Integrated Review Plan for the Primary National Ambient Air Quality Standard for Sulfur Dioxide

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Integrated Review Plan for the Primary National Ambient Air Quality Standard for Sulfur Dioxide

U. S. Environmental Protection Agency

National Center for Environmental Assessment
Office of Research and Development
and
Office of Air Quality Planning and Standards
Office of Air and Radiation

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DISCLAIMER

This integrated review plan serves as a public information document and as a management tool for the U.S. Environmental Protection Agency's National Center for Environmental Assessment and the Office of Air Quality Planning and Standards in conducting the review of the national ambient air quality standard for sulfur oxides. The approach described in this plan may be modified based on information developed during this review, and in consideration of advice and comments received from the Clean Air Scientific Advisory Committee and the public during the course of the review. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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LIST OF ACRONYMS/ABBREVIATIONS

AMMS	Air Monitoring and Methods Subcommittee
AQCD	Air Quality Criteria Document
AQS	EPA's Air Quality System
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CBSA	Core Based Statistical Area
CFR	Code of Federal Regulations
C-R	Concentration-response
ED	Emergency department
EPA	Environmental Protection Agency
FEM	Federal Equivalent Method
FEV_1	Forced expiratory volume in one second, volume of air exhaled in first second of exhalation
FR	Federal Register
FRM	Federal Reference Method
HA	Hospital admissions
IRP	Integrated Review Plan
ISA	Integrated Science Assessment
km	Kilometer
MSA	Metropolitan Statistical Area
NAAQS	National Ambient Air Quality Standards
NCEA	National Center for Environmental Assessment
NO_2	Nitrogen dioxide
O_3	Ozone
OAQPS	Office of Air Quality Planning and Standards
OAR	Office of Air and Radiation
OMB	Office of Management and Budget
ORD	Office of Research and Development
PA	Policy Assessment
PM	Particulate matter
ppb	Parts per billion
ppm	Parts per million
PRB	Policy-relevant background
PWEI	Population Weighted Exposure Index
REA	Risk and Exposure Assessment
SES	Socioeconomic status
SLAMS	State and local air monitoring stations
SO_x	Sulfur oxides
SO_2	Sulfur dioxide

1. INTRODUCTION

The U.S. Environmental Protection Agency (EPA) is conducting a review of the primary (health-based) national ambient air quality standard (NAAQS) for sulfur oxides (SO_X). This Integrated Review Plan (IRP) presents the planned approach for the review. This review will provide an integrative assessment of relevant scientific information for SO_X and will focus on the basic elements that define the NAAQS: the indicator,[1] averaging time,[2] form,[3] and level.[4] These elements will be considered collectively in evaluating the protection to public health afforded by the primary standard(s).

This document is organized into eight chapters. Chapter 1 presents the legislative requirements for the review of the NAAQS, background information on the review process, scope of the current review, and an overview of past reviews of the primary SO_2 NAAQS.[5] Chapter 2 presents the status and schedule for the current review. Chapter 3 summarizes the approach in the last review and presents a set of policy-relevant questions that will serve to focus the current review on the critical scientific and policy issues. Chapters 4 through 7 discuss the planned scope and organization of key assessment documents, the planned approaches for preparing these documents, specific ambient air quality monitoring considerations, as well as plans for scientific and public review of these documents. Complete reference citations are provided in chapter 8.

1.1 LEGISLATIVE REQUIREMENTS

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants that are listed. The Administrator is to list those pollutants that in her “judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare”; “the presence of

[1] The “indicator” of a standard defines the chemical species or mixture that is measured in determining whether an area attains the standard.
[2] The “averaging time” defines the time period over which ambient measurements are averaged (e.g., 1-hour, 8-hour, 24-hour, annual).
[3] The “form” of a standard defines the air quality statistic that is compared to the level of the standard in determining whether an area attains the standard. For example, the form of the current 1-hour SO_2 standard is the three-year average of the 99th percentile of the annual distribution of 1-hour daily maximum SO_2 concentrations.
[4] The “level” defines the allowable concentration of the criteria pollutant in the ambient air.
[5] The listed criteria pollutant is SOx (34 FR 1988), therefore in each NAAQS review EPA must evaluate health effects associated with all SOx species. In previous reviews, most all of the health information has been in terms of SO_2, and therefore, SO_2 has been used as the indicator for a NAAQS set to address the health effects associated with all gaseous SOx species (see section 3.1.2). In the current review, EPA will again evaluate health effects associated with all SOx species and then determine whether the indicator for the standard should be revised or retained.

which in the ambient air results from numerous or diverse mobile or stationary sources"; and for which she "plans to issue air quality criteria …." Air quality criteria are intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air . . . ." 42 U.S.C. § 7408(a)(2).

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants for which air quality criteria are issued.[6] 42 U.S.C. § 7409(a). Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."[7] A secondary standard, as defined in section 109(b)(2), must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is required to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."[8]

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980), cert. denied, 449 U.S. 1042 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981), cert. denied, 455 U.S. 1034 (1982); *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 617-18 (D.C. Cir. 2010). 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 pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration

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[6] As discussed in section 1.4 below, this document describes the review of the *primary* SO_2 standard. In a separate process, the *secondary* SO_2 standard is being reviewed in conjunction with the review of the secondary NO_2 standard.

[7] 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)].

[8] Welfare effects as defined in section 302(h) [42 U.S.C. 7602(h)] include, but are not limited to, "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

levels, see *Lead Industries v. EPA*, 647 F.2d at 1156 n.51, *Mississippi v. EPA*, 723 F. 3d 246, 255, 262-63 (D.C. Cir. 2013), but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s), and the kind and degree of uncertainties. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Association v. EPA*, supra, 647 F.2d at 1161-62; *Mississippi v. EPA*, 723 F. 3d at 265.

In setting primary and secondary standards that are "requisite" to protect public health and welfare, respectively, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary. In so doing, the EPA may not consider the costs of implementing the standards. See generally, *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001). Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards." *American Petroleum Institute v. Costle*, 665 F. 2d at 1185.

Section 109(d)(1) requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . ." Section 109(d)(2) requires that an independent scientific review committee "shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate . . . ." Since the early 1980s, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board. [9]

1.2 OVERVIEW OF THE NAAQS REVIEW PROCESS

The current process for reviewing the NAAQS includes four major phases: (1) planning, (2) science assessment, (3) risk/exposure assessment, and (4) policy assessment and rulemaking. Figure 1-1 provides an overview of this process, and each phase is described in more detail

[9] Lists of CASAC members and of members of the CASAC Sulfur Oxides Primary NAAQS Review Panel are available at: http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/CommitteesandMembership?OpenDocument.

below. [10]

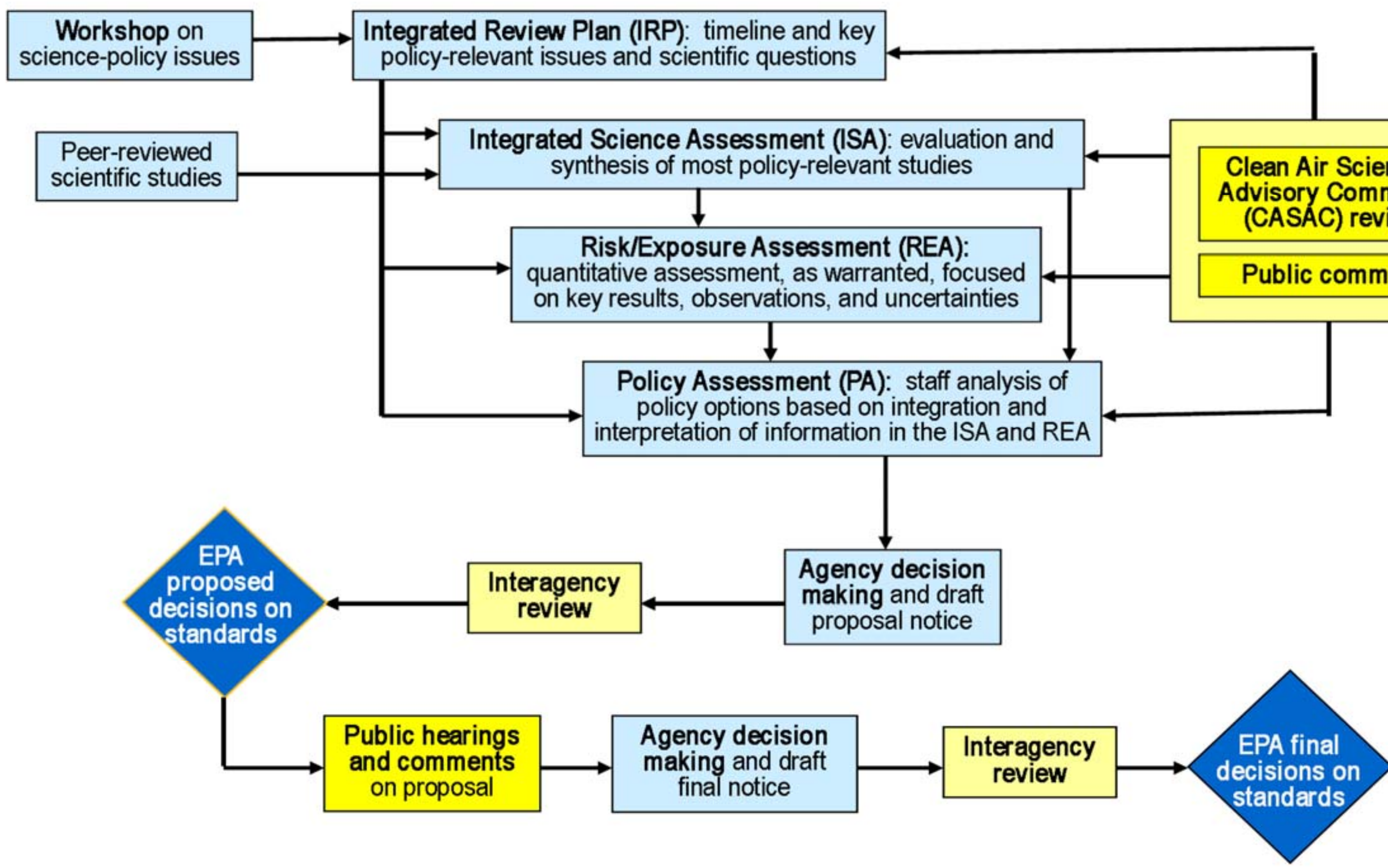

Figure 1-1 Overview of the NAAQS Review Process

[10] The EPA maintains a website on which key documents developed for NAAQS reviews are made available (http://www.epa.gov/ttn/naaqs/). The EPA's NAAQS review process has evolved over time. Information on the current process is available at: http://www.epa.gov/ttn/naaqs/review.html. As discussed in section 1.3 below, this process was generally followed in the primary SO_2 NAAQS review completed in 2010 with the exception that there was not a separate Policy Assessment document issued; rather the Risk and Exposure Assessment (U.S. EPA 2009,) included a policy assessment chapter (i.e., Chapter 10).

The planning phase of the NAAQS review process begins with a science policy workshop, which is intended to identify issues and questions to frame the review. Drawing from the workshop discussions, a draft IRP is prepared jointly by EPA's National Center for Environmental Assessment (NCEA), within the Office of Research and Development (ORD), and EPA's Office of Air Quality Planning and Standards (OAQPS), within the Office of Air and Radiation (OAR). The draft IRP is made available for CASAC review and for public comment. The final IRP is prepared in consideration of CASAC and public comments. This document presents the current plan and specifies the schedule for the entire review, the process for conducting the review, and the key policy-relevant science issues that will guide the review.

The second phase of the review, the science assessment, involves the preparation of an Integrated Science Assessment (ISA) and supplementary materials. The ISA, prepared by NCEA, provides a concise review, synthesis, and evaluation of the most policy-relevant science, including key science judgments that are important to the design and scope of exposure and risk assessments, as well as other aspects of the NAAQS review. The ISA and its supplementary materials provide a comprehensive assessment of the current scientific literature pertaining to known and anticipated effects on public health and welfare associated with the presence of the pollutant in the ambient air, emphasizing information that has become available since the last air quality criteria review in order to reflect the current state of knowledge. As such, the ISA forms the scientific foundation for each NAAQS review and is intended to provide information useful in forming judgments about air quality indicator(s), form(s), averaging time(s) and level(s) for the NAAQS. The current review process generally includes production of a first and second draft ISA, both of which undergo CASAC and public review prior to completion of the final ISA. Chapter 4 below provides a more detailed description of the planned scope, organization and assessment approach for the ISA and its supporting materials.

In the third phase, the risk/exposure assessment phase, OAQPS staff considers information and conclusions presented in the ISA, with regard to support provided for the development of quantitative assessments of the risks and/or exposures for health and/or welfare effects. As an initial step, staff prepare a planning document (REA Planning Document) that considers the extent to which newly available scientific evidence and tools/methodologies warrant the conduct of quantitative risk and exposure assessments. As discussed in Chapter 5 below, the REA Planning Document focuses on the degree to which important uncertainties in the last review may be addressed by new information available in this review. Specifically, this document will focus on consideration of the newly available data, methods and tools in light of areas of uncertainty in the assessments conducted for the last review and of the potential for new or updated assessments to provide notably different exposure and risk estimates with lower associated uncertainty. To the extent warranted, this document outlines a general plan, including scope and methods, for conducting assessments. The REA Planning Document is generally prepared in conjunction with the first draft ISA and is presented for consultation with CASAC and for public comment. When an assessment is performed, one or more drafts of each risk and exposure assessment document (REA) undergoes CASAC and public review, with the initial draft REA generally being reviewed in conjunction with review of the second draft ISA, prior to completion of the final REA. The REA provides concise presentations of methods, key results, observations, and related uncertainties. Chapter 5 below discusses consideration of potential quantitative human health-related assessments for this review.

The review process ends with the policy assessment and rulemaking phase. The Policy Assessment (PA) is a document, prepared prior to issuance of proposed and final rules, that provides a transparent presentation of OAQPS staff analysis and presents staff conclusions regarding the adequacy of the current standards and, if revision is considered, what revisions may be appropriate. The PA integrates and interprets the information from the ISA and REA to frame policy options for consideration by the Administrator. Such an evaluation of policy implications is intended to help ‘‘bridge the gap’’ between the Agency’s scientific assessments, presented in the ISA and REA, and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS. In so doing, the PA is also intended to facilitate CASAC’s advice to the Agency and recommendations to the Administrator on the adequacy of the existing standards or revisions that may be appropriate to consider, as provided for in the CAA. In evaluating the adequacy of the current standards and, as appropriate, a range of alternative standards, the PA considers the available scientific evidence and, as available, quantitative risk-based analyses, together with related limitations and uncertainties. The PA focuses on the information that is most pertinent to evaluating the basic elements of national ambient air quality standards: indicator, averaging time, form, and level. One or more drafts of a PA are released for CASAC review and public comment prior to completion of the final PA.

Following issuance of the final PA and consideration of conclusions presented therein, the Agency develops and publishes a notice of proposed rulemaking that communicates the Administrator’s proposed decisions regarding the standards review. A draft notice undergoes interagency review involving other federal agencies prior to publication.[11] Materials upon

[11] Where implementation of the proposed decision would have an annual effect on the economy of $100 million or more, e.g., by necessitating the implementation of emissions controls, the EPA develops and releases a draft regulatory impact analysis (RIA) concurrent with the notice of proposed rulemaking. This activity is conducted under Executive Order 12866. The RIA is conducted completely independent of and, by law, is not considered in decisions regarding the review of the NAAQS.

which this decision is based, including the documents described above, are made available to the public in the regulatory docket for the review.[12]

A public comment period, during which public hearings are generally held, follows publication of the notice of proposed rulemaking. Taking into account comments received on the proposed rule,[13] the Agency develops a final rule which undergoes interagency review prior to publication to complete the rulemaking process. Chapter 7 discusses the development of the PA and the rulemaking steps for this review.

1.3 HISTORY OF THE REVIEW OF AIR QUALITY CRITERIA FOR SULFUR OXIDES AND THE NAAQS FOR SULFUR DIOXIDE

The EPA completed the initial review of the air quality criteria for sulfur oxides in 1969 (34 FR 1988). Based on this review, the EPA in initially promulgating NAAQS for sulfur oxides in 1971, established the indicator as SO_2. The 1971 primary standards were set at 0.14 parts per million (ppm) averaged over a 24-hour period, not to be exceeded more than once per year, and 0.030 ppm annual arithmetic mean.[14] Since then, the Agency has completed multiple reviews of the air quality criteria and standards, as summarized in Table 1-1.

[12] All documents in the docket are listed in the www.regulations.gov index. Publicly available docket materials are available either electronically at www.regulations.gov or in hard copy at the Air and Radiation Docket and Information Center. The docket ID number for this review is EPA-HQ-OAR-2013-0566.
[13] When issuing the final rulemaking, the Agency responds to all significant comments on the proposed rule.
[14] Note that 0.14 ppm is equivalent to 140 parts per billion (ppb) and 0.030 ppm is equivalent to 30 ppb.

Table 1-1. History of the primary national ambient air quality standard(s) for sulfur dioxide since 1971[15]

Final Rule/Decision	Indicator	Averaging Time	Level	Form
1971 36 FR at 8186 Apr 30, 1971	SO_2	24-hour and Annual Avg	24-hour: 140 ppb Annual Avg: 30 ppb[16]	24-hour std: one allowable exceedance Annual std: Annual arithmetic average
1996 61 FR at 25566 May 22, 1996	Both the 24-hour and annual average standards retained without revision			
2010 75 FR at 35520 June 22, 2010	SO_2	1-hour	75 ppb	99th percentile, averaged over 3 years[17]
	24-hour and annual SO_2 standards revoked.			

In 1982, the EPA published the *Air Quality Criteria for Particulate Matter and Sulfur Oxides* (U.S. 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 (U.S. EPA 1982). In 1986, a second addendum was published presenting newly available evidence from epidemiologic and controlled human exposure studies (U.S. EPA 1986). In 1988, the EPA published a proposed decision not to revise the existing standards (53 FR 14926). However, the 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 to protect against short-term peak exposures.

As a result of public comments on the 1988 proposal and other post-proposal developments, the 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 short-term SO_2 exposures in asthmatics (U.S. EPA 1994). As in the 1988 proposal, the EPA proposed to retain the existing 24-hour and annual standards. The EPA also solicited comment on three regulatory alternatives to further reduce the health risk posed by exposure to high 5-minute peaks of SO_2 if additional protection were judged

[15] In 1971 (36 FR 8186), a 3-hour secondary standard was set at 500 ppb to provide protection against adverse welfare effects.
[16] The initial level of the 24-hr SO_2 standard was 0.140 ppm which is equal to 140 ppb. The initial level of the annual SO_2 standard was 0.03 ppm which is equal to 30 ppb.
[17] The current form of the 1-hour standard is the 3-year average of the 99th percentile of the yearly distribution of 1-hour daily maximum SO_2 concentrations.

to be necessary. The three alternatives were: 1) Revising the existing primary SO_2 NAAQS by adding a new 5-minute standard of 0.60 ppm SO_2; 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 0.60 ppm SO_2, 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_2.

In assessing the regulatory options mentioned above, the Administrator concluded that the likely frequency of 5-minute concentrations of concern should also be a consideration in assessing the overall public health risks. Based upon an exposure analysis conducted by the EPA, the Administrator concluded that exposure of asthmatics to SO_2 at levels that can reliably elicit adverse health effects was likely to be a rare event when viewed in the context of the entire population of asthmatics. As a result, the Administrator judged that 5-minute peak SO_2 levels did not pose a broad public health problem when viewed from a national perspective, and a 5-minute standard was not promulgated. In addition, no other regulatory alternative was finalized and the 24-hour and annual average primary SO_2 standards were retained in 1996 (61 FR 25566).

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 ("D.C. Circuit") found that the EPA had failed to adequately explain its determination that no revision to the SO_2 NAAQS was appropriate and remanded the decision back to EPA for further explanation. Specifically, the court required the EPA to provide additional rationale to support the Agency judgment that 5-minute peaks of SO_2 do not pose a public health problem from a national perspective even though these peaks will likely cause adverse health impacts in a subset of asthmatics. Following the remand, the EPA and American Lung Association entered into negotiations which resulted in EPA requesting that states voluntarily submit 5-minute SO_2 monitoring data. The Agency would then use this 5-minute monitoring data to conduct air quality analyses in order to gain a better understanding of the magnitude and frequency of high, 5-minute peak SO_2 concentrations. The data submitted by states and the analyses based on this data are described in chapter 5 of this document. Moreover, the data and analyses described in chapter 5 helped inform the last review of the SO_2 NAAQS, which ultimately addressed the issues raised in the 1998 remand.

On June 22, 2010, the EPA revised the primary SO_2 NAAQS to provide requisite protection of public health with an adequate margin of safety. Specifically, after concluding that the then-existing 24-hour and annual standards were inadequate to protect public health with an adequate margin of safety (see section 3.1.1), the EPA established a new 1-hour SO_2 standard at a level of 75 ppb, based on the 3-year average of the annual 99^{th} percentile of 1-hour daily maximum concentrations (see section 3.1.2). This standard was promulgated to provide substantial protection against SO_2-related health effects associated with short-term exposures ranging from 5-minutes to 24-hours. More specifically, EPA concluded that a 1-hour SO_2 standard at 75 ppb would substantially limit exposures associated with the adverse respiratory effects (e.g., decrements in lung function and/or respiratory symptoms) reported in exercising asthmatics following 5-10 minute exposures in controlled human exposure studies, as well as the more serious health associations reported in epidemiologic studies of mostly 1- and 24-hours (e.g., respiratory-related emergency department visits and hospitalizations). In the last review, the EPA also revoked the then-existing 24-hour and annual primary standards based largely on the recognition that a 1-hour standard at 75 ppb would have the effect of maintaining 24-hour and annual SO_2 concentrations generally well below the levels of the 24-hour and annual NAAQS (see section 3.1.2). The decision to set a 1-hour standard at 75 ppb to in part, substantially limit exposure to 5-minute concentrations of SO_2 resulting in adverse respiratory effects in exercising asthmatics, also satisfied the remand by the D.C. Circuit in 1998.

As mentioned above, in the last review considerable weight was placed on substantially limiting health effects associated with 5-minute peak SO_2 concentrations. Thus, as part of the final rulemaking, the EPA for the first time required state reporting of either the highest 5-minute concentration for each hour of the day, or all twelve 5-minute concentrations for each hour of the day (see chapter 6). The rationale for this requirement was that this additional monitored data could then be used in future reviews to evaluate the extent to which the 1-hour SO_2 NAAQS at 75 ppb provides protection against 5-minute peaks of concern.

After publication of the final rule, a number of industry groups and states filed petitions for review arguing that the EPA failed to follow notice-and-comment rulemaking procedures, and that the decision to establish the 1-hour SO_2 NAAQS at 75 ppb was arbitrary and capricious because it was lower than statutorily authorized. The D.C. Circuit rejected these challenges, thereby upholding the standard in its entirety *National Environmental Development Association's Clean Air Project v. EPA*, 686 F. 3d 803 (D.C. Cir. 2012).

1.4 SCOPE OF THE CURRENT REVIEW

Sulfur oxides include all forms of oxidized sulfur compounds including the gases SO_2 and SO_3 as well as their gaseous and particulate reaction products (e.g., sulfates; see 34 FR 1988). As in previous reviews of the SO_2 NAAQS, this review will focus on effects associated with the gaseous species only. Effects associated with the particulate species (e.g., sulfate) are addressed in the review of the NAAQS for particulate matter (PM) (78 FR 30866, January 15, 2013; U.S. EPA 2009).

Consistent with the review completed in 2010, this review is focused on the primary SO_2 standard and as such, will only consider relevant scientific information related to potential health effects associated with exposure to sulfur oxides. In a separate process, the EPA is reviewing the secondary SO_2 standard in conjunction with a review of the secondary NO_2 standard (78 FR 53452, August 29, 2013).[18]

[18] Additional information on the ongoing review of the secondary NO_2 and SO_2 standards is available at: http://www.epa.gov/ttn/naaqs/standards/no2so2sec/index.html.

2. STATUS AND SCHEDULE

In May of 2013, the EPA announced the initiation of the current periodic review of the air quality criteria for SOx and the primary SO_2 NAAQS, and also issued a call for information in the *Federal Register* (78 FR 27387). Also, as an initial step in the NAAQS review process described in Section 1.1 above, EPA invited a wide range of external and internal EPA experts, representing a variety of areas of expertise (e.g., epidemiology, human and animal toxicology, statistics, risk/exposure analysis, atmospheric science), to participate in a workshop to discuss the policy-relevant science to inform development of this plan. This workshop was held June 12-13, 2013, in Research Triangle Park, NC (78 FR 27387). This workshop provided an opportunity for the participants to broadly discuss the key policy-relevant issues around which EPA would structure the SO_2 NAAQS review and to discuss the most meaningful new science that would be available to inform our understanding of these issues. Based in part on the workshop discussions, the EPA developed this draft IRP outlining the schedule, the process, and the policy-relevant science issues identified as key to guiding the evaluation of the air quality criteria for sulfur oxides and the review of the primary SO_2 NAAQS.

Table 2-1 outlines the schedule under which the Agency is currently conducting this review. The scope of the review and the key documents to be prepared during the review are discussed throughout the rest of this document.

Table 2-1. Anticipated schedule for the SO_2 NAAQS Review

Stage of Review	Major Milestone	Draft Target Date
Integrated Plan (IRP)	Literature Search	Ongoing
	Call for Information	May 10, 2013
	Workshop on science/policy issues	June 12-13 2013
	Draft IRP	March 2014
	CASAC/public review on draft IRP	April 22, 2014
	Final IRP	October 2014
Integrated Science Assessment (ISA)	First draft ISA	February 2015
	CASAC/public review first draft ISA	May 2015
	Second draft ISA	November 2015
	CASAC/public review second draft ISA	January 2015
	Final ISA	June 2016
Risk/Exposure Assessment (REA)	REA Planning Document	July 2015
	CASAC consultation/public review REA[19] Planning Document	August 2015
	If warranted:	
	First draft REA	[20]
	CASAC/public review of first draft REA	
	Second draft REA	
	CASAC/public review of second draft REA	
	Final REA	
Policy Assessment (PA)/Rulemaking	First Draft PA	April 2016
	CASAC review/public review first draft PA	May 2016
	Second Draft PA (if warranted)	November 2016
	CASAC/public review second draft PA	December 2016[21]
	Final PA	May 2017
	Notice of proposed rulemaking	October 2018
	Notice of final rulemaking	July 2019

[19] If the REA planning document concludes that an REA is not required, the REA planning document will be submitted for CASAC review rather than for consultation.
[20] An updated REA may not be warranted for this review of the SO_2 primary NAAQS
[21] The anticipated schedule presented in Table 2-1 includes preparation of two draft PAs for CASAC and public review. In NAAQS reviews in which the newly available information calls into question the adequacy of the current standard(s), a second draft PA is typically prepared to include staff consideration of potential alternative standards. However, in NAAQS reviews where a new REA is not developed and where staff preliminarily conclude in a first draft PA that it is appropriate to consider retaining the current standards without revision, the EPA may decide that there is no new substantive information that we would intend to add that would provide a basis for preparing a second draft PA. If the Agency determines that a second draft PA is not warranted, CASAC and public comments on the first draft PA will be considered in preparing the final PA and the schedule for the review will be revised accordingly.

3. KEY POLICY-RELEVANT ISSUES

The overarching question in each NAAQS review is:

- **Does the currently available scientific evidence and exposure/risk-based information support or call into question the adequacy of the protection afforded by the current standard(s)?**

As appropriate, a review also addresses a second overarching question:

- **What alternative standard(s), if any, are supported by the currently available scientific evidence and exposure/risk-based information and are appropriate for consideration?**

To inform our consideration of these overarching questions in the current review, we have identified key policy-relevant issues to be considered. These key issues reflect aspects of the health effects evidence, air quality information, and exposure/risk information that, in our judgment, are likely to be particularly important to informing the Administrator's decisions. They build upon the key issues that were important in previous reviews.

Section 3.1 below describes the key considerations and conclusions from the last review with regard to the adequacy of the then-current primary SO_2 standards (section 3.1.1), and with regard to the elements for a revised standard judged in that review to provide requisite public health protection (section 3.1.2). Section 3.2 summarizes our general approach for reviewing the primary SO_2 standard in the current review and outlines the key policy-relevant issues. These issues are presented as a series of questions that will frame our approach to considering the extent to which the available evidence and information support retaining or revising the current primary standard for SO_2.

3.1 CONSIDERATIONS AND CONCLUSIONS IN LAST REVIEW

The last review of the primary NAAQS for SO_2 was completed in 2010 (75 FR at 35520, June 22, 2010). In that review, the EPA considered key controlled human exposure studies from previous reviews as well as the significantly expanded body of health effects evidence that had emerged since the last review was completed in 1996.[22] In addition, EPA also considered exposure and risk estimates regarding potential respiratory effects in exercising asthmatics following 5-10 minute exposures to SO_2, as well as CASAC advice and public comments. Taking all this information together, the EPA established a new short-term standard to provide

[22] Documents related to the SO_2 NAAQS reviews completed in 2010 and 1996 are available at: http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_index.html

increased protection for asthmatics and other at-risk populations[23] against an array of adverse respiratory effects that have been linked to short-term SO_2 exposures in both controlled human exposure and epidemiologic studies (75 FR at 35525 to 35527 and U.S. EPA 2008, section 5.5). Specifically, the EPA established a short-term standard defined by the 3-year average of the 99th percentile of the yearly distribution of 1-hour daily maximum SO_2 concentrations, with a level of 75 ppb. In addition to setting a new short-term standard, the then-existing 24-hour and annual standards were revoked based largely on the recognition that a 1-hour standard set at 75 ppb would have the effect of generally maintaining 24-hour and annual SO_2 concentrations well below the levels of those standards (75 FR at 35550).

Key policy-relevant aspects of the Administrator's decisions with regard to the need to revise the primary SO_2 NAAQS, and with regard to the elements of the revised standard, are described below in sections 3.1.1 and 3.1.2, respectively. Areas of uncertainty identified in the last review are noted in section 3.1.3.

3.1.1 Need for Revision

The Administrator concluded in the last review that the then-existing 24-hour and annual SO_2 standards were not adequate to protect public health, including the health of at-risk populations, from the effects associated with short-term exposures to SO_2 (75 FR at 35520, June 22, 2010). As described below, this conclusion was based on the extensive body of health evidence assessed in the 2008 ISA for SO_X – Health Criteria (U.S. EPA 2008), including the assessment of the policy-relevant aspects of that evidence,[24] quantitative exposure and risk analyses presented in the 2009 REA (U.S. EPA 2009), public comments, and the advice and recommendations of CASAC (Samet, 2009).

As an initial consideration in reaching this conclusion, the Administrator noted the ISA judgment that the findings of controlled human exposure, epidemiologic, and animal toxicological studies collectively provided evidence "sufficient to infer a causal relationship" between short-term SO_2 exposures ranging from 5-minutes to 24-hours and respiratory morbidity (75 FR at 35535). The ISA described the ''definitive evidence'' for this conclusion as being the results of 5–10 minute controlled human exposure studies demonstrating decrements in lung

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

[24] As noted in section 1.3 above, due to changes in the NAAQS process, the last review of the SO_2 NAAQS did not include a separate Policy Assessment. Rather, the REA for that review included a Policy Assessment chapter.

function and/or respiratory symptoms in exercising asthmatics (U.S. EPA 2008, section 5.2). In brief, the ISA examined numerous controlled human exposure studies and found that moderate or greater decrements in lung function (i.e., ≥ 15% decline in Forced Expiratory Volume (FEV_1) and/or ≥ 100% increase in specific airway resistance (sRaw)) occurred in some exercising asthmatics exposed to SO_2 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_2 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 (U.S. EPA 2008, 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., ≥ 20% decrease in FEV_1 and/or ≥ 200% increase in sRaw; U.S. EPA 2008, Table 3–1). Moreover, at SO_2 concentrations ≥ 400 ppb, moderate or greater decrements in lung function were often statistically significant at the group mean level and were frequently accompanied by respiratory symptoms (U.S. EPA 2008, Table 3–1).

In considering the controlled human exposure studies with respect to adequacy of the then-current standards, the Administrator first judged that 5–10 minute SO_2 exposures ≥ 400 ppb and ≥ 200 ppb can result in adverse health effects in exercising asthmatics (75 FR at 35536). This judgment was based on ATS guidelines, explicit CASAC consensus written advice, as well as recommendations and judgments made by EPA in previous NAAQS reviews (see 75 FR at 35526 and 75 FR at 35536). The Administrator therefore particularly noted analyses in the REA that utilized benchmark concentrations derived from the controlled human exposure evidence. In the REA, 5-minute benchmark concentrations ranged from 100 ppb to 400 ppb (see below, section 5.1), with 5-minute benchmark concentrations of 200 ppb and 400 ppb noted by the Administrator as being particularly important. These benchmark levels were highlighted because in free-breathing controlled human exposure studies: (1) 400 ppb represented the lowest concentration at which moderate or greater lung function decrements occurred which were often statistically significant at the group mean level and were frequently accompanied by respiratory symptoms; and (2) 200 ppb was the lowest level at which moderate or greater decrements in lung function were found in some individuals.[25]

[25] 200 ppb was also the lowest level tested in free-breathing controlled human exposure studies. Also note that very young children were not included in controlled human exposure studies and this absence of data on what is likely to be a sensitive lifestage was a source of uncertainty in the last review.

Given the emphasis on the 200 ppb and 400 ppb benchmarks, the Administrator particularly noted the modeled exposure analysis results for the St. Louis case study presented in the REA (see below, section 5.1). This analysis estimated that given air quality simulated to just meet the then-existing SO_2 NAAQS, substantial percentages of asthmatic children at moderate or greater exertion would be exposed, at least once annually, to air quality exceeding the 200 ppb and 400 ppb 5-minute benchmarks (75 FR at 35536). The Administrator judged these 5-minute exposures to be significant from a public health perspective due to their estimated frequency: approximately 24% of asthmatic children at moderate or greater exertion in St. Louis were estimated to be exposed at least once per year to air quality exceeding the 5- minute 400 ppb benchmark. Additionally, approximately 73% of asthmatic children in St. Louis at moderate or greater exertion were estimated to be exposed at least once per year to air quality exceeding the 5-minute 200 ppb benchmark (75 FR at 35536).

With respect to the epidemiologic evidence, the ISA characterized epidemiologic studies of respiratory symptoms, emergency department visits and hospital admissions as providing "supporting evidence" for the causal relationship between short-term exposure to SO_2 and respiratory morbidity. The ISA found that numerous epidemiologic studies reported positive associations between ambient SO_2 concentrations and respiratory symptoms in children, as well as emergency department visits and hospitalizations for all respiratory causes and asthma across multiple age groups. The ISA concluded that these epidemiologic studies were consistent and coherent. This evidence was consistent in that associations were reported in studies conducted in numerous locations and with a variety of methodological approaches (U.S. EPA 2008, 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_2 concentrations were generally in agreement with respiratory symptom results from controlled human exposure studies of 5–10 minutes. Moreover, while recognizing the uncertainties associated with separating the effects of SO_2 from those of co-occurring pollutants, the ISA concluded that ''the limited available evidence indicates that the effect of SO_2 on respiratory health outcomes appears to be generally robust and independent of the effects of gaseous co-pollutants, including NO_2 and O_3, as well as particulate copollutants, particularly $PM_{2.5}$'' (U.S. EPA 2008, section 5.3).

In considering the epidemiologic evidence, the Administrator acknowledged uncertainties with these studies (e.g., potential confounding by co-pollutants), but agreed with judgments in the ISA that the epidemiologic evidence, supported by the controlled human exposure evidence, generally indicated that the effects seen in these studies were attributable to exposure to SO_2, rather than co-pollutants. With respect to the adequacy of the SO_2 NAAQS, the Administrator noted that many of these epidemiologic studies reported associations between short-term (mostly 1-hour daily maximum and 24-hour average) SO_2 concentrations and respiratory symptoms, emergency department visits, and hospital admissions in locations meeting the then-existing 24-hour and annual standards (75 FR at 35535), thereby further indicating that the these standards were not adequately protecting public health.

The Administrator also agreed with CASAC advice when reaching the decision that the then-existing standards were not adequate to protect public health with an adequate margin of safety. Specifically, CASAC advised that: ''the current 24-hour and annual standards are not adequate to protect public health, especially in relation to short-term exposures to SO_2 (5–10 minutes) by exercising asthmatics'' (Samet, 2009, p. 15).

Based on the considerations summarized above, the Administrator concluded that the then-existing 24-hour and annual primary SO_2 NAAQS were not adequate to protect public health with an adequate margin of safety and that these standards should be revised in order to provide increased public health protection against respiratory effects associated with short-term exposures, particularly for susceptible populations such as asthmatics and children. Upon consideration of approaches to revising these standards, the Administrator concluded that it was appropriate to set a new short-term standard, as described below.

3.1.2 Elements of a Revised Standard

When considering alternative standards to provide requisite public health protection, the Administrator concluded it was appropriate to set a new 1-hour SO_2 standard at a level of 75 ppb, based on the 3-year average of the 99th percentile of the yearly distribution of 1-hour daily maximum concentrations. The rationale and approach for setting the 1-hour standard is presented below in terms of the individual elements of a NAAQS: indicator, averaging time, form, and level. Notably, given a new 1-hour standard at 75 ppb, the previous 24-hour and annual standards were revoked based largely on the recognition that a 1-hour standard set at 75 ppb would have the effect of generally maintaining 24-hour and annual SO_2 concentrations well below the levels of those standards (75 FR at 35550).

Indicator

In previous reviews, the EPA focused on SO_2 as the most appropriate indicator for sulfur oxides because the available scientific information regarding health effects was overwhelmingly indexed by SO_2. In the most recent review, this continued to be the case. Controlled human exposure studies and animal toxicological studies provided specific evidence for health effects following exposures to SO_2. In addition, epidemiologic studies typically reported effects associated with SO_2 concentrations. Thus, based on the information available in the last review and consistent with the views of CASAC that: ''for indicator, SO_2 is clearly the preferred choice'' (Samet 2009, p. 14), the Administrator concluded it was appropriate to continue to use SO_2 as the indicator for a standard that was intended to address effects associated with exposure to SO_2, alone or in combination with other gaseous sulfur oxides (75 FR at 35536). In so doing, the EPA recognized that measures leading to reductions in population exposures to SO_2 will also likely reduce exposures to other sulfur oxides (75 FR at 35536).

Averaging Time

When considering the level of support available for specific averaging times, the Administrator first considered the strength of evidence from controlled human exposure and epidemiologic studies. As noted above (see section 3.1.1), controlled human exposure studies exposed exercising asthmatics to SO_2 for 5 -10 minutes 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 existed a causal relationship between short-term (5-minutes to 24-hours) SO_2 exposure and respiratory morbidity (U.S. EPA 2008, section 5.2). Supporting the controlled human exposure evidence were epidemiologic studies describing positive associations between short-term (e.g., 1-hour daily maximum and 24-hour average) SO_2 levels and respiratory symptoms as well as hospital admissions and emergency department visits for all respiratory causes and asthma (U.S. EPA 2008, Tables 5.4 and 5.5). Taken together, it was judged that controlled human exposure studies provided support for an averaging time that protected against 5-10 minute peak exposures, while epidemiologic evidence provided support for an averaging time that protected against both 1-hour and 24-hour exposures (U.S. EPA 2009, section 10.5.2.1).[26]

In further considering an appropriate averaging time, the Administrator took into account air quality analyses from the REA examining the potential for 24-hour and 1-hour averaging times to protect against 5-minute peak concentrations. Results of these analyses suggested that a standard based on 24-hour average SO_2 concentrations would not likely be an effective or efficient approach for addressing 5-minute peak SO_2 concentrations. That is, 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 (U.S. EPA 2009, section 10.5.2.2). In contrast, these analyses suggested that a standard with a 1-hour averaging time would be more efficient and effective at limiting 5-minute peaks of SO_2 (U.S. EPA 2009, section 10.5.2.2). In additional air quality analyses, the REA suggested that a 1-hour standard (given an appropriate form and level) could likely provide protection against 99th percentile 1-hour daily maximum and 99th percentile 24-hour average SO_2 concentrations found in locations where emergency department visit and hospital admission studies using multi-pollutant models with PM reported statistically significant

[26] The ISA did note that effects observed in epidemiologic studies also may have been due, at least in part, and especially in 24-hour epidemiologic studies, to shorter-term peaks of SO_2 (see U.S. EPA 2008, section 5.2). More specifically, the ISA noted "that it is possible that these associations are determined in large part by peak exposures within a 24-hour period" (U.S. EPA 2008, section 5.2).

associations with ambient SO_2 (75 FR at 35539 and U.S. EPA 2009, section 10.5.2.2).[27] Considering this information, the Administrator concluded that a 1-hour standard (given an appropriate form and level) was an appropriate means of controlling short-term exposures to SO_2 ranging from 5-minutes to 24-hours (75 FR at 35539).

The Administrator further noted that establishing a 1-hour averaging time was in agreement with CASAC recommendations (75 FR at 35539). That is, 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). CASAC also stated that a ‘‘one-hour standard is the preferred averaging time’’ (Samet 2009, p.15).

Based solely on the controlled human exposure evidence, the Administrator also considered a 5-minute averaging time in the last review. However, such an approach was not favored. With respect to a 5-minute standard, there were concerns about standard stability (75 FR at 35539). Specific concerns related to the number of monitors needed and the placement of such monitors given the temporal and spatial heterogeneity of 5-minute SO_2 concentrations. However, as noted above, the Administrator judged that a 1-hour averaging time, given an appropriate form and level, could adequately limit 5-minute SO_2 exposures and provide a more stable regulatory target than setting a 5-minute standard. Consequently, the Administrator judged that a 5-minute averaging time was not the preferred approach to provide adequate public health protection (75 FR at 35539).

Form

The “form” of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the NAAQS. In the last review, controlled human exposure evidence presented in the ISA indicated that the percentage of asthmatics affected and the severity of the response increased with increasing SO_2 concentrations. Thus, a concentration-based form averaged over three years was judged by the Administrator to be most appropriate (75 FR at 35541). This was because compared to an exceedance-based form, a concentration-based form averaged over three years would give more weight to years when 1-hour SO_2 concentrations are well above the level of the standard, than to years when 1-hour SO_2 concentrations are just above the level of the standard. The Administrator also noted that a concentration-based form averaged over 3 years would likely be appreciably more stable than a no exceedance-based form (75 FR at 35541). Establishing a concentration-based form was also in agreement with specific CASAC advice stating that ‘‘there is adequate information to justify the use of a concentration-based form averaged over 3 years’’ (Samet 2009, p. 16)

[27] Since SO_2 is a pre-cursor to PM (e.g., sulfates), there was special consideration given to epidemiologic studies that used multipollutant models to separate the estimated SO_2 associations from that of PM.

In selecting a specific concentration-based form, the Administrator considered health evidence from the ISA as well as air quality and exposure information from the REA. In the ISA, it was noted that a few epidemiologic studies reported an increase in SO_2-related respiratory health effects at the upper end of the distribution of ambient SO_2 concentrations (i.e., above 90th percentile SO_2 concentrations; see U.S. EPA 2008, section 5.3). In the REA, air quality and exposure analyses suggested that a 99th percentile form was likely to be appreciably more effective at limiting 5-minute peak exposures of concern than a 98th percentile form (at a given standard level; U.S. EPA 2009, section 10.5.3, and U.S. EPA 2009, Figures 7–27 and 7–28). Taken together, the Administrator concluded that a 99th percentile form (at an appropriate level) would limit both the upper end of the distribution of ambient SO_2 concentrations reported in some epidemiologic studies to be associated with increased risk of SO_2-related respiratory morbidity effects (e.g., emergency department visits), as well as 5-minute peak SO_2 concentrations resulting in decrements in lung function and/or respiratory symptoms in controlled human exposure studies (75 FR at 35541).

Level

Controlled human exposure evidence was described in the ISA as providing the definitive evidence for a causal association between short-term exposure to SO_2 and respiratory morbidity. The Administrator therefore placed considerable emphasis on these studies when selecting the level of a new 1-hour standard. In particular, the Administrator concluded that the level of a 1-hour standard should provide substantial protection against the 200 ppb and 400 ppb 5-minute benchmarks identified from these studies. As noted above (see section 3.1.1), these benchmark levels were highlighted because in free-breathing controlled human exposure studies of exercising asthmatics: (1) 400 ppb represented the lowest concentration where moderate or greater lung function decrements occurred which were often statistically significant at the group mean level and were frequently accompanied by respiratory symptoms; and (2) 200 ppb was the lowest level at which moderate or greater decrements in lung function were found in some asthmatics.[28]

Analyses in the REA described the varying degrees of protection different 1-hour standard levels could provide against 5-minute benchmark concentrations of 200 ppb and 400 ppb (see below section 5.1). Considering these analyses, the Administrator judged that a 1-hour standard level of 100 ppb would appropriately limit the occurrence of 5-minute benchmark concentrations ≥ 200 or 400 ppb (75 FR at 35547). That is, the St. Louis exposure simulation estimated that a 1-hour standard at 100 ppb would likely protect > 99% of asthmatic children in that city at moderate or greater exertion from experiencing at least one 5-minute exposure ≥ 400

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[28] As noted in section 3.1.1, 200 ppb was also the lowest level tested in free-breathing controlled human exposure studies.

ppb per year, and approximately 97% of those asthmatic children at moderate or greater exertion from experiencing at least one exposure ≥ 200 ppb per year (75 FR at 35547). Moreover, the 40-county air quality analysis from the REA (see below section 5.1) estimated that a 100 ppb 1-hour standard would allow at most 2 days per year on average in any county when estimated 5-minute daily maximum SO_2 concentrations exceed the 400 ppb benchmark, and at most 13 days per year on average when 5-minute daily maximum SO_2 concentrations exceed the 200 ppb benchmark[29] (75 FR at 35546). Furthermore, given a simulated 1-hour 100 ppb standard level, most of the counties in that air quality analysis were estimated to experience 0 days per year on average when 5-minute daily maximum SO_2 concentrations exceed the 400 ppb benchmark and ≤ 3 days per year on average when 5-minute daily maximum SO_2 concentrations were estimated to exceed the 200 ppb benchmark (75 FR at 35546).

In considering the epidemiologic evidence with respect to level, the Administrator noted that there were more than 50 peer-reviewed epidemiologic studies published worldwide evaluating SO_2 since the prior review (75 FR at 35547). The Administrator also noted that these studies generally reported positive, although not always statistically significant associations between more serious health outcomes (i.e. respiratory-related emergency department visits and hospitalizations) and ambient SO_2 concentrations (75 FR at 35547). She further agreed with the ISA finding that the controlled human exposure evidence lends biological plausibility to the effects reported in epidemiologic studies (75 FR at 35547), and that when evaluated as a whole, the results of epidemiologic studies were generally independent of the effects of gaseous and particulate co-pollutants (75 FR at 35544 and 75 FR 35547). Taken together, the Administrator judged it appropriate to place emphasis on the epidemiologic evidence when further considering the appropriate level of a new 1-hour standard.

In considering the epidemiologic evidence with respect to level, the Administrator placed primary emphasis on ten U.S. epidemiologic studies (some conducted in multiple locations) reporting mostly positive and sometimes statistically significant associations between ambient SO_2 concentrations and emergency department visit and hospital admissions in locations where 99^{th} percentile 1-hour daily maximum SO_2 levels ranged from approximately 50–460 ppb (75 FR at 35547). The Administrator further noted that within this broader range of SO_2 concentrations there was a cluster of three epidemiologic studies between 78–150 ppb (for the 99^{th} percentile of the 1-hour daily maximum SO_2 concentrations) where the SO_2 effect estimate remained positive and statistically significant in multipollutant models with PM (NYDOH (2006), Ito et al., (2007),

[29] The REA considered 5-minute air quality data reported from the existing network of ambient monitors. However, since the number and geographic scope of monitors reporting 5-minute SO_2 concentrations was very limited, the REA used statistically estimated 5-minute concentrations derived from measured 1-hour SO_2 concentrations in the 40 county air quality analysis (see below, section 5.1).

and Schwartz et al., (1995)). The Administrator judged these three studies were of particular relevance because they supported both the conclusion that SO_2 effects were generally independent of PM and that these associations occurred in cities with 1-hour daily maximum, 99^{th} percentile concentrations in the range of 78–150 ppb (75 FR at 35547).

Weighing all of the evidence presented above, the Administrator concluded that the epidemiologic studies provided strong support for setting a standard that limited the 99^{th} percentile of the distribution of 1-hour daily maximum SO_2 concentrations to 75 ppb. This judgment took into account the strong determinations in the ISA, based on a much broader body of evidence, that there is a causal relationship between exposure to SO_2 and the types of respiratory morbidity effects reported in these studies (75 FR at 35548). This judgement also considered that a standard level of 75 ppb was consistent with the range of levels recommended by CASAC (75 FR at 35548). Finally, the Administrator acknowledged that there were some epidemiologic studies suggesting effects due to SO_2 at concentrations as low as 50 ppb, but did not find that evidence strong enough to warrant a standard at that level or below (75 FR at 35548).

Revoking the Then-Existing 24-hour and Annual Standards

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

3.1.3 Areas of Uncertainty

While the available scientific information informing the review completed in 2010 was stronger and more consistent than in previous reviews and provided a strong basis for decisions made in that review, the Agency recognized that important uncertainties and limitations remain in our understanding of several policy-relevant issues. These uncertainties were generally related to: (1) statistical relationships between 5-minute concentrations and longer averaging times (e.g., 1-hour, 3-hour, 24-hour), including the extent to which these longer averaging times can limit 5-minute concentrations of concern (i.e., 5-minute benchmarks) identified from controlled human exposure studies; (2) understanding the role of SO_2 within the complex ambient mixture of co-occurring pollutants (e.g., $PM_{2.5}$, ozone, NO_2); (3) understanding the range of ambient concentrations in which we have confidence that the health effects observed in epidemiologic studies are attributable to SO_2; (4) the extent to which monitored ambient SO_2

concentrations used in epidemiologic studies reflect exposures in study populations and; (5) characterization of SO_2 exposures and risk including alternative approaches for estimating risks associated with air quality simulated to just meet current or alternative standards.

3.2 GENERAL APPROACH FOR THE CURRENT REVIEW

The approach for this review builds on the substantial body of work done during the course of the last review, and will take into account the more recent scientific information and air quality data now available to inform our understanding of the key policy-relevant issues. The approach described below is most fundamentally based on using the EPA's assessment of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgments regarding primary standards for sulfur oxides that are requisite to protect public health with an adequate margin of safety. This approach will involve translating scientific and technical information into the basis for addressing a series of key policy-relevant questions using both evidence- and exposure/risk-based considerations.[30]

Figure 3-1 summarizes the general approach, including consideration of the policy-relevant questions which will frame the current review. The ISA, REA (if warranted), and PA developed in this new review will provide the basis for addressing the key policy-relevant questions and will inform the Administrator's judgment as to the adequacy of the current primary SO_2 standard and decisions as to whether to retain or revise this standard. This approach recognizes that the available health effects evidence generally reflects a continuum, consisting of ambient concentrations at which scientists generally agree that health effects are likely to occur, through lower concentrations at which the likelihood and magnitude of the response become increasingly uncertain. Furthermore, this approach is consistent with the requirements of the provisions of the CAA related to the review of NAAQS and with how the EPA and the courts have historically interpreted the CAA. As discussed in section 1.1 above, these provisions require the Administrator to establish primary standards that, in the Administrator's judgment, are requisite (i.e., neither more nor less stringent than necessary) to protect public health with an adequate margin of safety. The CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety. The four basic elements of the NAAQS (i.e., indicator, averaging time, form, and level) will be considered collectively in evaluating the health protection afforded by the current standard or any alternative standards considered.

[30] Evidence-based considerations include those related to the health effects evidence assessed and characterized in the ISA. Exposure/risk-based considerations draw from the results of the quantitative analyses.

We note that the final decision on the adequacy of the current standard and, if appropriate, on any potential alternative standards, is largely a public health policy judgment to be made by the Administrator. Scientific information and analyses about health effects, population exposure and risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses inform the Administrator's final decision. As in the previous review as well as other recent NAAQS reviews, the EPA will consider the implications of placing more or less weight or emphasis on different aspects of the scientific evidence and exposure/risk-based information to inform the public health policy judgments that the Administrator will make in reaching final decisions on whether to retain or revise the current standard in this review.

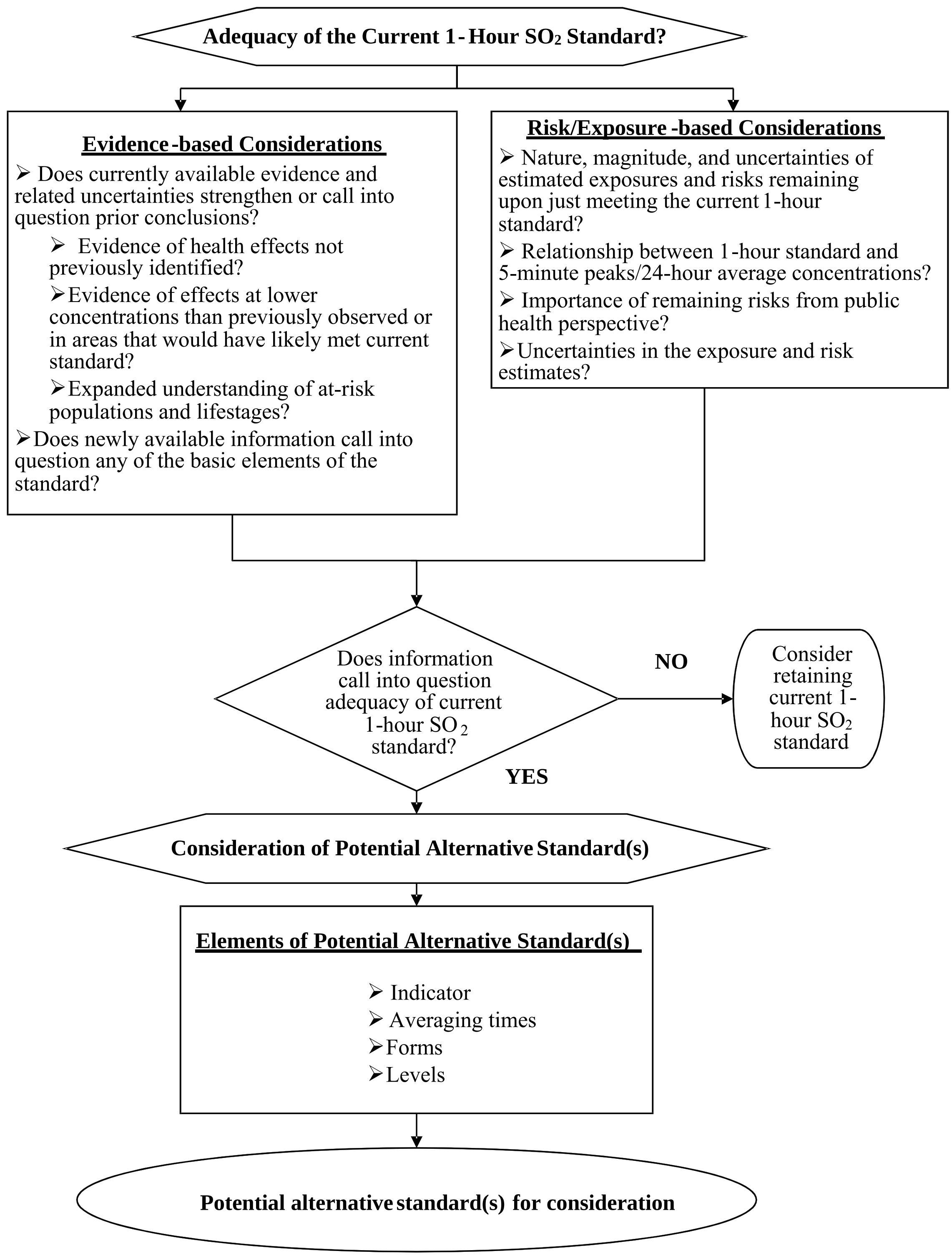

Figure 3-1 Overview of General Approach for Review of Primary SO_2 Standard

The initial overarching question in reviewing the adequacy of the current primary SO_2 NAAQS is whether the available body of scientific evidence, assessed in the ISA and used as a basis for developing or interpreting risk/exposure analyses, supports or calls into question the scientific conclusions reached in the last review regarding health effects related to exposures to sulfur oxides. The evaluation of the available scientific evidence and risk/exposure information with regard to adequacy of the current standard will focus on key policy-relevant issues by addressing a series of questions including the following:

- To what extent has new information altered the scientific support for the occurrence of health effects as a result of short- and/or long-term exposure to sulfur oxides in the ambient air?
    - What evidence is available from recent studies focused on specific chemical components within the broader group of sulfur oxides (e.g., SO_2, SO_3) to inform our understanding of the nature of exposures that are linked to various health outcomes?
    - To what extent is key scientific evidence becoming available to improve our understanding of the health effects associated with various time periods of exposures, including short-term (e.g., 5-minute, 1-hour, 24-hour) and long-term exposures (e.g., months to years)?
    - At what pollutant concentrations do these health effects occur? Is there evidence of effects at exposure concentrations lower than have been previously observed or in areas that would likely meet the current SO_2 primary standard?
    - To what extent are health effects associated with exposures to sulfur oxides, including SO_2, as opposed to one or more co-occurring pollutants (e.g., $PM_{2.5}$, ozone, NO_2)?
    - What are the important uncertainties and limitations associated with the scientific evidence?
- Has new information altered our understanding of human lifestages and populations that are particularly at increased risk for experiencing health effects associated with exposure to sulfur oxides?
    - Is there new information to shed light on the nature of the exposure-response relationship in different at-risk lifestages and/or populations?
    - Is there new or emerging evidence on health effects beyond respiratory effects in asthmatics, children, and the elderly that suggest additional at-risk populations and lifestages should be given increased focus in this review?
- What are the air quality relationships between short-term and longer-term exposures to SO_2?
    - As noted in section 1.3, as part of the final rulemaking the EPA for the first time required state reporting of either the highest 5-minute concentration for each hour of the day, or all twelve 5-minute concentrations for each hour of the day. To

what extent can this 5-minute monitoring data collected since the last review be used to further characterize the relationship between 5-minute peaks and longer term (e.g., 1-hour, 3-hour, 24-hour) average concentrations?

  - What are the important uncertainties associated with using a 1-hour NAAQS to protect against 5-minute peak concentrations of concern?

- To what extent does risk or exposure information suggest that exposures of concern (i.e., exposures above benchmark levels) are likely to occur in the general population, or in at-risk groups or lifestages considering recent ambient SO_2 concentrations or concentrations that just meet the current SO_2 standard?

  - Are the estimated risks/exposures considered in this review of sufficient magnitude such that the health effects might reasonably be judged to be important from a public health perspective?

  - What are the important uncertainties associated with any risk/exposure estimates?

- To what extent have important uncertainties identified in the last review been reduced and/or have new uncertainties emerged?
- To what extent does newly available information reinforce or call into question any of the basic elements of the current primary SO_2 standard? For example, does newly available 5-minute monitoring data and the air quality analyses based on this data call into question any of the basic elements of the current standard?

If the evidence suggests that revision of the current standard might be appropriate, the EPA will evaluate how the standard might be revised. Specifically, we will evaluate how the scientific information and assessments inform decisions regarding the basic elements of the primary SO_2 NAAQS: indicator, averaging time, form and level. These elements will be considered collectively in evaluating the health protection afforded by the current or any alternative standard(s) considered. Specific policy-relevant questions related to these standard elements include:

- To what extent does any new information provide support for the continued use of SO_2 as the *indicator* for sulfur oxides? Is there evidence to support using an *indicator* in addition to, or in place of SO_2?
- To what extent does the health effects evidence evaluated in the ISA continue to provide support for the existing 1-hour *averaging time*? Does the currently available information provide support for considering any different *averaging times*?
- To what extent do air quality analyses conducted since the last review suggest a standard with an *averaging time* of 1-hour or longer can protect against 5-minute and/or 24-hour concentrations of concern? Do these air quality analyses provide support for considering any different *averaging times*?

- To what extent do the ISA, air quality analyses, and other information provide support for consideration of alternative standard *forms*?
- What range of alternative standard *levels* should be considered based on the scientific evidence evaluated in the ISA, air quality analyses and, if warranted, in the REA[31] ?
- What are the important uncertainties and limitations in the available evidence and assessments and how might those uncertainties and limitations be taken into consideration in identifying alternative standard *indicators, averaging times, forms, and/or levels?*

[31] As outlined in Table 2-1 and discussed in Chapter 5 below, the REA Planning Document will consider the extent to which newly available scientific evidence and tools/methodologies warrant the conduct of new quantitative risk and exposure assessments. To the extent completely new assessments are not developed for this review, assessments from the last review may be interpreted in light of the newly available information in addressing the key policy questions for the review.

4. SCIENCE ASSESSMENT

The ISA comprises the science assessment phase of the SO_2 NAAQS review. As described in section 1.4 above, this assessment focuses on updating the air quality criteria associated with health evidence to inform the review of the primary SO_2 standard only.[32]

4.1 SCOPE OF THE ISA

The ISA will critically evaluate and integrate the scientific information on exposure and health effects associated with SO_X in ambient air in the discipline areas of atmospheric science, human exposure, dosimetry, epidemiology, controlled human exposure, and toxicology, with consideration of effects in both the general population and at-risk lifestages and populations. The purpose of the discussions within the ISA is not to provide a detailed literature review but to draw upon the existing body of evidence to synthesize the current state of knowledge on the most relevant issues pertinent to the review of the NAAQS for SO_2, to identify changes in the scientific evidence base since the previous review, and to describe remaining or newly identified uncertainties. The ISA discussions will be designed to focus on the key policy-relevant questions described in Chapter 3.

The current ISA will focus on literature published since the 2008 ISA for SO_X – Health Criteria and integrate this newer evidence with evidence considered in the last review. Key findings, conclusions, and uncertainties from the 2008 ISA for SO_X will be briefly summarized at the beginning of the ISA and individual sections. The results of recent studies will be integrated with previous findings. In evaluation of controlled human exposure and animal toxicological studies, emphasis will be placed on studies that examine health effects relevant to humans and on SO_X concentrations that represent the range of human exposures across various ambient microenvironments. However, in recognition of the fact that controlled human exposure and animal toxicological studies do not necessarily reflect effects in the most sensitive populations, studies at higher exposure concentrations will be included when they provide information relevant to previously unreported effects, evidence of the potential biological mechanism for an observed effect, or information on exposure-response relationships.

[32]Note that evidence related to environmental effects of SO_X will be considered in the separate science assessment conducted as part of the review of the secondary NAAQS for NO_2 and SO_2.

4.2 ORGANIZATION OF THE ISA

The organization of the ISA will be consistent with that used in the recent assessments for other criteria pollutants, e.g., the ISA for Ozone and Related Photochemical Oxidants (U.S. EPA, 2013b). The ISA will begin with a discussion of major legal and historical aspects of prior review documents as well as procedures for the assessment of scientific information. An integrative synthesis chapter will summarize the key information for each topic area, the causal determinations for relationships between exposure to SO_X and health effects, information describing the extent to which health effects can be attributable specifically to SO_X, and other uncertainties related to the interpretation of scientific information. The integrative synthesis chapter also will present a discussion of policy-relevant issues such as the exposure averaging times and lags associated with health effects, the concentration-response relationships including whether or not the evidence supports identification of a discernible threshold below which effects are not likely to occur, and the public health significance of health effects associated with exposure to SO_X. Subsequent chapters are organized by subject area (see draft outline of the ISA in Appendix A) and contain the detailed evaluation of results of recent studies integrated with previous findings (see section 4.4 for specific issues to be addressed). Sections for each major health effect category (e.g., respiratory effects) conclude with a causal determination about the relationship with relevant exposures to SO_X. The ISA will conclude with a chapter that examines exposure and health outcome data to draw conclusions about potential at-risk lifestages and populations.

The ISA may be supplemented with additional materials if required to support information contained within the ISA. These supplementary materials may include more detailed and comprehensive coverage of relevant publications and may accompany the ISA or be available in electronic form as output from the Health and Environmental Research Online (HERO) database developed by EPA (http://hero.epa.gov/). Supplementary information available in the HERO database will be presented as electronic links in the ISA.

4.3 ASSESSMENT APPROACH

4.3.1 Introduction

NCEA is responsible for preparing the ISA. In each NAAQS review, development of the science assessment begins with a "Call for Information" published in the *Federal Register*. This notice announces EPA's initiation of activities in the preparation of the ISA for the specific NAAQS review and invites the public to assist through the submission of research studies in the identified subject areas. This and subsequent key components of the process currently followed for the development of an ISA (i.e., the development process) are presented in Figure 4.1 and are described in greater detail in the Preamble to the ISA for Lead (U.S. EPA, 2013a). How the ISA fits into the larger NAAQS review process is briefly described in Section 1.2, the Overview of the Review Process.

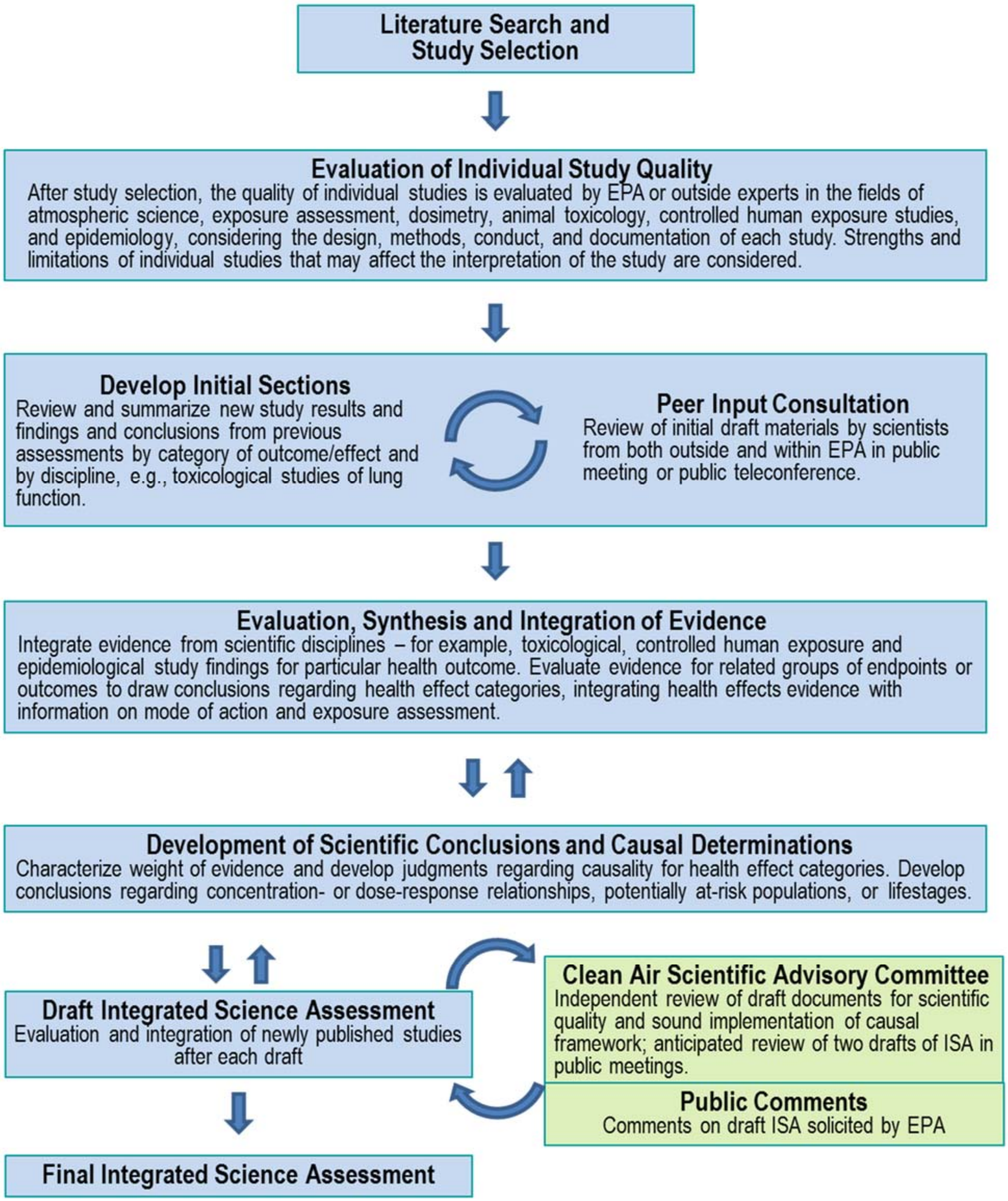

Figure 4-1. General Process for Development of Integrated Science Assessments (ISAs)
(Modified from Figure III of the Preamble to the ISA for Lead, U.S. EPA, 2013a)

Important aspects of the development of the ISA are described in the sections below, including the approach for searching the literature, identifying relevant publications, evaluating individual study quality, synthesizing and integrating the evidence, and developing scientific conclusions and causality determinations. These responsibilities are undertaken by expert authors of the ISA chapters which include EPA staff with extensive knowledge in their respective fields and extramural scientists solicited by EPA for their expertise in specific fields. This section of the IRP also presents specific policy-relevant questions developed from input received at the SO_X kickoff workshop on science policy issues. These questions are intended to guide the development of the ISA. The process for scientific and public review of drafts of the ISA is described in Section 4.5.

4.3.2 Literature Search and Selection of Relevant Studies

NCEA uses a structured approach to identify relevant studies for consideration and inclusion in the ISA. A *Federal Register* notice is published to announce the initiation of a review and to request information, including relevant literature, from the public. The EPA maintains an ongoing, multi-tiered literature search process that includes extensive manual and computer-aided citation mining of databases on specific topics in a variety of disciplines. The search strategies are designed a priori and iteratively modified to optimize identification of pertinent publications. In addition, papers are identified for inclusion in several other ways: relational citation searches that identify recent publications that have cited references from previous assessments; specialized searches on specific topics; identification of relevant literature by external scientific experts; recommendations from the public and CASAC during the call for information and external review process; and review of citations in previous assessments. The studies identified will include research published or accepted for publication from January 2008, which slightly precedes the publication end date for studies reviewed in the 2008 ISA, through approximately two months before the release of the second external review draft of the ISA (target of November 2015, see Table 2-1).

References identified through this multipronged search strategy are reviewed for relevance. Some publications are excluded based on screening of the title. Publications considered for inclusion in the ISA after reading the title are listed in the Health and Environmental Research Online (HERO) database (http://hero.epa.gov). Studies and reports that have undergone scientific peer review and have been published or accepted for publication are considered for inclusion in the ISA.

From the group of considered references, references are selected for inclusion in the ISA based on review of the abstract and full text. The references cited in the ISA include a hyperlink to the HERO database. The selection process is based on the extent to which the study is potentially informative, pertinent, and policy-relevant. These studies include those that provide a basis for or describe the relationship between the criteria pollutant and effects, in particular, those studies that offer innovation in method or design and studies that reduce uncertainty on critical issues. Uncertainty can be addressed, for example, by analyses of potential confounding or effect modification by copollutants or other factors, analyses of concentration-response or dose-response relationships, or analyses related to time between exposure and response. The ISA will include studies published since the 2008 ISA; however, evidence from previous studies will be included to integrate with results from recent studies and, in some cases, characterize the key policy-relevant information in a particular subject area. Analyses conducted by the EPA using publicly available data, for example, air quality and emissions data, also are considered for inclusion in the ISA. The combination of approaches described above is intended to produce the comprehensive collection of pertinent studies needed to address the key scientific issues that form the basis of the ISA.

4.3.3 Evaluation of Individual Study Quality

After selecting studies for inclusion, individual study quality is evaluated by considering the design, methods, conduct, and documentation of each study, but not the study results. This uniform approach aims to consider the strengths, limitations, and possible roles of chance, confounding, and other biases that may affect the interpretation of the results from individual studies. In general, in assessing the scientific quality of studies, the following parameters are considered:

- How clearly were the study design, study groups, methods, data, and results presented to allow for study evaluation?
- To what extent are the air quality data, exposure, or dose metrics of adequate quality to serve as credible exposure indicators?
- Were the study populations, subjects, or animal models adequately selected, and are they sufficiently well-defined to allow for meaningful comparisons between study or exposure groups?
- Are the statistical analyses appropriate, properly performed, and properly interpreted?
- Are likely covariates (i.e., potential confounding factors, modifying factors) adequately controlled for or taken into account in the study design or statistical analyses?
- Are the health endpoint measurements meaningful, valid, and reliable?

Additional considerations specific to particular scientific disciplines are discussed below.

Atmospheric Science and Exposure Assessment

Atmospheric science and exposure assessment studies focus on measurement of, behavior of, and exposure to ambient air pollution using quality-assured field, experimental, and/or modeling techniques. The most informative measurement-based studies will include detailed descriptive statistics for high-quality measurements taken at varying spatial and temporal scales.

These studies will also include a clear and comprehensive description of measurement techniques and quality control procedures used. Quality control metrics (e.g., method detection limits) and quantitative relationships between and within pollutant measurements (e.g., regression model coefficients, intercepts, and fit statistics) should be provided when appropriate. Measurements including contrasting conditions for various time periods (e.g., weekday/weekend, season), populations, regions, and categories (e.g., urban/rural, proximity to various source sectors) are particularly useful. The most informative modeling-based studies will incorporate appropriate chemistry, transport, dispersion, and/or exposure modeling techniques with a clear and comprehensive description of model science, evaluation procedures, and metrics.

Exposure measurement error, which refers to inaccuracies in the characterization of the exposures of study participants, can be an important contributor to uncertainty in air pollution epidemiologic study results. Exposure measurement error can influence observed epidemiologic associations between ambient pollutant concentrations and health outcomes by biasing effect estimates toward or away from the null and widening confidence intervals around those estimates (Zeger et al., 2000). Factors that could influence exposure estimates include, but are not limited to, nonambient sources of exposure, topography of the natural and built environment, meteorology, air quality measurement instrument or model uncertainties, time-activity patterns, and the infiltration into indoor environments. Additional information present in high-quality exposure studies includes location and activity information from diaries, questionnaires, global positioning system data, or other means, as well as information on commuting patterns. In general, atmospheric science and exposure studies focusing on the variety of locations pertinent to the range of exposures in the U.S. will have maximum value in informing review of the NAAQS.

Epidemiology

In evaluating quality of inference about health effects in epidemiologic studies, EPA additionally considers whether a given study: (1) presents quantitative information on associations of health effects with short- or long-term exposures that represent ambient concentrations of SO_X across various microenvironments; (2) examines health effects of SO_X; (3) assesses SO_X as a component of a complex mixture of air pollutants by considering concentrations of copollutants, correlations of SO_X with these copollutants, potential copollutant interactions (e.g., synergistic effects of SO_X with other pollutants), potential copollutant confounding (e.g., bias of associations observed between SO_X and health endpoints by the effects of copollutants), and other methods to assess the independent effect of SO_X; (4) evaluates health endpoints not previously extensively researched; (5) evaluates lifestages and populations that potentially are at increased risk of health effects related to SO_X; (6) examines other potential confounding factors or effect modifiers (e.g., socioeconomic status); and (7) examines important methodological issues (e.g., lag or time period between exposure and effects, model specifications, thresholds, mortality displacement) related to the health effects of exposure to SO_X. Among epidemiologic studies characterized as high quality by these parameters, emphasis will be given to multicity studies that employ standard methodological analyses for evaluating effects of SO_X across cities, provide overall estimates for effects by pooling information across cities, and examine consistency of results across cities. To address specific issues relevant to standard setting in the U.S., such as regional heterogeneity in effects, emphasis will be placed on studies that involve exposures that are relevant to current U.S. populations (e.g., studies conducted in the U.S. or Canada).

Controlled Human Exposure and Animal Toxicology

Controlled human exposure and animal toxicological studies experimentally evaluate the health effects of administered exposures in human volunteers and animal models under highly controlled laboratory conditions. Controlled human exposure studies are also referred to as human clinical studies and, as noted above, provided the definitive evidence for a causal relationship between short-term exposure to SO_2 and respiratory morbidity in the previous review. These experiments allow investigators to expose subjects to known concentrations of SO_X under carefully regulated environmental conditions and activity levels. In addition to the general quality considerations discussed previously, evaluation of controlled human exposure and animal toxicological studies includes assessing the design and methodology of each study with focus on (1) characterization of the exposure concentration, dosing regimen (e.g., duration, activity level), and exposure route; (2) characterization of the pollutant(s); (3) sample size and statistical power to detect differences; and (4) control of other variables that could influence the occurrence of effects. The evaluation of study design generally includes consideration of factors that minimize bias in results such as randomization, blinding and allocation concealment of study subjects, investigators, and research staff, and unexplained loss of animals or withdrawal/exclusion of subjects. Additionally, studies must include appropriate control groups and exposures to allow for accurate interpretation of results relative to exposure. Emphasis is placed on studies that address concentration-dependent responses or time-course of responses and studies that investigate potentially at-risk lifestages and populations (e.g., with pre-existing disease), recognizing that controlled human exposure studies typically examine effects in groups of relatively healthy individuals, often adults, who do not represent the full range of susceptibilities in the general population. In addition, consideration will be given to studies that investigate exposure to SO_X separately and in combination with other pollutants such as ozone and particulate matter.

Controlled human exposure or animal toxicological studies that approximate expected human exposures in terms of concentration, duration, and route of exposure are of particular interest. To best inform reviews of the NAAQS, evaluation of the evidence goes beyond a determination of causality at any dose or concentration to emphasize the relationship apparent at relevant pollutant exposures. Relevant pollutant exposures are considered to be those generally within two orders of magnitude of ambient concentrations measured across various microenvironments. Studies using higher concentration exposures or doses will be considered to the extent that they provide information relevant to understanding mode of action or mechanisms, interspecies variation, or at-risk human lifestages and populations. In vitro studies may be included if they provide mechanistic insight for effects examined in vivo or in epidemiologic studies.

4.3.4 Integration of Evidence and Determination of Causality

EPA has developed a consistent and transparent basis for integration of scientific evidence and evaluation of the causal nature of air pollution-related health or welfare effects for use in developing ISAs, as described in the online Preamble to the ISA for Lead (U.S. EPA, 2013a). Evidence from across scientific disciplines for related health effects is evaluated, synthesized, and integrated to develop conclusions and causality determinations. This includes consideration of strengths and weaknesses in the overall collection of studies across disciplines. Confidence in the collective body of evidence is based on evaluation of study design and quality. The relative importance of different types of evidence to the conclusions varies by pollutant or assessment, as does the availability of different types of evidence for causality determination. Consideration of human health effects is informed by controlled human exposure, epidemiologic, and toxicological studies. Other evidence including mechanistic evidence, toxicokinetics, and exposure assessment may be highlighted if it is relevant to the evaluation of health effects and if it is of sufficient importance to affect the overall evaluation. Causal inference can be strengthened by the integration of evidence across disciplines. A weak inference from one line of evidence can be bolstered by other lines of evidence and their coherence can add support to a cause-effect interpretation of the association. Scientists will also evaluate uncertainty in the scientific evidence, considering issues such as: generalizing results from a small number of controlled human exposure subjects to the broader population, including at-risk lifestages and populations; quantitative extrapolations of observed pollutant-induced pathophysiological alterations from laboratory animals to humans; confounding by co-exposure to other ambient pollutants or meteorological factors; the potential for effects due to exposure to air pollution mixtures; and the influence of exposure measurement error on epidemiologic study findings.

The ISA will evaluate the evidence for causal relationships between observed health outcomes and SO_X exposures using a five-level hierarchy that classifies the weight of evidence for causation. Determination of causality involves the evaluation and integration of evidence across disciplines for major outcome categories (e.g., respiratory effects) or groups of related endpoints. Key considerations in drawing conclusions about causality include consistency of findings for an endpoint across studies, biological plausibility, and coherence of the evidence across disciplines and across related endpoints, including key events that inform modes of action (see Table I in Preamble to the ISA for Lead, U.S. EPA, 2013a). In discussing the causal determination, EPA characterizes the evidence on which the judgment is based, including strength of evidence for individual endpoints within the outcome category or group of related endpoints. The ISA will place emphasis on studies conducted with SO_X exposure concentrations representative of those across various ambient microenvironments. In addition, EPA evaluates evidence relevant to understand the quantitative relationships between pollutant exposures and health effects. This includes evaluating the concentration-, exposure-, or dose-response relationships and, to the extent possible, drawing conclusions on the levels at which effects are observed.

4.3.5 Quality Management

NCEA participates in the Agency-wide Quality Management System, which requires the development of a Quality Management Plan (QMP; www.epa.gov/QUALITY/qmps.html). Implementation of the ORD-wide and NCEA QMP ensures that all data generated or used by NCEA scientists "have a degree of confidence in the quality of the data; and, are of the type and quality appropriate for their intended use" and that all information disseminated by NCEA adheres to a high standard for quality including objectivity, utility, and integrity. Quality assurance (QA) measures detailed in the QMP are being employed for the current SO_X review, including the development of the ISA. The NCEA QA staff are responsible for the review and approval of quality-related documentation. NCEA scientists are responsible for the evaluation (and documentation) of all inputs to the ISA, including primary (new) and secondary (existing) data, to ensure their quality is appropriate for their intended purpose. NCEA adheres to the use of Data Quality Objectives, which clarify project objectives, define the appropriate type of data used in the project, and specify tolerable levels of confidence in the data and tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to identify the most appropriate inputs to the science assessment. The approaches utilized to search the literature and criteria for study selection and evaluation were detailed in the two preceding subsections. Generally, NCEA scientists rely on scientific information found in peer-reviewed journal articles, books, and government reports. Where information is integrated, re-analyzed, modeled, or reduced from multiple sources to create new figures, tables, or summation, the data generated are considered to be new and are documented and subjected to rigorous quality assurance and quality control measures to ensure their accuracy, validity, and reproducibility.

4.4 SPECIFIC ISSUES TO BE ADDRESSED IN THE ISA

The organization of the ISA will be consistent with that used in the recent assessments for other criteria pollutants (e.g., ISA for O_3, U.S. EPA, 2013b). Development of the ISA will be guided by policy-relevant questions that frame the entire review of the primary SO_2 NAAQS. These policy-relevant questions are related to two overarching issues. The first issue is whether new evidence reinforces or calls into question the evidence presented and evaluated in the last NAAQS review with respect to factors such as the concentrations of SO_X exposure associated with health effects and plausibility of health effects caused by SO_X exposure. The second issue is whether uncertainties from the last review have been reduced and/or whether new uncertainties have emerged. This includes identifying research areas that lack adequate data. Specific questions that will be addressed in the ISA are listed subsequently by topic area. In the ISA, these topic areas will be discussed in separate chapters or sections. The beginning of the ISA will include an integrative synthesis chapter that summarizes the key information for each topic area and the causal determinations. The integrative synthesis chapter also presents a discussion of policy-relevant issues such as the exposure metrics, averaging times, and lags associated with health effects, the concentration-response relationship including threshold for effects, and public health significance of health effects associated with exposure to SO_X (see Appendix).

A. Air Quality and Atmospheric Chemistry: The ISA will present and evaluate data related to ambient concentrations of SO_X; sources leading to the presence of SO_X in the atmosphere; and chemical reactions that determine the formation, degradation, and lifetime of SO_X in the atmosphere. The 2008 ISA concluded that most anthropogenic SO_2 is emitted from elevated point sources such as the stacks of power plants and industrial facilities, many of which are located in the eastern U.S., leading to a strong east-west gradient in SO_2 concentrations. Non-anthropogenic sources, such as volcanoes, are important in some areas. SO_2 is removed from the atmosphere both by deposition and by oxidation to sulfate, resulting in a typical atmospheric lifetime of <1 to 4 days, depending on local conditions. Mean U.S. daily 1-hour max SO_2 concentrations in 2003-05 were approximately 13 ppb, with a 99th percentile value of 95 ppb and a maximum measured value of approximately 700 ppb. The large differences between 99th percentile and maximum values suggest that the maxima are strongly limited spatially and temporally and are not a major determinant of the mean values. At the time of the 2008 ISA, the very limited 5-minute SO_2 data available showed that the median of the maximum 5-minute value in an hour ranged from 1-8 ppb, while the 99th percentile ranged from 21-184 ppb, depending on location (U.S. EPA, 2008, section 5.1). In the current ISA, description of the atmospheric chemistry of SO_X will include both gaseous and particulate species in order to provide a complete analysis, although the health effects of particulate SO_X are discussed in the review of the NAAQS for particulate matter (PM). SO_2 is the most important of the gas-phase sulfur oxides for both atmospheric chemistry and health effects and is expected to be the focus of the ISA. SO_X is usually defined to include sulfur trioxide (SO_3) and gas-phase sulfuric acid (H_2SO_4) as well, but neither species is present in the atmosphere in concentrations significant for human exposures. In the current review, specific policy-relevant questions related to air quality and atmospheric chemistry that will be addressed include the following:

- What are the main and emerging sources of ambient gas-phase SO_X, and how have new fuels, emission standards, and technologies changed the magnitude and composition of SO_X emissions?
- What progress has been made in improving measurements and reducing interference problems in measuring SO_X, particularly for concentrations near the method detection limit? What limitations still remain?
- Based on recent air quality and emissions data, what are current emissions and concentrations of SO_X? How have emissions and concentrations of SO_X changed since the 2008 ISA? To what extent can other techniques, such as satellite data, photochemical modeling, and dispersion modeling, be used to improve the characterization of SO_X concentrations?
- What spatial and temporal patterns can be seen in SO_X concentrations? In particular, what patterns can be seen near point and other sources of SO_X? What do monitoring,

satellite data, and dispersion and photochemical modeling results indicate regarding spatial patterns on neighborhood, urban, regional, and national scales?

- What are the relationships among SO_X concentrations measured with different averaging times (e.g., 5-minute, 1-hour, 24-hour)?
- What are the relationships among SO_X concentrations and concentrations of other pollutants, such as sulfate, other components of particulate matter, and gaseous pollutants?
- What information is available regarding the capabilities of AERMOD and other air quality models for estimating SO_X concentrations, particularly at the upper end of the air quality distribution?
- Based on air quality and emissions data on SO_X and atmospheric chemistry models, what are likely background concentrations of SO_X in the absence of anthropogenic emissions?

B. Human Exposure to Ambient SO_X: The ISA will evaluate the factors that influence human exposure to ambient SO_X and the uncertainties associated with extrapolation from ambient concentrations to personal exposures to SO_X of ambient origin, particularly in the context of interpreting results from epidemiologic studies. As described in the 2008 ISA, many exposure studies were unable to characterize the relationship between personal exposure and ambient SO_2 due to indoor and outdoor concentrations that were below the detection limit of passive personal samplers. However, in studies with personal measurements above detection limits, a reasonably strong association was observed between personal SO_2 exposure and ambient concentrations (U.S. EPA, 2008, section 5.3). At the time of the 2008 ISA, no studies had evaluated the relationship between community average exposure and ambient concentrations, which is more directly relevant to many epidemiologic study designs, although the ISA concluded that intracommunity variations in the personal-ambient relationship would generally tend to widen the confidence interval rather than bias the effect estimate. Uncertainties differ according to the exposure period of interest as most short-term exposure studies (e.g., population-level studies using time-series analyses, field/panel studies) rely on temporal variation in exposure while long-term exposure studies (e.g., longitudinal cohort studies) rely on spatial variability of exposure. In the current review, specific policy-relevant questions related to exposure that will be addressed include the following:

- What are the relationships between SO_X measured at stationary monitoring sites and personal exposure to SO_X over different time scales? What evidence is available regarding these relationships in environments near point sources, ports, or other sources? What uncertainties remain regarding these exposures of interest?

- What new information is available regarding microenvironmental SO_X concentrations and personal exposures to SO_X? What are the capabilities of currently available exposure measurement techniques?
- What new information exists regarding characterization of error in SO_X exposure assessment and how it influences personal-ambient exposure relationships?
- What information is available regarding differences in SO_X exposure patterns and personal-ambient exposure relationships among various lifestages and populations, particularly at-risk groups?
- What new information exists regarding SO_X measurements in a multipollutant context? What are the relationships between SO_X exposures and exposures for other pollutants, such as sulfate, other components of particulate matter, and gaseous pollutants?
- How does uncertainty in exposure estimates inform interpretation of epidemiologic, controlled human exposure, and toxicological studies?

C. Dosimetry and Modes of Action: The ISA will evaluate literature focusing on dosimetry and modes of action that may underlie the health outcomes associated with exposure to SO_X. These topic areas will be evaluated using both human and animal data. The 2008 ISA concluded that SO_2 is readily absorbed in the nasal passages due to its high water solubility; with increased ventilation rates during exercise, the pattern of SO_2 absorption shifts from the upper airways to the tracheobronchial airways in conjunction with a shift from nasal to oronasal breathing (U.S. EPA, 2008, section 5.2). The compound most directly responsible for the health effects may be the inhaled SO_2 and/or its chemical reaction products such as hydrogen ions, bisulfite anions and sulfite anions which are formed when SO_2 contacts the fluids lining the airway. One of the principal effects of inhaled SO_2 is bronchoconstriction, mediated by chemosensitive receptors that trigger nervous system reflexes. Preexisting inflammation may lead to enhanced sensitivity in asthmatics due to enhanced release of mediators, alterations in the autonomic nervous system, and/or sensitization of the chemosensitive receptors. In the current review, specific policy-relevant questions related to dosimetry and modes of action that will be addressed include the following:

- What SO_X reaction products can be found in the respiratory tract cells, tissues, or fluids that may serve as markers of SO_X exposure and effect?
- What information is available on the following dosimetric and mechanistic factors:

- The regional pattern of SO_X-induced injury/perturbation in the respiratory tract?
- Inter-individual variability of responses that may enhance the risk of an adverse health effect?
- Homology of responses between animals and humans?

- What are the potential biological mechanisms underlying responses to SO_X at or near environmentally relevant exposures?
- What new information is available related to the modes of action for health effects associated with exposure to SO_X?
- Do interactions between inhaled SO_X and other inhaled pollutants influence the mechanisms underlying the toxic potential of SO_X?
- What are the effects of host factors such as lifestage, sex, pre-existing disease, genetic background, and physical activity on SO_X uptake, cellular and tissue responses, and their underlying mechanisms? Are there critical windows of exposure (e.g., prenatal) that result in different effects and/or effects at lower exposures?
- What information is available to discern the relative contribution of SO_X derived exogenously from ambient exposures to endogenous SO_2 and is there evidence for any alteration in function due to the former?

D. Health Effects: The 2008 ISA concluded that there is a causal relationship between respiratory morbidity and short-term exposure to SO_2, based on consistent and coherent evidence from controlled human exposure, epidemiologic, and animal toxicological studies. The definitive evidence for the causal relationship came from controlled human exposure studies that reported respiratory symptoms and decreased lung function in exercising asthmatics following 5-10 minute exposures to SO_2; in addition, numerous epidemiologic studies reported associations between short-term SO_2 exposures and respiratory symptoms and hospitalizations (U.S. EPA, 2008, section 5.2). The ISA also concluded that the evidence is suggestive of a causal relationship between short-term exposure to SO_2 and mortality, and that the evidence is inadequate to infer a causal relationship between short-term exposure to SO_2 and cardiovascular effects or between long-term exposure to SO_2 and morbidity and mortality. The current ISA will evaluate the literature related to respiratory, cardiovascular, reproductive and developmental health effects, mortality, and cancer associated with SO_X exposure. Other health effects may also be evaluated, such as those related to the central nervous system. Health effects that occur following both short- and long-term exposures will be evaluated as examined in epidemiologic, controlled human exposure, and animal toxicological studies, and causality determinations will be developed for each type of health effect. Efforts will be directed at identifying the lower concentrations at which effects are observed, including effects in populations and lifestages potentially at increased risk of SO_X-induced health effects, and assessing the role of SO_X within the broader mixture of ambient pollutants. Discussions about lack of associations at lower levels potentially due to insufficient statistical power will be included. The discussion of health effects also will be integrated with relevant information on dosimetry and modes of action. In the current review, specific policy-relevant questions related to health effects that will be addressed include the following:

- What do controlled human exposure, animal toxicological, and epidemiologic studies indicate regarding the relationship between short-term (i.e., minutes to one month) exposures to SO_X and health effects of concern, including the nature and time course, in healthy individuals and in those with pre-existing disease states (e.g., people with asthma or cardiovascular disease) or other factors (e.g., lifestage, genetic variants, nutritional deficiencies) that potentially modify the risk of SO_X-induced health effects? What information is available that reduces uncertainties identified in the previous ISA, such as exposure measurement error and the potential for copollutant confounding?
- How do results of recent studies expand current understanding of the relationships between long-term (i.e. more than one month to years) exposure to SO_X and chronic respiratory effects manifested as permanent lung tissue damage, a reduction in baseline lung function, or a reduction in lung function growth? To what extent does long-term SO_X exposure promote exacerbation and development of asthma or other chronic lung diseases, cardiovascular diseases, and other conditions? Are there certain lifestages that are especially vulnerable to the development of these chronic conditions? What is the relationship between SO_X exposure and all-cause mortality and cause-specific mortality?
- To what extent does the scientific evidence support the occurrence of health effects from long-term SO_X exposure at ambient concentrations that are lower than those previously observed? If so, what uncertainties are related to these associations and are the health effects in question important from a public health perspective?
- To what extent does short-term or long-term exposure to SO_X contribute to health effects beyond the respiratory and cardiovascular systems (e.g., reproductive, developmental, cancer)?
- What is the extent of coherence of findings for small changes in lung function, airway hyperresponsiveness, heart rate variability, and vasomotor function and changes in health effects such as hospital admissions, emergency department visits, and mortality? What other biomarkers of early effect may be used in the assessment of health effects?
- What evidence is available regarding the shape of concentration-response relationships between short-term and long-term SO_X exposure and health effects?

- What evidence is available regarding the nature of health effects from the combination of SO_X and other ambient air pollutants in comparison to health effects following exposure to SO_X alone? Does the evidence indicate differential effects of SO_X from different source types?
- What do results from studies conducted in environments near SO_X sources indicate about the health effects of long-term or repeated SO_X exposures?
- To what extent does information across scientific disciplines on the pattern and/or exposure regime of SO_X exposure (e.g., peak, repeated peak, average) provide understanding of the time course for changes in health effects? What information is available on time-activity patterns of study subjects such as time spent outdoors or activity levels that can aid in the understanding of the nature of exposure or dosimetry of ambient SO_X concentrations that are associated with health effects?
- To what extent do data across scientific disciplines provide information on health effects related to various short-term SO_X exposure indices or averaging times relevant to the 1-hour standard? What data exist comparing associations of health effects among various short-term SO_X exposure metrics (e.g., 1-hour versus 24-hour)?
- What evidence is available regarding health effects related to long-term exposure windows other than annual or lifetime average (e.g., preconception, pregnancy average)? What data are available comparing associations of health effects among various long-term SO_X exposure metrics (e.g., annual, seasonal, pregnancy average)? Are there critical windows of human development that are associated with the development of chronic respiratory disease?
- To what extent are the observed epidemiologic health effect associations attributable to ambient SO_X, another ambient pollutant, or to the pollutant mixtures that SO_X may be representing? To what extent do findings from experimental studies provide biological plausibility?

E. Populations and Lifestages Potentially at Increased Risk of SO_X-Induced Health Effects: The 2008 ISA found substantial evidence from epidemiologic and controlled human exposure studies that asthmatic individuals are more susceptible to respiratory health effects from SO_2 exposures than the general public (U.S. EPA, 2008, section 5.4). The ISA also presented limited evidence that children and older adults (≥ 65 years) are potentially at increased risk of SO_2-induced respiratory effects. Since completion of the 2008 ISA, EPA has developed an additional framework to provide a consistent and transparent basis for classifying the weight of evidence for populations and/or lifestages being at increased risk according to one of four levels: adequate evidence, suggestive evidence, inadequate evidence, and evidence of no effect (see Table 5-1 of ISA for Lead, U.S. EPA, 2013a). In the framework, key considerations in drawing such conclusions include consistency of findings for a factor within a discipline and coherence of the evidence across disciplines. The current ISA will examine exposure and health outcome data to draw conclusions about specific populations or lifestages that are potentially at increased risk of SO_X-induced health effects. Estimation of the sizes of potential populations and lifestages at increased risk and discussion of the public health significance of the health outcomes characterized to result from ambient SO_X exposure may be included. Potential populations or lifestages at increased risk can be characterized by a variety of factors: intrinsic factors (biological factors such as age, genetic variants), extrinsic factors (nonbiological factors such as diet, lower socioeconomic status), and/or factors affecting dose or exposure (age, outdoor activity or work). It is important to note that some factors could be in more than one category and some factors are interconnected (e.g., low socioeconomic status [extrinsic] and comorbidities [intrinsic]). In the current review, specific policy-relevant questions related to populations and lifestages potentially at increased risk of SO_X-induced health effects that will be addressed include:

- Based on evidence integrated across studies and disciplines that examine factors which may increase exposure to or dose of SO_X and/or risk of SO_X-induced health effects, what conclusions can be drawn about the presence of at-risk lifestages (e.g., children, older adults) and/or populations?
- Studies from which disciplines contribute information about particular at-risk lifestages and populations, and to what extent does limited or lack of information from specific disciplines produce uncertainty in conclusions about at-risk lifestages and populations?
- How does new information augment that evaluated in the 2008 ISA regarding populations with pre-existing respiratory disease or genetic variants as well as lifestages potentially at increased risk of SO_X-induced health effects?
- What is the extent of the coherence of evidence regarding potential at-risk lifestages or populations for both short- and long-term exposures to SO_X?
- What quantitative information is available that characterizes the magnitude of greater biological response or risk of health effects in at-risk lifestages or populations?

4.5 SCIENTIFIC AND PUBLIC REVIEW

Drafts of the ISA will be made available for review by the CASAC SO_X primary NAAQS review panel and the public as indicated in Figure 4-1 above; availability of draft documents will be announced in the *Federal Register*. The CASAC panel will review the draft ISA documents and discuss their comments in public meetings that will be announced in the

Federal Register. EPA will take into account comments, advice, and recommendations received from the CASAC panel and from the public in revising the ISA. EPA has established a public docket for the development of the ISA. After appropriate revision based on comments received from CASAC and the public, the final document will be made available on an EPA website and in hard copy. A notice announcing the availability of the final ISA will be published in the *Federal Register*.

5. QUANTITATIVE RISK AND EXPOSURE ASSESSMENTS

In reviewing primary NAAQS, the EPA develops quantitative analyses to estimate the human exposures and/or health risks that are associated with just meeting existing standards and, when appropriate, with just meeting potential alternative standards. These analyses can inform conclusions on the adequacy of the public health protection provided by the existing primary standard(s), and conclusions on the alternative standard(s), if any, that are appropriate to consider. In determining the extent to which it is appropriate in this review of the primary SO_2 standard to conduct new quantitative exposure and/or risk analyses, and in determining the scope of any such new analyses, the EPA staff will consider the updated scientific evidence, as assessed in the ISA; the updated air quality information now available; and updated tools and models available for assessing human exposures and health risks. Staff's initial conclusions on the extent to which it is appropriate in this review to conduct new quantitative analyses, together with the aspects of the evidence and information supporting those initial conclusions, will be presented in the Risk and Exposure Assessment (REA) Planning Document. Staff's final conclusions on the appropriateness of new quantitative analyses, and the scope of any such analyses, will consider CASAC advice, as well as public input, on that REA Planning Document.

The REA Planning Document will present the EPA staff's planned approach regarding the scope and the design of exposure and risk analyses. As a first step, the REA Planning Document will evaluate the exposure and risk analyses conducted as part of the previous review of the primary SO_2 standard, and will highlight the important uncertainties identified in that review. Based on the newly available scientific evidence, air quality information, and/or exposure and risk tools and models, the REA planning document will then consider the extent to which updated analyses in the current review could reduce these uncertainties, and the extent to which such updated analyses could change our understanding of the SO_2 exposures and risks associated with the current or alternative standards. With regard to the scientific evidence, the REA Planning Document will specifically consider (1) the extent to which the evidence for adverse health effects attributable to short- or long-term SO_2 exposures has been strengthened in the current review, (2) the extent to which the evidence for particular populations and lifestages being at increased risk for SO_2-attributable effects has been strengthened in the current review, and (3) the extent to which new evidence indicates SO_2-attributable effects at lower ambient SO_2 concentrations than in previous reviews. With regard to air quality information, the REA Planning Document will specifically consider the extent to which the information available in this review indicates important differences from the previous review in terms of (1) the ambient

SO_2 concentrations present throughout the U.S., (2) the spatial and/or temporal patterns of ambient SO_2, or (3) the relationships between SO_2 concentrations based on various averaging times (e.g., 5-minute versus 1-hour, 24-hour). With regard to exposure tools and models, the REA Planning Document will consider the extent to which (1) new exposure tools or models exist, (2) existing tools or models have been updated or improved (e.g. expanded data in CHAD for at-risk lifestages), or (3) scientific review has strengthened the association between area-site monitored levels and personal exposures.

Based on the considerations noted above, the REA Planning Document will reach conclusions on the extent to which the updated evidence and information supports new or updated exposure and/or risk analyses in the current review. These conclusions, together with consideration of the resources available, will inform the approach discussed in the REA Planning Document to presenting and assessing any new quantitative analyses (e.g., assessments presented in a separate REA document versus as part of the PA, as discussed in section 5.2.5 below), and the anticipated schedule for soliciting CASAC advice and public input on these analyses. The remainder of this chapter provides an overview of the risk and exposure assessment from the last review, including key observations and uncertainties from the 2009 REA (section 5.1); an overview of the types of newly available scientific evidence, air quality information, tools, and methodologies that could be considered in the REA Planning Document in this review and potential approaches for assessing and presenting any new exposure and risk analyses (section 5.2); and an overview of the approach to obtaining CASAC advice and public input on the REA Planning Document (section 5.3).

5.1 OVERVIEW OF RISK AND EXPOSURE ASSESSMENT FROM PRIOR REVIEW

In the previous review of the primary SO_2 NAAQS, the REA focused the quantitative exposure and risk analyses on 5-minute average concentrations of SO_2 in excess of potential health effect benchmark levels derived from the controlled human exposure literature. These benchmark levels were not potential standards, but rather were concentrations which represented “exposures of potential concern” which were used in the analyses to estimate exposures and risks associated with 5-minute concentrations of SO_2. The health effect benchmark levels used in the REA were derived primarily from the ISA’s evaluation of the 5 - 10 minute controlled human exposure literature. As noted above, 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_2 for 5 - 10 minutes. In addition, 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_2 for 5 - 10 minutes. The ISA also concluded that at SO_2

concentrations ≥ 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. Moreover, small SO_2-induced lung function decrements have been observed in exercising asthmatics at concentrations as low as 100 ppb when SO_2 is administered via mouthpiece. Taken together, the REA concluded it was appropriate to examine potential 5-minute benchmark levels in the range of 100 - 400 ppb.

The purpose of the assessments in the SO_2 REA was to characterize air quality, exposures, and health risks associated with recent ambient concentrations of SO_2, with SO_2 concentrations that could be associated with just meeting the then-existing SO_2 standards (i.e., 30 ppb annual average and 140 ppb daily average), and with SO_2 levels that could be associated with just meeting alternative 1-hour daily maximum standards. The SO_2 REA utilized three approaches, as described briefly below.

In the first approach, measured 5-minute maximum SO_2 concentrations (1997 - 2007) from 98 ambient monitors were evaluated for exceedances of the 5-minute potential health effect benchmark levels, counting the number of days (per monitor and per year) a particular 5-minute benchmark level was exceeded and considering unadjusted, *as is* annual average, daily average, and 1-hour daily maximum SO_2 concentrations. In addition, 5-minute SO_2 maximum concentrations were statistically estimated[33] using all available monitors that measured 1-hour SO_2 (1997 - 2006) to generate a similar output (i.e., the number of days per monitor per year a benchmark concentration was exceeded considering *as is* air quality). Then, 5-minute maximum concentrations were statistically estimated in 40 selected U.S. counties (2001 - 2006), though using 1-hour SO_2 concentrations *as is* and, those adjusted to just meet the then-existing annual and daily standards, and concentrations adjusted to just meet potential 1-hour daily maximum alternative standards. In this analysis, all U.S. monitoring sites where SO_2 data have been collected were included in this analysis and, as such, the results generated were considered a broad characterization of national air quality and potential human exposures that might be associated with these concentrations.

In the second approach, the REA used EPA's Air Pollutants Exposure (APEX) model (US EPA, 2012a,b), a Monte Carlo simulation model that can be used to simulate a large number of randomly sampled individuals within specified locations, generating estimates of population exposure. APEX simulates exposures in indoor, outdoor, and in-vehicle microenvironments

[33]The approach for statistically estimating 5-minute maximum concentrations from 1-hour concentrations was based on a characterization of ratios of measured 5-minute maximum concentrations to measured 1-hour average concentrations (Section 7.2.3 of the 2009 SO_2 REA). Nineteen separate ratio distributions were developed from the measurement data, stratified by seven 1-hour concentration levels and three concentration variability levels.

while taking into consideration the movement of individuals through time and space. APEX estimated 5-minute daily maximum exposures simulated asthmatics may experience while at moderate or greater exertion (e.g., while exercising) and compared these exposures to the same 5-minute potential health effect benchmark levels. Two case study areas were selected for this exposure modeling: Greene County, Missouri, and three counties within the St. Louis Metropolitan Statistical Area (MSA). For these two case study areas, year 2002 census block-level hourly SO_2 concentrations were estimated by EPA's AERMOD (a dispersion model), input to APEX and combined with the same statistical model used for estimating 5-minute peaks described from the hourly SO_2 concentrations above. Several modeled air quality scenarios were considered, including *as is* air quality, air quality adjusted to just meet the then-existing standards, and air quality adjusted to just meet potential alternative 1-hour daily maximum standards. Outputs from this exposure modeling were the number and percent of asthmatics in each study area experiencing at least one 5-minute daily maximum exposure at or above the potential health effect benchmark levels while at moderate or greater exertion.

In the third approach, exposure-response relationships derived from controlled human exposure studies were used in conjunction with the outputs of the St. Louis and Greene County exposure analysis to estimate health impacts. More specifically, in each location the REA estimated the number and percent of all asthmatics or asthmatic children at moderate or greater exertion expected to experience moderate or greater decrements in lung function defined in terms of sRaw or FEV_1 and considering the same air quality scenarios mentioned above.

As mentioned above for each of these approaches, ambient SO_2 concentrations and exposures were characterized by considering *as is* air quality (unadjusted concentrations) and several hypothetical air quality scenarios. Each of the hypothetical air quality scenarios had an ambient concentration target, derived from the form and level of the then-existing NAAQS or from potential alternative standards. Staff chose a proportional approach to adjust the SO_2 concentrations to simulate each of the current and alternative air quality standard scenarios. A proportional approach was selected based on the mostly linear relationship between older high concentration years of air quality when compared with recent low concentration years at several locations (2009 SO_2 REA, Section 7.4.2.5).

The approach used to evaluate uncertainty was adapted from guidelines outlining how to conduct a qualitative uncertainty characterization (WHO, 2008), though staff also performed several quantitative sensitivity analyses to iteratively inform both model development and the qualitative uncertainty characterization, where possible. While it may be considered ideal to follow a tiered approach in the REA to quantitatively characterize all identified uncertainties, staff selected the mainly qualitative approach given the limited data available to inform probabilistic analyses and time and resource constraints. Sections 5.1.1 and 5.12 identify the key observations and uncertainties from the prior SO_2 REA.

5.1.1 Key Observations

Ambient Air Quality Characterization

- An increased probability of any 5-minute benchmark exceedance was consistently related to either increased 24-hour average or 1-hour daily maximum concentrations.
- For any of the air quality scenarios considered, the probability of exceeding the 5-minute maximum benchmark levels was consistently greater at monitors sited in low-population density areas compared with high-population density areas.
- Unadjusted *as is* air quality at ambient monitors measuring 5-minute maximum concentrations:
    - Measured daily and annual average concentrations were below that of the existing standards at all monitors, though measured 5-minute maximum ambient concentrations were present above the potential health effect benchmark levels. (2009 SO_2 REA, Appendix A, Table A.5-1)
        - Nearly 70% of the monitor site-years analyzed had at least one daily 5-minute maximum concentration above 100 ppb and over 20% had ≥ 25 days with a daily 5-minute maximum concentration above 100 ppb.
        - About 44% of the monitor site-years analyzed had at least one 5-minute daily maximum concentration > 200 ppb, 25% had at least one > 300 ppb, and 17% had at least one > 400 ppb.
- Air quality adjusted to simulate just meeting the then-existing annual standard in the 40 selected U.S. counties
    - All counties evaluated were estimated to have multiple days per year where 5-minute daily maximum ambient SO_2 concentrations are > 100 ppb. For example, most counties are estimated to have, on average, 100 days or more per year with 5-minute daily maximum SO_2 concentrations > 100 ppb (2009 SO_2 REA, Table 7-11).
    - Fewer benchmark exceedances were estimated to occur with higher benchmark levels. For example, five of the forty counties were estimated to have 60 or more days per year with 5-minute maximum SO_2 concentrations that exceed 300 ppb (2009 SO_2 REA, Table 7-13).
- Air quality adjusted to potential 1-hour daily maximum alternative standard levels:
    - Far fewer days per year with 5-minute maximum SO_2 concentrations > 300 ppb and > 400 ppb (about 0 to 5 days/year) were estimated when adjusting air quality to just meet potential alternative standard levels of 100 and 150 ppb than compared with air quality adjusted to just meet the current standards (frequently

25 or more days/year) and the potential alternative standard levels of 200 and 250 ppb (about 5 to 20 days/year) (2009 SO_2 REA, Tables 7-13 and 7-14).

Exposure Assessment

- St. Louis had both a greater number and percent of asthmatic children and adults exposed above the benchmark levels than did Greene County for all air quality scenarios, largely a function of both the greater population density and the much greater SO_2 emissions density in St. Louis (2009 SO_2 REA, Section 8.9.2).
- Estimated exposures above 5-minute potential health effect benchmark levels at moderate or greater exertion using APEX occurred most frequently outdoors (around 50 to > 90%, depending on the air quality scenario and modeling domain) (2009 SO_2 REA, Figure 8-21).
- Simulating air quality that just meets the then-existing annual standard in either the Greene County or St. Louis Study areas resulted in the greatest number and percent of asthmatic persons exposed at all benchmark levels (2009 SO_2 REA, Figures 8-16 and 8-19).
- The exposure results using *as is* air quality were similar to that estimated using air quality adjusted to a 99^{th} percentile 1-hour daily maximum of 50 or 100 ppb in either study area (2009 SO_2 REA, Figures 8-16 and 8-19).

Health Risk Assessment

- In terms of estimated percentage of all asthmatics or asthmatic children experiencing one or more lung function responses, estimated risks are greater for asthmatic children (2009 SO_2 REA, Tables 9-5 and 9-8, respectively), likely because they spend more time outdoors and at higher exertion levels than adults.
  - For example, approximately 13% of all asthmatics were estimated to experience at least one moderate lung function response (defined as an increase in sRaw ≥ 100% (2009 SO_2 REA, Table 9-5), while approximately 19% of asthmatic children experienced a similar response (2009 SO_2 REA, Table 9-8).
- A broad range of SO_2 exposure concentration intervals selected, some as high as 500 ppb, contributes to the estimated risks of experiencing one or more lung function responses per year for some of the standards considered in the assessment. For potential alternative 1-hour standards in the range of 100 to 150 ppb, SO_2 exposure concentration intervals below 200 ppb contribute to most of the estimated risks of experiencing one or more lung function responses per year (2009 SO_2 REA, Figures 9-7 and 9-8).

5.1.2 Key Uncertainties

- Uncertainty in the statistical model used to estimate 5-minute maximum SO_2 concentrations from 1-hour SO_2 concentrations.

- Uncertainty in the spatial and temporal representativeness of the SO_2 ambient monitoring network.
- Uncertainties associated with the proportional air quality adjustment procedure that was used to simulate just meeting the then-existing standard and several alternative 1-hour daily maximum standards.
- Uncertainties related to the exposure model inputs and exposure estimates which are an important input to the risk assessment.
- Uncertainty about the shape of the exposure-response relationship for lung function responses at levels well below 200 ppb, the lowest level examined in free-breathing single-pollutant controlled human exposure studies.
- Uncertainty with respect to how well the estimated exposure-response relationships reflect asthmatics with more severe disease than those tested in chamber studies.
- Uncertainty about whether the presence of other pollutants in the ambient air would enhance the SO_2-related responses observed in the controlled human exposure studies.
- Uncertainty about the extent to which the risk estimates presented for the two modeled areas in Missouri are representative of other locations in the U.S. with significant SO_2 point and area sources.

5.2 CONSIDERATION OF QUANTITATIVE ASSESSMENTS FOR THIS REVIEW

As discussed above, the REA Planning Document will reach conclusions on the extent to which the updated scientific evidence, air quality information, or modeling tools and methods support new or updated exposure/risk analyses in the current review. These conclusions will reflect EPA staff consideration of the extent to which the newly available scientific evidence and technical information could reduce important uncertainties identified in the 2009 REA, and the extent to which updated analyses could lead to notably different conclusions than those reached in the previous review. Sections 5.2.1 to 5.2.3 below a more detailed discussion of important uncertainties associated with the air quality, exposure, and risk characterization from the last review, and the potential for newly available information to reduce those uncertainties. Section 5.2.4 discusses how uncertainty and variability will be characterized in the current review. Section 5.2.5 discusses the potential options for presenting and assessing new or updated exposure/risk analyses.

5.2.1 Ambient Air Quality Characterization

In the last review, the SO_2 ambient air quality characterization: (1) developed quantitative relationships between 5-minute peak concentrations and longer term average concentrations (e.g., 1-hour); (2) estimated 5-minute ambient SO_2 concentrations, based on unadjusted air quality and air quality adjusted to just meet the then-existing SO_2 standards and potential alternative standards; and (3) identified key assumptions and uncertainties. The results of the air quality characterization were considered, along with the scientific evidence and exposure and risk analyses, to inform conclusions on the adequacy of the then current standards and on the range of potential alternative standards appropriate for consideration.

Areas where additional information could reduce key uncertainties identified in the air quality assessment from the previous review, are presented in Table 5-1. For each component, the REA Planning Document will examine the extent to which newly available information could result in notably different air quality results than those reported in the 2009 REA and will use this information to help inform decisions on the extent to which new or updated air quality analyses are appropriate in this review.

Table 5-1. Primary uncertainties associated with the air quality analysis in the previous review and the potential use of new information for reducing these uncertainties

<table>
<tr><th>Component of Assessment</th><th>Uncertainty/Limitation Remaining From Prior REA</th><th>Consideration of Potential Utility of Information Newly Available in This Review For the Assessment</th></tr>
<tr><td>Characterize relationships between 5-minute peak concentrations and longer averaging times.</td><td>Ambient monitor spatial and temporal representativeness regarding the limited number of monitors reporting 5-minute SO_2 concentrations.</td><td rowspan="3">There are now substantially more monitors reporting 5-minute concentrations compared with that used in the last review.

A new characterization of monitor site attributes and emissions sources influencing both 5-minute and hourly SO_2 ambient monitoring concentrations could be performed.</td></tr>
<tr><td>Develop predictive relationships to approximate the probability of occurrence of 5-minute peak concentrations given hourly average concentrations and site specific data for use in locations without 5-minute ambient monitors.</td><td>Uncertainty of the statistical model used to estimate 5-minute maximum SO_2 concentrations at monitors that reported only 1-hour SO_2 concentrations.</td></tr>
<tr><td>The estimated number of exceedances of potential health effect benchmark levels occurring at monitors located across the U.S.</td><td>Ambient monitor spatial and temporal representativeness</td></tr>
<tr><td>Selection of potential health effect benchmark levels[34]</td><td>The health effect benchmark levels used in the SO_2 REA were derived from the ISA's</td><td>New estimates of benchmark exceedances could be developed if there are studies</td></tr>
</table>

[34] Note that the selection of health benchmark levels is also an uncertainty for the SO_2 exposure analysis.

Component of Assessment	Uncertainty/Limitation Remaining From Prior REA	Consideration of Potential Utility of Information Newly Available in This Review For the Assessment
	evaluation of the 5 - 10 minute controlled human exposure literature. The subjects participating in these human exposure studies were exercising asthmatics and do not include individuals who may be most susceptible to the respiratory effects of SO_2 (e.g., the most severe asthmatics). Since the majority of controlled human exposure studies investigating lung function responses to SO_2 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.	newly available in the ISA that indicate alternative benchmark levels exist outside of the range already considered in the 2009 SO_2 REA.
Approach used to simulate just meeting potential air quality standard scenarios	The proportional adjustment factors derived from an area's design monitor are applied to adjust all ambient monitors within the given study area. Deviation from proportionality at any monitor could result in either over or under-estimation of concentrations.	A different methodology could be used if there are studies newly available that indicate an improved alternative approach to adjusting air quality.

A key uncertainty, included in Table 5-1, with respect to the air quality characterization is the limited availability of 5-minute SO_2 monitoring data. In the last review, 5-minute SO_2 concentrations were available through mid-2007 from a relatively small number of monitors (see Table 5-2)[35]. In the current review, there are far more monitors reporting 5-minute SO_2

[35] 2006 was the most recent year with complete data at that time.

concentrations (see Table 5-2).[36] It is possible that this additional 5-minute monitoring data could indicate relationships between 5-minute SO_2 concentrations and 1-hour or 24-hour SO_2 concentrations that are different from those reported in the last REA. The REA Planning document will discuss the extent to which air quality relationships based on additional monitoring data are notably different from those reported in the last review to help inform decisions on the extent to which new or updated analyses are appropriate in this review. In addition, a review of selected references on relationships between SO_2 concentrations at different averaging times will also be performed and incorporated into this discussion (e.g., Gifford, 1960, 1972; Hanna, 1984; Larsen, 1969; Montgomery and Coleman, 1975; Ramsdell and Hinos, 1971).

Table 5-2. The numbers of SO_2 monitors 2003 to 2012[37]

Year	Monitors Reporting 5-Minute Continuous Concentrations[1]	Monitors Reporting 5-Minute Maximum Concentrations[2]	Monitors Reporting 1-Hour Concentrations[2]
2003	6	40	528
2004	6	32	524
2005	6	24	510
2006	4	24	498
2007	4	22	499
2008	3	20	471
2009	2	20	440
2010	149	31	435
2011	194	183	435
2012	195	185	450

[1] 5-minute continuous monitors with at least 20,000 values/year (about 20% data completeness).
[2] 5-minute maximum and hourly with at least 50% data completeness (4,380 values/year).

5.2.2 Exposure Assessment

In the last review, the SO_2 exposure assessment: (1) estimated short-term exposures to ambient SO_2 concentrations, based on unadjusted air quality and air quality adjusted to just meet the then-existing SO_2 standards and potential alternative standards; (2) compared estimated exposures to potential health effect benchmark levels; and (3) identified key assumptions and uncertainties in the exposure assessment. The results of the exposure assessment were considered, along with the scientific evidence and the results of air quality and risk analyses, to

[36] As previously noted in section 3.1, the 2010 final rulemaking made it a requirement that states report for every hour of the day, all twelve 5-minute concentrations in an hour, or the highest 5-minute concentration in a given hour.
[37] In the last review, the final rulemaking required States to report either the highest 5-minute concentration for each hour of the day, or all twelve 5-minute concentrations for each hour of the day (see section 1.3)

inform conclusions on the adequacy of the then current standards and on the range of potential alternative standards appropriate for consideration.

In the last review, the following were identified as key areas of uncertainty in the exposure analysis:

- Representativeness of the two study areas selected (i.e., St. Louis and Greene County, MO)
- Estimates of the number of asthmatics and asthmatic children at elevated ventilation rates above potential health effect benchmarks in St. Louis and Greene County[38]
- Factors that may contribute to greater personal exposures including the impacts of important sources of SO_2 (e.g., outdoor point sources).
- Factors that may contribute to lessened personal exposures including infiltration and the decay of SO_2 indoors.
- Impact of human behavior (e.g., time spent indoors or outdoors, averting behavior, time spent near sources, timing of exposure event, breathing rate) in influencing the magnitude and duration of exposures, and frequency of repeated short-term peak exposures.
- Population living in close proximity to local sources or otherwise living in areas with elevated SO_2 concentrations.
- Frequency and (temporal and spatial) variability of peak air quality levels at concentrations and averaging times of significance.
- Selection of potential health effect benchmark levels.

The REA Planning Document will evaluate the extent to which new information or modeling approaches could reduce these uncertainties in exposure estimates. Decisions on whether to conduct new or updated exposure analyses in this review will be informed by consideration of the extent to which the updated evidence and information could impact exposure estimates in important ways (e.g., providing broader geographic coverage, improved characterization of exposures, improved basis for benchmarks), and by consideration of the extent to which updated exposure estimates would be expected to alter our understanding from the last review of SO_2 exposures.

5.2.3 Risk Assessment

In the last review, the SO_2 risk assessment: (1) estimated the number and percent of people at risk of adverse respiratory effects following exposure to SO_2, based on unadjusted air quality and air quality adjusted to just meet the then-existing SO_2 standards and potential alternative standards; (2) provided distributions of health risk estimates over a range of ambient SO_2 concentrations; and (3) identified key assumptions and uncertainties in risk estimates. The

[38] For any exposure analyses done in the current review, it is likely that the latest version of the APEX model would be used to estimate 5-minute or longer-term SO_2 exposures of interest (US EPA, 2012a; 2012b). [38]

results of the risk assessment were considered, along with the scientific evidence and the results of air quality and exposure analyses, to inform conclusions on the adequacy of the then current standards and on the range of potential alternative standards appropriate for consideration.

In the last review, the following were identified as key areas of uncertainty in the risk assessment:

- The availability of exposure-response information for only a limited number of respiratory endpoints (i.e., sRaw and FEV_1), likely not reflecting the full range of SO_2-related health risks across the population.
- The lack of sufficient information to support a risk assessment based on epidemiologic studies of the most serious SO_2-related health outcomes (e.g., hospital admissions, emergency department visits).

The REA Planning Document will evaluate the extent to which new evidence, information, or modeling approaches are available in the current review that could reduce these uncertainties in our understanding of SO_2 health risks. As discussed above for air quality analyses and the exposure assessment, decisions on whether to conduct new or updated risk analyses in this review will be informed by consideration of the extent to which the evidence and information that has become available since the last review could impact SO_2 risk estimates in important ways (e.g., quantitative changes in risk estimates, risks estimated for new populations or health endpoints), and consideration of the extent to which updated estimates would be expected to alter our understanding from the last review of SO_2 health risks.

5.2.4 Uncertainty and Variability

Uncertainty reflects the degree of confidence in the representativeness of models or model components. Variability can be described in terms of empirical quantities that are inherently variable across time and space or between individuals (Cullen and Frey, 1999). Consistent with prior NAAQS REAs including the last SO_2 REA, EPA would use the approach described in WHO (2008) to assess uncertainty and variability in any new or updated air quality, exposure, or risk analyses. A tiered approach to assessing uncertainty and variability in exposure and risk estimates will be employed, beginning with a qualitative analysis and progressing to a quantitative analysis only if warranted and if data are available to support such an analysis.

5.2.5 Presentation of Updated Exposure and Risk Information

As discussed above, the REA Planning Document will reach preliminary conclusions regarding the appropriate approach to presenting and assessing any new quantitative analyses that are judged appropriate. Specifically, such new analyses could be presented and assessed in a separate REA document or could be presented and assessed as part of the PA. Conclusions on whether to generate a new REA document, or to present exposure/risk results only as part of the

PA, will depend in part on the scope of any new analyses judged appropriate. For example, to the extent extensive new analyses of air quality, exposures, and health risks are conducted, it could be judged that the most effective way to facilitate CASAC advice and public input would be to generate a separate REA document that undergoes its own review process, independent of the PA. To the extent the new analyses will be more limited in scope (e.g., limited to only analyses of new air quality data), those analyses could potentially be included as part of the PA, rather than in a separate REA. The final decision on whether to generate a new REA, or to include quantitative analyses only as part of the PA, will also reflect staff's consideration of CASAC advice and public input on the preliminary conclusions in the REA Planning Document.

5.3 SCIENTIFIC AND PUBLIC REVIEW

If the REA Planning Document concludes that an REA is not required, then the REA Planning Document will be subject to CASAC review and public comment. Similarly, draft versions of an REA, if one is generated, will be submitted for CASAC review and public comment. If an REA is not conducted, CASAC review of quantitative air quality, exposure, and/or risk analyses would occur as part of its review of the PA. As with all CASAC reviews, the SO_2 panel will discuss their comments in public meetings that are announced in the *Federal Register*. Based on CASAC's past practice, EPA expects that key CASAC advice and recommendations for revisions will be conveyed by the CASAC chair in a letter to the EPA Administrator. In revising the REA Planning Document or the draft REA, EPA will take into account any such advice and recommendations. EPA will also consider input from the public provided at the meeting itself, and any written public comments. If a first draft REA is prepared, EPA anticipates preparing a second draft of the REA for CASAC review and public comment. After appropriate revision, the final document will be made available on an EPA website and subsequently printed, with its public availability being announced in the *Federal Register*.

6. AMBIENT AIR MONITORING

In the course of NAAQS reviews, aspects of the methods for measuring ambient levels of the NAAQS pollutant, as well as the current network of monitors, including their physical locations and monitoring objectives, are reviewed. The methods for sampling and analysis of each NAAQS pollutant are generally reviewed in conjunction with consideration of the indicator element for each NAAQS. Consideration of the ambient air monitoring network generally informs the interpretation of current data on ambient air concentrations and includes an assessment of the adequacy of the monitoring network for determining compliance with the existing or, as appropriate, a potentially revised NAAQS. This chapter describes plans for considering these aspects of the ambient air monitoring program for sulfur oxides which includes the indicator SO_2.

6.1 CONSIDERATION OF SAMPLING AND ANALYSIS METHODS

In order for the data to be used to determine compliance, ambient SO_2 concentration data must be obtained using Federal Reference Methods (FRMs) or Federal Equivalent Methods (FEMs) which are designated by the Agency in accordance with 40 CFR Part 50 and Part 53. As described earlier, SO_2 is the indicator for the sulfur oxides NAAQS, and has been routinely measured by UV fluorescence methods since the 1980s. In the 2010 rulemaking the EPA promoted the automated federal equivalent UV fluorescence method to be a Federal Reference Method (FRM). This was done because of the need to update the cumbersome manual wet-chemistry (pararosaniline) method to a continuous-type automated method that can readily provide 1-hour SO_2 measurement capability. The UV fluorescence method was a clear and appropriate method to fulfill that need. The SO_2 concentration data produced by modern UV fluorescence analyzers are routinely logged by state and local agencies who report the hourly average and either the maximum 5-minute value (one of twelve 5-minute periods) in the hour or all twelve 5-minute averages within the hour to EPA's Air Quality System (AQS).

The Agency is unaware of any recent technological advances in SO_2 measurements beyond the current automated FRM or forthcoming modifications to existing methods that should be considered in this NAAQS review. Therefore, the EPA does not anticipate raising any specific sampling and analysis methods issues for consideration in this integrated review plan.

6.2 CONSIDERATION OF AIR MONITORING NETWORK REQUIREMENTS

The ambient air quality monitoring networks for criteria pollutants support three major objectives: (1) to provide air pollution data to the general public in a timely manner; (2) to support compliance with NAAQS and emissions strategy development; and (3) to support air pollution research studies. A review of the available SO_2 monitoring network and data was performed as part of the primary SO_2 NAAQS review completed in 2010. Subsequent to that review, and in conjunction with revising the primary standards, the Agency promulgated minimum monitoring requirements to support the implementation of a new primary 1-hour SO_2 standard. The 2010 action introduced minimum requirements based upon the use of a Population Weighted Emissions Index (PWEI). The PWEI utilizes both population and emissions data within Core Based Statistical Areas (CBSAs) to determine if monitoring is required in a CBSA and, if so, how many monitors are required. The intent of using the PWEI to require monitors is to focus monitoring into areas where there is a higher proximity of population and SO_2 emissions. In effect, areas with a higher calculated PWEI value are expected to have higher potential for population exposure to peak, short-term SO_2 emissions.

The size of any ambient air monitoring network changes on an annual basis due to state, local, and tribal air agencies, plus industry-run monitors that report data to AQS being shut-down, relocated, or installed for a variety of reasons. As of July 2014, the ambient SO_2 monitoring network is estimated to have 402 monitors in operation nationwide. This number far exceeds the approximately 129 required by PWEI-based requirements promulgated in 2010.

Historically, the data used to determine compliance with the SO_2 NAAQS have been largely based upon data obtained from ambient monitors operated by state, local, and tribal air monitoring agencies. These monitors are either required due to federal regulation contained in 40 CFR Part 58, Appendix D, state implementation plans, industrial permits, or other state or local requirements or voluntary actions. While monitoring data are a mainstay in determining compliance for all other criteria pollutants, SO_2 is unique in that there is a precedent to also use dispersion modeling in the implementation of its NAAQS. This is notable because the use of modeling in lieu of monitoring can potentially reduce the necessary size and distribution of a compliance monitoring network. As a result, the final monitoring requirements promulgated as part of the 2010 SO_2 NAAQS revision reflected this potentiality.

More recently, in August 2013, EPA completed an initial round of nonattainment area designations for 29 areas having ambient monitoring data that exceeded the level of the 2010 NAAQS, and EPA did not issue final designations for the rest of the country. For the portion of the country that remains undesignated, the EPA proposed the Data Requirements Rule for 1-hr SO_2 Primary NAAQS (79 FR 27445) on April 17, 2014, which will direct the state and tribal air agencies to provide data to characterize current air quality in areas with large sources of SO_2 emissions if such areas do not have sufficient air quality monitoring in place to identify maximum 1-hour SO_2 concentrations.

The proposed rule describes thresholds for identifying the sources around which air agencies would need to characterize SO_2 air quality. It also describes a process and timetables by which air agencies would characterize air quality around sources through ambient monitoring and/or air quality modeling techniques and submit such data to the EPA. States would have the flexibility on an area by area basis whether to choose to deploy new ambient monitors or to conduct air quality modeling to characterize air quality. The air quality data developed by the states in accordance with this rule would be used by the EPA in future rounds of area designations for the 1-hour SO_2 NAAQS in 2017 and 2020. The final rule is expected in 2015. The EPA also issued separate non-binding draft technical assistance documents (TADs) on monitoring and modeling issues to support this rule in December 2013. A main focus of the monitoring TAD is to describe analyses that can be done to identify potential monitoring site locations for monitoring maximum 1-hour SO_2 concentrations.

7. POLICY ASSESSMENT/RULEMAKING

7.1 POLICY ASSESSMENT

The PA, like the previous OAQPS Staff Paper, is a document that provides a transparent OAQPS staff analysis and staff conclusions regarding the adequacy of the current standard and potential alternatives that are appropriate to consider prior to the issuance of proposed and final rules. The PA integrates and interprets the information from the ISA and REA(s) to frame policy options for consideration by the Administrator. The PA is also intended to facilitate CASAC's advice to the Agency and recommendations to the Administrator on the adequacy of the existing standard or revisions that may be appropriate to consider. Staff conclusions in the PA are based on the information contained in the ISA and, as available, the REA, and any additional staff evaluations and assessments discussed in the PA. In so doing, the discussion in the PA is framed by consideration of a series of policy-relevant questions drawn from those outlined in chapter 3, including the fundamental questions associated with the adequacy of the current standard and, as appropriate, consideration of an alternative standard(s) in terms of the specific elements of the standard: indicator, averaging time, level, and form.

The PA for the current review will identify conceptual evidence-based and risk/exposure-based approaches for reaching public health policy judgments. It will discuss the implications of the science and quantitative assessments for the adequacy of the current primary standard and for any alternative standards under consideration. The PA will also describe a broad range of policy options for standard setting, identifying the range for which the staff identifies support within the available information. In so doing, the PA will describe the underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative policy options that could be considered by the Administrator in making decisions for the primary SO_2 standard. Additionally, the PA will identify key uncertainties and limitations in the underlying scientific information and in our assessments. The PA will also highlight areas for future health-related research, model development, and data collection.

In identifying a range of primary standard options for the Administrator to consider, it is recognized that the final decision will be largely a public health policy judgment. Scientific information and analyses about health effects and risks, as well as judgments about how to deal with the range of uncertainties that are inherent in the scientific evidence and analyses, inform a final decision. Staff's approach to informing these judgments recognizes that the available health effects evidence generally reflects a continuum consisting of ambient concentrations at which scientists generally agree that health effects are likely to occur, through lower concentrations at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the CAA and with how the EPA and the courts have historically interpreted the Act.

In setting primary standards that are "requisite" to protect public health, as provided in section 109(b), the Administrator is to establish standards that are neither more nor less stringent than necessary. As discussed in section 1.1 above, the provisions do not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety, including the health of at-risk populations.[39] In so doing, the EPA may not consider the costs of implementing the standards and "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards."[40]

Staff will prepare at least one draft of the PA document for CASAC review and public comment. The draft PA document will be distributed to the CASAC Sulfur Oxides Primary NAAQS Review Panel for their consideration and provided to the public for review and comment. Review by the CASAC Panel will be discussed at public meetings that will be announced in the *Federal Register*. Based on past practice by CASAC, the EPA expects that CASAC would summarize their key advice and recommendations for revision of the document in a letter to the EPA Administrator. In revising the draft PA document, OAQPS will take into account any such recommendations, and also consider comments received from CASAC and from the public, at the meeting itself, and any written comments received. The final document will be made available on an EPA website, with its public availability announced in the *Federal Register*[41].

7.2 RULEMAKING

Following issuance of the final PA and the EPA management consideration of staff analyses and conclusions presented therein, and taking into consideration CASAC advice and recommendations, the Agency will develop a notice of proposed rulemaking. The notice of proposed rulemaking conveys the Administrator's proposed conclusions regarding the adequacy of the current standard(s) and any revision that may be appropriate. A draft notice of proposed

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[39] The at-risk population groups identified in a NAAQS review may include low income or minority groups. Where low income/minority groups are among the at-risk populations, the rulemaking decision will be based on providing protection for these and other at-risk populations and lifestages (e.g., children, older adults, persons with pre-existing heart and lung disease). To the extent that low income/minority groups are not among the at-risk populations identified in the ISA, a decision based on providing protection of the at-risk lifestages and populations would be expected to provide protection for the low income/minority groups (as well as any other less sensitive population groups).

[40] See generally, *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001) and *American Petroleum Institute v. Costle*, 665 F. 2d at 1185.

[41] Note that the policy assessment/rulemaking process is also outlined in Figure 1-1.

rulemaking will be submitted to the Office of Management and Budget (OMB) for interagency review, in which OMB and other federal agencies are provided the opportunity for review and comment. After the completion of interagency review, the EPA will publish the notice in the *Federal Register* seeking comment on proposed agency action – namely whether or not to revise the current standard, and if so, how. Monitoring rule changes associated with review of the primary SO_2 standard, and drawing from considerations outlined in Chapter 6 above, will be developed and proposed, as appropriate, in conjunction with this NAAQS rulemaking.

At the time of publication of the notice of proposed rulemaking, all materials on which the proposal is based are made available in the public docket for the rulemaking.[42] Publication of the proposal notice is followed by a public comment period, generally lasting 60 to 90 days, during which time the public is invited to submit comments on the proposal to the rulemaking docket. EPA also will provide opportunity for a public hearing on any proposed action. Taking into account comments received on the proposed action, the Agency will then develop a notice of final rulemaking, which again undergoes OMB-coordinated interagency review prior to issuance by the EPA of the final rule. At the time of final rulemaking, the Agency responds to all significant comments on the proposed action.[43] Publication of the final action in the *Federal Register* completes the process.

[42] The rulemaking docket for the current primary SO_2 NAAQS review is identified as EPA-HQ-OAR-2013-0566. This docket has incorporated the ISA docket (EPA–HQ–ORD–2013-0357) by reference. Both dockets are publicly accessible at www.regulations.gov.

[43] For example, Agency responses to all significant comments on the 2009 notice of proposed rulemaking in the last review were provided in the preamble to the final rule and in a document titled *Responses to Significant Comments on the 2009 Proposed Rule on the Primary National Ambient Air Quality Standards for Sulfur Dioxide, available at: http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_cr_rc.html*

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APPENDIX A

DRAFT OUTLINE FOR INTEGRATED SCIENCE ASSESSMENT FOR SULFUR OXIDES – HEALTH CRITERIA

Preamble	Process of ISA Development
(will be available online)	EPA Framework for Causal Determination
	Public Health Impact
	Concepts in Evaluating Adversity of Health Effects
Preface	Legislative Requirements for the NAAQS Review
	History of the Primary NAAQS for Sulfur Dioxide
Executive Summary	
Chapter 1	**Integrative Summary**
1.1	Policy-relevant Questions for Sulfur Dioxide NAAQS Review
1.2	ISA Development and Scope
1.3	Sulfur Oxides Sources, Ambient Concentrations, Exposure
1.4	Health Effects Evidence
	Exposure, Dosimetry, and Modes of Action
	Comparison of 2008 ISA and Current Conclusions
	Key Evidence for Evaluated Health Effects
1.5	Policy-Relevant Considerations
	Concentration-Response and Thresholds
	Exposure Averaging Times and Lags
	At-risk Populations
	Adverse Health Effects, Public Health Significance
1.6	Summary
Chapter 2	**Atmospheric Behavior of Sulfur Oxides**
2.1	Introduction
2.2	Sources
2.3	Atmospheric Chemistry and Fate
2.4	Monitoring
2.5	Atmospheric Concentrations of Sulfur Oxides
2.6	Modeling
2.7	Summary and Conclusions
Chapter 3	**Exposure to Ambient Sulfur Oxides**
3.1	Introduction
3.2	General Considerations
3.3	Exposure Measurement
3.4	Exposure-related Metrics

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