 2009 <sup>a</sup> .....	June 18, 2009 <sup>a</sup> .
	2008	June 18, 2009 <sup>a</sup> .....	June 18, 2009 <sup>a</sup> .

TABLE 1—SCHEDULE OR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN DESIGNATIONS DECISIONS FOR NEW OR REVISED NAAQS—Continued

NAAQS pollutant/standard/(level)/promulgation date	Air quality data collected for calendar year	Event flagging and initial description deadline	Detailed documentation submission deadline
NO <sub>2</sub> /1-Hour Standard (80–100 PPB, final level TBD).	2009	60 Days after the end of the calendar quarter in which the event occurred or February 5, 2010, whichever date occurs first <sup>b</sup> .	60 Days after the end of the calendar quarter in which the event occurred or February 5, 2010, whichever date occurs first <sup>b</sup> .
	2008	July 1, 2010 <sup>a</sup> .....	January 22, 2011 <sup>a</sup> .
SO <sub>2</sub> /1-Hour Standard (50–100 PPB, final level TBD).	2009	July 1, 2010 <sup>a</sup> .....	January 22, 2011 <sup>a</sup> .
	2010	April 1, 2011 <sup>a</sup> .....	July 1, 2011 <sup>a</sup> .
	2008	October 1, 2010 <sup>b</sup> .....	June 1, 2011 <sup>b</sup> .
	2009	October 1, 2010 <sup>b</sup> .....	June 1, 2011 <sup>b</sup> .
	2010	June 1, 2011 <sup>b</sup> .....	June 1, 2011 <sup>b</sup> .
	2011	60 Days after the end of the calendar quarter in which the event occurred or March 31, 2011, whichever date occurs first <sup>b</sup> .	60 Days after the end of the calendar quarter in which the event occurred or March 31, 2011, whichever date occurs first <sup>b</sup> .

<sup>a</sup>These dates are unchanged from those published in the original rulemaking, or are being proposed elsewhere and are shown in this table for informational purposes—the Agency is not opening these dates for comment under this rulemaking.

<sup>b</sup>Indicates change from general schedule in 40 CFR 50.14.

**Note:** EPA notes that the table of revised deadlines only applies to data EPA will use to establish the final initial designations for new or revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

\* \* \* \* \*

4. A new 50.17 is added to read as follows:

**§ 50.17 National primary ambient air quality standards for sulfur oxides (sulfur dioxide).**

(a) The level of the national primary 1-hour annual ambient air quality standard for oxides of sulfur is (50–100) parts per billion (ppb, which is 1 part in 1,000,000,000), measured in the ambient air as sulfur dioxide (SO<sub>2</sub>).

(b) The 1-hour primary standard is met when the three-year average of the annual (99th percentile)(fourth highest) of the daily maximum 1-hour average concentrations is less than or equal to (50–100) ppb, as determined in accordance with Appendix T of this part.

5. Add Appendix A–1 to Part 50 to read as follows:

**Appendix A–1 to Part 50—Reference Measurement Principle and Calibration Procedure for the Measurement of Sulfur Dioxide in the Atmosphere (Ultraviolet Fluorescence Method)**

**1.0 Applicability.**

1.1 This ultraviolet fluorescence (UVF) method provides a measurement of the concentration of sulfur dioxide (SO<sub>2</sub>) in ambient air for determining compliance with the national primary and secondary ambient air quality standards for sulfur oxides (sulfur dioxide) as specified in § 50.4 and § 50.5 of this chapter. The method is applicable to the measurement of ambient SO<sub>2</sub> concentrations using continuous (real-time) sampling. Additional quality assurance procedures and guidance are provided in part 58, appendix A, of this chapter and in Reference 3.

**2.0 Principle.**

2.1 This reference method is based on automated measurement of the intensity of the characteristic fluorescence released by SO<sub>2</sub> in an ambient air sample contained in a measurement cell of an analyzer when the air sample is irradiated by ultraviolet (UV) light passed through the cell. The fluorescent light released by the SO<sub>2</sub> is also in the ultraviolet region, but at longer wavelengths than the excitation light. Typically, optimum instrumental measurement of SO<sub>2</sub> concentrations is obtained with an excitation wavelength in a band between approximately 190 to 230 nm, and measurement of the SO<sub>2</sub> fluorescence in a broad band around 320 nm, but these wavelengths are not necessarily constraints of this reference method. Generally, the measurement system (analyzer) also requires means to reduce the effects of aromatic hydrocarbon species, and possibly other compounds, in the air sample to control measurement interferences from these compounds, which may be present in the ambient air. References 1 and 2 describe UVF method.

2.2. The measurement system is calibrated by referencing the instrumental fluorescence measurements to SO<sub>2</sub> standard concentrations traceable to a National Institute of Science and Technology (NIST) primary standard for SO<sub>2</sub> (see Calibration Procedure below).

2.3. An analyzer implementing this measurement principle is shown schematically in Figure 1. Designs should include a measurement cell, a UV light source of appropriate wavelength, a UV detector system with appropriate wave length sensitivity, a pump and flow control system for sampling the ambient air and moving it into the measurement cell, sample air conditioning components as necessary to minimize measurement interferences, suitable control and measurement processing capability, and other apparatus as may be

necessary. The analyzer must be designed to provide accurate, repeatable, and continuous measurements of SO<sub>2</sub> concentrations in ambient air, with measurement performance as specified in subpart B of part 53 of this chapter.

2.4. Sampling considerations: The use of a particle filter on the sample inlet line of a UVF SO<sub>2</sub> analyzer is required to prevent interference, malfunction, or damage due to particles in the sampled air.

**3.0 Interferences.**

3.1 The effects of the principal potential interferences may need to be mitigated to meet the interference equivalent requirements of part 53 of this chapter. Polynuclear aromatic (PNA) hydrocarbons such as xylene and naphthalene can fluoresce and act as strong positive interferences. These gases can be removed by using a permeation type scrubber (hydrocarbon “kicker”). Nitrogen oxide (NO) in high concentrations can also fluoresce and cause positive interference. Optical filtering can be employed to improve the rejection of interference from high NO. Ozone can absorb UV light given off by the SO<sub>2</sub> molecule and cause a measurement offset. This effect can be reduced by minimizing the measurement path length between the area where SO<sub>2</sub> fluorescence occurs and the photomultiplier tube detector (e.g. <5 cm). A hydrocarbon scrubber, optical filter and appropriate distancing of the measurement path length may be required method components to reduce interference.

4.0 **Calibration Procedure.** Atmospheres containing accurately known concentrations of sulfur dioxide are prepared using a compressed gas transfer standard diluted with accurately metered clean air flow rates.

4.1 **Apparatus:** Figure 2 shows a typical generic system suitable for diluting a SO<sub>2</sub> gas cylinder concentration standard with clean air through a mixing chamber to produce the desired calibration concentration standards.

A valve may be used to conveniently divert the SO<sub>2</sub> from the sampling manifold to provide clean zero air at the output manifold for zero adjustment. The system may be made up using common laboratory components, or it may be a commercially manufactured system. In either case, the principle components are as follows:

4.1.1 Air and standard gas flow controllers, capable of maintaining constant gas flow rates to within ± 2 percent.

4.1.2 Air and standard gas flow meters, capable of measuring and monitoring air or N<sub>2</sub> (standard gas) flow rates to within ± 2 percent and properly calibrated to a NIST-traceable standard.

4.1.3 Mixing chamber, of an inert material such as glass and of proper design to provide thorough mixing of pollutant gas and diluent air streams.

4.1.4 Sampling manifold, constructed of glass, polytetrafluoroethylene (PTFE Teflon™), or other suitably inert material and of sufficient diameter to insure a minimum pressure drop at the analyzer connection, with a vent designed to insure a minimum over-pressure (relative to ambient air pressure) at the analyzer connection and to prevent ambient air from entering the manifold.

4.1.5 Standard gas pressure regulator, of clean stainless steel with a stainless steel diaphragm, suitable for use with a high pressure SO<sub>2</sub> gas cylinder.

4.1.6 Reagents.

4.1.6.1 SO<sub>2</sub> gas transfer standard, in N<sub>2</sub>, with the concentration traceable to a NIST Standard Reference Material (SRM) such as SRM 1693a (50 μmole/mole) or SRM 1694a (100 μmole/mole) Since UVF analyzers may be sensitive to O<sub>2</sub>-to-N<sub>2</sub> ratios, it is important that the SO<sub>2</sub> standard concentration be sufficiently high (50 to 100 ppm) such that the O<sub>2</sub> content in the diluent air is not significantly changed by the added standard gas.

4.1.6.2 Clean zero air, free of contaminants that could cause a detectable response or a change in sensitivity of the analyzer. Since ultraviolet fluorescence analyzers may be sensitive to aromatic hydrocarbons and O<sub>2</sub>-to-N<sub>2</sub> ratios, it is important that the clean zero air contains less than 0.1 ppm aromatic hydrocarbons and O<sub>2</sub> and N<sub>2</sub> percentages approximately the same as in ambient air. A procedure for generating zero air is given in reference 1.

4.2 Procedure

4.2.1 Obtain a suitable calibration apparatus, such as the one shown

schematically in Figure 1, and verify that all materials in contact with the pollutant are of glass, Teflon™, or other suitably inert material and completely clean.

4.2.2 Purge the SO<sub>2</sub> standard gas lines and pressure regulator to remove any residual air.

4.2.3 Ensure that there are no leaks in the system and that the flow measuring devices are properly and accurately calibrated under the conditions of use against a reliable volume or flow rate standard such as a soap-bubble meter or a wet-test meter traceable to a NIST standard. All volumetric flow rates should be corrected to the same reference temperature and pressure by using the formula below:

$$F_c = F_m \frac{298.15 P_m}{760 (T_m + 273.15)}$$

Where:

$F_c$  = corrected flow rate (L/min at 25° C and 760 mm Hg),

$F_m$  = measured flow rate, (at temperature,  $T_m$  and pressure,  $P_m$ ),

$P_m$  = measured pressure in mm Hg, (absolute), and

$T_m$  = measured temperature in degrees Celsius.

4.2.4 Allow the SO<sub>2</sub> analyzer under calibration to sample zero air until a stable response is obtained, then make the proper zero adjustment.

4.2.5 Adjust the airflow to provide an SO<sub>2</sub> concentration of approximately 80 percent of the upper measurement range limit of the SO<sub>2</sub> instrument and verify that the total air flow of the calibration system exceeds the demand of all analyzers sampling from the output manifold (with the excess vented).

4.2.6 Calculate the actual SO<sub>2</sub> calibration concentration standard as:

$$[SO_2] = C \frac{F_p}{F_t}$$

Where:

$C$  = the concentration of the SO<sub>2</sub> gas standard

$F_p$  = the flow rate of SO<sub>2</sub> gas standard

$F_t$  = the total air flow rate of pollutant and diluent gases

4.2.7 When the analyzer response has stabilized, adjust the SO<sub>2</sub> span control to obtain the desired response equivalent to the calculated standard concentration. If substantial adjustment of the span control is needed, it may be necessary to re-check the

zero and span adjustments by repeating steps 4.2.4 through 4.2.7 until no further adjustments are needed.

4.2.8 Adjust the flow rate(s) to provide several other SO<sub>2</sub> calibration concentrations over the analyzer's measurement range. At least five different concentrations evenly spaced throughout the analyzer's range are suggested.

4.2.9 Plot the analyzer response (vertical or Y-axis) versus SO<sub>2</sub> concentration (horizontal or X-axis). Compute the linear regression slope and intercept and plot the regression line to verify that no point deviates from this line by more than 2 percent of the maximum concentration tested.

**Note:** Additional information on calibration and pollutant standards is provided in Section 12 of Reference 3.

5.0 Frequency of calibration.

The frequency of calibration, as well as the number of points necessary to establish the calibration curve and the frequency of other performance checking will vary by analyzer; however, the minimum frequency, acceptance criteria, and subsequent actions are specified in Reference 3, Appendix D: Measurement Quality Objectives and Validation Template for SO<sub>2</sub> (page 9 of 30). The user's quality control program should provide guidelines for initial establishment of these variables and for subsequent alteration as operational experience is accumulated. Manufacturers of analyzers should include in their instruction/operation manuals information and guidance as to these variables and on other matters of operation, calibration, routine maintenance, and quality control.

6.0 References for SO<sub>2</sub> Method.

1. H. Okabe, P.L. Splitstone, and J.J. Ball, "Ambient and Source SO<sub>2</sub> Detector Based on a Fluorescence Method", *Journal of the Air Control Pollution Association*, vol. 23, p. 514–516 (1973).
2. F.P. Schwarz, H. Okabe, and J.K. Whittaker, "Fluorescence Detection of Sulfur Dioxide in Air at the Parts per Billion Level," *Analytical Chemistry*, vol. 46, pp. 1024–1028 (1974).
3. *QA Handbook for Air Pollution Measurement Systems—Volume II. Ambient Air Quality Monitoring Programs*. U. S. EPA. EPA-454/B-08-003 (2008). (Available at <http://www.epa.gov/ttn/amtic/qabook.html>.)

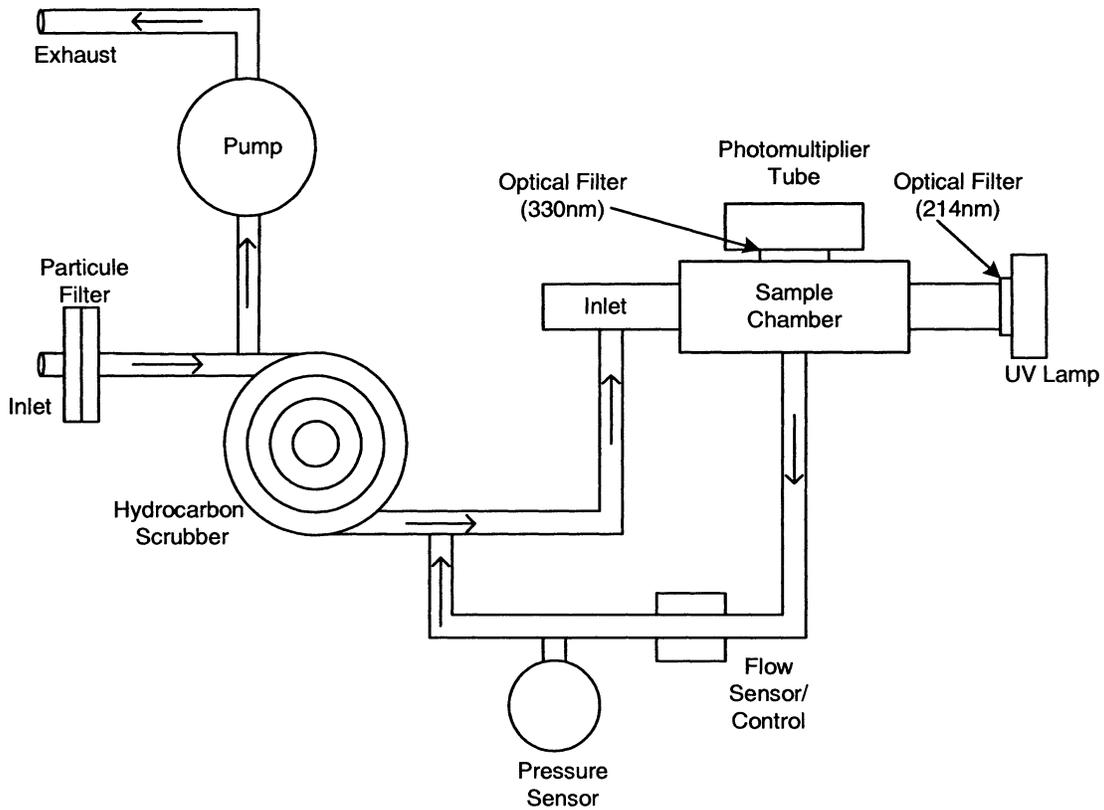


Figure 1. UVF SO<sub>2</sub> analyzer schematic diagram.

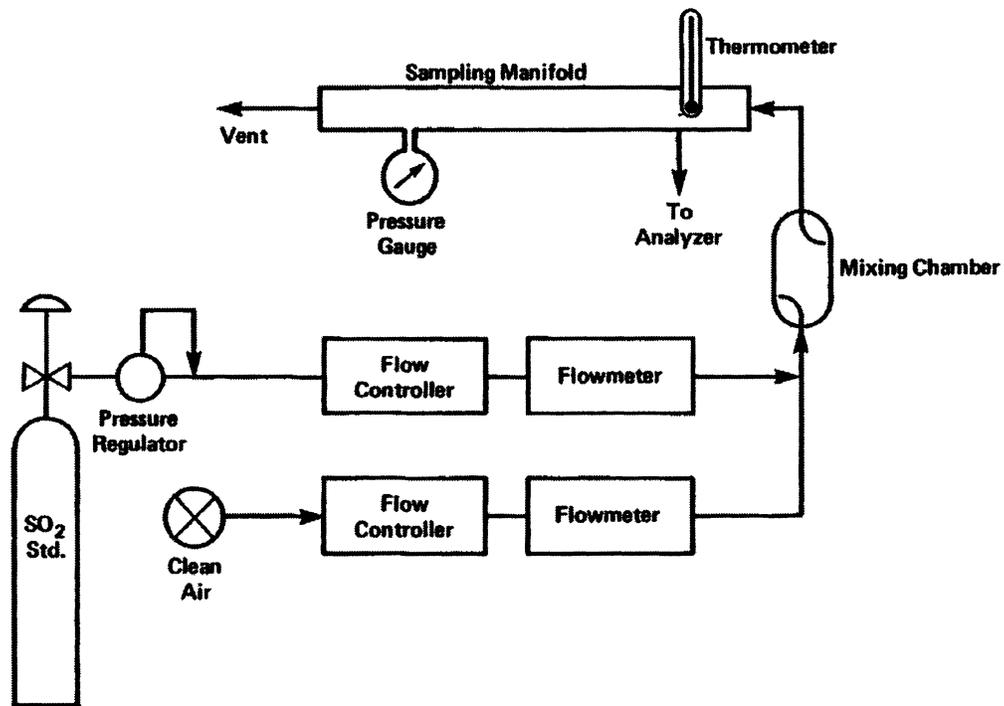


Figure 2. Calibration system using a compressed gas standard.

6. Appendix A to Part 50 is redesignated as Appendix A-2 to Part 50.

7. Appendix T to Part 50 is added to read as follows:

**Option 1 for Appendix T to Part 50**

**Appendix T to Part 50—Interpretation of the Primary National Ambient Air Quality Standards for Oxides of Sulfur (Sulfur Dioxide) [1-hour primary standard based on the 4th highest daily maximum value form]**

1. General.

(a) This appendix explains the data handling conventions and computations necessary for determining when the primary national ambient air quality standards for Oxide of Sulfur as measured by Sulfur Dioxide (“SO<sub>2</sub> NAAQS”) specified in § 50.4 are met. Sulfur Dioxide (SO<sub>2</sub>) is measured in the ambient air by a Federal reference method (FRM) based on appendix A to this part or by a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter. Data handling and computation procedures to be used in making comparisons between reported SO<sub>2</sub> concentrations and the levels of the SO<sub>2</sub> NAAQS are specified in the following sections.

(b) Decisions to exclude, retain, or make adjustments to the data affected by exceptional events, including natural events, are made according to the requirements and process deadlines specified in §§ 50.1, 50.14 and 51.930 of this chapter.

(c) The terms used in this appendix are defined as follows:

*Annual 4th highest daily maximum 1-hour value* refers to the 4th highest daily 1-hour maximum value at a site in a particular year.

*Daily maximum 1-hour values* for SO<sub>2</sub> refers to the maximum 1-hour SO<sub>2</sub> concentration values measured from midnight to midnight (local standard time) that are used in NAAQS computations.

*Design values* are the metrics (*i.e.*, statistics) that are compared to the NAAQS levels to determine compliance, calculated as specified in section 5 of this appendix. The design value for the primary NAAQS is the 3-year average of annual 4th highest daily maximum 1-hour values for a monitoring site (referred to as the “1-hour primary standard design value”).

*Quarter* refers to a calendar quarter.

*Year* refers to a calendar year.

**2. Requirements for Data Used for Comparisons With the SO<sub>2</sub> NAAQS and Data Reporting Considerations.**

(a) All valid FRM/FEM SO<sub>2</sub> hourly data required to be submitted to EPA’s Air Quality System (AQS), or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in design value calculations. Multi-hour average concentration values collected by wet chemistry methods shall not be used.

(b) When two or more SO<sub>2</sub> monitors are operated at a site, the state may in advance designate one of them as the primary monitor. If the state has not made this

designation in advance, the Administrator will make the designation, either in advance or retrospectively. Design values will be developed using only the data from the primary monitor, if this results in a valid design value. If data from the primary monitor do not allow the development of a valid design value, data solely from the other monitor(s) will be used in turn to develop a valid design value, if this results in a valid design value. If there are three or more monitors, the order for such comparison of the other monitors will be determined by the Administrator. The Administrator may combine data from different monitors in different years for the purpose of developing a valid 1-hour primary standard design value, if a valid design value cannot be developed solely with the data from a single monitor. However, data from two or more monitors in the same year at the same site will not be combined in an attempt to meet data completeness requirements, except if one monitor has physically replaced another instrument permanently, in which case the two instruments will be considered to be the same monitor, or if the state has switched the designation of the primary monitor from one instrument to another during the year.

(c) Hourly SO<sub>2</sub> measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

**3. Comparisons with the 1-hour Primary SO<sub>2</sub> NAAQS.**

(a) The 1-hour primary SO<sub>2</sub> NAAQS is met at a site when the valid 1-hour primary standard design value is less than or equal to [50–150] parts per billion (ppb).

(b) An SO<sub>2</sub> 1-hour primary standard design value is valid if it encompasses three consecutive calendar years of complete data. A year meets data completeness requirements when all 4 quarters are complete. A quarter is complete when at least 75 percent of the sampling days for each quarter have complete data. A sampling day has complete data if 75 percent of the hourly concentration values are reported.

(c) In the case of one, two, or three years that do not meet the completeness requirements of section 3(b) of this appendix and thus would normally not be usable for the calculation of a valid 3-year 1-hour primary standard design value, the 3-year 1-hour primary standard design value shall nevertheless be considered valid if either of the following conditions is true:

(i) If there are at least four days in each of the 3 years that have at least one reported hourly value, and the resulting 3-year 1-hour primary standard design value exceeds the 1-hour primary NAAQS. In this situation, more complete data capture could not possibly have resulted in a design value below the 1-hour primary NAAQS:

(ii)(A) A 1-hour primary standard design value that is below the level of the NAAQS can be validated if the substitution test in section 3(c)(ii)(B) results in a “test design value” that is below the level of the NAAQS. The test substitutes actual “high” reported daily maximum 1-hour values from the same site at about the same time of the year (specifically, in the calendar quarter) for

unknown hourly values that were not successfully measured. Note that the test is merely diagnostic in nature, intended to confirm that there is a very high likelihood that the original design value (the one with less than 75 percent data capture of hours by day and of days by quarter) reflects the true under-NAAQS-level status for that 3-year period; the result of this data substitution test (the “test design value,” as defined in section 3(c)(ii)(B)) is not considered the actual design value. For this test, substitution is permitted only if there are at least 200 days across the three matching quarters of the three years under consideration (which is about 75 percent of all possible daily values in those three quarters) for which 75 percent of the hours in the day have reported concentrations. However, maximum 1-hour values from days with less than 75 percent of the hours reported shall also be considered in identifying the high value to be used for substitution.

(B) The substitution test is as follows: Data substitution will be performed in all quarter periods that have less than 75 percent data capture but at least 50 percent data capture; if any quarter has less than 50 percent data capture, then this substitution test cannot be used. Identify for each quarter (*e.g.*, January–March) the highest reported daily maximum 1-hour value for that quarter, looking across those three months of all three years under consideration. All daily maximum 1-hour values from all days in the quarter period shall be considered when identifying this highest value, including days with less than 75 percent data capture. If after substituting the highest reported daily maximum 1-hour value for a quarter for as much of the missing daily data in the matching deficient quarter(s) as is needed to make them 100 percent complete, the procedure in section 5 yields a recalculated 3-year 1-hour standard “test design value” below the level of the standard, then the 1-hour primary standard design value is deemed to have passed the diagnostic test and is valid, and the level of the standard is deemed to have been met in that 3-year period. As noted in section 3(c)(i), in such a case, the 3-year design value based on the data actually reported, not the “test design value,” shall be used as the valid design value.

(d) A 1-hour primary standard design value based on data that do not meet the completeness criteria stated in 3(b) and also do not satisfy section 3(c), may also be considered valid with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(e) The procedures for calculating the 1-hour primary standard design values are given in section 5 of this appendix.

**4. Rounding Conventions for the 1-hour Primary SO<sub>2</sub> NAAQS.**

(a) Hourly SO<sub>2</sub> measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

(b) Daily maximum 1-hour values, including the annual 4th highest of those daily values, are not rounded.

(c) The 1-hour primary standard design value is calculated pursuant to section 5 and then rounded to the nearest whole number or 1 ppb (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

5. Calculation Procedures for the 1-hour Primary SO<sub>2</sub> NAAQS.

(a) When the data for a particular site and year meet the data completeness requirements in section 3(b), or if one of the conditions of section 3(c) is met, or if the Administrator exercises the discretionary authority in section 3(d), calculation of the 4th highest daily 1-hour maximum is accomplished as follows.

(i) For each year, select from each day the highest hourly value. All daily maximum 1-hour values from all days in the quarter period shall be considered at this step, including days with less than 75 percent data capture.

(ii) For each year, order these daily values and take the 4th highest.

(iii) The 1-hour primary standard design value for a site is mean of the three annual 4th highest values, rounded according to the conventions in section 4.

## Option 2 for Appendix T to Part 50

### Appendix T to Part 50—Interpretation of the Primary National Ambient Air Quality Standards for Oxides of Sulfur (Sulfur Dioxide) [1-hour primary standard based on the 99th percentile form]

#### 1. General.

(a) This appendix explains the data handling conventions and computations necessary for determining when the primary national ambient air quality standards for Oxides of Sulfur as measured by Sulfur Dioxide (“SO<sub>2</sub> NAAQS”) specified in § 50.4 are met. Sulfur Dioxide (SO<sub>2</sub>) is measured in the ambient air by a Federal reference method (FRM) based on appendix A to this part or by a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter. Data handling and computation procedures to be used in making comparisons between reported SO<sub>2</sub> concentrations and the levels of the SO<sub>2</sub> NAAQS are specified in the following sections.

(b) Decisions to exclude, retain, or make adjustments to the data affected by exceptional events, including natural events, are made according to the requirements and process deadlines specified in §§ 50.1, 50.14 and 51.930 of this chapter.

(c) The terms used in this appendix are defined as follows:

*Daily maximum 1-hour values* for SO<sub>2</sub> refers to the maximum 1-hour SO<sub>2</sub> concentration values measured from midnight to midnight (local standard time) that are used in NAAQS computations.

*Design values* are the metrics (*i.e.*, statistics) that are compared to the NAAQS levels to determine compliance, calculated as

specified in section 5 of this appendix. The design value for the primary 1-hour NAAQS is the 3-year average of annual 99th percentile daily maximum 1-hour values for a monitoring site (referred to as the “1-hour primary standard design value”).

*99th percentile daily maximum 1-hour value* is the value below which nominally 99 percent of all daily maximum 1-hour concentration values fall, using the ranking and selection method specified in section 5 of this appendix.

*Quarter* refers to a calendar quarter.

*Year* refers to a calendar year.

2. Requirements for Data Used for Comparisons With the SO<sub>2</sub> NAAQS and Data Reporting Considerations.

(a) All valid FRM/FEM SO<sub>2</sub> hourly data required to be submitted to EPA’s Air Quality System (AQS), or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in design value calculations. Multi-hour average concentration values collected by wet chemistry methods shall not be used.

(b) When two or more SO<sub>2</sub> monitors are operated at a site, the state may in advance designate one of them as the primary monitor. If the state has not made this designation, the Administrator will make the designation, either in advance or retrospectively. Design values will be developed using only the data from the primary monitor, if this results in a valid design value. If data from the primary monitor do not allow the development of a valid design value, data solely from the other monitor(s) will be used in turn to develop a valid design value, if this results in a valid design value. If there are three or more monitors, the order for such comparison of the other monitors will be determined by the Administrator. The Administrator may combine data from different monitors in different years for the purpose of developing a valid 1-hour primary standard design value, if a valid design value cannot be developed solely with the data from a single monitor. However, data from two or more monitors in the same year at the same site will not be combined in an attempt to meet data completeness requirements, except if one monitor has physically replaced another instrument permanently, in which case the two instruments will be considered to be the same monitor, or if the state has switched the designation of the primary monitor from one instrument to another during the year.

(c) Hourly SO<sub>2</sub> measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

3. Comparisons with the 1-hour Primary SO<sub>2</sub> NAAQS.

(a) The 1-hour primary SO<sub>2</sub> NAAQS is met at a site when the valid 1-hour primary standard design value is less than or equal to [50–150] parts per billion (ppb).

(b) An SO<sub>2</sub> 1-hour primary standard design value is valid if it encompasses three consecutive calendar years of complete data. A year meets data completeness requirements when all 4 quarters are complete. A quarter is complete when at least 75 percent of the

sampling days for each quarter have complete data. A sampling day has complete data if 75 percent of the hourly concentration values are reported.

(c) In the case of one, two, or three years that do not meet the completeness requirements of section 3(b) of this appendix and thus would normally not be useable for the calculation of a valid 3-year 1-hour primary standard design value, the 3-year 1-hour primary standard design value shall nevertheless be considered valid if one of the following conditions is true.

(i) At least 75 percent of the days in each quarter of each of three consecutive years have at least one reported hourly value, and the design value calculated according to the procedures specified in section 5 is above the level of the primary 1-hour standard.

(ii) (A) A 1-hour primary standard design value that is below the level of the NAAQS can be validated if the substitution test in section 3(c)(ii)(B) results in a “test design value” that is below the level of the NAAQS. The test substitutes actual “high” reported daily maximum 1-hour values from the same site at about the same time of the year (specifically, in the same calendar quarter) for unknown values that were not successfully measured. Note that the test is merely diagnostic in nature, intended to confirm that there is a very high likelihood that the original design value (the one with less than 75 percent data capture of hours by day and of days by quarter) reflects the true under-NAAQS-level status for that 3-year period; the result of this data substitution test (the “test design value”, as defined in section 3(c)(ii)(B)) is not considered the actual design value. For this test, substitution is permitted only if there are at least 200 days across the three matching quarters of the three years under consideration (which is about 75 percent of all possible daily values in those three quarters) for which 75 percent of the hours in the day have reported concentrations. However, maximum 1-hour values from days with less than 75 percent of the hours reported shall also be considered in identifying the high value to be used for substitution.

(B) The substitution test is as follows: Data substitution will be performed in all quarter periods that have less than 75 percent data capture but at least 50 percent data capture; if any quarter has less than 50 percent data capture then this substitution test cannot be used. Identify for each quarter (*e.g.*, January–March) the highest reported daily maximum 1-hour value for that quarter, looking across those three months of all three years under consideration. All daily maximum 1-hour values from all days in the quarter period shall be considered when identifying this highest value, including days with less than 75 percent data capture. If after substituting the highest reported daily maximum 1-hour value for a quarter for as much of the missing daily data in the matching deficient quarter(s) as is needed to make them 100 percent complete, the procedure in section 5 yields a recalculated 3-year 1-hour standard “test design value” below the level of the standard, then the 1-hour primary standard design value is deemed to have passed the diagnostic test and is valid, and the level of

the standard is deemed to have been met in that 3-year period. As noted in section 3(c)(i), in such a case, the 3-year design value based on the data actually reported, not the "test design value", shall be used as the valid design value.

(iii) (A) A 1-hour primary standard design value that is above the level of the NAAQS can be validated if the substitution test in section 3(c)(iii)(B) results in a "test design value" that is above the level of the NAAQS. The test substitutes actual "low" reported daily maximum 1-hour values from the same site at about the same time of the year (specifically, in the same three months of the calendar) for unknown hourly values that were not successfully measured. Note that the test is merely diagnostic in nature, intended to confirm that there is a very high likelihood that the original design value (the one with less than 75 percent data capture of hours by day and of days by quarter) reflects the true above-NAAQS-level status for that 3-year period; the result of this data substitution test (the "test design value", as defined in section 3(c)(iii)(B)) is not considered the actual design value. For this test, substitution is permitted only if there are a minimum number of available daily data points from which to identify the low quarter-specific daily maximum 1-hour values, specifically if there are at least 200 days across the three matching quarters of the three years under consideration (which is about 75 percent of all possible daily values in those three quarters) for which 75 percent of the hours in the day have reported concentrations. Only days with at least 75 percent of the hours reported shall be considered in identifying the low value to be used for substitution.

(B) The substitution test is as follows: Data substitution will be performed in all quarter periods that have less than 75 percent data capture. Identify for each quarter (e.g., January–March) the lowest reported daily maximum 1-hour value for that quarter, looking across those three months of all three years under consideration. All daily maximum 1-hour values from all days with at least 75 percent capture in the quarter period shall be considered when identifying this lowest value. If after substituting the lowest reported daily maximum 1-hour value for a quarter for as much of the missing daily data in the matching deficient quarter(s) as is needed to make them 75 percent complete, the procedure in section 5 yields a recalculated 3-year 1-hour standard "test design value" above the level of the standard, then the 1-hour primary standard design value is deemed to have passed the diagnostic test and is valid, and the level of the standard is deemed to have been exceeded in that 3-year period. As noted in section 3(c)(i), in such a case, the 3-year design value based on the data actually reported, not the "test design value", shall be used as the valid design value.

(d) A 1-hour primary standard design value based on data that do not meet the completeness criteria stated in 3(b) and also do not satisfy section 3(c), may also be considered valid with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site

closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(e) The procedures for calculating the 1-hour primary standard design values are given in section 5 of this appendix.

4. Rounding Conventions for the 1-hour Primary SO<sub>2</sub> NAAQS.

(a) Hourly SO<sub>2</sub> measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

(b) Daily maximum 1-hour values and therefore the annual 4th highest of those daily values are not rounded.

(c) The 1-hour primary standard design value is calculated pursuant to section 5 and then rounded to the nearest whole number or 1 ppb (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

5. Calculation Procedures for the 1-hour Primary SO<sub>2</sub> NAAQS.

(a) *Procedure for identifying annual 99th percentile values.* When the data for a particular site and year meet the data completeness requirements in section 3(b), or if one of the conditions of section 3(c) is met, or if the Administrator exercises the discretionary authority in section 3(d), identification of annual 99th percentile value is accomplished as follows.

(i) The annual 99th percentile value for a year is the higher of the two values resulting from the following two procedures.

(1) Procedure 1. For the year, determine the number of days with at least 75 percent of the hourly values reported.

(A) For the year, from only the days with at least 75 percent of the hourly values reported, select from each day the maximum hourly value.

(B) Sort all these daily maximum hourly values from a particular site and year by descending value. (For example: {x[1], x[2], x[3], \* \* \*, x[n]}). In this case, x[1] is the largest number and x[n] is the smallest value.) The 99th percentile is determined from this sorted series of daily values which is ordered from the highest to the lowest number. Using the left column of Table 1, determine the appropriate range (i.e., row) for the annual number of days with valid data for year y (cn<sub>y</sub>). The corresponding "n" value in the right column identifies the rank of the annual 99th percentile value in the descending sorted list of daily site values for year y. Thus, P<sub>0.99, y</sub> = the nth largest value.

(2) Procedure 2. For the year, determine the number of days with at least one hourly value reported.

(A) For the year, from all the days with at least one hourly value reported, select from each day the maximum hourly value.

(B) Sort all these daily maximum values from a particular site and year by descending value. (For example: {x[1], x[2], x[3], \* \* \*, x[n]}). In this case, x[1] is the largest number and x[n] is the smallest value.) The 99th percentile is determined from this sorted series of daily values which is ordered from the highest to the lowest number. Using the

left column of Table 1, determine the appropriate range (i.e., row) for the annual number of days with valid data for year y (cn<sub>y</sub>). The corresponding "n" value in the right column identifies the rank of the annual 99th percentile value in the descending sorted list of daily site values for year y. Thus, P<sub>0.99, y</sub> = the nth largest value.

(b) The 1-hour primary standard design value for a site is mean of the three annual 99th percentile values, rounded according to the conventions in section 4.

TABLE 1

Annual number of days with valid data for year "y" (cn <sub>y</sub> )	P <sub>0.99, y</sub> is the nth maximum value of the year, where n is the listed number
1–100 .....	1
101–200 .....	2
201–300 .....	3
301–366 .....	4

**PART 53—AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT METHODS**

8. The authority citation for part 53 continues to read as follows:

**Authority:** Sec. 301(a) of the Clean Air Act (42 U.S.C. sec. 1857g(a)), as amended by sec. 15(c)(2) of Public Law 91–604, 84 Stat. 1713, unless otherwise noted.

**Subpart A—[Amended]**

9. Section 53.2 is amended by revising paragraphs (a)(1) and (b) to read as follows:

**§ 53.2. General requirements for a reference method determination.**

\* \* \* \* \*

(a) *Manual methods—(1) Sulfur dioxide (SO<sub>2</sub>) and Lead.* For measuring SO<sub>2</sub> and lead, Appendixes A–2 and G of part 50 of this chapter specify unique manual FRM for measuring those pollutants. After [effective date of Appendix A–1], a new FRM for SO<sub>2</sub> must be an automated method that utilizes the measurement principle and calibration procedure specified in Appendix A–1 to part 50 of this chapter and must meet applicable requirements of this part, as specified in paragraph (b) of this section. Except as provided in § 53.16, other manual methods for lead will not be considered for a reference method determination under this part.

\* \* \* \* \*

(b) *Automated methods.* An automated FRM for measuring SO<sub>2</sub>, CO, O<sub>3</sub>, or NO<sub>2</sub> must utilize the measurement principle and calibration procedure specified in the appropriate appendix to part 50 of this chapter (appendix A–1 only for SO<sub>2</sub> methods) and must have been shown in accordance with this part to meet the

requirements specified in this subpart A and subpart B of this part.

10. Section 53.8 is amended by revising paragraph (c) to read as follows:

**§ 53.8 Designation of reference and equivalent methods.**

\* \* \* \* \*

(c) The Administrator will maintain a current list of methods designated as FRM or FEM in accordance with this part and will send a copy of the list to

any person or group upon request. A copy of the list will be available via the Internet and may be available from other sources.

11. Table A-1 to Subpart A is revised to read as follows:

**TABLE A-1 TO SUBPART A OF PART 53—SUMMARY OF APPLICABLE REQUIREMENTS FOR REFERENCE AND EQUIVALENT METHODS FOR AIR MONITORING OF CRITERIA POLLUTANTS**

Pollutant	Reference or equivalent	Manual or automated	Applicable part 50 appendix	Applicable subparts of part 53					
				A	B	C	D	E	F
SO <sub>2</sub>	Reference	Manual	A-2						
		Automated	A-1	✓	✓				
	Equivalent	Manual	A-1	✓		✓			
		Automated	A-1	✓	✓	✓			
CO	Reference	Automated	C	✓	✓				
		Manual	C	✓		✓			
O <sub>3</sub>	Reference	Automated	C	✓	✓	✓			
		Manual	D	✓	✓				
NO <sub>2</sub>	Reference	Automated	D	✓	✓	✓			
		Manual	D	✓	✓	✓			
Pb	Reference	Automated	F	✓	✓				
		Manual	F	✓		✓			
PM <sub>10-2.5</sub>	Reference	Automated	F	✓	✓	✓			
		Manual	G	✓		✓			
PM <sub>10</sub>	Reference	Manual	G	✓		✓			
		Automated	G	✓		✓			
PM <sub>10-2.5</sub>	Reference	Manual	Q	✓		✓			
		Automated	Q	✓		✓			
PM <sub>10</sub>	Equivalent	Manual	Q	✓		✓			
		Automated	Q	✓		✓			
PM <sub>10</sub>	Reference	Manual	J	✓			✓		
		Automated	J	✓			✓		
PM <sub>2.5</sub>	Reference	Manual	J	✓			✓		
		Automated	J	✓			✓		
PM <sub>2.5</sub>	Equivalent Class I	Manual	L	✓				✓	
		Automated	L	✓				✓	
PM <sub>10-2.5</sub>	Equivalent Class II	Manual	L <sup>1</sup>	✓		✓ <sup>2</sup>		✓	✓ <sup>1,2</sup>
		Automated	L <sup>1</sup>	✓		✓		✓	✓ <sup>1</sup>
PM <sub>10-2.5</sub>	Reference	Manual	L, O	✓				✓	
		Automated	L, O	✓				✓	
PM <sub>10-2.5</sub>	Equivalent Class I	Manual	L, O	✓				✓	
		Automated	L, O	✓				✓	
PM <sub>10-2.5</sub>	Equivalent Class II	Manual	L, O	✓		✓ <sup>2</sup>		✓	✓ <sup>1,2</sup>
		Automated	L <sup>1</sup> , O <sup>1</sup>	✓		✓		✓	✓ <sup>1</sup>

<sup>1</sup> Some requirements may apply, based on the nature of each particular candidate method, as determined by the Administrator.  
<sup>2</sup> Alternative Class III requirements may be substituted.

**Subpart B—[Amended]**

12. Section 53.20 is amended as follows:

A. By revising paragraph (b).

B. In paragraph (c), by revising Table B-1.

The revisions read as follows:

**§ 53.20 General provisions.**

\* \* \* \* \*

(b) For a candidate method having more than one selectable measurement range, one range must be that specified in table B-1 (standard range for SO<sub>2</sub>), and a test analyzer representative of the method must pass the tests required by this subpart while operated in that range. The tests may be repeated for one or more broader ranges (*i.e.*, ones extending to higher concentrations) than

the range specified in table B-1, provided that the range does not extend to concentrations more than four times the upper range limit specified in table B-1. For broader ranges, only the tests for range (calibration), noise at 80% of the upper range limit, and lag, rise and fall time are required to be repeated. The tests may be repeated for one or more narrower ranges (ones extending to lower concentrations) than that specified in table B-1. For SO<sub>2</sub> methods, table B-1 specifies special performance requirements for narrower (lower) ranges. For methods other than SO<sub>2</sub>, only the tests for range (calibration), noise at 0% of the measurement range, and lower detectable limit are required to be repeated. If the tests are conducted or passed only for the specified range (standard range for SO<sub>2</sub>), any FRM or

FEM method determination with respect to the method will be limited to that range. If the tests are passed for both the specified range and one or more broader ranges, any such determination will include the additional range(s) as well as the specified range, provided that the tests required by subpart C of this part (if applicable) are met for the broader range(s). If the tests are passed for both the specified range and one or more narrower ranges, any FRM or FEM method determination for the method will include the narrower range(s) as well as the specified range. Appropriate test data shall be submitted for each range sought to be included in a FRM or FEM method determination under this paragraph (b).

(c) \* \* \*

TABLE B-1—PERFORMANCE SPECIFICATIONS FOR AUTOMATED METHODS

Performance parameter	Units <sup>1</sup>	SO <sub>2</sub>		O <sub>3</sub>	CO	NO <sub>2</sub>	Definitions and test procedures
		Std. range <sup>3</sup>	Lower range <sup>2,3</sup>				
1. Range .....	ppm .....	0–0.5	<0.5	0–0.5	0–50	0–0.5	Sec. 53.23(a).
2. Noise .....	ppm .....	0.001	0.0005	0.005	50	0.005	Sec. 53.23(b).
3. Lower detectable limit .....	ppm .....	0.002	0.001	0.010	1.0	0.010	Sec. 53.23(c).
4. Interference equivalent							
Each interferent .....	ppm .....	±0.005	±0.005	±0.02	±1.0	±0.02	Sec. 53.23(d).
Total, all interferents .....	ppm .....	0.020	0.020	0.06	1.5	0.04	Sec. 53.23(d).
5. Zero drift, 12 and 24 hour .....	ppm .....	±0.004	±0.002	±0.02	±1.0	±0.02	Sec. 53.23(e).
7. Span drift, 24 hour:							
20% of upper range limit .....	Percent .....			±20.0	±10.0	±20.0	Sec. 53.23(e).
80% of upper range limit .....	Percent .....	±5.0	±5.0	±5.0	±2.5	±5.0	Sec. 53.23(e).
8. Lag time .....	Minutes .....	2	2	20	10	20	Sec. 53.23(e).
9. Rise time .....	Minutes .....	2	2	15	5	15	Sec. 53.23(e).
10. Fall time .....	Minutes .....	2	2	15	5	15	Sec. 53.23(e).
11. Precision:							
20% of upper range limit .....	ppm .....			0.010	0.5	0.020	Sec. 53.23(e).
	Percent .....	2	2				Sec. 53.23(e).
80% of upper range limit .....	ppm .....			0.010	0.5	0.030	Sec. 53.23(e).
	Percent .....	2	2				Sec. 53.23(e).

<sup>1</sup> To convert from parts per million (ppm) to µg/m<sup>3</sup> at 25 °C and 760 mm Hg, multiply by M/0.02447, where M is the molecular weight of the gas. Percent means percent of the upper range limit.

<sup>2</sup> Tests for interference equivalent and lag time do not need to be repeated for any lower SO<sub>2</sub> range provided the test for the standard range shows that the lower range specification is met for each of these test parameters.

<sup>3</sup> For candidate analyzers having automatic or adaptive time constants or smoothing filters, describe their functional nature, and describe and conduct suitable tests to demonstrate their function aspects and verify that performances for calibration, noise, lag, rise, fall times, and precision are within specifications under all applicable conditions. For candidate analyzers with operator-selectable time constants or smoothing filters, conduct calibration, noise, lag, rise, fall times, and precision tests at the highest and lowest settings that are to be included in the FRM or FEM designation.

\* \* \* \* \*

13. Section 53.21 is amended by revising paragraph (a) to read as follows:

**§ 53.21 Test conditions.**

(a) *Set-up and start-up* of the test analyzer shall be in strict accordance with the operating instructions specified in the manual referred to in § 53.4(b)(3). Allow adequate warm-up or stabilization time as indicated in the operating instructions before beginning the tests. The test procedures assume that the test analyzer has an analog measurement signal output that is connected to a suitable strip chart

recorder of the servo, null-balance type. This recorder shall have a chart width of a least 25 centimeters, chart speeds up to 10 cm per hour, a response time of 1 second or less, a deadband of not more than 0.25 percent of full scale, and capability either of reading measurements at least 5 percent below zero or of offsetting the zero by at least 5 percent. If the test analyzer does not have an analog signal output, or if other types of measurement data output are used, an alternative measurement data recording device (or devices) may be used for the tests, provided it is reasonably suited to the nature and

purposes of the tests and an analog representation of the analyzer measurements for each test can be plotted or otherwise generated that is reasonably similar to the analog measurement recordings that would be produced by a conventional chart recorder.

\* \* \* \* \*

14. Section 53.22(d) is amended by revising Table B-2 to read as follows:

**§ 53.22 Generation of test atmospheres.**

\* \* \* \* \*

(d) \* \* \*

TABLE B-2—TEST ATMOSPHERES

Test gas	Generation	Verification
Ammonia .....	Permeation device. Similar to system described in references 1 and 2.	Indophenol method, reference 3.
Carbon dioxide .....	Cylinder of zero air or nitrogen containing CO <sub>2</sub> as required to obtain the concentration specified in table B-3.	Use NIST-certified standards whenever possible. If NIST standards are not available, obtain 2 standards from independent sources which agree within 2 percent, or obtain one standard and submit it to an independent laboratory for analysis, which must agree within 2 percent of the supplier's nominal analysis.
Carbon monoxide .....	Cylinder of zero air or nitrogen containing CO as required to obtain the concentration specified in table B-3.	Use a FRM CO analyzer as described in reference 8.
Ethane .....	Cylinder of zero air or nitrogen containing ethane as required to obtain the concentration specified in table B-3.	Gas chromatography, ASTM D2820, reference 10. Use NIST-traceable gaseous methane or propane standards for calibration.
Ethylene .....	Cylinder of pre-purified nitrogen containing ethylene as required to obtain the concentration specified in table B-3.	Do.



TABLE B-3—INTERFERENT TEST CONCENTRATION,<sup>1</sup> PARTS PER MILLION—Continued

Pollutant	Analyzer type	Hydrochloric acid	Ammonia	Hydrogen sulfide	Sulfur dioxide	Nitrogen dioxide	Nitric oxide	Carbon dioxide	Ethylene	Ozone	M-xylene	Water vapor	Carbon monoxide	Methane	Ethane	Naphthalene
O <sub>3</sub>	Spectrophotometric-wet chemical (potassium iodide).		³0.1		0.5	0.5	³0.5			⁴0.08						
O <sub>3</sub>	Spectrophotometric-gas phase, including ultraviolet absorption and DOAS).				0.5	0.5	0.5			⁴0.08	0.02	20,000				
CO	Infrared							750				20,000	⁴10			
CO	Gas chromatography with flame ionization detector.											20,000	⁴10		0.5	
CO	Electrochemical						0.5		0.2			20,000	⁴10			
CO	Catalytic combustion-thermal detection.		0.1					750	0.2			20,000	⁴10	5.0	0.5	
CO	IR fluorescence							750				20,000	⁴10		0.5	
CO	Mercury replacement-UV photometric.								0.2				⁴10		0.5	
NO <sub>2</sub>	Chemiluminescent		³0.1		0.5	⁴0.1	0.5					20,000				
NO <sub>2</sub>	Spectrophotometric-wet chemical (azo-dye reaction).				0.5	⁴0.1	0.5	750		0.5						
NO <sub>2</sub>	Electrochemical	0.2	³0.1		0.5	⁴0.1	0.5	750		0.5		20,000	50			
NO <sub>2</sub>	Spectrophotometric-gas phase.		³0.1		0.5	⁴0.1	0.5			0.5		20,000	50			

<sup>1</sup> Concentrations of interferent listed must be prepared and controlled to ±10 percent of the stated value.  
<sup>2</sup> Analyzer types not listed will be considered by the Administrator as special cases.  
<sup>3</sup> Do not mix with the pollutant.  
<sup>4</sup> Concentration of pollutant used for test. These pollutant concentrations must be prepared to ±10 percent of the stated value.  
<sup>5</sup> If candidate method utilizes an elevated-temperature scrubber for removal of aromatic hydrocarbons, perform this interference test.  
<sup>6</sup> If naphthalene test concentration cannot be accurately quantified, remove the scrubber, use a test concentration that causes a full scale response, reattach the scrubber, and evaluate response for interference.

\* \* \* \* \*

**Subpart C—[Amended]**

16. Section 53.32 is amended by revising paragraph (e)(2) to read as follows:

**§ 53.32 Test procedures for methods for SO<sub>2</sub>, CO, O<sub>3</sub>, and NO<sub>2</sub>.**

\* \* \* \* \*

(e) \* \* \*  
 (2) For a candidate method having more than one selectable range, one range must be that specified in table B-1 of subpart B of this part, and a test analyzer representative of the method

must pass the tests required by this subpart while operated on that range. The tests may be repeated for one or more broader ranges (*i.e.*, ones extending to higher concentrations) than the one specified in table B-1 of subpart B of this part, provided that such a range does not extend to concentrations more than four times the upper range limit specified in table B-1 of subpart B of this part and that the test analyzer has passed the tests required by subpart B of this part (if applicable) for the broader range. If the tests required by this subpart are conducted or passed

only for the range specified in table B-1 of subpart B of this part, any equivalent method determination with respect to the method will be limited to that range. If the tests are passed for both the specified range and a broader range (or ranges), any such determination will include the broader range(s) as well as the specified range. Appropriate test data shall be submitted for each range sought to be included in such a determination.

\* \* \* \* \*

17. Table C-1 to Subpart C is revised to read as follows:

TABLE C-1 TO SUBPART C OF PART 53—TEST CONCENTRATION RANGES, NUMBER OF MEASUREMENTS REQUIRED, AND MAXIMUM DISCREPANCY SPECIFICATIONS

Pollutant	Concentration range, parts per million (ppm)	Simultaneous measurements required				Maximum discrepancy specification, parts per million
		1-hour		24-hour		
		First set	Second set	First set	Second set	
Ozone	Low 0.06 to 0.10	5	6			0.02
	Med. 0.15 to 0.25	5	6			0.03
	High 0.35 to 0.46	4	6			0.04
	Total	14	18			
Carbon monoxide	Low 7 to 11	5	6			1.5
	Med. 20 to 30	5	6			2.0
	High 25 to 45	4	6			3.0
	Total	14	18			
Sulfur dioxide	Low 0.02 to 0.05	5	6	3	3	0.02
	Med. 0.10 to 0.15	5	6	2	3	0.03
	High 0.30 to 0.50	4	6	2	2	0.04
	Total	14	18	7	8	

TABLE C-1 TO SUBPART C OF PART 53—TEST CONCENTRATION RANGES, NUMBER OF MEASUREMENTS REQUIRED, AND MAXIMUM DISCREPANCY SPECIFICATIONS—Continued

Pollutant	Concentration range, parts per million (ppm)	Simultaneous measurements required				Maximum discrepancy specification, parts per million
		1-hour		24-hour		
		First set	Second set	First set	Second set	
Nitrogen dioxide .....	Low 0.02 to 0.08 .....	.....	.....	3	3	0.02
	Med. 0.10 to 0.20 .....	.....	.....	2	2	0.02
	High 0.25 to 0.35 .....	.....	.....	2	2	0.03
	Total .....	.....	.....	7	8	.....

**PART 58—AMBIENT AIR QUALITY SURVEILLANCE**

18. The authority citation for part 58 continues to read as follows:

**Authority:** 42 U.S.C. 7403, 7410, 7601(a), 7611, and 7619.

**Subpart B—[Amended]**

19. Section 58.10 is amended by adding paragraph (a)(6) to read as follows:

**§ 58.10 Annual monitoring network plan and periodic network assessment.**

(a) \* \* \*

(6) A plan for establishing SO<sub>2</sub> monitoring sites in accordance with the requirements of appendix D to this part shall be submitted to the EPA Regional Administrator by July 1, 2011 as part of the annual network plan required in paragraph (a)(1) of this section. The plan shall provide for all required SO<sub>2</sub> monitoring sites to be operational by January 1, 2013.

\* \* \* \* \*

20. Section 58.12 is amended by adding paragraph (g) to read as follows:

**§ 58.12 Operating schedules.**

\* \* \* \* \*

(g) For continuous SO<sub>2</sub> analyzers, the maximum 5-minute block average concentration of the twelve 5-minute blocks in the hour must be collected except as noted in § 58.12(a).

21. Section 58.13 is amended by adding paragraph (d) to read as follows:

**§ 58.13 Monitoring network completion.**

\* \* \* \* \*

(d) The network of SO<sub>2</sub> monitors must be physically established no later than January 1, 2013, and at that time, must be operating under all of the requirements of this part, including the requirements of appendices A, C, D, and E to this part.

22. Section 58.16 is amended by adding paragraph (g) to read as follows:

**§ 58.16 Data submittal and archiving requirements.**

\* \* \* \* \*

(g) Any State, or where applicable, local agency operating an SO<sub>2</sub> monitor shall report the maximum 5-minute SO<sub>2</sub> block average of the twelve 5-minute block averages in each hour, in addition to the hourly SO<sub>2</sub> average.

23. Appendix A to Part 58 is amended by adding paragraph 2.3.1.6 to read as follows:

**Appendix A to Part 58—Quality Assurance Requirements for SLAMS, SPMs and PSD Air Monitoring**

\* \* \* \* \*

2.3.1.6 Measurement Uncertainty for SO<sub>2</sub>. The goal for acceptable measurement uncertainty for precision is defined as an upper 90 percent confidence limit for the coefficient of variation (CV) of 15 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent.

\* \* \* \* \*

24. Appendix C to Part 58 is amended by adding paragraph 2.1.2 to read as follows:

**Appendix C to Part 58—Ambient Air Quality Monitoring Methodology**

\* \* \* \* \*

2.1.2 Any SO<sub>2</sub> FRM or FEM used for making NAAQS decisions, as prescribed in 40 CFR Part 50 Appendix A-1, must be capable of providing 1-hour averaged and 5-minute averaged concentration data.

\* \* \* \* \*

25. Appendix D to Part 58 is amended by revising paragraph 4.4 to read as follows:

**Appendix D to Part 58—Network Design Criteria for Ambient Air Quality Monitoring**

\* \* \* \* \*

4.4 Sulfur Dioxide (SO<sub>2</sub>) Design Criteria.

4.4.1 General Requirements. State and, where appropriate, local agencies must operate a minimum number of required SO<sub>2</sub> monitoring sites as described below.

4.4.2 Requirement for Monitoring by the Population Weighted Emissions Index. (a) The population weighted emissions index (PWEI) shall be calculated by states for each CBSA they contain or share with another

state or states for use in the implementation of or adjustment to the SO<sub>2</sub> monitoring network. The PWEI shall be calculated by multiplying the population of each CBSA, using the most current census data, by the total amount of SO<sub>2</sub> in tons per year emitted within the CBSA area, using an aggregate of the most recent county level emissions data available in the National Emissions Inventory for each county in each CBSA. The resulting product shall be divided by one million, providing a PWEI value, the units of which are million persons-tons per year. For any CBSA with a calculated PWEI value equal to or greater than 1,000,000, a minimum of three SO<sub>2</sub> monitors are required within that CBSA. For any CBSA with a calculated PWEI value equal to or greater than 10,000, but less than 1,000,000, a minimum of two SO<sub>2</sub> monitors are required within that CBSA. For any CBSA with a calculated PWEI value equal to or greater than 5,000, but less than 10,000, a minimum of one SO<sub>2</sub> monitor is required within that CBSA.

(1) The SO<sub>2</sub> monitoring site(s) required as a result of the PWEI in each CBSA shall be sited by states through a process of identifying locations within the boundaries of that CBSA where maximum ground-level 1-hour SO<sub>2</sub> concentrations occur due to emissions that originate inside and/or outside of that CBSA. Where a state or local air monitoring agency identifies multiple acceptable candidate sites where maximum hourly SO<sub>2</sub> concentrations are expected to occur, the monitoring agency shall select the location with the greater population exposure. Where one CBSA is required to have more than one SO<sub>2</sub> monitor, the monitoring sites shall not be oriented to measure maximum hourly concentrations from the same SO<sub>2</sub> source or group of sources, but shall monitor a different source or group of sources. Any PWEI-triggered monitors shall not count toward satisfying any required monitors resulting from the state emissions triggered requirements described below.

(2) The number of SO<sub>2</sub> monitors operated as a result of the PWEI shall be reviewed and adjusted as needed as a part of the 5-year network assessment cycle required in § 58.10 of this part.

(b) [Reserved]

4.4.3 Requirement for State Emission Triggered SO<sub>2</sub> Monitoring. (a) Each State shall operate a minimum number of monitors based on that state's contribution of SO<sub>2</sub> emissions to the national, anthropogenic SO<sub>2</sub> inventory as identified in the most recent

National Emissions Inventory. Each state shall operate one monitor for each percent that it contributes to the NEI. The percent contribution shall be rounded to the nearest whole integer value. Every state shall operate a minimum of one monitor under this requirement.

(1) Each state emission triggered SO<sub>2</sub> monitoring station shall be sited by states through a process of identifying locations within the boundaries of that state where maximum ground-level 1-hour SO<sub>2</sub> concentrations occur due to SO<sub>2</sub> source emissions originate inside or outside the state. Where a state has CBSAs with PWEI-triggered monitoring, the PWEI-triggered monitors shall not count toward the emission-triggered monitors. State emission-triggered monitors shall not be sited to measure maximum hourly concentrations from the same SO<sub>2</sub> source or group of sources as another SO<sub>2</sub> monitor, but shall measure maximum hourly concentrations resulting from a different source or group of sources.

(2) The number of SO<sub>2</sub> monitors operated as a result of state-level emissions shall be reviewed and adjusted as needed as a part of the 5-year network assessment cycle required in § 58.10 of this part.

(b) [Reserved]

4.4.4 Regional Administrator Required Monitoring. The Regional Administrator may require additional SO<sub>2</sub> monitoring stations above the minimum number of monitors required in 4.4.2 and 4.4.3 of this appendix, where the minimum monitoring requirements are not sufficient to meet monitoring objectives. The Regional Administrator may require, at his/her discretion, additional monitors in situations where an area has the potential to have concentrations that may violate or contribute to the violation of the NAAQS and the area

is not monitored under the minimum monitoring provisions described above. The Regional Administrator and the responsible State or local air monitoring agency shall work together to design and/or maintain the most appropriate SO<sub>2</sub> network to provide sufficient data to meet monitoring objectives.

4.4.5 SO<sub>2</sub> Monitoring Spatial Scales. (a) The appropriate spatial scales for SO<sub>2</sub> SLAMS monitors are the microscale, middle, neighborhood, and possibly urban scales. Monitors sited at the microscale, middle, and neighborhood scales are suitable for determining maximum hourly concentrations for SO<sub>2</sub> and can be used for compliance actions. Monitors sited at urban scales are useful for identifying SO<sub>2</sub> transport, trends, and, if sited upwind of local sources, background concentrations.

(1) Microscale—This scale would typify areas in close proximity to SO<sub>2</sub> point and area sources. Emissions from stationary point and area sources, and non-road sources may, under certain plume conditions, result in high ground level concentrations at the microscale. The microscale typically represents an area impacted by the plume with dimensions extending up to approximately 100 meters.

(2) Middle scale—This scale generally represents air quality levels in areas up to several city blocks in size with dimensions on the order of approximately 100 meters to 500 meters. The middle scale may include locations of expected maximum short-term concentrations due to proximity to major SO<sub>2</sub> point, area, and/or non-road sources.

(3) Neighborhood scale—The neighborhood scale would characterize air quality conditions throughout some relatively uniform land use areas with dimensions in the 0.5 to 4.0 kilometer range. Emissions from stationary point and area

sources may, under certain plume conditions, result in high SO<sub>2</sub> concentrations at the neighborhood scale. Where a neighborhood site is located away from immediate SO<sub>2</sub> sources, the site may be useful in representing typical air quality values for a larger residential area, and therefore suitable for population exposure and trends analyses.

(4) Urban scale—Measurements in this scale would be used to estimate concentrations over large portions of an urban area with dimensions from 4 to 50 kilometers. Such measurements would be useful for assessing trends in area-wide air quality, and hence, the effectiveness of large scale air pollution control strategies. Urban scale sites may also support other monitoring objectives of the SO<sub>2</sub> monitoring network such as identifying trends, and when monitors are sited upwind of local sources, background concentrations.

(b) [Reserved]

4.4.6 NCore Monitoring. SO<sub>2</sub> measurements are included within the NCore multipollutant site requirements as described in paragraph (3)(b) of this appendix. NCore-based SO<sub>2</sub> measurements are primarily used to characterize SO<sub>2</sub> trends and assist in understanding SO<sub>2</sub> transport across representative areas in urban or rural locations and are also used for comparison with the SO<sub>2</sub> NAAQS.

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26. Appendix G to Part 58 is amended as by revising Table 2 to read as follows:

**Appendix G to Part 58—Uniform Air Quality Index (AQI) and Daily Reporting**

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TABLE 2—BREAKPOINTS FOR THE AQI

These breakpoints							Equal these AQIs	
O <sub>3</sub> (ppm) 8-hour	O <sub>3</sub> (ppm) 1-hour <sup>1</sup>	PM <sub>2.5</sub> (µg/m <sup>3</sup> )	PM <sub>10</sub> (µg/m <sup>3</sup> )	CO (ppm)	SO <sub>2</sub> (ppm) 1-hour	NO <sub>2</sub> (ppm) 1-hour	AQI	Category
0.000–0.059 ..	.....	0.0–15.4	0–54	0.0–4.4	0–(0.025–0.050)	0–(0.040–0.053)	0–50	Good.
0.060–0.075 ..	.....	15.5–40.4	55–154	4.5–9.4	(0.026–0.051)–(0.050–0.100)	(0.041–0.054)–(0.080–0.100)	51–100	Moderate.
0.076–0.095 ..	0.125–0.164	40.5–65.4	155–254	9.5–12.4	(0.051–0.101)–(.175–.200)	(0.081–0.101)–(0.360–0.370)	101–150	Unhealthy for Sensitive Groups.
0.096–0.115 ..	0.165–0.204	<sup>3</sup> 65.5–150.4	255–354	12.5–15.4	(0.176–0.201)–(.304)	(0.361–0.371)–0.64	151–200	Unhealthy.
0.116–0.374 ..	0.205–0.404	<sup>3</sup> 150.5–250.4	355–424	15.5–30.4	0.305–0.604	0.65–1.24	201–300	Very Unhealthy.
( <sup>2</sup> ) .....	0.405–0.504	<sup>3</sup> 250.5–350.4	425–504	30.5–40.4	0.605–0.804	1.25–1.64	301–400	
( <sup>2</sup> ) .....	0.505–0.604	<sup>3</sup> 350.5–500.4	505–604	40.5–50.4	0.805–1.004	1.65–2.04	401–500	Hazardous.

<sup>1</sup> Areas are generally required to report the AQI based on 8-hour ozone values. However, there are a small number of areas where an AQI based on 1-hour ozone values would be more precautionary. In these cases, in addition to calculating the 8-hour ozone index value, the 1-hour ozone index value may be calculated, and the maximum of the two values reported.

<sup>2</sup> 8-hour O<sub>3</sub> values do not define higher AQI values (≥301). AQI values of 301 or greater are calculated with 1-hour O<sub>3</sub> concentrations.

<sup>3</sup> If a different SHL for PM<sub>2.5</sub> is promulgated, these numbers will change accordingly.

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