Policy Assessment for the Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides

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Policy Assessment for the Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides

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LIST OF ACRONYMS AND ABBREVIATIONS

AHR	airway hyperresponsiveness
APEX	Air Pollutants Exposure model
AQCD	Air Quality Criteria Document
AQS	Air Quality System
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CHAD	Consolidated Human Activity Database
DV	design value
ED	emergency department
EGU	Electricity generating unit
EPA	Environmental Protection Agency
FEM	federal equivalent method
FEV_1	forced expiratory volume in one minute
FRM	federal reference method
IRP	Integrated Review Plan
ISA	Integrated Science Assessment
ME	microenvironment
NAAQS	National Ambient Air Quality Standard
NCEA	National Center for Environmental Assessment
NEI	National Emissions Inventory
NO_2	nitrogen dioxide
O_3	ozone
OAQPS	Office of Air Quality Planning and Standards
ppb	parts per billion
ppm	parts per million
PA	Policy Assessment
PM	particulate matter
REA	Risk and Exposure Assessment
SLAMS	State and Local Air Monitoring Stations
SO_2	sulfur dioxide
SO_3	sulfur trioxide
SO_X	oxides of sulfur
sRaw	specific airway resistance
USB	United States background
UVF	ultraviolet fluorescence

1 INTRODUCTION

1.1 PURPOSE

This document, *Policy Assessment for the Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides* (hereafter referred to as *PA*), presents the policy assessment for the U.S. Environmental Protection Agency's (EPA's) current review of the primary (health-based) national ambient air quality standard (NAAQS) for sulfur oxides (SO_X).[1] The overall plan for this review was presented in the *Integrated Review Plan for the Primary National Ambient Air Quality Standard for Sulfur Dioxide, Final* (IRP; U.S. EPA, 2014a). The IRP also identified key policy-relevant issues to be addressed in this review and discussed the key documents that generally inform NAAQS reviews, including an Integrated Science Assessment (ISA), a Risk and Exposure Assessment (REA), and a Policy Assessment (PA).

The PA presents a staff evaluation of the policy implications of the key scientific and technical information in the ISA and REA for consideration by the EPA Administrator.[2] Ultimately, a final decision on the primary standard for SO_X will reflect the judgments of the Administrator. The role of the PA is to help "bridge the gap" between the Agency's scientific assessments presented in the ISA and REA, and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the NAAQS.

In evaluating the adequacy of the current standard and whether it is appropriate to consider alternative standards, the PA focuses on information that is most pertinent to evaluating the basic elements of the NAAQS: indicator, averaging time, form, and level.[3] These elements,

[1] This review focuses on the presence in ambient air of sulfur oxides, a group of closely related gaseous compounds that include sulfur dioxide and sulfur trioxide and of which sulfur dioxide (the indicator for the current standard) is the most prevalent in the atmosphere and the one for which there is a large body of scientific evidence on health effects. The health effects of particulate atmospheric transformation products of SO_X, such as sulfates, are addressed in the review of the NAAQS for particulate matter. Additionally, the ecological welfare effects of sulfur oxides and particulate atmospheric transformation products are being considered in the review of the secondary NAAQS for Oxides of Nitrogen, Oxides of Sulfur, and Particulate Matter (U.S. EPA, 2017a), while the visibility, climate, and materials damage-related welfare effects of particulate sulfur compounds are being evaluated in the review of the secondary NAAQS for particulate matter (U.S. EPA, 2016a).

[2] The terms "staff," "we," and "our" throughout this document refer to the staff in the EPA's Office of Air Quality Planning and Standards (OAQPS).

[3] The indicator defines the chemical species or mixture to be measured in the ambient air for the purpose of determining whether an area attains the standard. The averaging time defines the period over which air quality measurements are to be averaged or otherwise analyzed. 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 standard. For example, the form of the annual NAAQS for fine particulate matter is the average of annual mean concentrations for three consecutive years, while the form of the 8-hour NAAQS for carbon monoxide is the second-highest 8-hour average in a year. The level of the standard defines the air quality concentration used for that purpose.

which together serve to define each standard, must be considered collectively in evaluating the health protection afforded by the primary standard for SO_X.

The development of the PA is also intended to facilitate advice to the Agency and recommendations to the Administrator from an independent scientific review committee, the Clean Air Scientific Advisory Committee (CASAC), as provided for in the Clean Air Act (CAA). As discussed below in section 1.2.1, the CASAC is to advise on subjects including the Agency's assessment of the relevant scientific information and on the adequacy of the current standards, and to make recommendations as to any revisions of the standards that may be appropriate. The EPA makes available to the CASAC and the public one or more drafts of the PA for CASAC review and public comment.[4]

In this PA, we take into account the available scientific and technical information, as assessed in the *Integrated Science Assessment for Sulfur Oxides – Health Criteria* (2017 ISA [U.S. EPA, 2017b]) and *Risk and Exposure Assessment for the Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides* (REA [U.S. EPA, 2018]). The evaluation and staff conclusions in this PA have been informed by the advice received from the CASAC based on its review of the draft PA (U.S. EPA, 2017c) and other draft Agency documents prepared thus far in this review, and also by public comment received thus far.

Beyond informing the Administrator and facilitating the advice and recommendations of the CASAC, the PA is also intended to be a useful reference to all parties interested in the review of the primary NAAQS for SO_X. In these roles, it is intended to serve as a source of policy-relevant information that informs the Agency's review of the primary NAAQS for SO_X, and it is written to be understandable to a broad audience.

1.2 BACKGROUND

1.2.1 Legislative Requirements

Two sections of the 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. The Administrator is to list those pollutants "emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare," "the presence of which in the ambient air

[4] The decision whether to prepare one or more drafts of the PA is influenced by preliminary staff conclusions, taking into consideration CASAC advice and public comments, among other factors. Typically, a second draft PA has been prepared in cases where the available information calls into question the adequacy of the current standard and where analyses of potential alternative standards are developed. In such cases, a second draft PA includes preliminary staff conclusions regarding potential alternative standards and undergoes CASAC review and public comment prior to preparation of the final PA. When such analyses are not undertaken, a second draft PA may not be warranted, as is the case in this review of the primary NAAQS for SO_X.

results from numerous or diverse mobile or stationary sources"; and for which he "plans to issue air quality criteria…" 42 U.S.C. § 7408(a)(1). Air quality criteria are intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the 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 [42 U.S.C. § 7409(a)]. Section 109(b)(1) defines primary standards as ones "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."[5] Under section 109(b)(2), a secondary standard must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."[6]

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); *Mississippi v. EPA*, 744 F. 3d 1334, 1353 (D.C. Cir. 2013). 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 levels, see *Lead Industries*

[5] 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).

[6] Under CAA section 302(h) (42 U.S.C. § 7602(h)), effects on welfare 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."

v. EPA, 647 F.2d at 1156 n.51, *Mississippi v. EPA*, 744 F.3d at 1351, 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*, 647 F.2d at 1161-62; *Mississippi v. EPA*, 744 F.3d at 1353.

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 "[n]ot later than December 31, 1980, and at five-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 CASAC of the EPA's Science Advisory Board.[7]

1.2.2 History of the Reviews of the Primary NAAQS for SO_X

The initial air quality criteria for SO_X were issued in 1969 (34 FR 1988, February 11, 1969). Based on these criteria, the EPA, in initially promulgating NAAQS for SO_X in 1971, established the indicator as SO_2. The two primary standards set in 1971 were 0.14 parts per million (ppm) averaged over a 24-hour period, not to be exceeded more than once per year, and 0.03 ppm, as an annual arithmetic mean.

[7] Lists of the CASAC members and of members of the CASAC Sulfur Oxides Panel are available at: https://yosemite.epa.gov/sab/sabpeople.nsf/WebCommitteesSubcommittees/CASAC%20Sulfur%20Oxides%20Panel

The first review of the air quality criteria and standards for SO_X was completed in several stages. In the first stage, the EPA released the Air Quality Criteria Document (AQCD) for PM and SO_X in December 1981, and an addendum presenting information from subsequently available controlled human exposure studies in 1982 (U.S. EPA, 1982a, 1982b). The policy aspects of the air quality criteria, and preliminary exposure analyses were evaluated by OAQPS staff in the 1982 Staff Paper (U.S. EPA, 1982c).

In 1986, the EPA published a second addendum to the 1982 AQCD, presenting newly available evidence from epidemiologic and controlled human exposure studies (U.S. EPA, 1986a). Policy-relevant aspects of the new evidence and staff findings from a companion population exposure assessment were evaluated in a 1986 Addendum to the 1982 Staff Paper (U.S. EPA, 1986b, 1986c). The CASAC reviewed all of these documents and provided advice and recommendations with regard to decisions for the review of the standards. Based on the evidence in the 1982 and 1986 documents, staff evaluations and CASAC recommendations, in 1988, the EPA proposed to retain the existing standards and solicited comment on the alternative of retaining the existing standards while additionally establishing a 1-hour standard of 0.4 ppm to protect against short-term exposures (53 FR 14926, April 26, 1988). In 1992, the American Lung association brought a lawsuit to compel the EPA to review and, if appropriate, revise the primary standards for SO_X, and the remainder of the review was then completed under court order (59 FR 58962, November 15, 1994; 61 FR 25566, May 22, 1996).

In 1994, the EPA prepared a supplement to the second addendum to the 1982 AQCD in response to publication of additional relevant controlled human studies on health effects of short-term SO_2 concentrations (1994 AQCD supplement [U.S. EPA, 1994a]). Policy-relevant aspects of the full body of evidence, including that newly available, along with the 1986 exposure analysis were evaluated in the 1994 Supplement to the 1982 Staff Paper (U.S. EPA, 1994b). Also in 1994, based on the available evidence, staff evaluations, CASAC advice, and public comment on the 1988 proposal, the EPA re-proposed to retain the existing standards and also solicited comment on retaining the existing standards in combination with one of three policy options to further reduce the health risk posed by exposure to high 5-minute peaks of SO_2 if additional protection were judged to be necessary (59 FR 58958, November 15, 1994). 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, not to be exceeded more than once per calendar year; (2) establishing a new regulatory program under section 303 of the CAA to supplement protection provided by the existing NAAQS, with a trigger level of 0.60 ppm SO_2, not to be exceeded more than once per calendar year; 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.

This review was completed in 1996 with the EPA's decision to retain without revision the existing standards (61 FR 25566, May 22, 1996). In reaching this decision, the Administrator concluded, based on the staff exposure analysis, that exposure of individuals with asthma to SO_2 levels that can reliably elicit adverse health effects was likely a rare event when viewed in the context of the entire population of people with asthma. As a result, the Administrator judged that 5-minute peaks of SO_2 did not pose a broad public health problem when viewed from a national perspective, and a 5-minute standard was not promulgated (61 FR 25566, May 22, 1996).

In 1996, the American Lung Association and the Environmental Defense Fund challenged the 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 determined that the EPA had not provided adequate rationale to support the judgment that 5-minute peaks of SO_2 do not pose a public health problem from a national perspective, given that the record for the rule indicated that these peaks would likely significantly affect a subset of individuals with asthma (*American Lung Ass'n v. EPA*, 134 F. 3d 388, 392-393 [D.C. Cir. 1998]). Following the remand, the EPA requested that states voluntarily submit 5-minute SO_2 monitoring data for the EPA to use to gain a better understanding of the magnitude and frequency of high, 5-minute peak SO_2 concentrations.

The next and most recent review of the air quality criteria and primary standards for SO_X was completed in 2010 (75 FR 35520, June 22, 2010; 74 FR 64810, December 8, 2009). The scientific evidence for this review was assessed in the 2008 ISA (U.S. EPA, 2008) and the exposure/risk analyses were presented in the 2009 REA (U.S. EPA, 2009). As a result of this review, the EPA promulgated a new 1-hour standard to provide the requisite protection for at-risk populations such as people with asthma against respiratory health effects related to short-term SO_2 exposures. The 1-hour standard was set with SO_2 as the indicator based on its common occurrence in the atmosphere and the predominance of SO_2 studies in the health effects information for SO_X. The standard was set at a level of 75 parts per billion (ppb), based on the 3-year average of the annual 99^{th} percentile of 1-hour daily maximum SO_2 concentrations. The EPA also revoked the then-existing 24-hour and annual primary standards based largely on the conclusion that the 1-hour standard would also control longer-term average concentrations, maintaining 24-hour and annual concentrations generally well below the levels of those standards, and on the lack of evidence indicating the need for such longer-term standards. The 2010 action also addressed the remand by the D.C. Circuit in 1998. The 2010 and prior standards are summarized in Table 1-1.

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

Final Rule/Decision	Indicator	Averaging Time	Level	Form
April 30, 1971 (36 FR 8186)	SO_2	24 hours	140 ppb[a]	one allowable exceedance per year
		1 year	30 ppb[a]	arithmetic average
May 22, 1996 (61 FR 25566)	Both the 24-hour and annual average standards retained without revision			
June 22, 2010 (75 FR 35520)	SO_2	1 hour	75 ppb	99th percentile of yearly distribution of 1-hour daily maximums, averaged over 3 years
		24-hour and annual standards revoked		

[a] Although the levels were set in terms of ppm (0.14 ppm for the 24-hour standard and 0.03 ppm for the annual standard), they are shown here in ppb for consistency with units of current standard.

In conjunction with the 2010 revisions to the standards, the EPA revised the SO_2 ambient air monitoring regulations to require that monitoring agencies using continuous SO_2 methods report the highest 5-minute concentration for each hour of the day (along with the hourly average); many agencies additionally report all twelve 5-minute concentrations for each hour of the day (75 FR 35554, June 22, 2010; 40 CFR 58.16). The rationale for this requirement was to provide additional monitoring data for use in subsequent reviews of the primary standard, particularly in considering the extent of protection provided by the 1-hour standard against 5-minute peak SO_2 concentrations of concern (75 FR 35554, June 22, 2010).

After publication of the final rule, a number of industry groups and states filed petitions for review arguing (1) that the EPA failed to follow notice-and-comment rulemaking procedures because the proposal did not indicate that EPA was considering changing its method of determining attainment from an air-monitoring approach to a hybrid approach using computer modeling in combination with air monitoring, and (2) that the decision to establish a 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, dismissing the first argument for lack of jurisdiction and denying the petitions with respect to the second argument, explaining that the EPA did not act arbitrarily in setting the 2010 standard (*National Environmental Developmental Association's Clean Air Project v. EPA*, 686 F. 3d 803[D.C. Cir. 2012]). Accordingly, the 2010 standard was upheld (*Id*.)

1.2.3 Current SO_2 NAAQS Review

In May 2013, the EPA announced the initiation of the current periodic review of the air quality criteria for SO_X and the primary NAAQS for sulfur oxides and issued a call for

information in the *Federal Register* (78 FR 27387, May 10, 2013). A wide range of external experts as well as EPA staff representing a variety of areas of expertise (e.g., epidemiology, human and animal toxicology, statistics, risk/exposure analysis, atmospheric science) participated in a workshop, held by the EPA on June 12-13, 2013 in Research Triangle Park, NC. The workshop provided for a public discussion of the key policy-relevant issues around which the EPA has structured the review and of the most meaningful new scientific information that would be available in this review to inform our understanding of these issues.

Building from the workshop discussions, the EPA developed the draft *Integrated Review Plan for the Primary National Ambient Air Quality Standards for Sulfur Dioxide, External Review Draft* (draft IRP, U.S. EPA, 2014b; 79 FR 14035, March 12, 2014) outlining the schedule, process, and key policy-relevant questions that would guide the evaluation of the air quality criteria for SO_2 and the review of the primary NAAQS for SO_X. The draft IRP was released in March 2014 (79 FR 14035, March 12, 2014) and was the subject of a consultation with the CASAC on April 22, 2014 (79 FR 16325, March 25, 2014). Comments received from the CASAC and the public were considered in the preparation of the final IRP, which was released in October 2014 (U.S. EPA, 2014a; 79 FR 66721, November 10, 2014).

The process for development of the first draft ISA included review of preliminary drafts of key ISA chapters by subject matter experts at a public workshop hosted by the EPA's National Center for Environmental Assessment (NCEA) on June 23-24, 2014 (79 FR 33750, June 12, 2014). Comments received from this review as well as comments from the public and the CASAC on the draft IRP were considered in preparation of the *Integrated Science Assessment for Sulfur Oxides – Health Criteria (External Review Draft – November 2015,* U.S. EPA, 2015), released in November 2015 (80 FR 73183, November 24, 2015). The first draft ISA was reviewed by the CASAC at a public meeting in January 2016 and a public teleconference in April 2016 (80 FR 79330, December 21, 2015; 80 FR 79330, December 21, 2015; Diez Roux, 2016).

The EPA released the *Integrated Assessment for Sulfur Oxides – Health Criteria (Second External Review Draft – December 2016,* U.S. EPA, 2016b) in December 2016, which was reviewed by the CASAC at a public meeting in March 2017 and a public teleconference in June 2017 (82 FR 11449, February 23, 2017; 82 FR 23563, May 23, 2017). The final ISA was released in December 2017 (U.S. EPA, 2017b; 82 FR 58600, December 13, 2017).

As part of the planning process for development of the REA, the EPA completed the *Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides: Risk and Exposure Assessment Planning Document* (REA Planning Document, U.S. EPA, 2017d) in February 2017 (82 FR 11356, February 22, 2017), and held a consultation with the CASAC at a public meeting in March 2017 (82 FR 11449, February 23, 2017). In consideration of CASAC

comments at that consultation, as well as public comments, the EPA developed the draft REA (U.S. EPA, 2017e) and the draft PA (U.S. EPA 2017c), which were released on August 24, 2017 (82 FR 43756, September 19, 2017). The draft REA and draft PA were reviewed by the CASAC at a a public meeting on September 18-19, 2017 (82 FR 37213, August 9, 2017), with CASAC advice and comments provided in letters to the Administrator dated April 30, 2018 (Cox and Diez Roux, 2018a,b). Staff considered CASAC advice and public comments in completing these documents.

The schedule for completion of this review is governed by a consent decree, which, in relevant part, specifies signature on the notice setting forth the EPA's proposed decision concerning its review of the primary NAAQS for SO_X no later than May 25, 2018; and sign a notice setting forth EPA's final decision concerning its review of the primary NAAQS for SO_X no later than January 28, 2019 (Consent Decree at 4, *Center for Biological Diversity et al. v. Pruitt*, Case No. 3:16-cv-03796-VC (N.D. Cal. April 28, 2017), Document No. 37 entered by the court on April 28, 2017).

1.3 GENERAL APPROACH AND ORGANIZATION OF THIS DOCUMENT

This PA draws on the policy-relevant aspects of the scientific evidence and quantitative air quality, exposure and risk analyses. With regard to the health effects evidence, we consider the nature of the key effects associated with SO_2 in ambient air, the types and magnitudes of exposures associated with effects, and populations at greatest risk, as well as the uncertainties. Based on this information, we summarize associated potential public health impacts of SO_2 in ambient air. We additionally consider the magnitude of exposures and risks estimated in the REA, along with the associated uncertainties. This evaluation supports staff conclusions with regard to the key policy-relevant questions for the review, including whether the currently available information appears to call into question the adequacy of public health protection afforded by the current standard.

Following this introductory chapter, chapter 2 focuses on current air quality, including sources of SO_2 to ambient air, the ambient monitoring network for SO_2, and trends and current conditions. Chapter 3 has three areas of focus. Section 3.1 focuses on the review of the primary NAAQS for SO_X presenting background information on the rationale for previous reviews and the approach followed in the current review. Section 3.2 considers the evidence and exposure and risk information for the current standard, as well as CASAC advice, and presents staff conclusions regarding these considerations in this review. Section 3.3 identifies key uncertainties and areas for future research.

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2 CURRENT AIR QUALITY

This chapter presents a summary of our current understanding of SO_X in ambient air largely drawn from the more detailed discussion provided in the ISA (ISA, chapter 2). Section 2.1 summarizes the current information on sources and emissions and section 2.2 summarizes current ambient air monitoring methods and networks. Recent concentrations of SO_2 in ambient air are summarized in section 2.3.

2.1 SOURCES TO AMBIENT AIR

In this section, we describe the most recently available information on sources and emissions of SO_X into the ambient air. The section does not provide a comprehensive list of all sources, nor does it provide estimates of emission rates or emission factors for all source categories. Rather, the discussion here is intended to identify the larger source categories, either on a national or local scale, and generally describe their emissions and distribution within the U.S. based on the U.S. EPA 2014 National Emissions Inventory (NEI).

Sulfur oxides are emitted into air from specific sources (e.g., fuel combustion processes) and also formed in the atmosphere from other atmospheric compounds (e.g., as an oxidation product of reduced sulfur compounds, such as sulfides). Sulfur oxides are also transformed in the atmosphere to particulate sulfur compounds, such as sulfates. Sulfur oxides known to occur in the troposphere include SO_2 and sulfur trioxide (SO_3) (ISA, section 2.3). As a result of rapid atmospheric chemical reactions involving SO_3, the most prevalent sulfur oxide in the atmosphere is SO_2 (ISA, section 2.3).

Fossil fuel combustion is the main anthropogenic source of SO_2 emissions, while volcanoes and landscape fires (wildfires as well as controlled burns) are the main natural sources (ISA, section 2.1).[1] Industrial chemical production, pulp and paper production, natural biological activity (plants, fungi, and prokaryotes), and volcanoes are among many sources of reduced sulfur compounds that contribute, through various oxidation reactions in the atmosphere, to the formation of SO_2 in the atmosphere (ISA, section 2.1). Anthropogenic SO_2 emissions originate primarily from point sources, including coal-fired electricity generating units (EGUs) and other industrial facilities (ISA, section 2.2.1). The largest SO_2-emitting sector within the U.S. is

[1] The 2008 ISA (U.S. EPA, 2008) described a modeling analysis that estimated SO_2 concentrations for 2001 in the absence of any U.S. anthropogenic emissions of SO_2 (2008 ISA, section 2.5.3). Such concentrations are referred to as United States background or USB. The 2008 ISA analysis estimated USB concentrations of SO_2 to be below 0.01 ppb over much of the U.S., ranging up to a maximum of 0.03 ppb. In the U.S. Northwest, geothermal sources (e.g., volcanoes) were estimated to be responsible for up to 80% of the ambient air concentrations resulting solely from natural sources and sources outside of the U.S. (ISA, section 2.5.5).

electricity generation, as shown in Figure 2-1, of which 97% of SO_2 from electricity generation is from coal combustion.

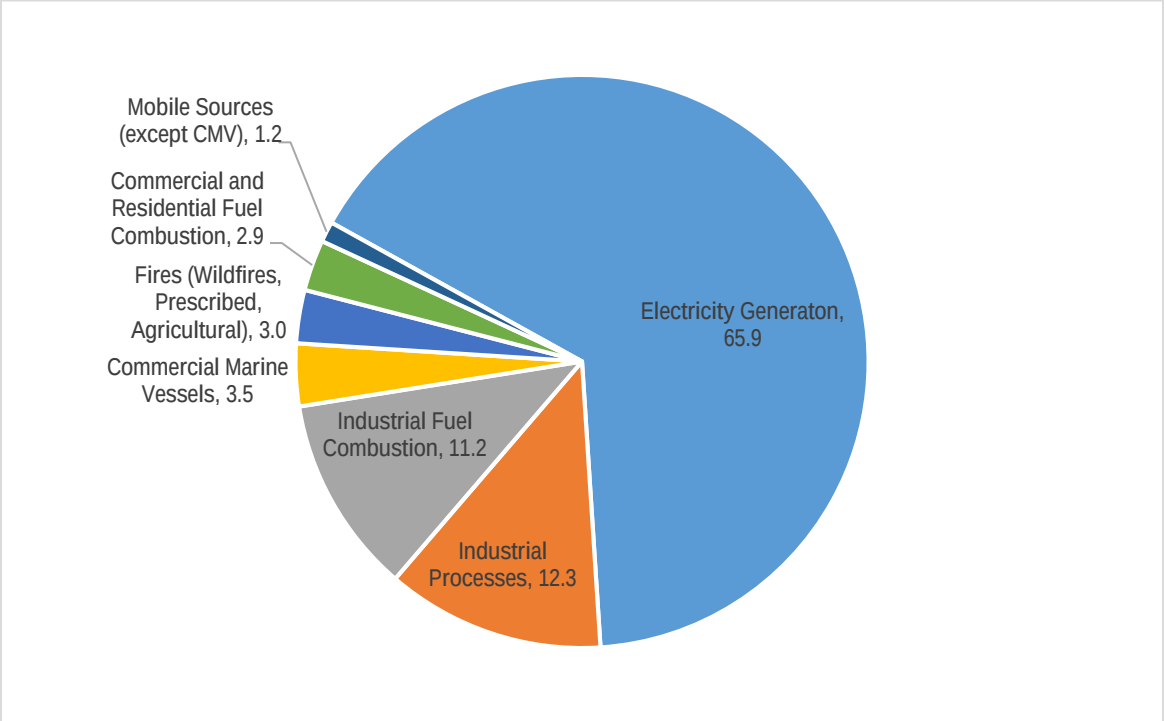

Figure 2-1. Percent contribution of SO_2 emissions by sector (Source: 2014 NEI).[2]

Other anthropogenic sources of SO_2 emissions include industrial fuel combustion and process emissions, industrial processing, commercial marine activity, and fire used in landscape management and agriculture (ISA, section 2.2.1). While electricity generation is the dominant industry sector contributing to SO_2 emissions on a national scale, other sectors can also have a significant influence on local air quality. Large emissions facilities other than EGUs that may substantially impact local air quality include copper smelters, kraft pulp mills, Portland Cement plants, iron and steel mill plants, sulfuric acid plants, petroleum refineries, and chemical processing plants (ISA, p. 2-5). For example, ambient air monitoring sites that have recorded some of the highest 1-hour daily maximum SO_2 concentrations in the U.S. are located near copper smelters in Arizona (ISA, sections 2.5.2 and 2.5.4; Figure 2-11). The two smelters in this area had estimated annual emissions of approximately 17,000 and 5,000 tpy in the 2014 NEI (ISA, p. 2-50).

[2] Total SO_2 emissions from the 2014 NEI were 4,942,063 tons.

Figure 2-2 illustrates the national emissions trends from 1990 to 2016. Declines in SO_2 emissions are likely related to the implementation of national control programs developed under the Clean Air Act Amendments of 1990, including Phase I and II of the Acid Rain Program, the Clean Air Interstate Rule, and the Cross-State Air Pollution Rule. An additional factor is changes in market conditions, e.g., reduction in energy generation by coal (U.S. EIA, 2017).[3] Declines between 1971, when SO_X NAAQS were first established, and 1990, when the Amendments were adopted, were on the order of 5,000 tpy deriving primarily from reductions in emissions from the metals processing sector (ISA, Figure 2-5).

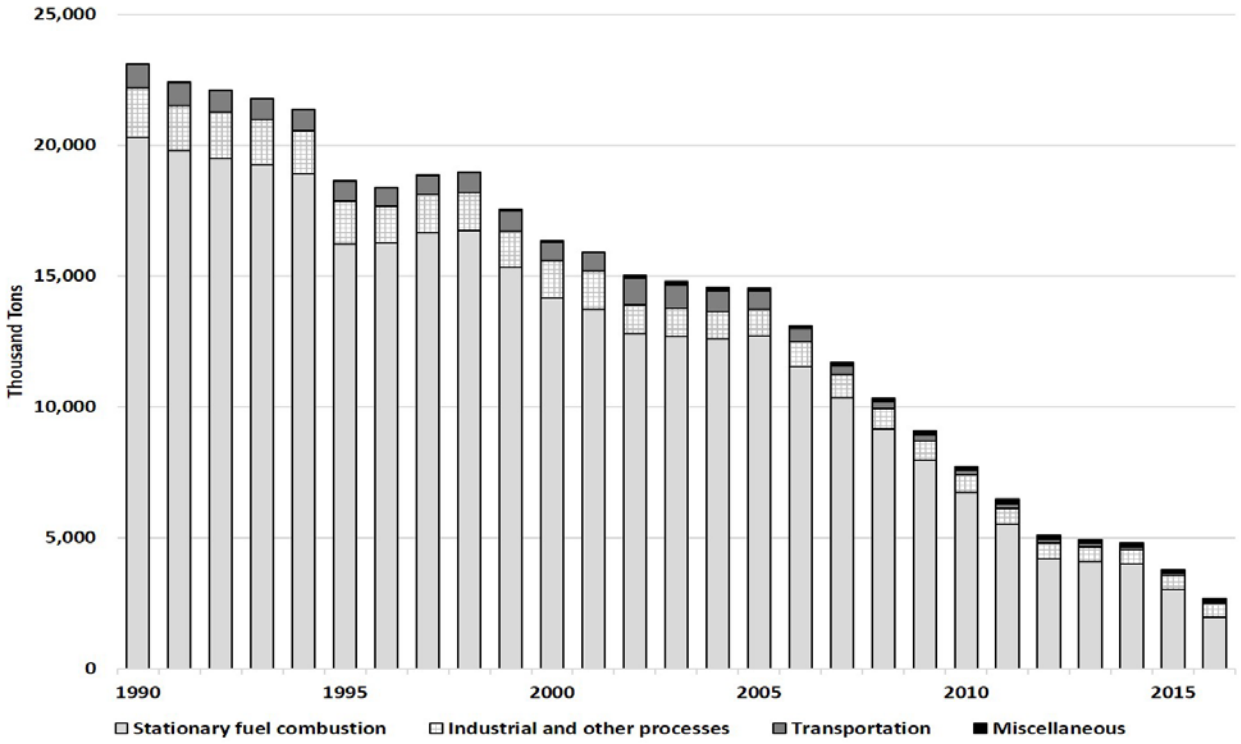

Figure 2-2. National SO_2 emission trends by sector.

2.2 AMBIENT AIR MONITORING METHODS AND NETWORK

To promote uniform enforcement of the air quality standards set forth under the CAA, the EPA has established federal reference methods (FRMs) and federal equivalent methods (FEMs) for ambient air sample collection and analysis. Measurements for determinations of NAAQS compliance must be made with FRMs or FEMs. The current SO_2 monitoring network relies on

[3] The reduction in energy generation by coal resulted in the use of fuels that emit less SO_2 in energy generation (U.S. EIA, 2016).

the automated pulsed ultraviolet fluorescence (UVF) FRM (40 CFR Appendix A-1 to Part 50; 40 CFR Appendix A-2 to Part 50). The UVF method is a continuous automated method that quantifies SO_2 concentrations, providing averages across desired time periods, such as 5-minute and 1-hour averages.

Measurements of SO_2 concentrations in ambient air are collected by networks of FRM monitors, primarily operated by state and local monitoring agencies in the U.S. The main network providing ambient data for NAAQS surveillance monitoring purposes is the State and Local Air Monitoring Stations (SLAMS) network. In 2016, there were 363 SLAMS sites reporting SO_2 concentrations to the Air Quality System (AQS), the EPA's repository for detailed air pollution data. For each SO_2 monitoring site, the SLAMS monitoring agencies report hourly concentrations and either the maximum 5-minute concentration in the hour (one of twelve 5-minute periods within an hour) or all twelve 5-minute average SO_2 concentrations within the hour.

Five minute SO_2 data have become much more widely available due to regulatory requirements promulgated in 2010 (Figure 2-3).[4] Although 5-minute concentration measurements were available for fewer than 10% of monitoring sites at the time of the last review, such data (either all 12 values in each hour or just the maximum 5-minute concentrations) are currently available for nearly all of the SO_2 sites operating nationwide, providing a more robust foundation for characterization of 5-minute ambient air concentrations in this review. Further, the newly available monitoring data also include more monitors reporting the 12 consecutive 5-minute concentrations for each hour than were available in the last review (Figure 2-3). Of the monitors reporting 5-minute data in 2016, almost 40% are reporting all twelve 5-minute SO_2 measurements in each hour while about 60% are reporting the maximum 5-minute SO_2 concentration in each hour.[5]

[4] At SO_2 NAAQS compliance monitoring sites, air monitoring agencies are now required to report, for every hour of the day, 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 (75 FR 35554, June 22, 2010).

[5] In 2016, three sites reported both the continuous 5-minute data and the maximum 5-minute data separately. Therefore, these monitors are included in the count for each of the categories of 5-minute measurements.

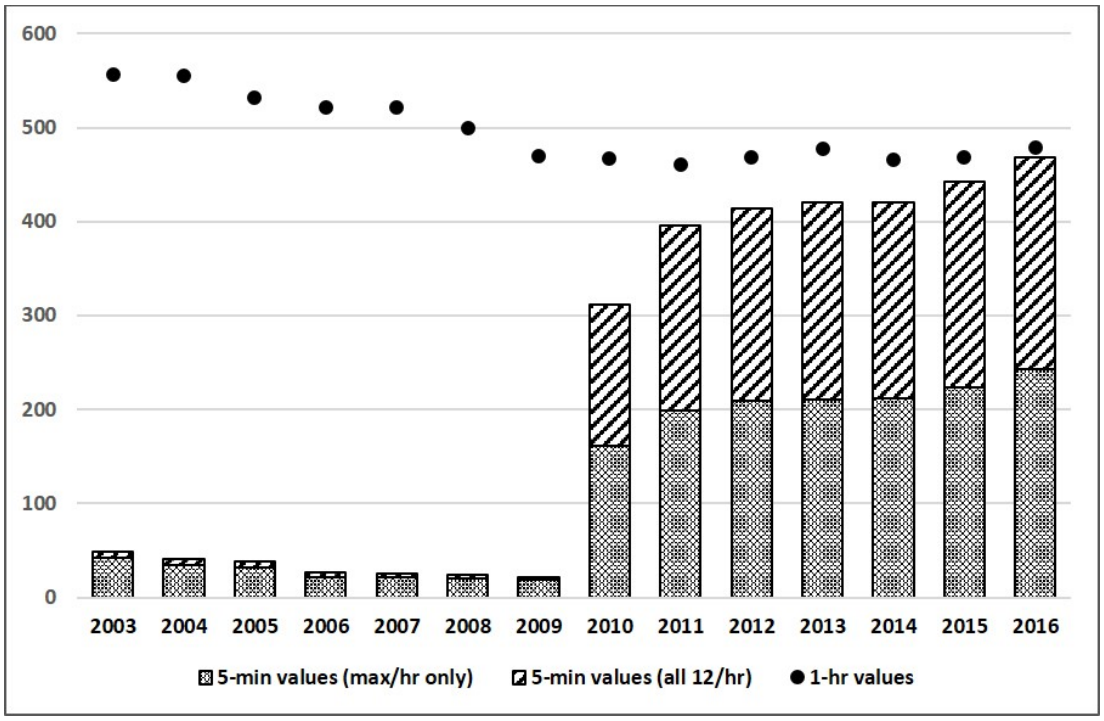

Figure 2-3. Temporal trend in number of monitors reporting 5-minute concentrations.

2.3 AMBIENT AIR MONITORING CONCENTRATIONS

This section briefly summarizes trends in ambient air SO_2 concentrations and current conditions based on recent ambient air monitoring data.

2.3.1 Trends

Ambient air concentrations of SO_2 in the U.S. have declined substantially from 1980 to 2016. Figure 2-4 illustrates this decline in terms of the distribution of 3-year averages of annual 99th percentile daily maximum 1-hour concentrations[6] at 24 monitoring sites that have been operating across this period. The average of this dataset has declined by more than 82% over the 36-year period (the white line in Figures 2-4 and 2-5). Over the past 16 years, a larger dataset of 193 sites operating from 2000-2016 also indicates a decline, which is on the order of 69% for the

[6] The form of the current 1-hour SO_2 NAAQS is the 99th percentile of the yearly distribution of 1-hour daily maximums, averaged over 3 years.

average of that dataset (Figure 2-5).[7] Daily maximum 5-minute SO_2 concentrations have also consistently declined over time from 2011 to 2016 (Figure 2-6).[8]

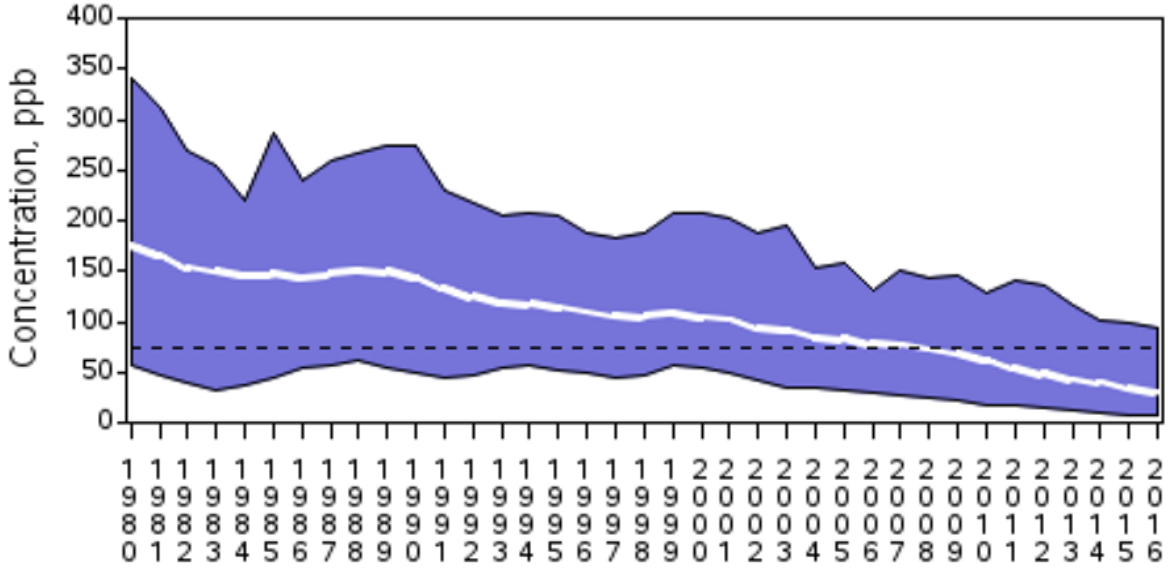

Figure 2-4. National temporal trend in SO_2 concentrations: 1980-2016 (24 sites). Three-year average of annual 99th percentile of daily maximum 1-hour concentrations. *(Note: Dashed line indicates the current standard [75 ppb].)*

[7] In Figures 2-4 and 2-5, the year on the x-axis represents the last year of the 3-year average (e.g., 2015 represents the average of 2013-2015). Additionally, the lower and upper bounds of the shaded area are the 10th and 90th percentiles, respectively.

[8] In Figure 2-6, the number of sites with monitors for 2011, 2012, 2013, 2014, 2015, and 2016 were 301, 321, 366, 359, 352, and 366, respectively.

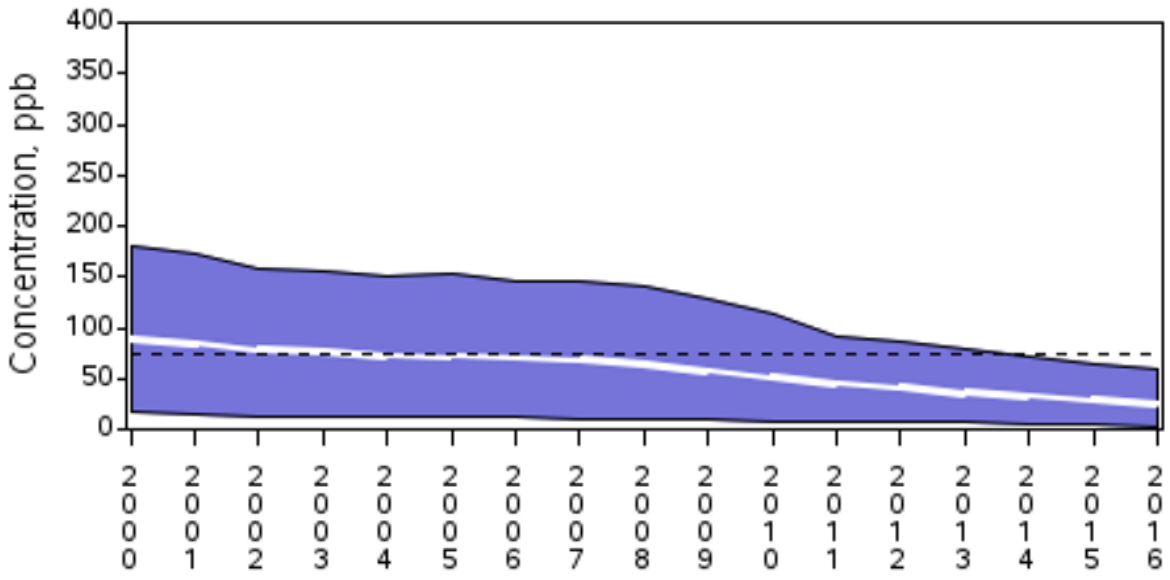

Figure 2-5. Temporal trend in SO_2 concentrations: 2000-2016 (193 sites). Three-year average of annual 99th percentile of daily maximum 1-hour concentrations. *(Note: Dashed line indicates the current standard [75 ppb]).*

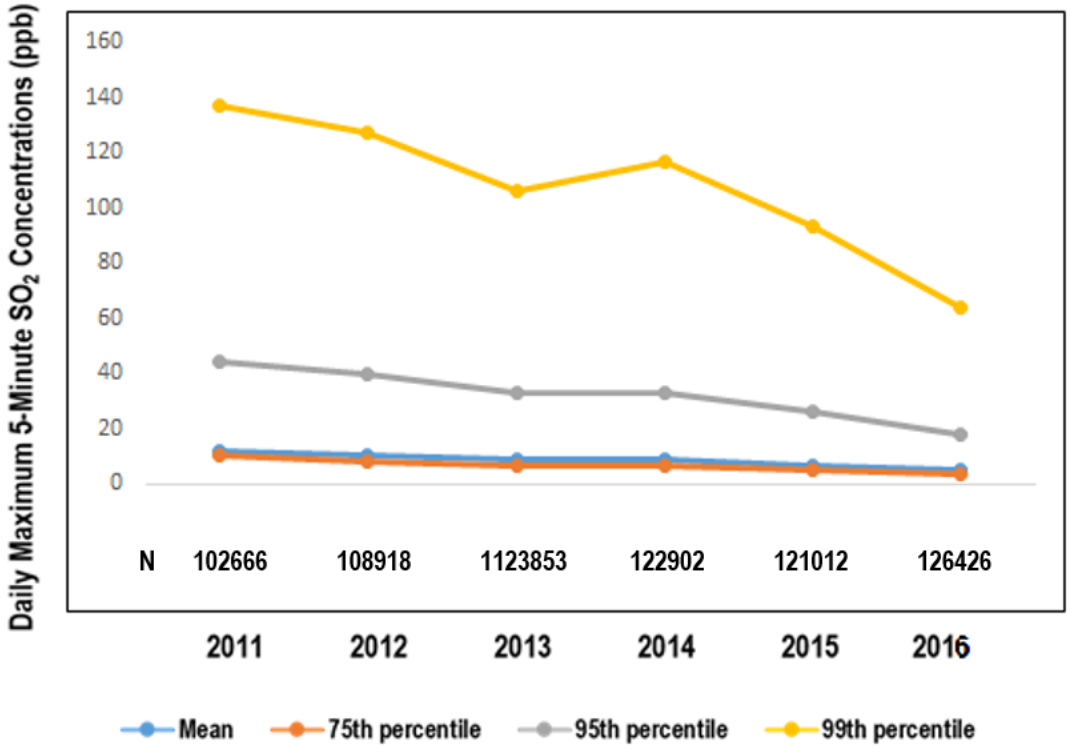

Figure 2-6. Temporal trend in daily maximum 5-minute SO_2 concentrations: 2011-2016. (N = number of measurements)

2.3.2 Current Concentrations

2.3.2.1 Geographic Variation in Concentrations

Concentrations of SO_2 vary across the U.S. and tend to be higher in areas with sources having relatively higher SO_2 emissions (e.g., EGUs).[9] Consistent with the locations of larger anthropogenic SO_2 sources, higher concentrations are primarily located in the eastern half of the continental U.S., especially in the Ohio River valley, upper Midwest, and along the Atlantic coast (Figure 2-7). The point source nature of SO_2 emissions contribute to the relatively high spatial variability of SO_2 concentrations compared with pollutants such as ozone (O_3) and PM (ISA, section 3.2.3). Another contributing factor to the spatial variability is the dispersion and oxidation of SO_2 in the atmosphere, resulting in decreasing SO_2 concentrations with increasing distance from the source. Sulfur oxides emitted from point sources tends to travel away from the emissions source as a plume, which may or may not impact large portions of surrounding populated areas depending on meteorological conditions and terrain (ISA, section 3.2.3).

[9] Volcano emissions contribute to the elevated concentrations observed on the island of Hawaii.

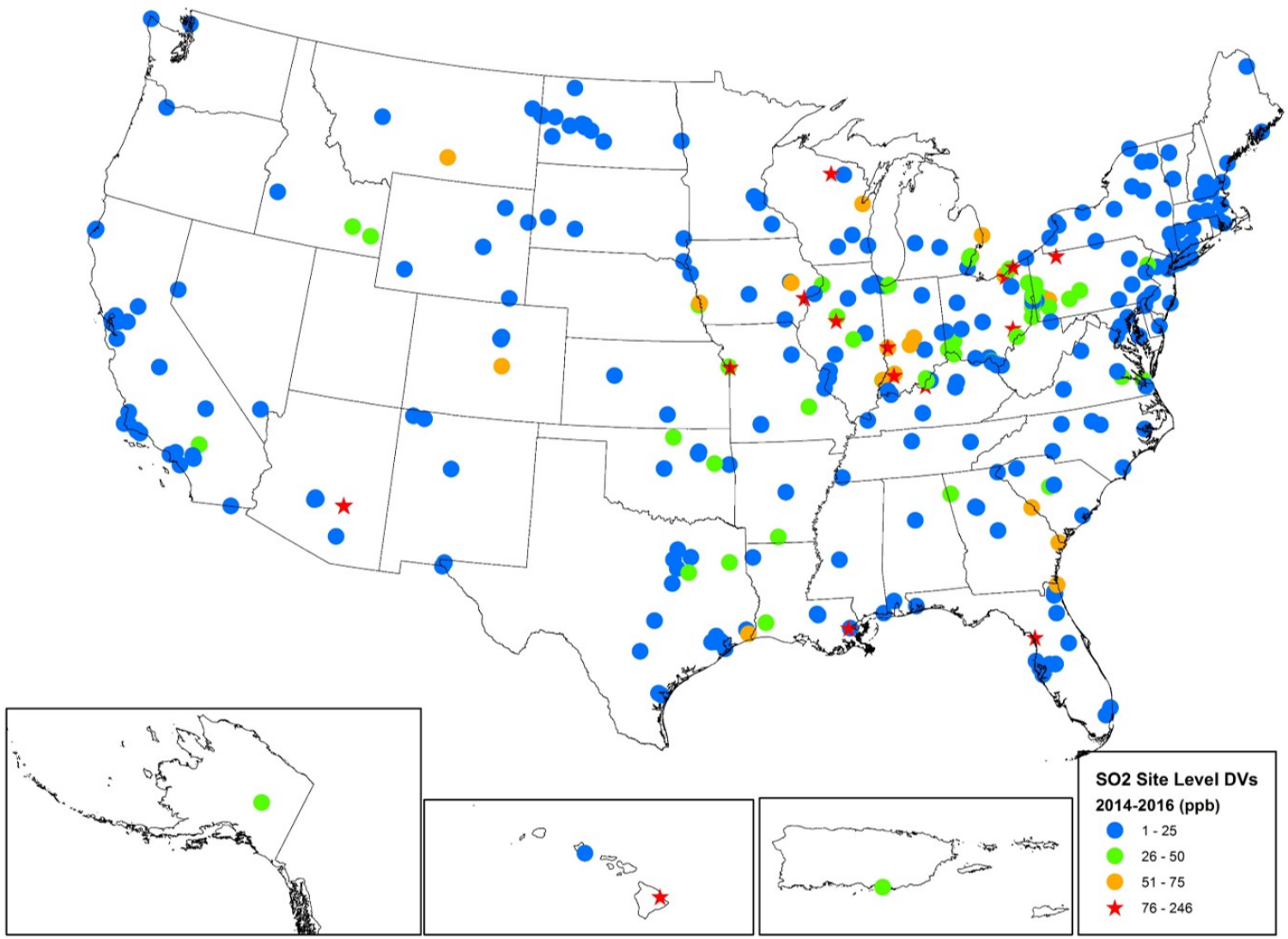

Figure 2-7. Concentrations of SO_2 in terms of the current standard (3-year average of annual 99th percentile daily maximum 1-hour concentrations) at sites with datasets meeting completeness requirements for 2014-2016.

2.3.2.2 Seasonal and Diel Variability in Concentrations

Recent (2013-2015) data indicate that 1-hour daily maximum SO_2 concentrations vary across seasons, with the greatest variations seen in the upper percentile concentrations (versus average or lower percentiles) for each season (ISA, section 2.5.3.2). This is seen in the data presented for six areas in the draft ISA[10] (ISA, section 2.5.3.2). This variation, along with month-to-month variations in 1-hour daily maximum SO_2 concentrations also presented in the ISA, were generally consistent with month-to-month emissions patterns and the expected atmospheric chemistry of SO_2 for a given season. For example, "summertime minima, observed in the New York City, NY and Houston, TX, sites may correspond to enhanced oxidation of SO_2 to SO_4^{2-} by photochemically derived atmospheric oxidants that are more prevalent during the humid summer (Khoder, 2002)" (ISA, p. 2-63). The differences in seasonal pattern (as well as magnitude) of concentrations among areas studied indicate the variability of SO_2 concentrations across local and regional scales (ISA, section 2.5.3.2).

Consistent with the nationwide diel patterns reported in the last review, 1-hour average and 5-minute hourly maximum SO_2 concentrations for 2013-2015 in the six areas evaluated in the ISA were generally low during nighttime and approached maxima values during daytime hours (ISA, section 2.5.3.3, Figures 2-23 and 2-24). The timing and duration of daytime maxima in the six areas evaluated were likely related to a combination of source emissions and meteorological parameters (ISA, section 2.5.3.3; U.S. EPA 2008, section 2.5.1). For example, SO_2 emitted from elevated point sources (e.g., power plants and industrial sources) may be entrained into the mixed boundary layer, which expands during the day with rising surface temperatures (U.S. EPA 2008, section 2.5.1, Figures 2-23 and 2-24).

2.3.2.3 Relationship Between 1-hour and 5-minute Concentrations

Peak concentrations within a plume of SO_2 downwind from, but relatively nearby to, a source can greatly exceed mean concentrations across the plume (ISA, section 2.5.4). Further, measured 5-minute concentrations at a particular location can be much higher than the average concentration at the same location for the associated hour. However, as emissions travel further downwind and experience ever increasing dispersion, these differences lessen both spatially and temporally. This can contribute to greater spatial and temporal variability in 5-minute than in 1-hour concentrations, as is seen in the six locations evaluated in the ISA (second draft ISA, p. 2-56).

[10] The six locations evaluated are: Cleveland, OH, Pittsburgh, PA, New York City, NY, St. Louis, MO-IL, Houston, TX, and Gila County, AZ (ISA, section 2.5.2.2). These six locations were chosen for the ISA "focus area" analysis based on (1) their relevance to current health studies (i.e., areas with peer-reviewed, epidemiologic analysis), (2) the existence of four or more monitoring sites located within the area boundaries, and (3) the presence of several diverse SO_2 sources within a given focus area boundary (ISA, section 2.5.2.2).

Using monitoring data from 2014-2016, Figure 2-8 illustrates the general pattern of lower 5-minute concentrations with lower 1-hour concentrations. The left panel of Figure 2-8 shows that across the monitors meeting data completeness criteria, on days when the maximum 1-hour concentrations are relatively low, the daily maximum 5-minute concentrations are also relatively low. Similarly, as shown in the right panel of Figure 2-8, at sites with relatively lower design values,[11] the distribution of maximum 5-minute concentrations is also lower. This is documented by the distinct reduction in 99th percentile daily maximum 5-minute concentrations at lower design values. For example, in areas with design values at or below the current standard (75 ppb), 99.9 percent of daily maximum 5-minute concentrations are at or below approximately 131 ppb.[12] This contrasts with the much higher distribution of daily maximum 5-minute concentrations at sites with design values exceeding the current standard. The 99th percentile of these daily maximum 5-minute concentrations is 359 ppb, meaning that one percent of the days at these sites has a maximum 5-minute concentration above 359 ppb (i.e., 186 occurrences).

[11] The design value (DV) is a statistic that describes the air quality status of a given area relative to a particular NAAQS. A design value summarizes the concentrations of a criteria pollutant in terms of the statistical form of the standard for that pollutant, thus indicating whether the area meets or exceeds the standard. Consistent with the form of the SO_2 standard, SO_2 design values are calculated as the 3-year average of the annual 99th percentile of the daily maximum 1-hour average concentrations (see 40 CFR 50.17). By regulation, design values calculated from monitoring data are considered to be valid if they meet specified completeness criteria, which for SO_2 are data for at least 75 percent of the sampling days in all four quarters of all three years of the period (see Appendix T to Part 50).

[12] Additional information related to data in Figure 2-8 is presented in Appendix B, Tables B-1 and B-2.

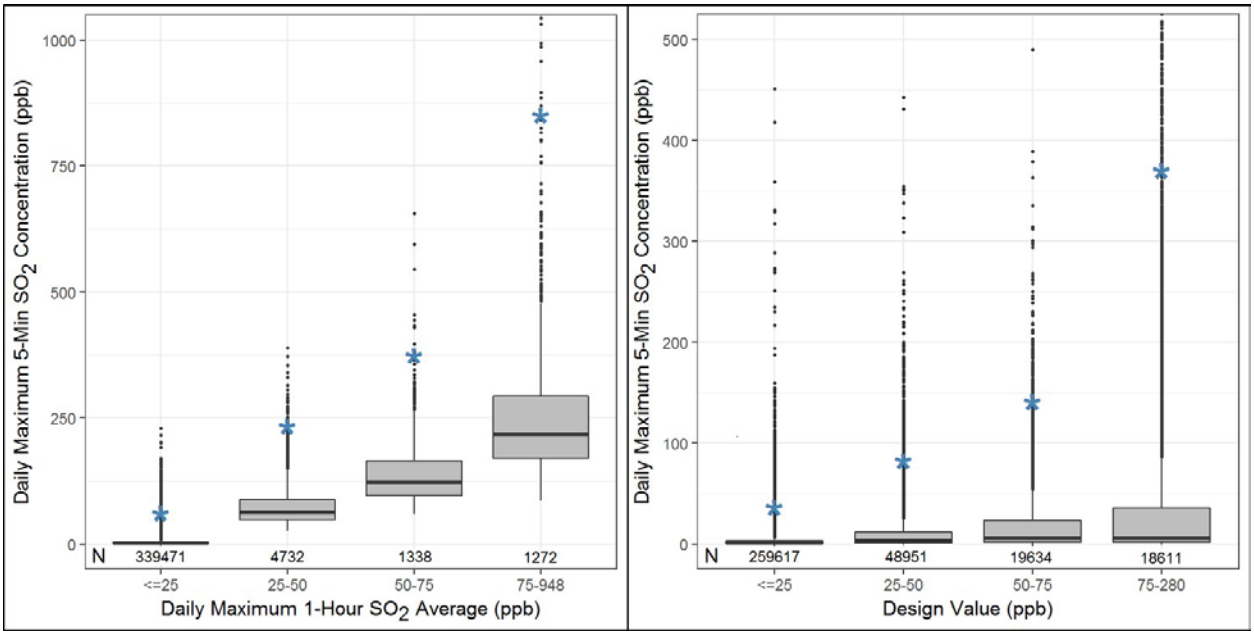

Figure 2-8. Distributions of daily maximum 5-minute concentrations during 2014-2016. Left panel presents varying distributions with varying daily maximum 1-hour concentrations. Right panel presents varying distributions with varying design values; the last bin (>75 ppb) presents data for sites not meeting the current standard. *(Note: The values represented in the boxplots are the 25th percentile, the median, and the 75th percentile. The asterisk represents the 99th percentile.)*

Analyses of the current monitoring dataset, expanded since the last review, provide information on the occurrence of daily maximum 5-minute concentrations of interest at monitors having differing design values. For example, analysis of these data for the years 2014 to 2016 indicates that among monitors with design values meeting the current standard (i.e., at or below 75 ppb), the vast majority have zero days with a daily maximum 5-minute concentration above 400 ppb or even 100 ppb (Appendix C). Among the few monitors with any days recording a 5-minute concentration above 400 ppb, the maximum number of such days in a year was seven; for monitors with any days recording 5-minute concentrations above 200 ppb, the maximum number of such days/year was 32 (Appendix C, Figures C-2 and C-4, lower panel).

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3 REVIEW OF THE PRIMARY STANDARD FOR SULFUR OXIDES

This chapter evaluates the policy implications of the key scientific and technical information in the ISA and REA. This evaluation is based on consideration of the available body of evidence assessed in the ISA and of quantitative analyses of SO_2 air quality, exposures and risks presented in the REA and in this document. Based on this information, the staff offer conclusions regarding each of the critical elements of the standard, including indicator, averaging time, form, and level. This final PA is also informed by the advice and recommendations received from the CASAC during its review of the draft PA, and by public comments received on the draft document. The final PA is designed to help the Administrator in considering the currently available scientific and risk information and formulating judgments regarding the adequacy of the current primary standard.

3.1 APPROACH

Staff's approach in this review of the primary standard for SO_X takes into consideration the approaches used in the previous review. The past and current approaches described below are both based, most fundamentally, on using the EPA's assessment of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding a primary standard for SO_X that is requisite to protect public health with an adequate margin of safety. In reaching conclusions on options for the Administrator's consideration, we note that the final decision to retain or revise the current SO_2 primary standard is a public health policy judgment to be made by the Administrator.

The final decision by the Administrator will draw upon the available scientific evidence for SO_2-attributable health effects, and on quantitative analyses of population exposures and health risks, including judgments about the appropriate weight to assign the various uncertainties inherent in the evidence and analyses. Therefore, in developing conclusions in this PA, we are mindful that the Administrator's judgments on the standard will reflect an interpretation of the available scientific evidence and exposure/risk information in consideration of the strengths and limitations of that evidence and information. Our general approach to informing these judgments, discussed more fully below, recognizes that the available health effects evidence reflects a continuum from relatively higher SO_2 concentrations, at which scientists generally agree that health effects are likely to occur, through lower concentrations at which the likelihood and magnitude of a response become increasingly uncertain. This approach is consistent with the requirements of sections 108 and 109 of the CAA, as well as with how the EPA and the courts

have historically interpreted the Act. These provisions require the Administrator to establish primary standards that in the Administrator's judgment are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act 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.[1]

Section 3.1.1 below summarizes the approach used in the last review of the primary NAAQS for SO_X and section 3.1.2 summarizes the general approach for the current review.

3.1.1 Approach in the Previous Review

The last review of the primary NAAQS for SO_X was completed in 2010 and resulted in substantial revisions to the standards (75 FR 35520, June 22, 2010). In consideration of the evidence of respiratory effects in people with asthma in response to exposures as short as five minutes, the EPA established a new short-term standard to provide increased protection for this at-risk group and other potentially at-risk populations[2] 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 35525-35526, June 22, 2010; 2008 ISA, section 5.5). Specifically, the EPA replaced the then-existing 24-hour standard with a 1-hour standard of 75 ppb in terms of the 3-year average of the 99th percentile of the yearly distribution of 1-hour daily maximum SO_2 concentrations. In addition to replacing the 24-hour standard with a new 1-hour standard, the EPA revoked the then-existing annual standard, based largely on the lack of sufficient health evidence to support a long-term standard and a recognition that a 1-hour standard set at 75 ppb would have the effect of generally maintaining annual SO_2 concentrations well below the level of the revoked annual standard (75 FR 35550, June 22, 2010).

The emphasis on short-term exposures of people with asthma reflected the health effects evidence that has expanded in this area over the four decades since the then-existing 24-hour and annual standards were set in 1971 (2008 ISA; U.S. EPA, 1982, 1986, 1994). A key element of the expanded evidence base was a series of controlled human exposure studies which

[1] The four basic elements of the NAAQS (indicator, averaging time, level and form) are considered collectively in evaluating the health protection afforded by the current standard.

[2] As used here and similarly throughout the 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.

documented bronchoconstriction-related effects on lung function in people with asthma exposed while breathing at elevated rates[3] for periods as short as five minutes. In the 2010 review, the EPA also conducted quantitative analyses of air quality data, including 5-minute ambient air measurements, and of potential exposures for people with asthma. Consideration of these key aspects of the evidence and quantitative analyses informed the decision in the 2010 review, which additionally addressed the court remand[4] to the EPA of the EPA's 1996 decision to retain the 1971 standards without revision.

The quantitative assessment for the review focused particularly on the issue of exposures to SO_2 in ambient air for a duration as short as five minutes (2008 ISA; 2009 REA). The quantitative analyses documented in the REA included characterizations of the likelihood of people with asthma being exposed (while breathing at elevated rates, such as associated with many common outdoor activities) to concentrations of SO_2 from ambient air of a magnitude documented to elicit decrements in lung function (2009 REA). These analyses were performed both for air quality conditions associated with just meeting the then-existing standards and for conditions associated with just meeting potential alternative standards. The REA additionally included air quality analyses that explored the extent to which potential alternative standards with 1-hour, 24-hour, and annual averaging times might be expected to control 5-minute ambient air concentrations (2009 REA, section 7.3). The quantitative assessments together with the health effects evidence informed the policy options considered by the Administrator. Considerations, conclusions and judgments by the Administrator that provided the basis for her decisions in the 2010 review are summarized below.

3.1.1.1 Considering the Need for Revision

The conclusions reached by the Administrator in the last review were based on the extensive body of scientific evidence on SO_2-related health effects and quantitative analyses of air quality, exposure and risk. In her conclusion on the adequacy of the then-existing standards, which were set in 1971, the Administrator emphasized the evidence and quantitative analyses concerning 5-minute exposures. The Administrator gave particular attention to the robust evidence base, comprised of findings from controlled human exposure, epidemiologic, and animal toxicological studies that collectively were judged "sufficient to infer a causal

[3] The phrase "elevated ventilation" (or "moderate or greater exertion") was used in the 2009 REA and Federal Register notices in the last review to refer to activity levels that in adults would be associated with ventilation rates at or above 40 liters per minute; an equivalent ventilation rate was derived in order to identify corresponding rates for the range of ages and sizes of the simulated populations (2009 REA, section 4.1.4.4). Accordingly, these phrases are used in this draft PA when referring to the REA from the last review. Otherwise, however, the REA and PA for this review generally use the phrase "elevated breathing rates" to refer to the same occurrence.

[4] See *Am. Lung Ass'n v. EPA*, 134 F.3d 388 (D.C. Cir. 1998) (remanding the 1996 decision to EPA).

relationship" between short-term SO_2 exposures ranging from 5 minutes to 24 hours and respiratory morbidity (75 FR 35535, June 22, 2010). The "definitive evidence" for this conclusion came from studies of 5- to 10-minute controlled exposures that reported respiratory symptoms and decreased lung function in exercising individuals with asthma (2008 ISA, section 5.2). Supporting evidence was provided by epidemiologic studies of a broader range of respiratory outcomes, with uncertainty noted about the magnitude of the study effect estimates, quantification of the exposure concentration-response relationship, potential confounding by co-pollutants, and other areas (75 FR 35535-35536, June 22, 2010; 2008 ISA, section 5.3).

In the controlled human exposure studies of exercising individuals with asthma, a dose-response relationship was documented for bronchoconstriction-related effects, with both the percentage of individuals affected and the severity of the response increasing with increasing SO_2 concentrations (75 FR 35525, June 22, 2010). The evidence from these studies documents the occurrence of SO_2-related decrements in lung function based on reductions in forced expiratory volume in one second (FEV_1) and increases in specific resistance of the airways (sRaw). Moderate[5] or greater decrements in lung function were reported in response to short (5- to 10-minute) exposures to concentrations as low as 200 to 300 ppb in approximately 5-30% of exercising individuals with asthma. In response to exposures at or above 400 ppb, approximately 20-60% experienced such decrements, frequently accompanied by respiratory symptoms; in many studies, responses at these concentrations were often statistically significant at the group mean level[6] (75 FR 35525-35526, June 22, 2010).

In reaching conclusions regarding the significance of the reported responses to the 5- to 10-minute controlled exposures, the Administrator considered guidelines from the American Thoracic Society (ATS), the CASAC's written advice and recommendations, and judgments made by the EPA in considering similar effects in previous NAAQS reviews (75 FR 35526 and 35536, June 22, 2010). Based on these considerations, the Administrator judged that the effects reported in exercising people with asthma following 5- to 10-minute SO_2 exposures at or above

[5] In assessments for NAAQS reviews, the lung function responses described as indicative of a moderate functional response include increases in sRaw of at least 100% (e.g., 2008 ISA; U.S. EPA, 1994, Table 8; U.S. EPA, 1996, Table 8-3). The moderate category has also generally included reductions in FEV_1 of 10 to 20% (e.g., U.S. EPA, 1996, Table 8). For the 2008 ISA, the midpoint of that range (15%) was used to indicate a moderate response. A focus on 15% reduction in FEV_1 is also consistent with the relationship observed between sRaw and FEV_1 responses in the Linn et al. studies for which "a 100% increase in sRaw roughly corresponds to a 12 to 15% decrease in FEV_1" (U.S. EPA, 1994, p. 20). Thus, in the 2008 review, moderate or greater SO_2-related bronchoconstriction or decrements in lung function referred to the occurrence of at least a doubling in sRaw or at least a 15% reduction in FEV_1 (2008 ISA, p. 3-5).

[6] At concentrations of 400 to 500 ppb, the 2008 ISA notes that the evidence shows "stronger evidence with some statistically significant increases in respiratory symptoms," and at 600 ppb to 1 ppm, the 2008 ISA notes the evidence to show "clear and consistent increases in SO_2 induced respiratory symptoms" (2008 ISA, Table 3-1).

200 ppb, especially at or above 400 ppb, can result in adverse health effects (75 FR 35536, June 22, 2010).[7] In so doing, she recognized that effects reported for exposures below 400 ppb are appreciably less severe than those at and above 400 ppb (75 FR 35547, June 22, 2010).

In applying the health effects evidence to her consideration of the adequacy of the then-existing standards, the Administrator gave particular attention to the quantitative analyses that evaluated the potential for exercising individuals with asthma to experience exposures of a magnitude associated with adverse effects under air quality conditions that just met the then-existing standards. In addition to comparison of 5-minute air concentrations in 40 U.S. counties to 5-minute concentrations of potential concern (benchmark concentrations ranging from 100-400 ppb), the analyses included a population exposure-based assessment in two study areas, St. Louis, MO and Greene County, MO. Five-minute exposure concentrations were estimated for people with asthma while breathing at elevated rates. The 5-minute exposure concentrations were compared to benchmark concentrations, and also used to estimate the risk of lung function decrements in simulated at-risk populations. Among these analyses, the Administrator emphasized those that utilized the 5-minute benchmark concentrations that were derived from the controlled human exposure evidence and ranged from 100 ppb to 400 ppb. Based on her judgments regarding the significance of effects associated with 5-minute concentrations at or above 200 ppb and 400 ppb, the Administrator considered results of comparisons of exposure estimates to those benchmark concentrations to be particularly important, giving greater emphasis to those at or above 400 ppb (75 FR 35547, June 22, 2010).

The exposure-based assessment estimated the portion of the population with asthma in these two areas that would be expected to experience 5-minute exposures at or above 400 ppb and 200 ppb while engaged in activities causing them to be breathing at elevated rates. The Administrator particularly noted the exposure analysis results for the St. Louis case study. This analysis estimated that for air quality simulated to just meet the then-existing standards, substantial percentages of children with asthma would be exposed at least once annually, while engaged in activities associated with moderate or greater exertion,[8] to air quality exceeding the 200 ppb and 400 ppb 5-minute benchmarks (75 FR 35536, June 22, 2010). The Administrator judged these 5-minute exposures to be significant from a public health perspective due to their

[7] The 2010 decision notice additionally stated that "[t]he Administrator notes that although these decrements in lung function have not been shown to be statistically significant at the group mean level, or to be frequently accompanied by respiratory symptoms, she considers effects associated with exposures as low as 200 ppb to be adverse in light of CASAC advice, similar conclusions in prior NAAQS reviews, and the ATS guidelines" (75 FR 35546, June 22, 2010).

[8] In the 2009 REA, an equivalent ventilation rate of 22 L/min-m^2 was identified as the minimum value to reflect "moderate" or greater exertion that would correspond to the elevated ventilation rate for the exercising subjects in the controlled human exposure studies, which was 40-50 L/min (2009 REA, p. 236).

estimated frequency: approximately 24% of children with asthma in St. Louis were estimated to be exposed while at moderate or greater exertion at least once per year to air quality exceeding the 5-minute 400 ppb benchmark. Additionally, approximately 73% of children with asthma 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 35536, June 22, 2010).

The Administrator also took note of the CASAC conclusion that the then-existing standards did not adequately protect public health. Specifically, the 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 all of the considerations summarized above, the Administrator concluded that the then-existing 24-hour and annual primary standards were not providing the requisite protection of public health with an adequate margin of safety. In considering approaches to revising the standards, the Administrator concluded it to be appropriate to set a new standard that would provide requisite protection with an adequate margin of safety to people with asthma at elevated ventilation and that would afford protection from the adverse health effects of 5-minute to 24-hour SO_2 exposures (75 FR 35536, June 22, 2010).

3.1.1.2 Approach for Considering Revisions to the Standards

With regard to revisions to provide requisite public health protection, the Administrator concluded it was appropriate to set a 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 selecting the 1-hour standard is presented below in terms of the individual elements of a NAAQS: indicator, averaging time, form, and level.

3.1.1.2.1 Indicator

In reaching her decision on the indicator for the new standard, the Administrator considered the conclusions of the ISA and REA, as well as advice from the CASAC and public comments (75 FR 35536, June 22, 2010). The EPA continued to focus 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. Although the presence of SO_X species other than SO_2 in ambient air had been recognized, no alternative to SO_2 had been advanced as a more appropriate surrogate for SO_X (75 FR 35536, June 22, 2010). Controlled human exposure studies and animal toxicological studies provided specific evidence for health effects following exposures to SO_2, and epidemiologic studies typically analyzed associations of health outcomes with concentrations of SO_2. Based on the information available in the last review and consistent with the views of the 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 sulfur oxides (75 FR 35536, June 22, 2010). 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 35536, June 22, 2010).

3.1.1.2.2 Averaging Time

With regard to the setting of the new standard, the Administrator agreed with the staff conclusion, based on conclusions in the ISA, advice from the CASAC, and quantitative analyses, that the standard should be set to provide protection from short-term exposures of 5 minutes to 24 hours (75 FR 35539, June 22, 2010). Based on air quality analyses presented in the REA, the Administrator judged that the requisite protection from 5- to 10-minute exposure events could be provided without having a standard with a 5-minute averaging time (75 FR 35539, June 22, 2010). She judged that a standard with a 5-minute averaging time would result in significant and unnecessary instability in public health protection (75 FR 35539, June 22, 2010).[9] Accordingly, she considered other averaging times.

Results of air quality analyses in the REA 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, likely over-controlling in some areas, while under-controlling in others (2009 REA, section 10.5.2.2). In contrast, these analyses suggested that a 1-hour averaging time would be more efficient and effective at limiting 5-minute peaks of SO_2 (2009 REA, section 10.5.2.2.). Drawing on this information, the Administrator concluded that a 1-hour standard, with the appropriate form and level, would be likely to substantially reduce 5- to 10-minute peaks of SO_2 that had been shown in controlled human exposure studies to result in increased prevalence of respiratory symptoms and/or decrements in lung function in exercising people with asthma (75 FR 35539, June 22, 2010). Further she found that a 1-hour standard could substantially reduce the upper end of the distribution of SO_2 concentrations in ambient air that were more likely to be associated with respiratory outcomes (75 FR 35539, June 22, 2010).

The Administrator additionally took note of advice from the CASAC. The CASAC stated that the REA had presented a "convincing rationale" for a 1-hour standard, and that "a one-hour standard is the preferred averaging time" (Samet, 2009, pp. 15, 16). The CASAC further stated that it was "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). Thus, in consideration of the available information summarized here and the CASAC's advice, the Administrator concluded that a 1-hour standard (given the appropriate level and form) was an appropriate

[9] Such instability could reduce public health protection by disrupting an area's ongoing implementation plans and associated control programs (75 FR 35537, June 22, 2010).

means of controlling short-term exposures to SO_2 ranging from 5 minutes to 24 hours (75 FR 35539, June 22, 2010).

3.1.1.2.3 Form

In considering the statistical form for the new short-term standard, the Administrator judged that the form of the standard should reflect the health effects evidence presented in the ISA that indicated that the percentage of people with asthma affected and the severity of the response increased with increasing SO_2 concentrations (75 FR 35541, June 22, 2010). She additionally found it reasonable to consider stability (e.g., to avoid disruption of programs implementing the standard and the related public health protections from those programs) as part of her consideration of the form for the standard (75 FR 35541, June 22, 2010). In so doing, she noted that a concentration-based form averaged over three years would likely be appreciably more stable than a no-exceedance based form, which had been the form of the then-existing 24-hour standard (75 FR 35541, June 22, 2010). The CASAC additionally stated that "[t]here is adequate information to justify the use of a concentration-based form averaged over 3 years" (Samet, 2009, p. 16). In consideration of this information, the Administrator judged a concentration-based form averaged over three years to be most appropriate (75 FR 35541, June 22, 2010).

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 so doing, the Administrator concluded that the form of a new 1-hour standard should be especially focused on limiting the upper end of the distribution of ambient SO_2 concentrations (i.e., above 90^{th} percentile SO_2 concentrations) in order to provide protection with an adequate margin of safety against effects reported in epidemiologic and controlled human exposure studies (75 FR 35541, June 22, 2010). The Administrator further noted, based on results of air quality and exposure analyses in the REA, that a 99^{th} percentile form was likely to be appreciably more effective at limiting 5-minute peak exposures of concern than a 98^{th} percentile form (75 FR 35541, June 22, 2010). Thus, the Administrator selected a 99^{th} percentile form averaged over three years (75 FR 35541, June 22, 2010).

3.1.1.2.4 Level

In selecting the level of a new 1-hour standard, the Administrator gave primary emphasis to the body of health effects evidence assessed in the ISA. In so doing, she noted that the controlled human exposure studies provided the most direct evidence of respiratory effects from exposure to SO_2. The Administrator drew on evidence from these studies in reaching judgments on the magnitude of adverse respiratory effects and associated potential public health

significance for the air quality exposure and risk analysis results of air quality scenarios representing just meeting alternative levels for a new 1-hour standard.

In particular, the Administrator considered effects in exercising people with asthma after 5- to 10-minute exposures as low as 200 ppb to be adverse in light of the CASAC advice on relevance of these effects, conclusions on similar effects in prior NAAQS reviews, and ATS guidelines (75 FR 35546, June 22, 2010; ATS, 1985, 2000). This judgment was based on several findings from the controlled human exposures studies. Five- to 10-minute exposures to 400 ppb or greater resulted in moderate or greater decrements in lung function in 20-60% of exercising individuals with asthma. These decrements are often statistically significant at the group mean level and frequently accompanied by respiratory symptoms. Thus, exposures to SO_2 concentrations at or above 400 ppb were concluded to clearly result in adverse respiratory effects based on the ATS guidelines (ATS, 1985). Further, 5- to 10-minute exposures to 200 to 300 ppb resulted in moderate or greater decrements in lung function in 5-30% of exercising individuals with asthma (75 FR 35546, June 22, 2010). Although such effects have not been shown to be statistically significant at the full study group mean level,[10] or to be frequently accompanied by respiratory symptoms, the Administrator considered effects associated with exposures as low as 200 ppb to be adverse in light of the CASAC's advice[11] and similar conclusions in prior reviews as well as the ATS guidelines (ATS, 1985, 2000).

The Administrator then considered what the findings of the REA exposure analyses indicated with regard to varying degrees of protection that different 1-hour standard levels might be expected to provide against 5-minute exposures to concentrations of 200 ppb and 400 ppb.[12] For example, the exposure assessment for St. Louis[13] estimated that a 1-hour standard at 100 ppb would likely protect more than 99% of children with asthma in that city from experiencing any days in a year with at least one 5-minute exposure at or above 400 ppb while at moderate or greater exertion, and approximately 97% of those children with asthma from experiencing any days in a year with at least one exposure at or above 200 ppb while at moderate or greater

[10] As summarized in section 3.2.1.1 below and described more fully in the ISA for the current review, study subjects have since been described as falling into two subpopulations that differ in susceptibility to SO_2. Thus, the extent to which the more susceptible subpopulation is represented among the full study group may influence study mean responses.

[11] The CASAC letter on the first draft SO_2 REA to the Administrator stated: "CASAC believes strongly that the weight of clinical and epidemiology evidence indicates there are detectable clinically relevant health effects in sensitive subpopulations down to a level at least as low as 0.2 ppm SO_2" (Henderson, 2008).

[12] The Administrator additionally noted the results of the 40-county analysis of limited available 5-minute concentration data that indicated for a 1-hour standard level of 100 ppb a maximum annual average of two days per year with 5-minute concentrations above 400 ppb and 13 days with 5-minute concentrations above 200 ppb (76 FR 35546, June 22, 2010).

[13] St. Louis was one of two study areas assessed in the REA (2009 REA).

exertion (75 FR 35547, June 22, 2010). Results for the air quality scenario for a 1-hour standard level of 50 ppb suggested that such a standard would somewhat further limit exposures, such that more than 99% of children at moderate or greater exertion would likely be protected from experiencing any days in a year with a 5-minute exposure at or above the 200 ppb benchmark concentration (75 FR 35542-47, June 22, 2010).

In considering the implications of the exposure assessment results the Administrator noted that although she considered the health effects resulting from 5-minute SO_2 exposures as low as 200 ppb to be adverse, she also recognized that such effects are appreciably less severe than those at SO_2 concentrations at or above 400 ppb and found little difference between the results for standard levels of 50 and 100 ppb with regard to 5-minute exposures at or above 400 ppb (75 FR 35547, June 22, 2010). She recognized that a standard level below 100 ppb may somewhat further limit 5-minute SO_2 ambient air concentrations and exposures above 200 ppb, although she did not judge that a standard level of 50 ppb was warranted.

Before reaching her conclusion with regard to level for the 1-hour standard, the Administrator additionally considered the epidemiological evidence among the 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 visits and hospital admissions. She noted there was a cluster of three studies for which 99th percentile 1-hour daily maximum concentrations were estimated to be between 78 and 150 ppb and for which the SO_2 effect estimate remained positive and statistically significant in copollutant models with particulate matter (PM) (75 FR 35547, June 22, 2010).[14]

Given the above considerations and the comments received on the proposal, the Administrator determined that the appropriate judgment, based on the entire body of evidence and information available in this review, and the related uncertainties,[15] was a standard level of 75 ppb. She concluded that such a standard, with a 1-hour averaging time and 99th percentile form, would provide a significant increase in public health protection compared to the then-existing standards and would be expected to provide protection, with an adequate margin of safety, against the respiratory effects that have been linked with SO_2 exposures in both controlled human exposure and epidemiologic studies. Specifically, she concluded that such a standard would limit 1-hour exposures at and above 75 ppb. (75 FR 35548, June 22, 2010). Such a

[14] Regarding the monitor concentrations in these studies, the EPA noted that although they may be a reasonable approximation of concentrations occurring in the areas, the monitored concentrations were likely somewhat lower than the absolute highest 99th percentile 1-hour daily maximum SO_2 concentrations occurring across these areas (75 FR 35547, June 22, 2010).

[15] Such uncertainties included both those with regard to the epidemiologic evidence and also those with regard to the information from controlled human exposure studies for at-risk groups, including representation of individuals with more severe asthma than that in study subjects (75 FR 35546, June 22, 2010).

standard was also considered likely "to maintain SO_2 concentrations below those in locations where key U.S. epidemiologic studies have reported that ambient SO_2 is associated with clearly adverse respiratory health effects, as indicated by increased hospital admissions and emergency department visits." The Administrator also found that "a 1-hour standard at a level of 75 ppb is expected to substantially limit asthmatics' exposure to 5–10 minute SO_2 concentrations $\geq$ 200 ppb, thereby substantially limiting the adverse health effects associated with such exposures." Lastly, the Administrator noted "that a standard level of 75 ppb is consistent with the consensus recommendation of CASAC." The Administrator also considered the likelihood of public health benefits at lower standard levels, and judged a 1-hour standard at 75 ppb to be sufficient to protect public health with an adequate margin of safety (75 FR 35547-35548, June 22, 2010).

This judgment included consideration of the appropriate degree of protection with an adequate margin of safety for populations at increased risk for adverse respiratory effects from short-term exposures to SO_2 for which the evidence supports a causal relationship with SO_2 exposures. In reaching these conclusions, the Administrator considered the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognized that the CAA does not require that primary NAAQS be set at a zero-risk level or to protect the most susceptible individual, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety (75 FR 35548, June 22, 2010).

3.1.1.2.5 Revoking the Then-Existing 24-Hour and Annual Standards

In addition to setting a new 1-hour standard at 75 ppb, 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 35550, June 22, 2010). In addition, with regard to the annual standard, there was a lack of evidence supporting a relationship between long-term SO_2 exposures and adverse health effects. That is, the 2008 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 35550, June 22, 2010; 2008 ISA, section 5.5).

3.1.2 Approach for the Current Review

For evaluation in the current review of whether it is appropriate to consider retaining the current SO_2 primary standard, or whether consideration of revision is appropriate, we have adopted an approach that builds on the general approach used in the last review and reflects the body of evidence and information now available. As summarized above, the Administrator's decisions in the prior review were based on an integration of information on health effects associated with exposure to SO_2, expert judgments on the adversity and public health significance of key health effects, air quality and related analyses and quantitative exposure and

risk assessments, and policy judgments as to when the standard is requisite to protect public health with an adequate margin of safety.

In conducting this assessment, we draw on the current evidence and quantitative assessments of exposure pertaining to the public health risk of SO_2 in ambient air. In considering the scientific and technical information, we consider both the information available at the time of the last review and information newly available since the last review, including the ISA and REA for this review. Figure 3-1 below illustrates the basic construct of our two-part approach in developing conclusions regarding options to consider with regard to the adequacy of the current primary standard. In the boxes of Figure 3-1, the range of questions that we consider in sections 3.2.1 and 3.2.2 below are represented by a summary of policy-relevant questions that frame our consideration of the scientific evidence and quantitative analyses.

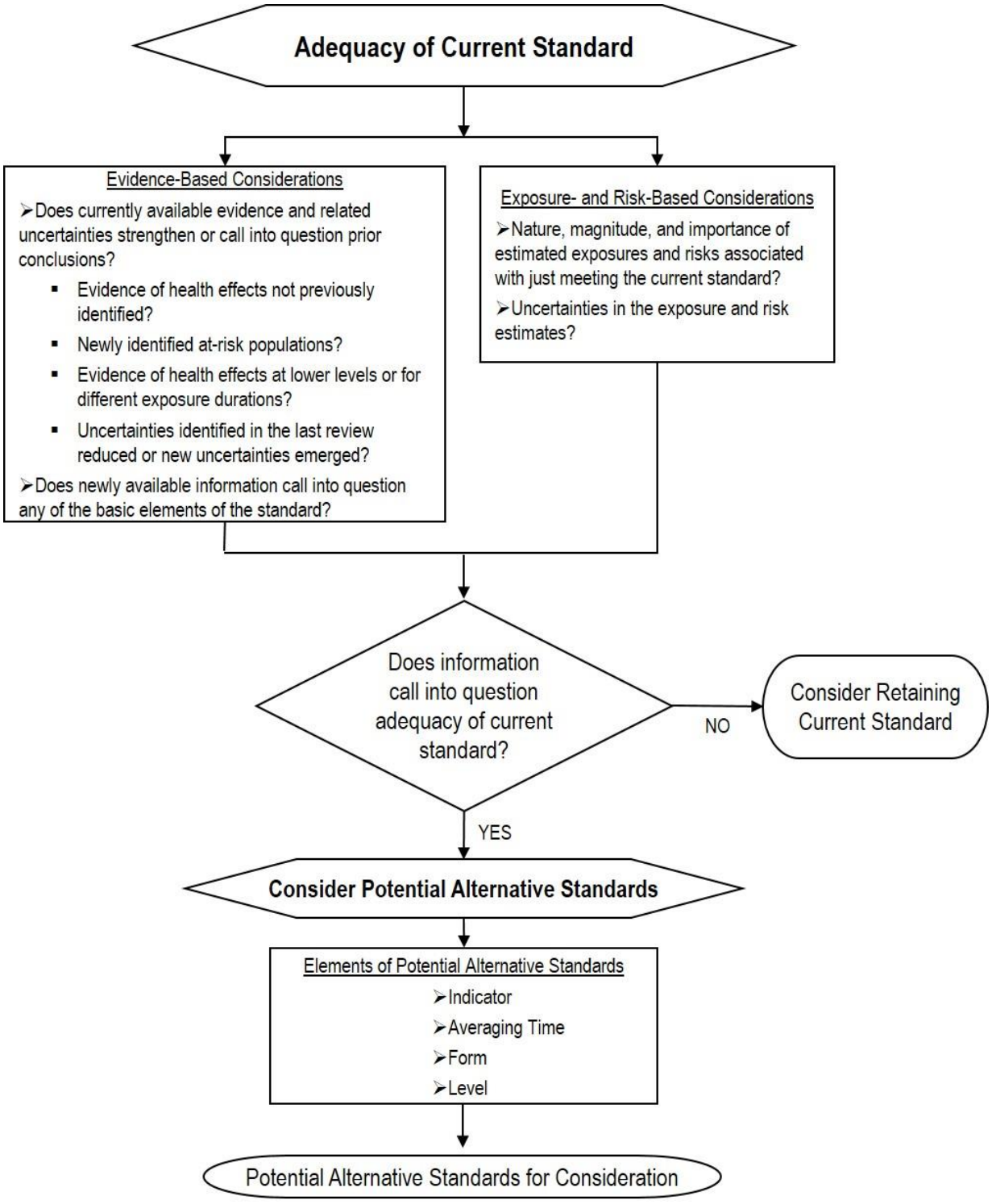

Figure 3-1. Overview of the approach for review of the current primary standard.

3.2 ADEQUACY OF THE CURRENT STANDARD

In considering the adequacy of the current SO_2 primary standard, the overarching question we consider is:

- **Does the currently available scientific evidence- and exposure/risk-based information, as reflected in the ISA and REA, support or call into question the adequacy of the protection afforded by the current SO_2 primary standard?**

To assist us in interpreting the currently available scientific evidence and the results of recent quantitative exposure/risk analyses to address this question, we have focused on a series of more specific questions, as detailed in sections 3.2.1 and 3.2.2 below. In considering the scientific and technical information, we consider both the information available at the time of the last review and information newly available since the last review which have been critically analyzed and characterized in the 2008 ISA for the last review and the ISA for the current review. In so doing, a primary consideration is whether the information newly available in this review alters our overall conclusions from the last review regarding health effects associated with SO_X in ambient air.

3.2.1 Evidence-based Considerations

In considering the evidence with regard to the overarching question posed above regarding the adequacy of the current standard, we address a series of more specific questions that focus on policy-relevant aspects of the evidence. These questions begin with consideration of the available evidence on health effects associated with exposure to SO_X, and particularly SO_2 (section 3.2.1.1). The subsequent questions consider identification of populations at-risk of SO_2-related health effects (section 3.2.1.2), and the exposure durations and levels of SO_2 associated with health effects (section 3.2.1.3). Important uncertainties associated with the evidence are considered in section 3.2.1.4 and public health implications are discussed in section 3.2.1.5.

3.2.1.1 Health Effects Associated with Exposure to SO_X

Among the species of SO_X (a group of closely related gaseous compounds including SO_2 and SO_3), SO_2 is the most commonly occurring in the atmosphere and the one most clearly associated with human health effects. Accordingly, the large body of scientific evidence has over the past reviews been predominantly focused on exposures to SO_2.

- **Is there newly available evidence that indicates the importance of SO_X other than SO_2 with regard to abundance in ambient air, and potential for human exposures and health effects?**

As in the last review, the health effects evidence evaluated in the ISA for SO_X is focused on SO_2 (ISA, p. 5-1). This is consistent with the conclusion that "[o]f the sulfur oxides, SO_2 is the most abundant in the atmosphere, the most important in atmospheric chemistry, and the one

most clearly linked to human health effects" (ISA, p. 2-1). With regard to SO_3, it "is known to be present in the emissions of coal-fired power plants, factories, and refineries, but it reacts with water vapor in the stacks or immediately after release into the atmosphere to form H_2SO_4" and "gas-phase H_2SO_4…quickly condenses onto existing atmospheric particles or participates in new particle formation" (ISA, section 2.3). Thus, the ISA states that "only SO_2 is present at concentrations in the gas phase that are relevant for chemistry in the atmospheric boundary layer and troposphere, and for human exposures" (ISA, p. 2-18), and also that the available health evidence for SO_X is focused on SO_2 (ISA, p. 5-1). Thus, we conclude that the current evidence, including that newly available in this review, continues to support a focus on SO_2 in considering the adequacy of public health protection provided by the primary NAAQS for SO_X.

- **Does the current evidence alter our conclusions from the previous review regarding the health effects associated with exposure to SO_2?**

Rather than altering our conclusions from the last review, the current evidence continues to support our prior conclusions regarding the key health effects associated with SO_2 exposure. Specifically, the full body of evidence continues to support the conclusion that short-term SO_2 exposures of durations as short as a few minutes are causally related to respiratory effects in at-risk individuals (ISA, section 5.2.1.9). With regard to respiratory effects and long-term exposures,[16] as well as total mortality and short-term exposures, the evidence available in this review is "suggestive of, but not sufficient to infer," a causal relationship (ISA, sections 5.2.2.7 and 5.5.1.6). The evidence is inadequate for reaching conclusions regarding causality for other categories of effects (ISA, section 1.6.2).[17]

Respiratory Effects

As in the last review, the currently available evidence in this review supports the conclusion that there is a causal relationship between short-term SO_2 exposure and respiratory effects, particularly in individuals with asthma (ISA, p. l-17).[18] The clearest evidence for this conclusion comes from controlled human exposure studies available at the time of the previous

[16] In evaluating the health effects studies in the ISA, the EPA has generally categorized exposures of durations longer than a month to be "long-term" (ISA, p. 1-2).

[17] Based on the currently available evidence, the ISA concluded that the evidence was inadequate to infer the presence or absence of a causal relationship between SO_2 exposures and reproductive and developmental effects; between long-term SO_2 exposures and mortality or cancer; and, between short- or long-term SO_2 exposures and cardiovascular effects (ISA, section 1.6.2).

[18] While effects have been documented for short (5- to 10- minute) exposures lower than 1.0 ppm in controlled exposure studies of individuals with asthma, the exposure concentrations consistently eliciting effects in study subjects without asthma are higher. Such exposures are generally above 1.0, with most studies reporting no respiratory symptoms at concentrations up to 2.0 ppm (ISA, section 5.2.1.7, pp. 116-117, 132-133).

review and included in the 2008 ISA. These studies demonstrate asthma exacerbation-related lung function decrements[19] and respiratory symptoms in people with asthma exposed to SO_2 for 5 to 10 minutes at elevated breathing rates (ISA, section 5.2.1). The epidemiologic evidence, including recent evidence not available at the time of the previous review, includes studies reporting positive associations for asthma-related hospital admissions and emergency department visits with short-term SO_2 exposures (ISA, section 5.2.1). These findings are generally supportive of the causal relationship conclusion for which the controlled exposure studies are the primary basis (ISA, section 5.2.1.9).

Sulfur dioxide is a highly reactive and water-soluble gas that once inhaled is absorbed almost entirely in the upper respiratory tract[20] (ISA, sections 4.2 and 4.3). Under conditions of elevated breathing rates (e.g., while exercising), SO_2 penetrates into the tracheobronchial region,[21] where it may contribute to responses linked to asthma exacerbation in individuals with asthma (ISA, sections 4.2, 4.3 and 5.2). More specifically, bronchoconstriction, which is characteristic of an asthma attack, is the most sensitive indicator of SO_2-induced lung function effects. Associated with this bronchoconstriction response is an increase in airway resistance which is an index of airway hyperresponsiveness (AHR).[22] Exercising individuals without asthma have also been found to exhibit such responses, but at much higher SO_2 exposure concentrations, above 1000 ppb (ISA, section 1.5.2).

Bronchoconstriction, evidenced by decrements in lung function, is observed in controlled human exposure studies in response to exposures as short as 5- to 10-minutes and can occur at SO_2 concentrations as low as 200 ppb in some people with asthma exposed while breathing at elevated rates, such as during exercise (ISA, section 5.2.1.2).[23] More consistent decrements in lung function are seen in such individuals with asthma following exposures to 400 ppb and greater (ISA, section 5.2.1.2). In contrast, respiratory effects are not observed in other people with asthma (nonresponders) and healthy adults exposed while exercising to SO_2 concentrations

[19] The specific responses reported in the evidence base that are described in the ISA as lung function decrements are increased specific airway resistance (sRaw) and reduced forced expiratory volume in 1 second (FEV_1) (ISA, section 5.2.1.2).

[20] The term "upper respiratory tract" refers to the portion of the respiratory tract, including the nose, mouth and larynx, that precedes the tracheobronchial region (ISA, sections 4.2 and 4.3).

[21] The term "tracheobronchial region" refers to the region of the respiratory tract subsequent to the larynx and preceding the deep lung (or alveoli). This region includes the trachea and bronchii.

[22] Airway hyperresponsiveness, which is an increased propensity of the airways to narrow in response to bronchoconstrictive stimuli, is a characteristic feature of people with asthma (ISA, section 5.2.1.2).

[23] The data from controlled human exposure studies of people with asthma indicate there to be two subpopulations that differ in their airway responsiveness to SO_2, with the second subpopulation being insensitive to SO_2 bronchoconstrictive effects at concentrations as high as 1.0 ppm (ISA, pp. 5-14 to 5-21; Johns et al., 2010).

below 1000 ppb (ISA, sections 5.2.1.2 and 5.2.1.7). Across studies, bronchoconstriction in response to SO_2 exposure is mainly seen during conditions of elevated breathing rates, such as exercise or laboratory-facilitated rapid, deep breathing.[24] These conditions lead to a shift from nasal breathing to oral/nasal breathing, which increases the concentration of SO_2 reaching the tracheobronchial region of lower airways, where depending on dose and the exposed individual's susceptibility, it may cause bronchoconstriction (ISA, sections 4.1.2.2, 4.2.2 and 5.2.1.2).

The evidence base of controlled human exposure studies for people with asthma is the same in this review as in the last review. Such studies reporting asthma exacerbation-related effects for individuals with asthma are summarized in Tables 5-1 and 5-2, and section 5.2.1.2 of the ISA. The main responses observed include increases in specific airway resistance (sRaw) and reductions in forced expiratory volume in one second (FEV_1) after 5- to 10-minute exposures. As in the last review, the ISA in this review quantifies the percentage of exposed study subjects with at least 100%, 200% or 300% increases in sRaw (i.e., a doubling, tripling or greater increase) and also those with at least 15%, 20% or 30% reduction in FEV_1. As recognized in the last review, the results of these studies indicate that among individuals with asthma, some individuals have a greater response to SO_2 than others or a measurable response at lower exposure concentrations (ISA, p. 5-14). The SO_2-induced bronchoconstriction in these studies occurs rapidly, in as little as two minutes from exposure start, and is transient, with recovery following cessation of exposure (ISA, p. 5-14).

The studies of subjects with asthma breathing at elevated rates have found effects to become more pronounced with increased exposure concentrations. Among individuals with asthma, both the percentage of individuals affected and the severity of the response increases with increasing SO_2 concentrations. For example, at concentrations ranging from 200 to 300 ppb, as many as 5 to 30% of exercising study subjects with asthma experienced moderate[25] or greater decrements in lung function (ISA, Table 5-2). At concentrations at or above 400 ppb, moderate or greater decrements in lung function occurred in 20 to 60% of exercising study subjects with asthma, and compared to exposures at 200 to 300 ppb, a larger percentage of subjects experienced severe decrements in lung function (i.e., an increase in sRaw of at least 200%, and/or a reduction in FEV_1 of at least 20%) (ISA, Table 5-2). Moreover, at the higher SO_2 concentrations, moderate or greater decrements in lung function were frequently accompanied by

[24] In the laboratory, study subjects perform this rapid, deep breathing through a mouthpiece that provides a mixture of oxygen with enough carbon dioxide to prevent the imbalance of gases in the blood usually resulting from hyperventilation. Breathing in the laboratory with this technique is referred to as eucapnic hyperpnea.

[25] As in the last review (described in section 3.1.1.1 above), the ISA describes moderate or greater lung function decrements as the occurrence of at least a doubling in sRaw or at least a 15% reduction in FEV_1 (ISA, section 1.6.1.1).

respiratory symptoms, such as cough, wheeze, chest tightness, or shortness of breath (ISA, Table 5-2).

With regard to newly available epidemiological studies, there are a limited number of such studies that have investigated SO_2 effects related to asthma exacerbation, with the most cohesive evidence coming from studies on asthma-related emergency department (ED) visits (ISA, section 5.2.1.2). As in the last review, areas of uncertainty in the epidemiologic evidence relate to the characterization of exposure through the use of fixed site monitor concentrations as surrogates for population exposure (often over a substantially sized area and for durations greater than an hour) and the potential for confounding by PM[26] or other copollutants (ISA, section 5.2.1). In general, the pattern of associations across the newly available studies is consistent with the studies available in the last review (ISA, p. 5-75).

As in the last review, the evidence base for short-term SO_2 exposures and respiratory effects other than asthma exacerbation is limited and inconsistent (ISA, sections 5.2.1.3-5.2.1.8, p. 5-155). The ISA finds the evidence for an effect of SO_2 exposure on allergy exacerbation, COPD exacerbation, respiratory infection, respiratory effects in healthy populations, and respiratory mortality to be inconsistent within and across disciplines and outcomes and/or lacking in biological plausibility (ISA, p. 5-155). Additional uncertainty associated with the epidemiological evidence for these endpoints is related to potential confounding by copollutants (ISA, section 5.2.1.9, p. 5-155).

The evidence base for long-term SO_2 exposure and respiratory effects is somewhat augmented since the last review such that the ISA in the current review concludes it to be suggestive of, but not sufficient to infer, a causal relationship (ISA, section 5.2.2). The support for this conclusion comes mainly from the limited epidemiological study findings of associations between long-term SO_2 concentrations and increases in asthma incidence combined with findings of laboratory animal studies involving newborn rodents that indicate a potential for SO_2 exposure to contribute to the development of asthma, especially allergic asthma, in children (ISA, section 1.6.1.2). For example, the evidence showing increases in asthma incidence is coherent with results of animal toxicological studies that provide a pathophysiologic basis for the development of asthma. The overall body of evidence, however, lacks consistency (ISA, section 1.6.1.2). Further there are uncertainties, discussed in section 3.2.1.4 below, that apply to the epidemiologic evidence, including that newly available, across the respiratory effects examined for long-term SO_2 exposure (ISA, section 5.2.2.7).

[26] The potential for confounding by PM is of particular interest given that SO_2 is a precursor to PM (ISA, p. 1-7).

Other Health Effects

For effects other than respiratory effects, the current evidence is generally similar to the evidence available in the last review, and leads to similar conclusions. With regard to a relationship between short-term SO_2 exposure and total mortality, the ISA reaches the same conclusion as in the previous review that the evidence is suggestive of, but not sufficient to infer, a causal relationship (ISA, section 5.5.1). This conclusion is based on previously available and recent multicity epidemiologic studies providing consistent evidence of positive associations coupled with uncertainty regarding the potential for SO_2 to have an independent effect on mortality. While recent studies have analyzed some key uncertainties and data gaps from the previous review, uncertainties still exist, given the limited number of studies that examined copollutant confounding, the evidence for a decrease in the size of SO_2-mortality associations in copollutant models with NO_2 and PM_{10}, and the lack of a potential biological mechanism for mortality following short-term SO_2 exposures (ISA, section 1.6.2.4).

For other categories of health effects,[27] the evidence is inadequate to infer the presence or absence of a causal relationship, mainly due to inconsistent evidence across specific outcomes and uncertainties regarding exposure measurement error, copollutant confounding, and potential modes of action (ISA, sections 5.3.1, 5.3.2, 5.4, 5.5.2, 5.6). These conclusions are consistent with those made in the previous review.

In summary, rather than altering our conclusions from the previous review, the current evidence provides continued support for our previous conclusions regarding the health effects associated with exposure to SO_2 and most particularly respiratory effects following short-term SO_2 exposure, particularly in individuals with asthma. Accordingly, as in prior reviews, this review gives primary focus to those effects most pertinent to exposures related to current concentrations in ambient air, in particular, asthma exacerbation in individuals with asthma.

3.2.1.2 Populations At-Risk of SO_2-Related Health Effects

Populations or lifestages can be at increased risk of an air pollutant-related health effect due to one or more of a number of factors. These factors can be intrinsic, such as physiological factors that may influence the internal dose or toxicity of a pollutant, or extrinsic, such as sociodemographic, or behavioral factors (ISA, p. 6-1). The questions considered in this section address what the currently available evidence indicates regarding which populations are particularly at risk of health effects related to exposure to SO_2 in ambient air.

[27] The other categories evaluated in the ISA include cardiovascular effects with short or long term exposures; reproductive and developmental effects; and cancer and total mortality with long-term exposure (ISA, Table 1-1).

- **Does the current evidence alter our understanding of populations that are particularly at-risk from SO_2 exposures? Is there new evidence that suggests additional at-risk populations that should be given increased focus in this review?**

The currently available evidence continues to support our primary conclusions from the previous review that people with asthma are at increased risk for SO_2-related health effects, specifically for respiratory effects, and specifically asthma exacerbation, associated with short-term exposures while breathing at elevated rates (ISA, sections 5.2.1.2 and 6.3.1). This conclusion of the at-risk status of people with asthma is based on the well-established and well-characterized evidence from controlled human exposure studies, supported by the evidence on mode of action for SO_2 and with limited additional support from epidemiologic studies (ISA, sections 5.2.1.2 and 6.3.1). Somewhat similar to the conclusion in the last review that children and older adults are potentially susceptible populations, the ISA (relying on a framework that is new in this review for evaluating the evidence for risk factors) indicates the evidence to be suggestive of increased risk for these groups, with some limitations and inconsistencies (ISA, sections 6.5.1.1 and 6.5.1.2).[28]

Further, the ISA finds that children with asthma may be particularly at risk compared to adults with asthma (ISA, section 6.3.1). This conclusion reflects several characteristics of children as compared to adults, which include their greater responsiveness to methacholine,[29] a chemical that can elicit bronchoconstriction in people with asthma, as well as their greater use of oral breathing, particularly by boys (ISA, sections 5.2.1.2 and 4.1.2). Oral breathing (vs. nasal breathing) and increased breathing rate are factors that allow for greater SO_2 penetration into the tracheobronchial region of the lower airways, and reflect conditions of individuals with asthma in which bronchoconstriction-related responses have been observed in the controlled exposure studies (ISA, sections 4.2.2, 5.2.1.2 and 6.3.1).

We additionally recognize the well-documented finding that some individuals with asthma have a greater response to SO_2 than others with similar disease status (ISA, section

[28] The current evidence for risk to older adults relative to other lifestages comes from epidemiological studies, for which the findings are somewhat inconsistent, and studies for which there are uncertainties in the association with the health outcome (ISA, section 6.5.1.2).

[29] The ISA concluded that potential differences in airway responsiveness of children to SO_2 relative to adolescents and adults may be inferred by the responses to methacholine (ISA, section 5.2.1.2). Methacholine is a chemical that can elicit bronchoconstriction through its action on airway smooth muscle receptors. It is commonly used to identify people with asthma and accordingly has been used to screen subjects for studies of SO_2 effects. However, results of studies of the extent to which airway response to methacholine is predictive of SO_2 responsiveness have varied somewhat. For example, an analysis of the extent to which airway responsiveness to methacholine, a history of respiratory symptoms, and atopy were significant predictors of airway responsiveness to SO_2, found that about 20 to 25% of subjects ranging in age from 20 to 44 years that were hyperresponsive to methacholine were also hyperresponsive to SO_2 (ISA, section 5.2.1.2; Nowak et al., 1997). Another study focused on individuals with airway responsiveness to methacholine found only a weak correlation between airway responsiveness to SO_2 and methacholine (ISA, section 5.2.1.2; Horstman et al., 1986).

5.2.1.2; Horstman et al., 1986; Johns et al., 2010). This occurrence is quantitatively analyzed in a study newly available in this review. This study uses the available individual subject data from five studies involving exposure of individuals with asthma to multiple concentrations of SO_2 for 5 to 10 minutes while breathing at elevated rates to examine the differences in lung function response (Johns et al., 2010). As noted in the ISA, "these data demonstrate a bimodal distribution of airway responsiveness to SO_2 in individuals with asthma, with one subpopulation that is insensitive to the bronchoconstrictive effects of SO_2 even at concentrations as high as 1.0 ppm, and another subpopulation that has an increased risk for bronchoconstriction at low concentrations of SO_2" (ISA, p. 5-20). To date, the characteristics that may define the subpopulation of responders have not been identified. The current evidence for factors other than those discussed above (asthma status and lifestage) is inadequate to determine whether they might contribute to an increased risk of SO_2-related effects (ISA, section 6.6).

3.2.1.3 Exposure Concentrations Associated with Health Effects

At the time of the last review, the EPA's conclusions regarding concentrations of SO_2 associated with respiratory effects were based primarily on the strong evidence base of controlled human exposure studies of individuals with asthma. These studies have documented bronchoconstriction-related moderate or greater decrements in lung function following 5- to 10-minute exposures during exercise. The severity of observed responses, the percentage of individuals responding, statistical significance at the study group level and the accompanying occurrence of respiratory symptoms have been found to increase with increasing exposure concentration (75 FR 35526, June 22, 2010). This information was critical in the REA analyses in the last review, the results of which were a primary consideration in reaching a conclusion on the level for the 2010 standard.

- **Does the current evidence alter our conclusions from the previous review regarding the exposure duration and concentrations associated with health effects?**

Our understanding of exposure duration and concentrations associated with SO_2-related health effects is largely based, as it was in the last review, on the longstanding evidence base of controlled human exposure studies that demonstrates a dose-response relationship between 5- and 10-minute SO_2 exposure concentrations and decrements in lung function (e.g., increased sRaw and reduced FEV_1) in individuals with asthma exposed while breathing at elevated rates (ISA, section 1.6.1.1). At the higher concentrations, there are clear and consistent increases in SO_2-induced respiratory symptoms (ISA, Table 5-2 and pp. 5-35, 5-39).

The available and well characterized evidence documents an effect of short-term exposures on the respiratory system. As summarized in section 3.2.1.1, SO_2-induced bronchoconstriction occurs rapidly in responding study subjects with asthma exposed for just a

few minutes while breathing at elevated rates (ISA, section 5.2.1.2). Additionally, exposures as short as 5 minutes have been found to elicit a similar bronchoconstrictive response at somewhat longer exposures. For example, during exposure to SO_2 over a 30-minute period with continuous exercise, the response to SO_2 has been found to develop rapidly and is maintained throughout the 30-minute exposure (ISA, p. 5-14). In a study involving short exercise periods within a 6-hour exposure period, the effects observed following exercise were documented to return to baseline levels within one hour after the cessation of exercise, even with continued exposure (Linn et al., 1984). In considering the epidemiological evidence with regard to the question of exposure duration, while we note the associations of asthma-related emergency room visits and hospital admissions with 1-hour to 24-hour ambient air concentration metrics, we recognize that current methods are not able to address whether these associations are indicative of a potential response to exposure on the order of hours or much shorter-term exposure to peaks in SO_2 concentration. As noted in the ISA, the air quality metrics in the epidemiological studies are for time periods longer than the 5- to 10-minute exposures eliciting effects in the controlled human exposure studies and also may not adequately capture the spatial and temporal variation in SO_2 concentrations (ISA, pp. 5-49, 5-59, 5-25).

With regard to the evidence for exposure concentrations eliciting effects, we focus primarily on the controlled human exposure study findings for which data are available to the EPA for individual subjects with asthma that were exposed while breathing at elevated rates, summarized in Table 3-1 (ISA, Table 5-2).[30] These data demonstrate that SO_2 concentrations as low as 200 to 300 ppb for 5 to 10 minutes elicited moderate or greater bronchoconstriction, measured as a decrease in FEV_1 of at least 15% or an increase in sRaw of at least 100%, in a subset of the subjects (ISA, section 5.2.1). Both the percent of individuals affected and the severity of response increased with increasing SO_2 concentrations. At concentrations ranging from 200 to 300 ppb, the lowest levels for which there are study results that provide for assessment of the SO_2-related effect independent of any effect of exercise in clean air, 5 to 30% of exercising individuals with asthma experienced moderate or greater decrements in lung function (ISA, section 5.2.1). At concentrations at or above 400 ppb, moderate or greater decrements in lung function occurred in 20 to 60% of exercising individuals with asthma and a larger percentage of individuals with asthma experienced more severe decrements in lung function (i.e., an increase in sRaw of at least 200%, and/or a 20% or more decrease in FEV_1), compared to exposures at 200 to 300 ppb (ISA, section 5.2.1). Additionally, at concentrations at or above 400 ppb, moderate or greater decrements in lung function were frequently accompanied

[30] The findings summarized in Table 5-2 of the ISA and in Table 3-1 of this PA are based on results that have been adjusted for effects at exercise in clean air so that they have separated out any effect of exercise in causing bronchoconstriction and reflect the SO_2-specific effect.

by respiratory symptoms, with some of these findings reaching statistical significance (ISA, section 5.2.1).

Table 3-1. Percentage of adults with asthma in controlled human exposure studies experiencing sulfur dioxide-induced decrements in lung function and respiratory symptoms.

SO_2 Conc (ppm)	Exposure Duration (min)	N	Ventil-ation (L/min)	Percentage of Responders (Number of Subjects)[a]				Study	Respiratory Symptoms: Supporting Studies
				sRaw	≥100% ↑	≥200% ↑	≥300% ↑		
				FEV_1	≥15% ↓	≥20% ↓	≥30% ↓		
0.2	5	23	~48	sRaw	9% (2)[b]	0	0	Linn et al. (1983b)	Limited evidence of SO_2-induced increases in respiratory symptoms in some people with asthma: Linn et al., 1983b; Linn et al., 1987; Linn et al., 1988; Linn et al. 1990; Schachter et al., 1984
	10	40	~40	sRaw	7.5% (3)[c]	2.5% (1)[c]	0[c]	Linn et al. (1987)[c]	
	10	40	~40	FEV_1	9% (3.5)[c]	2.5% (1)[c]	1% (0.5)[c]	Linn et al. (1987)[c]	
0.25	5	19	~50−60	sRaw	32% (6)	16% (3)	0	Bethel et al. (1985)	
	5	9	~80−90	sRaw	22% (2)	0	0		
	10	27	~42	sRaw	0	0	0	Horstman et al. (1986)	
	10	28	~40	sRaw	4% (1)	0	0	Roger et al. (1985)	
0.3	10	20	~50	sRaw	10% (2)	5% (1)	5% (1)	Linn et al. (1988)[d]	
	10	21	~50	sRaw	33% (7)	10% (2)	0	Linn et al. (1990)[d]	
	10	20	~50	FEV_1	15% (3)	0	0	Linn et al. (1988)	
	10	21	~50	FEV_1	24% (5)	14% (3)	10% (2)	Linn et al. (1990)	
0.4	5	23	~48	sRaw	13% (3)	4% (1)	0	Linn et al. (1983b)	Stronger evidence with some statistically significant increases in respiratory symptoms: Balmes et al., 1987;[f] Gong et al., 1995 ; Linn et al., 1983b; Linn et al., 1987 ; Roger et al., 1985
	10	40	~40	sRaw	24% (9.5)[c]	9% (3.5)[c]	4% (1.5)[c]	Linn et al. (1987)[c]	
	10	40	~40	FEV_1	27.5% (11)[c]	17.5% (7)[c]	10% (4)[c]	Linn et al. (1987)[c]	
0.5	5	10	~50−60	sRaw	60% (6)	40% (4)	20% (2)	Bethel et al. (1983)	
	10	27	~42	sRaw	22.2% (6)	3.7% (1)	11% (3)	Horstman et al. (1986)	
	10	28	~40	sRaw	18% (5)	4% (1)	4% (1)	Roger et al. (1985)	

SO_2 Conc (ppm)	Exposure Duration (min)	N	Ventil-ation (L/min)	Percentage of Responders (Number of Subjects)[a]				Study	Respiratory Symptoms: Supporting Studies
				sRaw	≥100% ↑	≥200% ↑	≥300% ↑		
				FEV_1	≥15% ↓	≥20% ↓	≥30% ↓		
	10	45	~30	sRaw	36% (16)	16% (7)	13% (6)	Magnussen et al. (1990)[f]	
0.6	5	23	~48	sRaw	39% (9)	26% (6)	17% (4)	Linn et al. (1983b)	Clear and consistent increases in SO_2-induced respiratory symptoms: Gong et al., 1995; Horstman et al., 1988; Linn et al., 1983b; Linn et al., 1987; Linn et al., 1988; Linn et al., 1990
	10	40	~40	sRaw	34% (13.5)[c]	24% (9.5)[c]	19% (7.5)[c]	Linn et al. (1987)[c]	
	10	20	~50	sRaw	60% (12)	35% (7)	10% (2)	Linn et al. (1988)	
	10	21	~50	sRaw	62% (13)	29% (6)	14% (3)	Linn et al. (1990)	
	10	40	~40	FEV_1	47.5% (19)[c]	39% (15.5)[c]	17.5% (7)[c]	Linn et al. (1987)[c]	
	10	20	~50	FEV_1	55% (11)	55% (11)	5% (1)	Linn et al. (1988)	
	10	21	~50	FEV_1	43% (9)	38% (8)	14% (3)	Linn et al. (1990)	
1.0	10	28	~40	sRaw	50% (14)	25% (7)	14% (4)	Roger et al. (1985)[e]	
	10	10	~40	sRaw	60% (6)	20% (2)	0	Kehrl et al. (1987)	
	10	27	~42	sRaw	55.6% (15)	25.9% (7)	11% (1)	Horstman et al. (1986)	

Conc = concentration; FEV_1 = forced expiratory volume in 1 sec; sRaw = specific airway resistance; SO_2 = sulfur dioxide.

This table is adapted from ISA Table 5-2. Information in Horstman et al (1986) is an addition (ISA, pp. 5-14 and 5-19).

[a]Data presented from all references from which individual data were available in the published paper or were provided to EPA (Johns, 2009; Johns and Simmons, 2009; Smith, 1993). Percentage of individuals who experienced greater than or equal to a 100, 200, or 300% increase in specific airway resistance, or a 15, 20, or 30% decrease in FEV_1. Lung function decrements are adjusted for the effects of exercise in clean air (calculated as the difference between the percent change relative to baseline with exercise/SO_2 and the percent change relative to baseline with exercise/clean air).

[b]Numbers in parenthesis represent the number of subjects experiencing the indicated effect.

[c]Responses of people with mild and moderate asthma reported in Linn et al. (1987) have been combined. Data are the average of the first and second round exposure responses following the first 10 min period of exercise. In some cases, the average had a first decimal place value of 5, which is reported in the table to avoid a high bias in values due to rounding. In all other cases, the calculated percentages were rounded to the nearest integer.

[d]Analysis includes data from only people with mild (Linn et al., 1988) and moderate (Linn et al., 1990) asthma who were not receiving supplemental medication.

[e]One subject was not exposed to 1 ppm due to excessive wheezing and chest tightness experienced at 0.5 ppm. For this subject, the values used for 0.5 ppm were also used for 1.0 ppm under the assumption that the response at 1.0 ppm would be equal to or greater than the response at 0.5 ppm.

[f]Indicates studies in which exposures were conducted using a mouthpiece rather than a chamber.

The lowest exposure concentration in Table 3-1 is 200 ppb. This is the lowest exposure concentration for which individual study subject data are available in terms of the sRaw and FEV_1 metrics presented in Table 3-1 that have been calculated with assessment of the SO_2 effect *versus* that of exercise in clean air. In nearly all of the studies in this table (and all of the studies for concentrations below 500 ppb), study subjects breathed freely (e.g., without using a mouthpiece).[31] In studies that tested 200 ppb, a portion of the exercising study subjects with asthma (approximately 8 to 9%) responded with at least a doubling in sRaw or an increase in FEV_1 of at least 15% (Table 3-1; Linn et al., 1983b; Linn et al., 1987).

With regard to exposure concentrations below 200 ppb, the available evidence is very limited. In the studies testing this concentration, subjects were exposed by mouthpiece rather than freely breathing in an exposure chamber (Sheppard et al., 1981; Sheppard et al., 1984; Koenig et al., 1989; Koenig et al., 1990; Trenga et al., 2001).[32] Additionally, only a few of these studies included an exposure to clean air while exercising that would have allowed for determining the effect of SO_2 *versus* that of exercise in causing bronchoconstriction (Sheppard et al., 1981, 1984; Koenig et al., 1989). In those cases, a limited number of adult and adolescent study subjects were reported to experience small changes in sRaw, with the magnitudes of change appearing to be smaller than responses reported from studies at exposure concentrations of 200 ppb or more. For example, the increase in sRaw reported for two young adult subjects exposed to 100 ppb in the study by Sheppard et al. (1981) was slightly less than half the response of these subjects at 250 ppb and the results for the study by Sheppard et al. (1984) indicate that none of the 8 study subjects experienced as much as a doubling in sRaw in response to the mouthpiece exposure to 100 ppb, while exercising. In the study of adolescents (aged 12 to 18 years), among the three individual study subjects for which respiratory resistance appears to have increased with SO_2 exposure, the magnitude of any increase after consideration of the response to exercise appears to be less than 100% in each subject (Koenig et al., 1989).

In considering what may be indicated by these mouthpiece studies of 100 ppb, we note that in a mouthpiece exposure system, the inhaled breath completely bypasses the nasal passages where SO_2 is efficiently removed, thus allowing more of the inhaled SO_2 to penetrate into the

[31] Studies of free-breathing subjects generally make use of small rooms in which the atmosphere is experimentally controlled such that study subjects are exposed by freely breathing the surrounding air (e.g., Linn et al., 1987).

[32] A subset of these studies is cited in the ISA; additionally, three of them (Sheppard et al., 1981; Koenig et al., 1990; Trenga et al., 2001) are cited in the 2008 ISA and a fourth (Sheppard et al., 1984) is cited in the 1986 Addendum and 1994 Supplement to the 1982 AQCD. The fifth study (Koenig et al., 1989) is not cited in the prior AQCDs, the 2008 ISA, or the ISA for the current review. This study is an investigation involving nine adolescent subjects with allergic asthma (positive response to a methacholine challenge test at or below 20 mg/mL) exposed by mouthpiece to 0.1 ppm during exercise. Measurements of FEV_1 and R_T were taken at baseline and subsequent to SO_2 and air only exposures during exercise (Koenig et al., 1989).

tracheobronchial airways (2008 ISA, p. 3-4; ISA, section 4.1.2.2). This occurrence, as well as limited evidence comparing responses by mouthpiece and chamber exposures, leads to the expectation that SO_2-responsive people with asthma breathing SO_2 using a mouthpiece, particularly while breathing at elevated rates, would experience greater lung function responses than if exposed to the same test concentration while freely breathing in an exposure chamber (ISA, p. 5-23; Linn et al., 1983a). Thus, we conclude that the set of studies for the 100 ppb exposure concentration, while quite limited, does not indicate as much as a doubling in sRaw in the extremely few adults and adolescents tested (Sheppard et al., 1981, 1984; Koenig et al., 1989).

We have also considered what may be indicated by the epidemiological studies regarding exposure concentrations associated with health effects. Although exposure concentrations eliciting respiratory responses are not available from such studies, studies that find associations with outcomes such as asthma-related ED visits and hospitalizations have the potential to indicate ambient air concentrations that may contribute to exposures that may be eliciting effects. For example, in recognizing the general coherence of epidemiological study findings for 24-hour ambient air concentrations with the findings of the controlled human exposure studies for exercising study subjects with asthma exposed for 5 to 10 minutes, the 2008 ISA recognized that "it is possible that these epidemiologic associations are determined in large part by peak exposures within a 24-h period" (2008 ISA, p. 5-5). In considering the epidemiological studies in this light, we additionally note that given the important role of SO_2 as a precursor to PM in ambient air, a key uncertainty in the epidemiological evidence available in the last review was potential confounding by copollutants, particularly PM (ISA, p. 5-5). Among the U.S. epidemiologic studies reporting mostly positive and sometimes statistically significant associations between ambient SO_2 concentrations and ED visits and hospital admissions (some conducted in multiple locations), few studies have attempted to address this uncertainty, e.g., through the use of copollutant models. For example, as in the last review, there are three U.S. studies for which the SO_2 effect estimate remained positive and statistically significant in copollutant models with PM (Appendix D).[33] No additional such studies have been newly identified in this review. Such uncertainty regarding copollutant confounding, as well as exposure measurement error, remain in the currently available epidemiologic evidence base (ISA, p. 5-6).

[33] Based on data available for specific time periods at some monitors in the areas of these studies, the 99th percentile 1-hour daily maximum concentrations were estimated in the last review to be between 78-150 ppb (Thompson and Stewart, 2009).

3.2.1.4 Uncertainties in the Health Effects Evidence

A number of key uncertainties and limitations were identified in the previous review with respect to the health effects evidence, as described in the 2009 REA. This section considers the currently available information, including that newly available in this review, with regard to such areas of uncertainty.

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

We have not identified any new uncertainties since the last review. However, we continue to recognize important uncertainties that also existed in the last review. These important areas of uncertainty relate to the current health evidence, including that newly available in this review, are summarized below.

Although the evidence clearly demonstrates that short-term SO_2 exposures cause respiratory effects, particularly asthma exacerbation in exercising individuals with asthma, as in the previous review, we continue to recognize uncertainties that remain in several aspects of our understanding of these effects. Such uncertainties include those associated with the severity and prevalence of responses to very short (5- to 10-minute) SO_2 exposures below 200 ppb and with the potential extent of such responses in individuals of some population groups not included in the controlled exposure studies (e.g., those with more severe asthma and children). There are also uncertainties concerning the potential influence of exposure history and co-exposure to other pollutants on the relationship between short-term SO_2 exposures and respiratory effects. With regard to the evidence base, we also recognize a complication associated with interpreting the epidemiologic evidence related to uncertainty in the exposure estimates. The following discussion touches on each of these types of uncertainty.

With regard to the potential for and magnitude of these effects in at-risk populations exposed to 5- to 10-minute concentrations below 200 ppb, there is very limited evidence from a small set of studies of exposure concentrations as low as 100 ppb, as discussed in section 3.2.1.3 above. Although only a few of these studies included an exposure to clean air while exercising that would have allowed for determining the effect of SO_2 versus that of exercise, these studies indicate the likelihood of an appreciable reduction in SO_2-induced response in exercising people with asthma from that observed for exposures at 200 ppb, with no evidence provided for as much as a doubling in sRaw at an exposure concentration of 100 ppb. Given the limited number of subjects in these studies and study design differences from free breathing chamber studies, however, uncertainties remain with regard to a complete characterization of the extent of response in exercising individuals with asthma exposed through natural or free breathing to exposure concentrations below 200 ppb. The extent to which the epidemiological evidence,

including that newly available, can inform this area of uncertainty is limited, at best.[34] Accordingly, this remains an area of uncertainty in this review.

Some uncertainty also remains with regard to the extent to which the controlled human exposure study evidence describes the responses of the populations most at risk of SO_2-related respiratory effects (e.g., those with the greatest likelihood of the most severe response or of responding at the lowest exposure concentration). For example, the available studies have generally involved subjects with mild or moderate asthma, such that the response of individuals with more severe asthma is unknown.[35] Further, while it is well documented that some individuals have a greater response to SO_2 than others with the same disease status, the factors contributing to this greater susceptibility are not yet known (ISA, pp. 5-14 to 5-21).

Uncertainty also remains related to the responses for children with asthma. Although the epidemiological evidence includes a number of studies focused on health outcomes in children that are supportive of the qualitative conclusions of causality (ISA, section 5.2.1.2), there are few controlled human exposure studies to inform our understanding of exposure concentrations associated with effects in this population group. Those studies have not included subjects younger than 12 years (ISA, p. 5-22). Some characteristics particular to school age children younger than 12 years, such as increased propensity for mouth breathing (ISA, p. 4-5), however, suggest that this age group of children with asthma might be expected to experience larger lung function decrements than adults with asthma (ISA, p. 5-25).

Other areas of uncertainty concerning the potential influence of SO_2 exposure history and co-exposure to other pollutants on the relationship between short-term SO_2 exposures and respiratory effects also remain from the last review. There is some limited evidence regarding the potential for an increased response to SO_2 exposures occurring in the presence of other common pollutants such as PM (potentially including particulate sulfur compounds), nitrogen dioxide and

[34] As associations reported in the epidemiologic analyses are associated with air quality concentration metrics as surrogates for the actual pattern of exposures experienced by study population individuals over the period of a particular study, the studies are limited in what they can convey regarding the specific patterns of exposure circumstances (e.g., magnitude of concentrations over specific durations and frequency) that might be eliciting reported health outcomes.

[35] The ISA identifies two studies that have investigated the influence of asthma severity on responsiveness to SO_2, with one finding that a larger change in lung function observed in the moderate/severe asthma group was attributable to the exercise component of the study protocol while the other did not assess the role of exercise in differences across individuals with asthma of differing severity (Linn et al., 1987; Trenga et al., 1999). The ISA states, "[h]owever, both studies suggest that adults with moderate/severe asthma may have more limited reserve to deal with an insult compared with individuals with mild asthma" (ISA, p. 5-22). Based on the criteria used in the study by Linn et al (1987) for placing individuals in the "moderate/severe" group, the ISA concluded that the asthma of these individuals "would likely be classified as moderate by today's classification standards" (ISA, p. 5-22; Johns et al., 2010; Reddel, 2009).

ozone, although the studies are limited (e.g., with regard to their relevance to ambient exposures) and/or provide inconsistent results (ISA, pp. 5-23 to 5-26, pp. 5-143 to 5-144; 2008 ISA, section 3.1.4.7). For example, "studies of mixtures of particles and sulfur oxides indicate some enhanced effects on lung function parameters, airway responsiveness, and host defense," however, "some of these studies lack appropriate controls and others involve [sulfur-containing species] that may not be representative of ambient exposures" (ISA, p.5-144).[36] There is also some evidence suggestive of a potential for SO_2 exposure to contribute to an increased sensitivity to allergens; however, the studies are very few and are limited to experimental animal models (ISA, section 5.2.1.9).

There are additional complications associated with interpretation of epidemiologic studies of SO_2 in ambient air that pertain to exposure measurement error and copollutant confounding (ISA, sections 3.4, 5.2.1.1 and 5.2.1.2). With regard to the former, a key uncertainty in the epidemiologic evidence is whether study findings reflect an independent association for SO_2 given that the studies assigned exposure from fixed site monitors while SO_2 concentrations in ambient air tend to show high spatiotemporal variability within a city, and correlations with personal exposure are poorly characterized. Accordingly, there is uncertainty regarding the extent to which measurements at the study monitors, and the associated air quality concentration metric for the study, adequately represent the spatiotemporal variability in ambient SO_2 concentrations in the study area (ISA, sections 5.2.1.2 and 3.4.1.3).

With regard to copollutant confounding, not only is SO_2 but one component of a complex mixture of pollutants present in the ambient air, an issue not unique to SO_2 epidemiological studies, but SO_2 is also a precursor to sulfate, which can be a principal component of PM, an air pollutant commonly occurring across the U.S. (ISA, section 2.3; U.S. EPA, 2009, Table 3-2 and section 3.3.2). This uncertainty affects the extent to which effect estimates from epidemiologic studies reflect the independent contribution of SO_2 to the adverse respiratory outcomes assessed in these studies. This area of uncertainty was recognized in the last review and remains in the current review. In first summarizing the epidemiological evidence from the last review, the ISA

[36] These toxicological studies in laboratory animals, which were newly available in the last review, were discussed in greater detail in the 2008 ISA. That ISA stated that "[r]espiratory responses observed in these experiments were in some cases attributed to the formation of particular sulfur-containing species" yet, "the relevance of these animal toxicological studies has been called into question because concentrations of both PM (1 mg/m^3 and higher) and SO_2 (1 ppm and higher) utilized in these studies are much higher than ambient levels" (2008 ISA, p. 3-30). The 2008 ISA further stated that "the SO_2-adsorbed PM utilized in some of these studies is not representative of ambient PM," providing the example that "some of the laboratory-generated aerosols contained sulfite but atmospheric chemistry studies do not indicate significant amounts of sulfite ion in atmospheric PM" (2008 ISA, p. 3-30). Thus, the 2008 ISA concluded that "animal toxicological studies conducted since the [prior] review suggest that SO_2 effects may be potentiated by coexposure to PM but the relevance of these results to ambient exposures is not clear" (2008 ISA, p. 3-30).

indicated that it was strongest for increased respiratory symptoms and respiratory-related hospital admissions and ED visits, especially in children, while noting that "a key uncertainty was potential confounding by copollutants, particularly PM" (ISA, p. 5-5). With regard to the newly available evidence, "uncertainties related to exposure measurement error and copollutant confounding remain" (ISA, p. 5-6).[37]

There remains uncertainty in the evidence with regard to the potential role of long-term exposure to SO_2 in eliciting SO_2-related respiratory effects. As noted in section 3.2.1.1 above, the ISA has determined the evidence to be suggestive of this being a causal relationship. The strongest evidence supporting this conclusion is provided by epidemiological study findings of associations between long-term SO_2 concentrations and increases in asthma incidence combined with findings of laboratory animal studies involving newborn rodents that indicate a potential for SO_2 exposure to contribute to the development of asthma, especially allergic asthma, in children. However, "some uncertainty remains regarding an independent effect of long-term SO_2 exposure on the development of asthma" and "potential confounding by other pollutants is unexamined, and largely unavailable, for epidemiologic studies of asthma among children" (ISA, p. 5-182).

Another area of uncertainty recognized by the ISA relates to conclusions regarding the potential for SO_2 in ambient air to contribute to health effects other than respiratory effects. As noted in section 3.2.1.1 above, the ISA has determined the evidence to be suggestive of, but insufficient to infer, a causal relationship between short-term SO_2 exposure and mortality and to be inadequate to infer the presence or absence of a causal relationship for other types of exposures and health effects for which there are studies available (ISA, section 1.6.2).

In summary, a variety of uncertainties from the last review remain, including those related to the extent of effects at concentrations below those evaluated in controlled human exposure studies of exercising individuals with asthma, and the potential for greater impacts in individuals with more severe asthma and in children with asthma, as well as exposure measurement error and potential copollutant confounding in the epidemiologic studies (ISA, section 5.2.1.9).

3.2.1.5 Public Health Implications

In general, implications and the magnitude of potential impacts on public health are dependent upon the type and severity of the effect, as well as the size of population affected.

[37] With regard to asthma-related outcomes, "a small number of epidemiologic studies examined copollutant models" and while "[s]ome associations were relatively unchanged in magnitude after adjustment for a copollutant; others did not persist" (ISA, p. 5-154). The ISA concludes that "inference from copollutant models is limited given potential differences in exposure measurement error for SO_2 compared to NO_2, CO, PM, and O_3 and in many cases, high copollutant correlations" (ISA, p. 5-154). The evidence for nonasthma-related outcomes is described as "limited and inconsistent" (ISA, pp. 5-155 to 5-156).

With regard to SO_2 concentrations in ambient air, the public health implications and potential public health impacts relate to the effects causally related to SO_2 exposures of interest in this review. These are respiratory effects of short-term exposures, and particularly those effects associated with asthma exacerbation in people with asthma. As summarized in section 3.2.1.1, the most strongly demonstrated effects are bronchoconstriction-related effects resulting in decrements in lung function elicited by short term exposures during periods of elevated breathing rate, while asthma-related health outcomes such as ED visits and hospital admissions have also been statistically associated with ambient air SO_2 concentration metrics in epidemiological studies (ISA, section 5.2.1.9).

In considering public health implications, in addition to the difference in severity of different effects, it is important to consider aspects of the same effect with regard to its impact on population groups of differing susceptibility. For example, with regard to bronchoconstriction-related effects, the same percentage increase in sRaw or reduction in FEV_1 for two groups of individuals that differ in their baseline sRaw or FEV_1 may result in the two groups being affected differently with regard to increased susceptibility to other physiological threats or challenges. Accordingly, consideration of such baseline differences and also the relative transience or persistence of these responses, as well as other factors, is important to characterizing implications for public health, as recognized by the ATS in their statements on evaluating adverse health effects of air pollution (ATS, 2000; Thurston et al., 2017).

Building on the earlier policy statement by the ATS that was considered in the last review (ATS, 2000), the recent policy statement by the ATS on what constitutes an adverse health effect of air pollution provides a general framework for interpreting evidence that proposes a a "set of considerations that can be applied in forming judgments" for this context (Thurston et al., 2017). The earlier ATS statement, in addition to emphasizing clinically relevant effects (e.g., the adversity of small transient changes in lung function metrics in combination with respiratory symptoms), also emphasized both the need to consider changes in "the risk profile of the exposed population," and effects on the portion of the population that may have a diminished reserve that puts its members at potentially increased risk if affected by another agent (ATS, 2000). The consideration of effects on individuals with pre-existing diminished lung function continues to be recognized as important in the more recent ATS statement (Thurston et al., 2017). For example, in adding emphasis in this area, this statement conveys the view that "small lung function changes" in individuals with compromised function, such as that resulting from asthma, should be considered adverse, even without accompanying respiratory symptoms (Thurston et al., 2017). All of these concepts, including the consideration of the magnitude of effects occurring in

just a subset of study subjects, continue to be recognized as important in the more recent ATS statement (Thurston et al., 2017) and continue to be relevant to the evidence base for SO_2.[38]

As summarized in section 3.2.1.3 above, people with asthma are the key population at risk for SO_2-related effects and children with asthma are considered to be at relatively greater risk than other age groups within this at-risk population (ISA, section 6.3.1). In recognizing that asthma as a disease can vary in its severity, we take note of the relative lack of evidence for individuals with the most severe asthma. The evidence base of controlled exposure studies of exercising people with asthma provides limited information that indicates there to be similar relative responses of individuals with differences in severity of their asthma,[39] although the evidence from one study indicates that the absolute changes in lung function are larger for individuals with more severe asthma compared to those characterized as having mild asthma. In that study, the larger absolute change in lung function was attributable to a larger response to the exercise component of the exposure protocol in the moderate/severe asthma group compared to the mild asthma group (ISA, p. 5-22; Linn et al., 1987). Because the role of exercise was not determined in the second study, it is unclear whether a greater response to the exercise itself (vs the SO_2 exposure) played a role in its findings (ISA, p. 5-22; Trenga et al., 1999). However, the two available studies "suggest that adults with moderate/severe asthma may have more limited reserve to deal with an insult compared with individuals with mild asthma" (ISA, p. 5-22; Linn et al., 1987; Trenga et al., 1999).

The information below characterizes the size and other features of the populations in the U.S. concluded to be at risk of SO_2-related effects (when breathing at elevated rates). As a whole, the discussion in this section indicates the potential for exposures to SO_2 in ambient air to be of appreciable public health importance. Such considerations contributed to the basis for the 2010 decision to appreciably strengthen the primary SO_2 NAAQS and to establish a 1-hour standard to protect the at-risk populations from short term exposures of concern. Such considerations remain relevant in the current review.

[38] In the Administrator's judgments on the then-existing standard in the last review, as well as on the appropriate level for the new 1-hour standard, the Administrator considered the 2000 ATS policy statement, as well as advice from CASAC and recommendations and judgments made by EPA in previous NAAQS reviews (section 3.1.1 above).

[39] These studies categorized with regard to asthma severity based mainly on the individual's use of medication to control asthma, such that individuals not regularly using medication were classified as minimal/mild, and those regularly using medication as moderate/severe (Linn et al., 1987). The ISA indicates that the moderate/severe grouping would likely be classified as moderate by today's asthma classification standards due to the level to which their asthma was controlled and ability to engage in moderate to heavy levels of exercise (ISA, p. 5-22; Johns et al., 2010; Reddel, 2009).

- **What does the information available in this review indicate with regard to the size of at-risk populations and their distribution in the U.S.?**

The magnitude and characterization of a public health impact is dependent upon the size and characterization of the populations affected, as well as the type or severity of the effect. As summarized above, the population group most at risk of health effects associated with exposure to SO_2 in ambient air is people with asthma.[40] The National Center for Health Statistics data from the National Health Information Survey (NHIS)[41] for 2015 indicate that approximately 8% of the U.S. population has asthma (Table 3-2; CDC, 2017). These data indicate the size of the key at-risk population for SO_2 in ambient air. It is this population that the primary NAAQS for SO_2 is intended to protect. Table 3-2 below considers the currently available information that helps to characterize key features of this population.

Population groups with relatively greater asthma prevalence might be expected to have a potential for relatively greater population-level SO_2 impacts. Among all U.S. adults, asthma prevalence is estimated to be 7.6%, with women having a higher estimate (9.7%) than men (5.4%). The estimated prevalence is greater in children (less than 18 years of age) than adults (Table 3-2). Asthma was the leading chronic illness affecting children in 2012, the most recent year for which such an evaluation is available (Bloom et al., 2013).

Among all U.S. children, the asthma prevalence estimate is greater for boys (9.9%) than girls (6.9%), and, with regard to age, is generally greatest in young teenagers (Table 3-2). Among populations of different races or ethnicities, black non-Hispanic and Puerto Rican Hispanic children are estimated to have the highest estimated prevalences, at 13.4% and 13.9%, respectively. For the age group 5-14 years, the estimates are 16.3% and 14.7% for black non-

[40] We additionally note, that some individuals with asthma have a greater response to SO_2 than others with asthma (ISA, p. 5-14). Analyses of publicly available primary data from five studies demonstrated a bimodal distribution of SO_2 responses in study subjects with asthma, "with one subpopulation that is insensitive to the bronchoconstrictive effects of SO_2 even at concentrations as high as 1.0 ppm, and another subpopulation that has an increased risk of bronchoconstriction … at low concentrations" (ISA, p. 5-19 to 5-20; Johns et al., 2010).

[41] The NHIS is conducted annually by the U.S. Centers for Disease Control and Prevention. The NHIS collects health information from a nationally representative sample of the noninstitutionalized U.S. civilian population through personal interviews. Participants (or parents of participants if the survey participant is a child) who have ever been told by a doctor or other health professional that the participant had asthma and reported that they still have asthma were considered to have current asthma. Data are weighted to produce nationally representative estimates using sample weights; estimates with a relative standard error greater than or equal to 30% are generally not reported (Mazurek and Syamlal, 2018). The NHIS estimates described here are drawn from the 2015 NHIS, Table 4-1 (https://www.cdc.gov/asthma/nhis/2015/table4-1.htm) and current asthma prevalence table (https://www.cdc.gov/asthma/most_recent_data.htm).

Hispanic and Puerto Rican children, respectively (Table 3-2).[42] Asthma prevalence is also increased among populations in poverty (e.g., 11.1% among people living in households below the poverty level compared to 7.2% of those living above it).[43]

The information on which to base estimates of asthma prevalence in other subgroups of children is much more limited (e.g., as discussed in the REA, section 4.1.2). For example, the more limited information from the National Health Information Survey (NHIS) for 2011-2015 indicates there to be a greater prevalence of asthma in children that are obese compared to those that are not (REA, section 4.1.2, Figure 4-2).[44]

[42] Interestingly, in black, non-Hispanic children aged 5 to 14 years, the estimated asthma prevalence is greater in boys (19.0%) than girls (13.5%). While in Puerto Rican children aged 5 to 14 years, the estimated prevalence is greater in girls (18.5%) than boys (11.6%) (https://www.cdc.gov/asthma/nhis/2015/table4-1.htm).

[43] There is also a correlation between asthma prevalence and obesity (REA, section 4.1.2).

[44] In consideration of the limited information regarding factors related to breathing habit (whether one is breathing through their nose or mouth) and recognizing the lack of evidence from controlled human exposure studies of SO_2-induced lung function decrements in children, approximately 5 to 11 years of age, with asthma, the ISA suggests that this age group of children and "particularly boys and perhaps obese children, might be expected to experience greater responsiveness (i.e., larger decrements in lung function) following exposure to SO_2 than normal-weight adolescents and adults" (ISA, p. 4-7 and 5-36). However, the ISA does not find the evidence to be adequate to conclude differential risk status for subgroups of children with asthma (ISA, Chapter 6).

Table 3-2. 2015 National Asthma Prevalence.

Characteristic [1]	Number with Current Asthma (in thousands) [2]	Percent with Current Asthma
Total	**24,633**	**7.8**
Child (Age <18)	6,188	8.4
Adult (Age 18+)	18,445	7.6
All Age Groups		
0-4 years	935	4.7
5-14 years	4,033	9.8
15-19 years	2,107	10.2
20-24 years	1,655	7.6
25-34 years	2,916	6.8
35-64 years	9,907	8.0
65+ years	3,079	6.6
Child Age Group		
0-4 years	935	4.7
5-11 years	2,761	9.6
12-17 years	2,492	10.0
12-14 years	1,272	10.3
15-17 years	1,219	9.8
Sex		
Males	9,998	6.5
Boys (Age <18)	3,705	9.9
Boys (Age 5-14)	2,428	11.6
Men (Age 18+)	6,293	5.4
Females	14,634	9.1
Girls (Age <18)	2,483	6.9
Girls (Age 5-14)	1,605	8.0
Women (Age 18+)	12,151	9.7
Race/Ethnicity		
White NH [3]	15,244	7.8
Child (Age <18)	2,810	7.4
Child (Age 5-14)	1,750	8.2
Adult (Age 18+)	12,435	7.9
Black NH	3,931	10.3
Child (Age <18)	1,336	13.4
Child (Age 5-14)	911	16.3
Adult (Age 18+)	2,595	9.1
Other NH	1,793	6.9
Child (Age <18)	605	8.4
Child (Age 5-14)	389	9.4
Adult (Age 18+)	1,188	6.3
Hispanic, all	3,665	6.6
Child (Age <18)	1,438	8.0
Child (Age 5-14)	983	9.7
Adult (Age 18+)	2,227	5.9
Hispanic, Puerto Rican	715	13.7
Child (Age<18)	198	13.9
Child (Age 5-14)	117	14.7
Adult (Age 18+)	516	13.6

Characteristic [1]	Number with Current Asthma (in thousands) [2]	Percent with Current Asthma
Hispanic, Mexican/Mexican-American	2,126	6.0
Child (Age<18)	899	7.3
Child (Age 5-14)	646	9.2
Adult (Age 18+)	1,226	5.3
Federal Poverty Threshold		
Below 100% of poverty level	5,086	11.1
100% to less than 250% of poverty level	7,664	8.4
250% to less than 450% of poverty level	4,989	6.3
450% of poverty level or higher	6,894	6.9

[1] Numbers within selected characteristics may not sum to total due to rounding
[2] Includes persons who answered "yes" to the questions "Have you EVER been told by a doctor or other health professional that you had asthma" and "Do you still have asthma?"
[3] NH = non-Hispanic
Adapted from https://www.cdc.gov/asthma/most_recent_data.htm and https://www.cdc.gov/asthma/nhis/2015/table4-1.htm (CDC, 2017).

3.2.2 Exposure/Risk-based Considerations

Our consideration of the scientific evidence available in the current review, as at the time of the last review (summarized in section 3.1 above), is informed by results from a quantitative analysis of estimated population exposure and associated risk. The overarching consideration is whether the current exposure/risk information alters our overall conclusions from the previous review regarding health risk associated with exposure to SO_2 in ambient air. As in our consideration of the evidence in section 3.2.1 above, we have organized the discussion regarding the exposure/risk information around a set of key questions to assist us in considering the exposure/risk analyses of at-risk populations living in three urban areas under air quality conditions simulated to just meet the existing SO_2 primary standard.

Prior to addressing the individual exposure/risk questions, we provide a summary of key aspects of the assessment, including the study areas, populations simulated, modeling tools and exposure and risk metrics derived (section 3.2.2.1). We then consider aspects of the questions beginning with the magnitude of exposure and risk estimated for the simulated at-risk populations (section 3.2.2.2), followed by the key uncertainties associated with the quantitative analyses with regard to drawing conclusions as to the adequacy of protection afforded by the current SO_2 standard (section 3.2.2.3). Lastly, we consider the exposure and risk estimates from the quantitative assessment with regard to the extent to which such estimates may be judged to be important from a public health perspective (section 3.2.2.4).

3.2.2.1 Exposure/Risk Analyses

In the assessment conducted for this review, described in detail in the REA, we have estimated SO_2 exposure and risk associated with air quality conditions that just meet the current

standard. These analyses inform our understanding of the protection provided by the current SO_2 standard from effects that the health effects evidence indicates to be elicited in some portion of exercising people with asthma by short (e.g., 5- to 10-minute) elevations in SO_2 exposure concentrations. The analyses estimate exposure and risk for at-risk populations in three urban study areas in: (1) Fall River, MA; (2) Indianapolis, IN; and, (3) Tulsa, OK. The three study areas present a variety of circumstances with regard to population exposure to short-term peak concentrations of SO_2 in ambient air. This set of study areas and the associated exposed populations are intended to be informative to the EPA's consideration of potential exposures and risks that may be associated with the air quality conditions that meet the current SO_2 standard.

The three study areas range in total population size from approximately 180,000 to 540,000 and reflect different mixtures of SO_2 emissions sources, including utilities using fossil fuel and non-utility sources, such as petroleum refineries and secondary lead smelting (REA, section 3.1). The three study areas – in Massachusetts, Indiana and Oklahoma –are in three different climate regions of the U.S.: the Northeast, Ohio River Valley (Central), and South (Karl and Koss, 1984). The latter two regions comprise the part of the U.S. with generally the greatest prevalence of elevated SO_2 concentrations and large emissions sources (Figure 2-7, Appendix F). Additionally, continuous 5-minute ambient air monitoring data (i.e., all 12 5-minute values for each hour) are available in all three study areas (REA, section 3.2).

Consistent with the health effects evidence in this review (summarized in section 3.2.1 above), the focus of the REA is on short-term exposures of individuals in the population with asthma during times when they are breathing at an elevated rate. Exposure and risk is characterized for two population groups: adults (individuals older than 18 years) with asthma and school-aged children (aged 5 to 18 years)[45] with asthma. The focus on these populations is consistent with the ISA's identification of individuals with asthma as the population at risk of SO_2-related effects, and its conclusion that within this population, children with asthma may be at greater risk than adults with asthma (ISA, section 6.6). Asthma prevalence estimates for the populations simulated in the three study areas ranges from 8.0 to 8.7% (REA, section 5.1). For children, the study area prevalence rates range from 9.7 to 11.2% (REA, section 5.1). Variation within each study area related to age, sex and family income was also accounted for (section 4.1.2 and Appendix E of REA).[46] For children, this variation is greatest in the Fall River study

[45] The child population group focuses on ages 5 to 18 in recognition of data limitations and uncertainties, including those related to accurately simulating activities performed, estimating physiological attributes, as well as challenges in asthma diagnoses for very young children.

[46] As described in section 4.1.2 and Appendix E of the REA, asthma prevalence in the exposure modeling domain is estimated based on national prevalence information and study area demographic information related to age, sex and family income from the NHIS.

area, with census block level, age-specific prevalence estimates ranging from 7.9 to 18.6% for girls and from 10.7 to 21.5% for boys (REA, Table 4-2).

In the REA, 1-hour SO_2 concentrations were estimated across a 3-year period (consistent with the period represented by the form of the standard) using air quality modeling of SO_2 emissions sources in each area,[47] and were adjusted, as described in the REA, such that the air quality modeling receptor location with the highest concentrations just met the current standard.[48] In addition, sensitivity analyses were performed using an alternative adjustment approach and are summarized in section 3.2.2.2. Relationships between 1-hour and 5-minute concentrations at local monitors were then used to estimate 5-minute concentrations associated with the adjusted 1-hour concentrations across the 3-year period at all receptor locations in each area (REA, section 3.5).

The exposure modeling, presented in detail in the REA, relied on the EPA's Air Pollutant Exposure model (APEX), which estimates human exposure using a stochastic, event-based microenvironmental approach. This model has a history of application, evaluation, and progressive model development in estimating human exposure and dose for reviews of NAAQS for gaseous pollutants (U.S. EPA, 2008; 2010; 2014). This general exposure modeling approach was also used in the 2009 REA for the last review of the primary standard for SO_X, although a number of updates have been made to the model and various datasets used with it (2009 REA; U.S. EPA, 2017b, section 3.4). For example, exposure modeling for the REA includes reliance on updates to several key inputs to the model including (1) a significantly expanded Consolidated Human Activity Database (CHAD), that now has over 55,000 diaries, with over 25,000 for school-aged children; (2) the updated NHANES data (2009-2014), which are the basis for the age- and sex-specific body mass distributions from which APEX samples to specify the individuals in the modeled population; (3) the algorithms used to estimate age- and sex-specific resting metabolic rate, a key input to estimating a simulated individual's activity-specific ventilation (or breathing) rate; and (4) the ventilation rate algorithm itself. Further, the current model uses updated population demographic data based on the most recent Census.

The APEX model probabilistically generates a sample of hypothetical individuals from an actual population database and simulates each individual's movements through time and space (e.g., indoors at home, inside vehicles) to estimate his or her exposure to a pollutant.

[47] As described in chapter 3 of the REA, the air quality modeling utilized emissions estimates and meteorological data for the years 2011 through 2013 as conditions in this time period are close to those just meeting the current standard, thus requiring a smaller adjustment to create the current standard scenario.

[48] As described in more detail in section 3.4 of the REA, the adjustments were implemented with a focus on reducing emissions from the source contributing to the standard exceedances until the areas just met the standard.

Population characteristics are taken into account to represent the demographic profile of the population in each study area. Age and gender demographics for the simulated at-risk population (adults and children with asthma) were drawn from the prevalence estimates provided by the 2011-2015 National Health Interview Survey.[49] The APEX model generates each simulated person or profile by probabilistically selecting values for a set of profile variables, including demographic variables, status and physical attributes (e.g., residence with air conditioning, height, weight, body surface area) and ventilation rate.

Based on minute-by-minute activity levels, and physiological characteristics of the simulated person (see REA, section 4.1), APEX estimates an equivalent ventilation rate (EVR), based on normalizing the simulated individuals' activity-specific ventilation rate to their body surface area; the EVR is used to identify exposure periods during which an individual is at or above a specified ventilation level (REA, section 4.1.3.3). The level specified is based on the ventilation rates of subjects in the controlled human exposure studies of exercising people with asthma (Table 3-1). The APEX simulations performed for this review have focused on exposures to SO_2 emitted into ambient air that occurs in microenvironments,[50] without additional contribution from indoor SO_2 emissions sources.[51]

As in the last review, the REA for this review uses the APEX model estimates of 5-minute exposure concentrations for simulated individuals with asthma while breathing at elevated rates to characterize health risk in two ways based on information from the controlled human exposure studies on the occurrence of bronchoconstriction-related effects in some study subjects with asthma who are exposed during exercise (REA, section 4.6). In drawing on this evidence base for this purpose, the REA has given primary focus to the well-documented studies summarized in Table 5-2 and Figure 5-1 of the ISA for 5- to 10-minute exposure concentrations ranging from 200 ppb to 600 ppb (Table 3-1 of this document). The first risk metric is based on comparison of the estimated 5-minute exposure concentrations for individuals breathing at elevated rates to 5-minute concentrations of potential concern (benchmark concentrations), and the second utilizes exposure-response information for study subjects experiencing

[49] Information about the National Health Interview Survey is available at http://www.cdc.gov/nchs/nhis.htm.

[50] Five microenvironments (MEs) are modeled in the REA as representative of a larger number of microenvironments. The 2009 REA results indicated that the majority of peak SO_2 exposures occurred while individuals were within outdoor microenvironments (2009 REA, Figure 8-21). Based on that finding and the objective (i.e., understanding how often and where short-term peak SO_2 exposures occur), the approach implemented in the REA recognizes the added efficiency of minimizing the number of MEs, particularly indoor MEs, that are parameterized and included in the modeling. Accordingly, the number of MEs was aggregated to address exposures of ambient origin that occur within a core group of indoor, outdoor, and vehicle MEs (REA, section 4.4).

[51] Indoor sources are generally minor in comparison to SO_2 from ambient air (ISA, p. 3-6; REA, sections 2.1.1 and 2.1.2).

bronchoconstriction-related effects on lung function (specifically a doubling or more in sRaw) to estimate the portion of the simulated at-risk population likely to experience one or more days with an SO_2-related increase in sRaw of at least 100%. Both of these metrics are used in the REA to characterize health risk associated with 5-minute peak SO_2 exposures among the simulated at-risk population during periods of elevated breathing rates. These risk metrics were also derived in the REA for the last review and the associated estimates informed the Administrator's 2010 decision on the new standard (75 FR 35546-35547, June 22, 2010).

For the benchmarks metric, the REA for this review, like the 2009 REA in the last review, uses benchmark concentrations that range from 400 ppb down to 100 ppb (REA, section 4.6.1). At the upper end of this range, 400 ppb represents the lowest concentration in free-breathing controlled human exposure studies of exercising people with asthma where moderate or greater lung function decrements occurred that were often statistically significant at the group mean level and were frequently accompanied by respiratory symptoms, including statistically significant increased occurrences (ISA, section 5.2.1.2). At 300 ppb, statistically significant increases in lung function decrements (specifically reduced FEV_1) have been documented in analyses of the subset of controlled human exposure study subjects with asthma that are responsive to SO_2 at concentrations below 600 or 1000 ppb (ISA, p. 153 and Table 5-21; Johns et al., 2010). The 200 ppb benchmark concentration represents the lowest level tested in studies where subjects were freely breathing in exposure chambers, and where comparisons with exposures to clean air while exercising were conducted, thus providing for conclusions regarding SO_2-attributable responses. At this concentration, moderate or greater lung function decrements occurred in a percentage of exercising study subjects and there was also limited evidence of SO_2-related respiratory symptoms (ISA, section 5.2.1.2). For exposure concentrations below 200 ppb, limited data are available that while not completely comparable to the data at higher concentrations do not indicate responses on the order of a doubling in sRaw (section 3.2.1.3 above). However, in consideration of the nonzero percentage of subjects with asthma experiencing moderate transient decrements in lung function at the 200 ppb exposure concentration (approximately 8 to 9%) and the scarcity or lack of specific controlled human exposure study data for some groups of individuals with asthma, such as primary-school-age children and those with more severe asthma,[52] a benchmark concentration of 100 ppb (one half

[52] Recognizing that even the study subjects described as "moderate/severe" group (had well-controlled asthma, were generally able to withhold medication, were not dependent on corticosteroids, and were able to engage in moderate to heavy levels of exercise) would likely be classified as moderate by today's classification standards (ISA, pp. 5-22; Johns et al., 2010; Reddel, 2009), we have considered the evidence with regard to the response of individuals with severe asthma that are not generally represented in the full set of controlled human exposure studies. There is no evidence to indicate such individuals would experience moderate or greater lung function decrements at lower SO_2 exposure concentrations than individuals with moderate asthma. With regard to the

the lowest exposure concentration for which the ISA provides quantified SO_2-attributable responses resulting from free breathing exposure studies), has been included.

The exposure-response (E-R) function for the risk of lung function decrements was developed from the individual subject results for sRaw from the controlled exposure studies of exercising freely breathing people with asthma exposed to SO_2 concentrations from 1000 ppb down as low as 200 ppb (REA, Table 4-12). Beyond the assessment of these studies and their results in past reviews, there has been extensive evaluation of the individual subject results, including a data quality review in the last SO_2 NAAQS review (Johns and Simmons, 2009), and detailed analysis in two subsequent publications (Johns et al., 2010; Johns and Linn, 2011). The sRaw responses reported in these studies have been summarized in the ISA, as in the last review, in terms of percent of study subjects experiencing responses of a magnitude equal to a doubling or tripling or more. Across the exposure range from 200 to 1000 ppb, the percentage of exercising study subjects with asthma having at least a doubling of sRaw increases from about 8-9% (at exposures of 200 ppb) up to approximately 50-60% (at exposures of 1000 ppb) (REA, Table 4-11). The E-R function used in the main analysis of the REA was derived from these data using a probit function (REA, section 4.6.2).

In summary, while the general approach and methodology for the exposure-based assessment in this review is similar to that in the last review, there are a number of ways in which these analyses differ (see 2009 REA and REA for this review). In addition to the expansion in the number and type of study areas assessed, we note the number of improvements to input data and modeling approaches, including the availability of continuous 5-minute air monitoring data at monitors within the three study areas. The REA for the current review extends the time period of simulation to a 3-year simulation period, consistent with the form established for the now-current standard. Further, the years simulated reflect more recent emissions and circumstances subsequent to the 2010 decision.

3.2.2.2 At-Risk Population Exposures and Risk

In this section, we summarize the exposure and risk estimates from the REA and consider the following question.

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severity of the response, the limited data that are available indicate a similar magnitude SO_2-specific response (in sRaw) as that for individuals with less severe asthma, although the individuals with more severe asthma are indicated to have a greater response to exercise prior to SO_2 exposure, indicating that those individuals "may have more limited reserve to deal with an insult compared with individuals with mild asthma" (ISA, p. 5-22). As noted in sections 3.2.1.3 and 3.2.1.4 above, evidence from controlled human exposure studies are not available for children younger than 12 years old, and the ISA indicates that the information regarding behavior and methacholine responsiveness for the subset of this age group that is of school age (e.g., 5-12 years) indicates a potential for greater response (ISA, pp. 5-22 to 5-25).

- **What is the magnitude of population exposure and risk in at-risk populations in areas simulated to just meet the current SO_2 standard? What portion of the at-risk populations are estimated to experience exposures of concern or lung function decrements at levels of potential health concern?**

Given these overarching questions, the air quality scenario analyzed in the REA focuses on air quality conditions that just meet the current standard. In addressing these questions, we consider the population estimates provided by the REA simulations (REA, Chapters 5 and 6) and in considering these REA estimates, we particularly focus on the extent of protection provided by the standard from SO_2 exposures of potential concern. As described in the prior section, the REA presents two sets of risk estimates for the 3-year simulation in each study area: (1) the number (and percent) of simulated persons experiencing exposures at or above the particular benchmark concentrations of interest, while breathing at elevated rates; and (2) the number and percent of people estimated to experience at least one SO_2-related lung function decrement in a year and the number and percent of people estimated to experience multiple lung function decrements associated with SO_2 exposures.

As an initial matter, we note that, as indicated by the use of a case study approach (summarized in section 3.2.2.1 above), the REA analyses are not intended to provide a comprehensive national assessment. The REA objective is not to present an exhaustive analysis of exposure and risk in the areas that currently just meet the current standard and/or of exposure and risk associated with air quality adjusted to just meet the current standard in areas that currently do not meet the standard. Rather, the analyses are intended to provide assessments of an air quality scenario just meeting the current standard for a small, diverse set of study areas and associated exposed at-risk populations. The purpose is to assess, based on current tools and information, the potential for exposures and risks beyond those indicated by the information available at the time the standard was established. Accordingly, capturing an appropriate diversity in study areas and air quality conditions (that reflect the current standard scenario)[53] is important to the role of the REA in informing the EPA's conclusions on the public health protection afforded by the current standard.

In this light, we present the REA results from two different approaches to adjusting air quality. The first approach uses the highest design value across all modeled air quality receptors to adjust the air quality concentrations in each area to just meet the standard (REA, section 3.4).

[53] A broad variety of spatial and temporal patterns of SO_2 concentrations can exist when ambient air concentrations just meet the current standard. These patterns will vary due to many factors including the types of emissions sources in a study area and several characteristics of those sources, such as magnitude of emissions and facility age, use of various control technologies, patterns of operation, and local factors, as well local meteorology. Variability and uncertainty in these patterns is indicated by the estimates derived by the particular analytical approaches and methodologies used to describe the study area-specific air quality.

This is done by estimating the amount of SO_2 concentration reduction needed for concentrations at this highest receptor to be adjusted to just meet the current standard, and based on this amount, all other receptors impacted by the highest source(s) are adjusted accordingly. The second approach is included in the REA as a sensitivity analysis in recognition of the potential uncertainty associated with the estimated concentrations across the modeling domain, particularly the very highest concentrations. Accordingly, the second approach uses the air quality receptor having the 99th percentile of the distribution of design values (instead of the receptor having the maximum design value) to estimate the SO_2 concentration reductions needed to adjust the air quality to just meet the standard (REA, section 6.2.2.1). In study areas in which estimated concentrations at a very small number of receptors are substantially higher than those at all other air quality receptors, these two different approaches can result in very different SO_2 concentrations across an area. In such study areas in particular, the first approach generally results in much more significant reductions being applied to reduce SO_2 concentrations at the small group of highest receptor locations such that concentrations at those receptors are just at or just below the standard and concentrations at the other receptors across the area are appreciably lower. We have represented both sets of results in the tables below in recognition of the uncertainty and variability inherent in representing air quality conditions just meeting the current standard.[54]

Of the two types of risk metrics derived in the REA, we turn first to the results for the benchmark-based risk metric with regard to the percent of the simulated populations of children with asthma estimated to experience at least one daily maximum 5-minute exposure per year at or above the different benchmark concentrations while breathing at elevated rates under air quality conditions just meeting the current standard (Table 3-3). The estimates for adults are lower, generally due to the lesser amount and frequency of time spent outdoors (REA, section 5.2). As an initial matter, we note that the estimates for the Tulsa study area are much lower than those for the other two areas. For Tulsa, the fraction of the simulated child population with asthma was less than 0.5% for the 100 ppb benchmark and zero for the other benchmarks.

Under air quality conditions just meeting the current standard in the other two study areas (Indianapolis and Fall River), approximately 20% to just over 25% of a study area's simulated children with asthma, on average across the 3-year period, are estimated to experience one or more days per year with a 5-minute exposure at or above 100 ppb while breathing at elevated rates (Table 3-3). With regard to the 200 ppb benchmark, the two study areas' estimates are as

[54] Details regarding the sensitivity analyses focused on the impact of the adjustment approach are presented in the REA, section 6.2.2.1.

high as 0.7 percent,[55] on average across the 3-year period, and range up to as high as 2.2%[56] in a single year (Table 3-3). Less than 0.1% of either area's children with asthma were estimated to experience multiple days with such an exposure at or above 200 ppb (REA, Table 6-9). Additionally, in the study area with the highest estimates (Indianapolis), approximately a quarter of a percent of simulated children with asthma were estimated to experience a day with a 5-minute exposure at or above 300, on average across the 3-year period; the percentage was 0.1% for the 400 ppb benchmark (Table 3-3). Across all three areas, no children were estimated to experience multiple days with a daily maximum 5-minute exposure (while breathing at an elevated rate) at or above 300 ppb (REA, Table 6-9).

Table 3-3. Air quality conditions adjusted to just meet the current standard: Percent of simulated populations of children with asthma estimated to experience at least one daily maximum 5-minute exposure per year at or above indicated concentrations while breathing at an elevated rate.

5-minute Exposure Concentration (ppb)	Percent (%) of Population of Children (5-18 years) with Asthma Average per year [A]		
	Fall River, MA	Indianapolis, IN	Tulsa, OK
≥ 100	19.4 – 26.7	22.4 – 23.0	0.1 – 0.4
≥ 200	<0.1 [B] – 0.7	0.6 – 0.7 [C]	0
≥ 300	0	0.2 – 0.3 [D]	0
≥ 400	0	<0.1 – 0.1 [D]	0

[A] The values presented in each cell are the average of the results for the three years simulated based on the two approaches to air quality adjustment (drawn from Table 6-8 of the REA).

[B] <0.1 is used to represent nonzero estimates below 0.1%. A value of zero (0) indicates there were no individuals estimated to have the selected exposure in any year.

[C] The highest single year result for 200 ppb was for Fall River where the estimate ranged up to 2.2% (for the second air quality adjustment approach in REA, Table 6-8).

[D] The highest single year results for 300 and 400 ppb were for Indianapolis where the estimates ranged up to 0.8% and 0.3%, respectively (REA, Table 6-8).

We next consider the estimates for risk of lung function decrements in terms of a doubling or more in sRaw, focusing on results for children with asthma (Table 3-4). The estimates for the Tulsa study area are lower than for the other two areas (Table 3-4), the results for which are summarized next.

[55] This percentage in the Fall River study area corresponds to 28 children with asthma, while in the larger Indianapolis study area, it corresponds to 71 such children (REA, section 5.2 and Appendix J).

[56] This percentage, estimated for the Fall River study area, corresponds to 88 children with asthma (REA, Appendix J).

Under air quality conditions just meeting the current standard in the Indianapolis and Fall River study areas, as many as 1.3% and 1.1%, respectively,[57] of children with asthma, on average across the 3-year period, were estimated to experience at least one day per year with a SO_2-related doubling in sRaw (Table 3-4). The corresponding percentage estimates for experiencing two or more such days ranged as high as 0.7%, on average across the 3-year simulation period, and 1% in a single year (REA, Table 6-11). Additionally, as much as 0.2% and 0.3%, in Fall River and Indianapolis, respectively, of the simulated populations of children with asthma, on average across the 3-year period, was estimated to experience a single day with a SO_2-related tripling in sRaw (Table 3-4), with 0.2% or less estimated to experience multiple such days (REA, Table 6-11).

Table 3-4. Air quality conditions adjusted to just meet the current standard: Percent of simulated population of children with asthma estimated to experience at least one day per year with a SO_2-related increase in sRaw of 100% or more.

Lung function decrement (increase in sRaw)	**Percent (%) of Population of Children (5-18 years) with Asthma[A]** Average per year		
	Fall River, MA	**Indianapolis, IN**	**Tulsa, OK**
≥ 100%	0.9 – 1.1 [C]	1.3 – 1.3	<0.1 [B] - <0.1
≥ 200%	0.1 – 0.2 [D]	0.3 – 0.3 [D]	0

[A] The values presented in each cell are the average of the results for the three years simulated based on two approaches to air quality adjustment (drawn from Table 6-7 of the REA).
[B] <0.1 is used to represent nonzero estimates below 0.1%. A value of zero (0) indicates there were no individuals estimated to have the selected decrement in any year.
[C] The highest single year result for at least 100% increase in sRaw was for Fall River where the estimate ranged up to 1.9% (for the second air quality adjustment approach in REA, Table 6-10).
[D] The highest single year results for at least 200% increase in sRaw were for Indianapolis and Fall River where the estimates ranged up to 0.4%,(REA, Table 6-10).

In understanding these results, we note that the three study areas provide a variety of circumstances with regard to population exposure to short-term peak concentrations of SO_2 in ambient air. These three study areas reflect different combinations of different types of SO_2 emissions sources, including utilities using fossil fuels and non-utility sources (REA, section 3.1), and illustrate three different patterns of exposure to SO_2 concentrations in a populated area in the U.S. (REA, section 5.1). In this way, the three areas provide a variety of examples of exposure patterns that can be informative to the EPA's consideration of potential exposures and risks that may be associated with air quality conditions occurring under the current SO_2 standard.

[57] The 1.3% estimate in the Indianapolis study area corresponds to approximately 140 children with asthma, and the 1.1% estimate for Fall River corresponds to 55 such children (REA, section 5.3 and Appendix J).

While the same conceptual air quality scenario is simulated in all three study areas (i.e., conditions that just meet the existing standard), source and population characteristics in the study areas contribute to variability in the estimated magnitude of exposure and associated risk across study areas.

Where the higher SO_2 concentrations that result from the sizeable SO_2 sources in a study area do not strongly coincide with parts of the area in which people reside and/or frequent, the exposure and risk estimates for the 3-year period are relatively lower. The Tulsa study area provides an example of such an area (REA, section 5.4). The relationship between SO_2 concentrations and population in this area is illustrated in Figure 5-7 of the REA, which illustrates the relationships between population distribution and locations with relatively lower design values that contribute to this study area having exposure and risk estimates that are lower than those estimated for the other two study areas (REA, section 5.1). These differences occur even though total study area population size is similar to that for the Fall River study area (REA, sections 5.1 and 5.4).

Where the simulated air quality conditions for a study area includes relatively large spatial extents of higher concentrations – i.e., areas with design values in proximity to the level of the standard – that overlap with the more populated parts of the study area, exposure and risk results are relatively higher (REA, section 5.4). Among the three study areas, this best describes the Fall River and Indianapolis study areas, which are areas where source characteristics contribute to a sizeable spread of source-influenced relatively higher concentrations that coincide or overlap with locations where people reside and/or frequent. This association between concentrations and population in these two areas is illustrated in Figures 5-5 and 5-6 of the REA. Inclusion of areas with these characteristics in the REA provides some insight into the potential exposure and risk associated with other areas across the U.S. with similar characteristics and is therefore particularly informative to evaluation of the level of protection provided by the standard.

The REA provides exposure and risk estimates associated with air quality that might occur in an area under conditions that just meet the current standard and, in so doing, it illustrates the differences likely to occur across various locations with such air quality as a result of area-specific differences in emissions and population characteristics. In the context of the overarching question for the review regarding whether the currently available information calls into question the adequacy of the current standard (see section 3.1.2 above), our discussions here and in the sections below, accordingly, focus particularly on results for the areas with combinations of emissions and population characteristics that contribute to relatively higher exposures and risk (Indianapolis and Fall River).

For these areas, the REA indicates that the percent of children with asthma that might be expected to experience 5-minute SO_2 concentrations at or above the 200 ppb benchmark concentration, in an urban area that just meets the current standard, may be as high as 0.7%, on average across the three years, and 2.2% in a single-year period (Table 3-3). With regard to the 300 ppb and 400 ppb benchmarks, these percentages may be as high, respectively, as 0.3 and 0.1% on average across the three years and 0.8% and 0.3% in a single-year period (Table 3-3). With regard to the lung function risk, the REA indicates the percent of children that might be expected to experience at least a doubling of specific airway resistance, under conditions just meeting the current standard, may be as high as 1.3%, on average across the 3-year period, and 1.9% in a single year (Table 3-4).

In framing these same exposure estimates from the perspective of estimated protection indicated to be provided by the current standard, these results for the Fall River and Indianapolis study areas indicate that, in the single year with the highest concentrations across the 3-year period, nearly 98% to just over 99% of the population of children with asthma would not be expected to experience such a day with an exposure at or above the 200 ppb; between 99.7% and just over 99.9% would not be expected to experience such a day with exposure at or above the 400 ppb benchmark. These and the similar estimates for a doubling or more in sRaw are of a magnitude roughly consistent with the level of protection that was described in establishing the now-current standard in 2010 (as summarized in section 3.1.1.2.4 above).[58] As noted in section 3.2.2.1 above, the current REA additionally provides estimates for a 3-year simulation period, consistent with the form established for the now-current standard. Such estimates for the Indianapolis study area, on average across the 3-year period, indicate that 99.9% and 99.3% of the population of children with asthma would not be expected to experience a day with an exposure at or above 400 ppb and 200 ppb, respectively (Table 3-3 above).

3.2.2.3 Uncertainties

In this section, we consider the uncertainties associated with the quantitative estimates of exposure and risk, including those recognized by the characterization of uncertainty in the REA

[58] Although the 2009 REA did not include an air quality scenario representing the now-current standard, among the scenarios it did include were single-year air quality scenarios representing standard levels of 100 and 50 ppb. For the single-year scenario representing a standard level of 100 ppb in the study area with the highest population exposure and risk (St. Louis), the 2009 REA estimated 2.7% of children with asthma to experience at least one day with exposure at or above 200 ppb, while at elevated ventilation (2.1-2.9% to experience one or more SO_2-attributable increases in sRaw of at least 100%); this estimate was 0.09% for the scenario representing a standard level of 50 ppb (0.4-0.9% to experience one or more SO_2-attributable increases in sRaw of at least 100%) (2009 REA, Table 9-8 and Appendix B). While we recognize a number of differences between the 2009 REA and the quantitative modeling and analyses performed in the current REA, we note that the single year estimates for the Indianapolis and Fall River study areas in the current REA fall between the estimates for the two most similar air quality scenarios assessed in the last review.

(REA, section 6.2). The characterization in the REA is based on an approach intended to identify and compare the relative impact that important sources of uncertainty may have on the exposure and risk estimates. The approach used has been applied in REAs for past NAAQS reviews for ozone, nitrogen oxides, carbon monoxide (U.S. EPA, 2008; 2010; 2014) and SO_X (U.S. EPA, 2009). In the characterization of uncertainty for the current analysis, the REA utilized a qualitative uncertainty characterization approach adapted from the WHO approach for characterizing uncertainty in exposure assessment (WHO, 2008) accompanied by quantitative sensitivity analyses of key aspects of the assessment approach. This characterization and analyses are described in detail in chapter 6 of the REA. The approach used in the REA varies from that of WHO (2008) in that the REA approach placed a greater focus on evaluating the direction and the magnitude of the uncertainty (i.e., qualitatively rating how the source of uncertainty, in the presence of alternative information, may affect the estimated exposures and health risk results).

The characterization and analyses in the REA involve consideration of the various types of inputs and approaches that together result in the exposure and risk estimates for the three study areas. In so doing, the REA considers the limitations and uncertainties underlying these inputs and approaches and the extent of their influence on the resultant exposure/risk estimates. Consistent with the WHO (2008) guidance, the overall impact of the uncertainty is scaled by considering the extent or magnitude of the impact of the uncertainty as implied by the relationship between the source of the uncertainty and the exposure/risk output. The REA also evaluated the direction of influence, indicating how the source of uncertainty was judged to affect the exposure/risk estimates (e.g., likely to over- or under-estimation).

- **What are the key uncertainties associated with the exposure and risk estimates, including those of particular significance with regard to drawing conclusions as to the adequacy of the protection afforded by the current SO_2 standard?**

Based on the uncertainty characterization and associated analyses in the REA and consideration of associated policy implications, we recognize several areas of uncertainty as particularly important in our consideration of the exposure and risk estimates, as was also the case in the last review. Generally, these areas include estimation of the spatial distribution of SO_2 concentrations across each study area under air quality conditions just meeting the existing standard, including the fine-scale temporal pattern of 5-minute concentrations. Among other areas, we additionally recognize the uncertainty with regard to population groups and exposure concentrations for which the health effects evidence base is limited or lacking.

With regard to the spatial distribution of SO_2 concentrations, the REA recognizes some uncertainty associated with the model estimates of 1-hour concentrations and the approach used to adjust the air quality surface to concentrations just meeting the current standard. The REA

analyzed the potential quantitative impact of this uncertainty on the exposure and risk estimates by deriving estimates based on an alternative adjustment approach (described in section 6.2.2.1 of the REA). As discussed in section 3.2.2.2 above, we have considered estimates from both approaches in summarizing the REA estimates. Additionally, we recognize uncertainty in the estimation of concentrations associated with SO_2 emissions sources not explicitly modeled (e.g., REA, Table 6-3) and in the estimates of 5-minute concentrations in ambient air across the modeling receptors in each study area. While the ambient air monitoring dataset available to inform these estimates is much expanded in this review over the dataset available in the last review, we are still drawing on relationships occurring at one location and over one range of concentrations to estimate the fine-scale temporal pattern in concentrations at other locations. This is an important area of uncertainty in the REA results because the ambient air 5-minute concentrations are integral to the 5-minute estimates of exposure. While we recognize this as an important area of uncertainty, the approach used has taken into account the currently available information and is considered to provide a reasonable representation of fine-scale temporal variability in the three study areas.

We also recognize an important area of uncertainty that is particular to our interpretation of the lung function risk estimates. This area concerns estimates of lung function risk derived for exposure concentrations below those represented in the evidence base. The exposure-response function on which the primary risk estimates are based generates non-zero predictions of a percent of the at-risk population exposure expected to experience a day with at least a doubling of sRaw for all exposures experienced while breathing at an elevated rate. In considering these estimates, we recognize that the uncertainty in the response estimates increases substantially with decreasing exposure concentration below those supported by study data. In so doing, we note the appreciable contribution to the risk estimates of exposure concentrations below 200 ppb; the large majority of 5-minute exposure concentrations contributing to estimated occurrences of a doubling or more in sRaw were between 50 and 150 ppb, while none were below 40 ppb (REA, section 5.3).

Other areas of uncertainty concern the potential influence of SO_2 exposure history and co-exposure to other pollutants on the relationship between short-term SO_2 exposures and respiratory effects. With regard to the former, we note that the assessment focuses on the daily maximum 5-minute exposure during a period of elevated breathing rate, summarizing results in terms of the days on which the magnitude of such exposure exceeds a benchmark or contributes to increased sRaw. While the health effects evidence indicates the lack of a cumulative effect of multiple exposures over several hours or a day (ISA, section 5.2.1.2), and a reduced response to

repeated exercising exposure events over an hour (Kehrl et al., 1987),[59] information is somewhat limited with regard to the length of time after recovery from one exposure by which a repeat exposure would elicit a similar effect as that of the initial event. With regard to the potential influence of copollutants on SO_2-related health risk, we note the very limited information regarding the potential for the presence of other commonly occurring pollutants to affect individual response to SO_2, as summarized in section 3.2.1.4 above.

Another area of uncertainty, which remains from the last review and is important to our consideration of the REA results, concerns the extent to which the quantitative results represent the populations at greatest risk of effects associated with exposures to SO_2 in ambient air. As recognized in sections 3.2.1.1 and 3.2.1.4, the controlled human exposure study evidence base does not include studies of children younger than 12 years old, and is extremely limited with regard to studies of people with more severe asthma.[60] The limited evidence that informs our understanding of potential risk to these groups is uncertain but indicates the potential for them to experience greater effects or have lesser reserve to protect against such effects than other population groups with asthma under similar exposure circumstances, as summarized in section 3.2.1.4 above. Further we note the lack of information on the factors contributing to increased susceptibility to SO_2-induced bronchoconstriction among some people with asthma. Thus, there is uncertainty associated with our interpretation of the exposure/risk estimates with regard to the extent to which they represent the populations at greatest risk of SO_2-related respiratory effects that is important to consideration of the exposure and risk results with regard to the adequacy of protection provided by the current standard.

In summary, among the multiple uncertainties and limitations in data and tools that affect the quantitative estimates of exposure and risk and their interpretation in the context of considering the current standard, we recognize several here as particularly important, noting that they are generally similar to uncertainties recognized in the last review. These include uncertainty related to estimation of the spatial and temporal pattern of 5-minute concentrations in ambient air for the current standard scenario; the prevalence of different exposure circumstances represented by the three study areas; the lack of information from controlled human exposure studies for the lower, more prevalent, concentrations of SO_2; and, characterization of risk for particular subgroups of people with asthma that may be at greater risk.

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[59] This study exposed mild asthmatic males to 1.0 ppm SO_2 during three 10-minute exercise periods separated by 15-minute rest periods within the chamber. The sRaw response to SO_2 decreased linearly from the first to the second and the third SO_2 exposures with the response following the third exposure being statistically less than after the first (Kehrl et al., 1987).

[60] We additionally recognize that limitations in the activity pattern information for children younger than five years old precluded their inclusion in the populations of children simulated in the REA.

3.2.2.4 Potential Public Health Implications

In considering public health implications of the quantitative exposure and risk estimates that may inform the Administrator's judgments in this area, this section discusses the information pertaining to the following question.

- **To what extent are the estimates of exposures and risks to at-risk populations that remain under conditions just meeting the current SO_2 standard important from a public health perspective?**

Several factors are important to consideration of public health implications. These include the magnitude or severity of the effects associated with the exposures estimated in the REA, as well as their adversity at the individual and population scale. Other important considerations include the size of the population estimated to experience such effects or to experience exposures associated with such effects. These considerations are discussed below.

Based on the currently available evidence which is largely consistent with that available in the last review (as summarized in section 3.2.1 above), the quantitative exposure and risk analyses focus on the potential for lung function decrements in people with asthma exposed to SO_2 while breathing at an elevated rate. Additionally, we have again focused on estimates for two types of risk metrics, one involving comparison to benchmark concentrations and the second involving estimates of lung function risk with regard to moderate or greater increases in sRaw. In considering these estimates, we recognize that although the lung function decrements, which are related to bronchoconstriction, are expected to be transient, we additionally recognize that such decrements, while occurring, may contribute to a diminished reserve in lung function (ISA, p. 1-17, section 5.2.1.2). For population groups already at diminished reserve, such as those with more severe asthma, this may be particularly important. Thus, the discussion here reflects consideration of the health evidence, and exposure and risk estimates, as well as the consideration of potential public health implications in previous NAAQS decisions and ATS policy statements (as also discussed in section 3.2.1.5).

In light of the conclusion that among all people with asthma, children may be particularly at risk (summarized in section 3.2.1.2 above) and the REA findings of higher exposures and risks for children (in terms of percent of that population), we have focused the discussion here on children. We recognize that the REA estimates indicate that in some areas of the U.S. where SO_2 concentrations just meet the current standard, on average across the 3-year period simulated (consistent with the form of the current standard), less than 1%, 0.3% and 0.1% of the simulated population of children with asthma might be expected to experience a single day per year with a 5-minute exposure at or above 200 ppb, 300 ppb and 400 ppb, respectively, while breathing at an elevated rate. With regard to the lowest benchmark considered (100 ppb), the corresponding percentage is approximately 20 to 25%, with higher percentages in some individual years.

With regard to estimates of lung function decrements, the REA indicates that in some such areas, approximately 1% of children with asthma, on average across a 3-year period, might be expected to experience at least one day per year with a SO_2-related increase in sRaw of 100% or more; the estimate for two or more days is lower, at 0.4% (REA, Table 6-8). Additionally, under such conditions (just meeting the current standard), the estimated percent of children with asthma that might be expected to experience a single day per year with a SO_2-related increase in sRaw of 200% or more, on average across the 3-year period, is 0.2 to 0.3% (Table 3-4).

In considering the severity of responses associated with the REA estimates, we take note of the health effects evidence for the different benchmark concentrations and judgments made with regard to the severity of these effects in the last review. As in the last review, we recognize that the responses documented for exposures of 400 ppb are frequently accompanied by respiratory symptoms and thus are appropriately considered to be adverse respiratory effects consistent with past and recent ATS position statements. At 300 ppb, statistically significant increases in lung function decrements (specifically reduced FEV_1) have been documented in analyses of the subset of controlled human exposure study subjects with asthma that are responsive to SO_2 at concentrations below 600 or 1000 ppb (ISA, p. 153 and Table 5-21; Johns et al., 2010). With regard to the lower benchmark concentration of 200 ppb, we recognize that, while the responses documented in studies of exercising subjects with asthma are not consistently accompanied by respiratory symptoms, conclusions in past NAAQS reviews recognized that moderate decrements in lung function can be clinically significant in some individuals with asthma (75 FR 35526, June 22, 2010). Accordingly, the Administrator in the last review considered effects associated with exposures as low as 200 ppb to be adverse in light of CASAC advice,[61] ATS statements and conclusions in past NAAQS reviews (75 FR 35546, June 22, 2010). While noting the very limited or lack of such information for some population groups with asthma, including primary-school-age children and people with more severe asthma, we additionally recognize the uncertainty with regard to effects that might be associated with exposures as low as 100 ppb (as discussed in section 3.2.1.3 and 3.2.1.4 above).

The size of the at-risk population (people with asthma, particularly children) in the U.S. is substantial. As summarized in section 3.2.1.5, nearly eight percent of the total U.S. population (more than 24 million people) and 8.4% of U.S. children have asthma. The asthma prevalence in U.S. child populations of different races or ethnicities ranges from 7.4% to 13.4% (Table 3-2 above). This is well reflected in the REA study areas in which the asthma prevalence ranged from 8% to 8.7% of the total populations and 9.7% to 11.2% of the children, with the highest

[61] In the last review, the CASAC letter on the first draft SO_2 REA to the Administrator stated: "CASAC believes strongly that the weight of clinical and epidemiology evidence indicates there are detectable clinically relevant health effects in sensitive subpopulations down to a level at least as low as 0.2 ppm SO_2" (Henderson, 2008).

prevalence represented in the Fall River study area. In each study area, the prevalence varies among census tracts, with the highest tract in Fall River having a prevalence in boys of 21.5% and the highest tract in Indianapolis having a prevalence in girls of 19.4% (REA, Table 4-1).

In considering the public health implications of the REA estimates, we recognize that current SO_2 concentrations measured in ambient air in all three of the REA study areas are lower than those simulated in the air quality assessed. In so doing, we note the purpose for the study areas is to provide examples of exposure circumstances that may occur in areas that just meet the current standard, and not to estimate exposure and risk associated with conditions occurring in those specific locations today. However, concentrations in numerous areas across the U.S. contribute to air quality that is near or above the existing standard. For example, 15 core-based statistical areas[62] were identified with 2014-2016 design values above the existing standard level of 75 ppb, including areas with sizeable populations.[63] Accordingly, we recognize that, while concentrations in the specific areas simulated in the REA may be lower today than the three year period simulated in the assessment, the exposure and risk estimates for these areas are informative to consideration of exposures and risks in areas still existing across the U.S. that have source and population characteristics similar to the study areas assessed, and with ambient concentrations of SO_2 that just meet the current standard today or that will be reduced to do so at some period in the future. Thus, such air quality and exposure circumstances are of particular importance in considering whether the currently available information calls into question the adequacy of public health protection afforded by the current standard.

In considering the potential extent of similar areas is in the U.S. today, we recognize that the monitoring network information on SO_2 concentrations in populated areas across the U.S. provides evidence of the occurrence of such exposure circumstances of interest in multiple regions of the U.S. (as indicated by the 2014-2016 design values referenced above). There are, however, limitations with regard to the extent that it might be expected to capture all areas with the potential to exceed the standard and uncertainty related to the extent to which monitors in the SO_2 monitoring network are located in populated areas with air quality impacted by large sources of SO_2 emissions. In recognition of this limitation, we also examined the proximity of populations to sizeable SO_2 point sources using the most recently available emissions inventory

[62] Core-based statistical area (CBSA) is a geographic area defined by the U.S. Office of Management and Budget to consist of an urban area of at least 10,000 people in combination with its surrounding or adjacent counties (or equivalents) with which there are socioeconomic ties through commuting. Populations in the 15 CBSAs referred to here range from approximately 30,000 to more than a million (based on 2016 U.S. Census Bureau estimates).

[63] Table 5c. Monitoring Site Listing for Sulfur Dioxide 1-Hour NAAQS in the Excel file labeled So2_designvalues_20142016_final_07_19_16.xlsx downloaded from https://www.epa.gov/air-trends/air-quality-design-values on January 26, 2018.

information (2014). For example, this information indicates there to be many densely-populated areas in the U.S. in which there are facilities with sizeable SO_2 emissions (e.g., Appendix F).[64] Information is not currently available to estimate numbers of children with asthma in such areas, making it difficult to estimate the numbers of people potentially at risk. However, the available information indicates that there are more than 300,000 children living within 1 km of facilities emitting at least 1,000 tpy of SO_2 and more than a million within 5 km (Table 3-5). Simply considering the asthma prevalence at the national scale of approximately 8%, this information indicates on the order of 24,000 to more than 100,000 children with asthma living in areas with sources such as those assessed in the REA. It is important to clarify, however, that ambient air concentrations of SO_2 in the vast majority of the U.S. are well below the current standard, as indicated by Figure 2-7 above.[65] Thus, while the population counts in Table 3-5 may convey information regarding the size of populations living near sources, the concentrations in most areas are currently well below the conditions assessed in the REA.

Table 3-5. Population size near larger sources of SO_2 emissions.

Sources emitting at least 1,000 tpy (N = 527 facilities)					
	Population within:				
	1 km	**2 km**	**3 km**	**5 km**	**10 km**
All Ages	1,309,212	1,529,478	2,625,196	6,067,574	23,161,915
Younger Than 18 Years	300,966	341,817	603,261	1,440,466	5,436,439
Sources emitting at least 2,000 tpy (N = 372 facilities)					
	Population within:				
	1 km	**2 km**	**3 km**	**5 km**	**10 km**
All Ages	248,007	438,760	1,281,473	2,969,007	14,280,740
Younger Than 18 Years	61,823	103,169	308,289	713,235	3,401,327
Sources: SO_2 Facilities – NEI 2014 v2, Population – U.S. Census 2010 tpy = tons per year					

[64] Although source characteristics and meteorological conditions - in addition to magnitude of emissions - influence the distribution of concentrations in ambient air, Appendix F focuses on the distribution of large sources, rather than ambient concentrations, due to limitations in the available information with regard to spatial (and temporal) patterns of SO_2 concentrations in the proximity of such sources in urban areas (ISA, section 2.5.2.2).

[65] As discussed in the ISA, "the point source nature of these emissions contributes to the relatively high spatial variability of SO_2 concentrations (both ambient and exposure)" and "[a]nother contributing factor to spatial variability is the dispersion and oxidation of SO_2 in the atmosphere" which results in "decreasing ambient SO_2 concentrations with increasing distance from sources" (ISA, section 3.2.3). The ISA additionally notes that "SO_2 from point sources travels as a plume, which may or may not impact portions of an urban area depending on meteorological conditions" (ISA, section 3.2.3).

Although exposure and risk estimates were not available in the last review for air quality conditions just meeting the now-current standard, the findings and considerations summarized here are generally similar to those considered in the last review, and indicate a level of protection consistent with that described in the 2010 decision. The exposure and risk estimates for the three study areas assessed in the REA for this review reflect differences in exposure circumstances among those areas and illustrate the exposures and risk that might be expected to occur in other areas with such circumstances under air quality conditions that just meet the current standard. Thus, the REA estimates indicate the magnitude of exposure and risk that might be expected in some areas and illustrate the importance to consideration of the public health protection afforded by the current standard of those areas where locations of relatively higher SO_2 concentrations in ambient air across the area coincide with the locations of higher population density.

In summary, the considerations raised here are important to conclusions regarding the public health significance of the REA results. We recognize that such conclusions also depend in part on public health policy judgments that will weigh in the Administrator's decision in this review with regard to the adequacy of protection afforded by the current standard. Such judgments that are common to NAAQS decisions include those related to public health implications of effects of differing severity (75 FR 355260 and 35536, June 22, 2010; 76 FR 54308, August 31, 2011; 80 FR 65292, October 26, 2015). Such judgments also include those concerning the public health significance of effects at exposures for which evidence is limited or lacking, such as effects at the lower benchmark concentrations considered and lung function risk estimates associated with exposure concentrations lower than those tested in the controlled exposure studies.

3.2.3 CASAC Advice

In our consideration of the adequacy of the current standard, in addition to the evidence- and risk/exposure-based information discussed above, we have also considered the advice and recommendations of the CASAC, based on their review of the ISA, the REA Planning Document, the draft REA, and the earlier draft of this document, as well as comments from the public on the earlier draft of this document.

A limited number of public comments have been received in this review to date, including comments focused on the draft IRP, the REA Planning Document, the draft REA or the draft PA. Of the five commenters that addressed adequacy of the current primary SO_2 standard, two are in agreement with staff conclusions in the draft PA. One expressed the view

that the standard should be revised to be more restrictive and two others recommended consideration be given to a less restrictive standard.[66]

In their comments on the draft PA, the CASAC SO_X Panel concurred with staff's overall preliminary conclusions that it is appropriate to consider retaining the primary current standard without revision, stating that "the current scientific literature does not support revision of the primary NAAQS for SO_2" (Cox and Diez Roux, 2018, p. 1 of letter). The CASAC further noted that "the new scientific information in the current review does not lead to different conclusions from the previous review" (Cox and Diez Roux, 2018, p. 3 of letter). Thus, the CASAC stated that "based on review of the current state of the science, the CASAC supports retaining the current standard, and specifically recommends that all four elements (indicator, averaging time, form, and level) should remain the same" (Cox and Diez Roux, 2018, p. 3 of letter). The CASAC further stated the following (Cox and Diez Roux, 2018, p. 3 of the letter):

> *With regard to indicator, SO_2 is the most abundant of the gaseous SO_X species. Because, as the PA states, "the available scientific information regarding health effects was overwhelmingly indexed by SO_2", it is the most appropriate indicator. The CASAC affirms that the one-hour averaging time will protect against high 5-minute exposures and reduce the number of instances where the 5-minute concentration poses risks to susceptible individuals. The CASAC concurs that the 99th percentile form is preferable to a 98th percentile form to limit the upper end of the distribution of 5-minute concentrations. Furthermore, the CASAC concurs that a three-year averaging time for the form is appropriate.*
>
> *The choice of level is driven by scientific evidence from the controlled human exposure studies used in the previous NAAQS review, which show a causal effect of SO_2 exposure on asthma exacerbations. Specifically, controlled five-minute average exposures as low as 200 ppb lead to adverse health effects. Although there is no definitive experimental evidence below 200 ppb, the monotonic dose-response suggests that susceptible individuals could be affected below 200 ppb. Furthermore, short-term epidemiology studies provide supporting evidence even though these studies cannot rule out the effects of co-exposures and are limited by the available monitoring sites, which do not adequately capture population exposures to SO_2. Thus, the CASAC concludes that the 75 ppb average level, based on the three-year average of 99th percentile daily maximum one-hour concentrations, is protective and that levels above 75 ppb do not provide the same level of protection.*

The comments from the CASAC also took note of the uncertainties that remain in this review, stating that the PA "clearly identifies most of the key uncertainties," while additionally

[66] All written comments submitted to the Agency will be available in the docket for this rulemaking, as will be CASAC letters reflecting its review of the earlier draft of this document, of the REA Planning Document and draft REA and of drafts of the ISA.

recognizing several additional uncertainties, including uncertainties in quantifying risk to some subpopulations of people with asthma for which there may be potential for increased SO_2 sensitivity but for which the scientific evidence is limited or lacking. In so doing, it stated that the "CASAC notes that there are many susceptible subpopulations that have not been studied and which could plausibly be more affected by SO_2 exposures than adults with mild to moderate asthma," providing as examples people with severe asthma and obese children with asthma, and citing physiologic and clinical understanding (Cox and Diez Roux, 2018b, p. 3 of letter). The CASAC stated that "[i]t is plausible that the current 75 ppb level does not provide an adequate margin of safety in these groups[, h]owever because there is considerable uncertainty in quantifying the sizes of these higher risk subpopulations and the effect of SO_2 on them, the CASAC does not recommend reconsideration of the level at this time" (Cox and Diez Roux, 2018b, p. 3 of letter).

The CASAC additionally recognized a number of areas for future research and data gathering that would inform the next primary SO_2 NAAQS review (Cox and Diez Roux, 2018). These are reflected in section 3.3 below.

3.2.4 Staff Conclusions on the Current Standard

This section describes staff conclusions regarding the adequacy of the current primary SO_2 standard. These conclusions are based on considerations described in the sections above, and in the discussion below regarding the currently available scientific evidence (as summarized in the ISA, and the ISA and AQCDs from prior reviews), and the risk and exposure information drawn from the REA. Further, these staff conclusions have taken into account advice from the CASAC and public comment on the draft PA and the associated preliminary staff conclusions.

Taking into consideration the discussions responding to specific questions above in this and the prior chapter, this section addresses the following overarching policy question.

- **Does the currently available scientific evidence- and exposure/risk-based information, as reflected in the ISA and REA, support or call into question the adequacy of the protection afforded by the current SO_2 standard?**

In considering this question, we recognize as an initial matter that, as is the case in NAAQS reviews in general, the extent to which the current primary SO_2 standard is judged to be adequate will depend on a variety of factors, including science policy judgments and public health policy judgments. These factors include public health policy judgments concerning the appropriate benchmark concentrations on which to place weight, as well as judgments on the public health significance of the effects that have been observed at the exposures evaluated in the health effects evidence. The factors relevant to judging the adequacy of the standards also include the interpretation of, and decisions as to the weight to place on, different aspects of the

results of the exposure assessment for the three areas studied and the associated uncertainties. Thus, we recognize that the Administrator's conclusions regarding the adequacy of the current standard will depend in part on public health policy judgments, science policy judgments regarding aspects of the evidence and exposure/risk estimates, and judgments about the level of public health protection with an adequate margin of safety that is requisite under the Clean Air Act.

Our response to the overarching question above takes into consideration the discussions that address the specific policy-relevant questions in prior sections of this document (see sections 3.2.1-3.2.2) and the approach described in section 3.1 that builds on the approach from the last review. We focus first on consideration of the evidence, including that newly available in this review, and the extent to which it alters key conclusions supporting the current standard. We then turn to consideration of the quantitative exposure and risk estimates drawn from the REA, including associated limitations and uncertainties, and the extent to which they indicate differing conclusions regarding the magnitude of risk, as well as level of protection from adverse effects, associated with the current standard. We additionally consider the key aspects of the evidence and exposure/risk estimates emphasized in establishing the now-current standard, and the associated public health policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that are integral to decisions on the adequacy of the current primary SO_2 standard.

As an initial matter, we recognize the support in the current evidence for SO_2 as the indicator for SO_X. As recognized in section 3.2.1.1 above, "[o]f the sulfur oxides, SO_2 is the most abundant in the atmosphere, the most important in atmospheric chemistry, and the one most clearly linked to human health effects" (ISA, p. 2-1). Controlled human exposure studies and animal toxicological studies provided specific evidence for health effects following exposures to SO_2, and epidemiologic studies typically analyzed associations of health outcomes with concentrations of SO_2. The advice received from the CASAC in this review concurs with the use of SO_2 as the indicator for the standard. We additionally note that measures taken to meet the standard in terms of SO_2 that may reduce population exposures to SO_2 are also likely to reduce exposures to other sulfur oxides. Thus, we conclude that the current evidence, including that newly available in this review, continues to support a focus on SO_2 for the primary NAAQS for SO_X.

In considering the currently available evidence, staff gives great weight to the long-standing body of health effects evidence for SO_2, augmented in some aspects since the last review, that provides the foundation of our understanding of the health effects of SO_2 in ambient air. In so doing, we give particular attention to the evidence from controlled human exposure studies that demonstrates that very short exposures to less than 1000 ppb SO_2, while breathing at

an elevated rate, induces bronchoconstriction in some people with asthma; and, supports the identification of people with asthma as the population at risk from short-term peak concentrations in ambient air (ISA; 2008 ISA; 1994 AQCD supplement).

It is such effects associated with short-term exposures against which the current standard, with its averaging time of one hour, was established to protect. As summarized in section 3.2.1 above and addressed in detail in the ISA, the evidence base in this review does not include new evidence of effects associated with other exposure durations. Thus, in considering the information available at this time, we continue to focus on short-term exposures as those of importance in this review. Air quality analyses summarized in chapter 2 above demonstrate the relationship between 1-hour and 5-minute SO_2 concentrations in ambient air as did those available at the time the standard was set. Further, the chapter 2 analyses indicate the appreciably lower prevalence of elevated 5-minute concentrations in areas meeting the current standard compared to those that do not (e.g., Figure 2-8 above). As discussed below, protection is also provided against exposures associated with such ambient air concentrations.

Further, while the evidence base has been augmented since the time of the last review, we note that the newly available evidence does not lead to different conclusions regarding the primary health effects of SO_2 in ambient air or regarding exposure concentrations associated with those effects; nor does it identify different populations at risk of SO_2-related effects. In this way, the health effects evidence available in this review is consistent with evidence available in the last review when the current standard was established. This strong evidence base continues to demonstrate a causal relationship between short-term SO_2 exposures and respiratory effects, particularly in people with asthma. This conclusion is primarily based on evidence from controlled human exposure studies available at the time of the last review that reported lung function decrements and respiratory symptoms in people with asthma exposed to SO_2 for 5 to 10 minutes while breathing at an elevated rate. Support is also provided by the epidemiological evidence that is coherent with the controlled exposure studies. The epidemiological evidence, including that recently available, includes studies reporting positive associations for asthma-related hospital admissions and emergency department visits (of individuals of all ages, including adults and children) with short-term SO_2 exposures (ISA, section 5.2.1.2).[67]

The health effects evidence newly available in this review also does not extend our understanding of the range of 5-minute exposure concentrations that elicit effects in people with asthma exposed while breathing at an elevated rate beyond what was understood in the last review. As in the last review, 200 ppb remains the lowest concentration tested in exposure

[67] While uncertainties remain related to the potential for confounding by PM or other co-pollutants and the representation of fine-scale temporal variation in personal exposures, the findings of the epidemiological studies continue to provide supporting evidence for the conclusion on the causal relationship (ISA, section 5.2.1.2).

studies where study subjects are freely breathing in exposure chambers. At that exposure concentration, approximately eight to nine percent of study subjects with asthma, breathing at an elevated rate, experienced moderate or greater lung function decrements following 5- to 10-minute controlled exposures. The limited information available for exposure concentrations below 200 ppb, while not amenable to direct quantitative comparisons with information from studies at higher concentrations, generally indicates somewhat lesser response. In considering what may be indicated by the epidemiological evidence with regard to exposure concentrations eliciting effects, we recognize complications associated with interpretation of epidemiologic studies of SO_2 in ambient air that relate to whether measurements at the study monitors adequately represent the spatiotemporal variability in ambient SO_2 concentrations in the study areas and associated population exposures (ISA, section 5.2.1.9).

In this review, as in the last review, we recognize some uncertainty with regard to exposure levels eliciting effects in some population groups not included in the available controlled human exposure studies, such as individuals with severe asthma, as well as uncertainty in the extent of effects at exposure levels below those studied. Collectively, these aspects of the evidence and associated uncertainties contribute to a recognition that for SO_2, as for other pollutants, the available evidence base in a NAAQS review generally reflects a continuum, consisting of ambient levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain.

As at the time of the last review, the exposure and risk estimates developed from modeling exposures to SO_2 emitted into ambient air are critically important to consideration of the potential for exposures and risks of concern under air quality conditions of interest, and consequently are critically important to judgments on the adequacy of public health protection provided by the current standard. In considering the public health implications of estimated occurrences of exposures of different magnitudes, we take note of guidance from the ATS, the CASAC's written advice and recommendations in past reviews, and judgments made by the EPA in considering similar effects in previous NAAQS reviews (75 FR 35526 and 35536, June 22, 2010). As recognized in section 3.2.1.5, an additional publication by the ATS that further addresses judgments on what constitutes an adverse health effect of air pollution is newly available in this review (Thurston et al., 2017). The more recent statement expands upon the 2000 statement, that was considered in the last SO_2 NAAQS review, and recognizes additional considerations with regard to such judgments that remain consistent with the EPA's judgments in the 2010 review. In that review, the Administrator judged that the effects reported in exercising people with asthma following 5- to 10-minute SO_2 exposures at or above 200 ppb, and especially at or above 400 ppb (often accompanied by respiratory symptoms and for which the evidence is

stronger), can result in adverse health effects (75 FR 35536, June 22, 2010). In so doing, she also recognized that effects reported for exposures below 400 ppb are less severe than those at and above 400 ppb (75 FR 35547, June 22, 2010).

In considering the REA analyses available in this review, we are aware of a number of ways in which these analyses differ from and improve upon those available in the last review. In addition to the expansion in the number and type of study areas assessed, we note the number of improvements to input data and modeling approaches, including the availability of continuous 5-minute air monitoring data at monitors within the three study areas. The current REA extends the time period of simulation by including a 3-year simulation period consistent with the form established for the now-current standard. Further, the years simulated reflect more recent emissions and circumstances subsequent to the 2010 decision. In considering the REA results, we also take note of the array of emissions and exposure circumstances represented by the three study areas. As summarized in section 3.2.2 above, the areas fall into three different geographic regions of the U.S. They range in total population size from approximately 180,000 to approximately one half million, and vary in population demographic characteristics. Additionally, the types of large sources of SO_2 emissions represented in the three study areas vary with regard to emissions characteristics and include EGUs, petroleum refineries, glass-making facilities, secondary lead smelters (from battery recycling), and chemical manufacturing.

As at the time of the last review, people with asthma are the population at risk of respiratory effects related to SO_2 in ambient air. Children with asthma may be particularly at risk (section 3.2.1.2 above). While there are more adults in the U.S. with asthma than children with asthma, the REA results in terms of percent of the simulated at-risk populations, indicate higher exposures and risks for children with asthma as compared to adults. This finding relates to children's greater frequency and duration of outdoor activity (section 3.2.2.2 above). In light of these conclusions and findings, we have focused our consideration of the REA results here on children.

As can be seen by the variation in exposure estimates, the three study areas in the REA represent an array of exposure circumstances, including those contributing to relatively higher and relatively lower exposures and associated risk. As recognized in the REA and in section 3.2.2.2 above, the analyses in the REA are not intended to provide a comprehensive national assessment. Rather, the analyses for this array of study areas and air quality patterns are intended to indicate the magnitude of exposures and risks that may be expected in areas of the U.S. that just meet the current standard but that may differ in ways affecting population exposures of interest. In that way, the REA is intended to be informative to the EPA's consideration of potential exposures and risks associated with the current standard and the Administrator's decision on the adequacy of protection provided by the current standard. As discussed in sections

3.2.2.2 and 3.2.2.4 above, consideration of exposures occurring in those areas where locations of relatively higher SO_2 concentrations in ambient air across an area that just meets the current standard coincide with the locations of higher population density are particularly important to consideration of the public health protection afforded by the current standard, particularly to the overarching question concerning the availability of information that calls into question the standard's adequacy.

With regard to the REA representation of air quality conditions associated with just meeting the current standard, while we note reduced uncertainty in a few aspects of the approach for developing this air quality scenario, we recognize the uncertainty associated with the application of adjustments to the highest model receptor in the study area. As summarized in sections 3.2.2.2 and 3.2.2.3 above, sensitivity analyses described in section 6.2.2 of the REA indicate the quantitative impact potentially associated with this area of uncertainty, which appears to be generally small for the Indianapolis study area and somewhat higher for Fall River. Given the importance of this aspect of the REA to consideration of the level of protection provided by the current standard, we have considered the results for each study area in terms of a range bounded on the low end by the results for the main analysis and on the upper end by those based on the alternative adjustment approach used in the sensitivity analysis.

In this context for the air quality scenario for the current standard, with its 1-hour averaging time and 99th percentile form, we note that across all three study areas, which provide an array of SO_2 emissions and exposure situations, the percent of children with asthma estimated to experience at least one day with as much as a doubling in sRaw (attributable to SO_2), on average across the 3-year period, ranges from <0.1 % to 1.3%; the highest study area estimate is just under 2% for the highest single year (Table 3-4). Accordingly, results for the three case study areas indicate 98.7% or more of at-risk populations to be protected from a SO_2-related doubling in sRaw, as an average across the 3-year period, and approximately 98% or more protected from as much as a single occurrence in a single year. Greater protection (e.g., 99% or more) is indicated for multiple occurrences and more severe sRaw increases.

With regard to exposures compared to benchmark concentrations, less than 1% of children with asthma are estimated to experience, while breathing at an elevated rate, a daily maximum 5-minute exposure per year at or above 200 ppb, on average across the 3-year period, with a maximum for the study area with the highest estimates just over 2% in the highest single year (Table 3-3). Further, the percentage for at least one day with such an exposure above 400 ppb is 0.1% or less, as an average across the 3-year period (and 0.3% or less in each of the three years simulated across the three study areas). No simulated at-risk individuals were estimated to experience multiple such days. Thus, in light of current ATS guidance and CASAC advice, as well as EPA conclusions in prior NAAQS reviews, the REA exposure and risk estimates for the

current review indicate that the current standard is likely to provide a high level of protection from SO_2-related health effects to at-risk populations of children and adults with asthma.

As recognized above, the protection afforded by the current standard stems from its elements collectively, including the level of 75 ppb, the averaging time of one hour and the form of the 99th percentile of daily maximum concentrations averaged across three years. The current evidence as considered in the ISA, the current air quality information as analyzed in the REA and earlier in this document, and the current risk and exposure information presented in the REA and summarized here provide continued support to these elements, as well as to the current indicator, as discussed earlier in this section.

In summarizing the information discussed thus far, we reflect on the key aspects of the 2010 decision that established the current standard. As an initial matter, effects associated with 5- to 10-minute exposures as low as 200 ppb of people with asthma while breathing at an elevated rate were considered to be adverse; this judgment was based on consideration of the CASAC's advice and EPA decisions in prior NAAQS reviews, as well as ATS guidance (75 FR 35546, June 22, 2010). We note that the newly available information in this review includes an additional statement from ATS on adversity which is generally consistent with the earlier statement (available at the time of the 2010 decision).

While recognizing the differences between the current and past analyses, including the lack of an air quality scenario specific to the now-current standard in the last review, as well as uncertainties associated with such analyses, we note a rough consistency of the associated estimates when considering the array of study areas in both reviews. Overall, the newly available quantitative analyses appear to comport with the conclusions reached in the last review regarding control expected to be exerted by the now-current 1-hour standard on 5-minute exposures of concern. With regard to the results for the REA in the last review (which were for a single-year simulation), the 2010 decision recognized those results for the area with the highest estimates and largest population (St. Louis) to indicate that a one-hour standard with a level between the two levels assessed (50 and 100 ppb) might be expected to protect more than 97% of children with asthma (and somewhat less than 100%) from experiencing exposures at or above a 200 ppb benchmark concentration, and more than 99% of that population group from experiencing exposures at or above a 400 ppb benchmark. Single-year results in the current REA for the two study areas with the highest estimates (including the area with the most sizeable population, Indianapolis) indicate protection of approximately 98 to 99% of the populations of children with asthma from experiencing exposures at or above a 200 ppb benchmark concentration and 99.7% or more of the study area at-risk populations from exposures at or above 400 ppb. Additionally, the 2010 decision also took note of the magnitude of the SO_2 concentrations in ambient air in U.S. epidemiological studies of associations between ambient air concentrations and emergency

department visits and hospital admissions, for which the effect estimate remained positive and statistically significant in copollutant models with PM. In considering these studies, the Administrator judged that the level chosen for the new 1-hour standard provided an adequate margin of safety. No additional such studies are available in the current review (as noted in section 3.2.1.3 above). Thus, in considering the main aspects of the decision in the last review, we find the currently available information to be consistent with that on which the decision establishing the current standard was based.

Based on all of the above, and taking into consideration related information, limitations and uncertainties, such as those recognized above, we draw conclusions regarding the extent to which the newly available information in this review supports or calls into question the adequacy of protection afforded by the current standard. In considering the conclusions that may be supported by the exposure and risk estimates, we take note of the more than 24 million people with asthma in the U.S., including more than 6 million children, with potentially 100,000 living within 5 km of large sources of SO_2 emissions. We additionally note the uncertainties or limitations of the current evidence base with regard to the exposure levels at which effects may be elicited in some population groups (e.g., children with asthma and individuals with severe asthma), as well as the severity of the effects. In so doing, we recognize that the controlled human exposure studies, on which the depth of our understanding of SO_2-related health effects is based, provide little or no information with regard to responses in people with more severe asthma or in children younger than 12 years. Additionally, some aspects of our understanding continue to be limited; among these aspects are the potential for effects in some people with asthma exposed to concentrations below 200 ppb, as well as the potential for other air pollutants to affect responses to SO_2. In light of this we note the REA results for the lowest benchmark that indicate that in some areas of the U.S. with air quality conditions that just meet the current standard, approximately 20 to 25% of children with asthma may experience one or more exposures, on average across a 3-year period, to concentrations at or above 100 ppb while breathing at an elevated rate. Thus, the evidence and exposure/risk information related to the lowest exposures studied lead us to conclude that the combined consideration of the body of evidence and the quantitative exposure estimates continue to provide support for a standard as protective as the current one.

We additionally recognize that conclusions regarding the adequacy of the current standard depend in part on public health policy judgments identified above and judgments about the level of public health protection that is appropriate, allowing for an adequate margin of safety. In so doing, we take note of the long-standing health effects evidence that documents the effects of SO_2 exposures as short as a few minutes on people with asthma that are exposed while breathing at elevated rates and recognize that such effects have been documented in the lowest

concentration studied in exposure chambers with appropriate clean-air controls (200 ppb). In so doing, we recognize the limitations, and associated uncertainty, in the evidence available for lower exposure concentrations (e.g., 100 ppb), as was the case in the last review, and we note the lower responses reported. Thus, in focusing on the potential for 5-minute exposures at and above 200 ppb, and recognizing that it has been previously recognized that exposures to such concentrations can result in adverse health effects in people with asthma (June 22, 2010; 75 FR 35547), we take note of the REA results that indicate the current standard may be expected to protect approximately 98% and nearly 99% of populations of children with asthma from experiencing any days with such exposures, in a single- and 3-year period, respectively. We additionally note the REA results that indicate protection of at least 99.7% and 99.9% of children with asthma from experiencing any days with a 5-minute exposure of 400 ppb or higher in a single and 3-year period, respectively. In light of ATS guidance, CASAC advice and EPA conclusions in past NAAQS reviews, these results indicate a high level of protection of at-risk populations from SO_2-related health effects that we note is consistent with the level of protection specified when the standard was set. Thus, we reach the conclusion that the currently available evidence and quantitative information, including the associated uncertainties, do not call into question the adequacy of protection provided by the current standard, and thus support consideration of retaining the current standard, without revision.

In summary, the newly available health effects evidence, critically assessed in the ISA as part of the full body of evidence, reaffirms conclusions on the respiratory effects recognized for SO_2 in the last review. Further, we observe the general consistency of the current evidence with the evidence that was available in the last review with regard to key aspects on which the current standard is based. We additionally note the quantitative exposure and risk estimates for conditions just meeting the current standard that indicate a similar level of protection, for at-risk populations from respiratory effects considered to be adverse, as that described in the last review for the now-current standard. We also recognize, as in the last review, the limitations and uncertainties associated with the available information. Collectively, these considerations (including those discussed above) provide the basis for the staff conclusion that consideration should be given to retaining the current standard of 75 ppb SO_2, as the 99^{th} percentile of daily maximum 1-hour concentrations averaged across three years, without revision. Accordingly, and in light of this conclusion that it is appropriate to consider the current standard to be adequate, we have not identified any potential alternative standards for consideration in this review.

3.3 KEY UNCERTAINTIES AND AREAS FOR FUTURE RESEARCH AND DATA COLLECTION

In this section, we highlight key uncertainties associated with reviewing and establishing the primary NAAQS for sulfur oxides. Such key uncertainties and areas for future research, model development, and data gathering are outlined below. In some cases, research in these areas can go beyond aiding standard setting to aiding in the development of more efficient and effective control strategies. We note, however, that a full set of research recommendations to meet standards implementation and strategy development needs is beyond the scope of this discussion. Rather, listed below are key uncertainties, research questions and data gaps that have been thus far highlighted in this review of the primary standard.

- A critical aspect of our consideration of the evidence and the quantitative dose estimates is our understanding of SO_2 effects below the lowest concentrations studied in controlled human exposure studies. Additional information in several areas would reduce uncertainty in our interpretation of the available information for purposes of risk characterization and, accordingly, reduce uncertainty in characterization of SO_2-related health effects.
  - A key area of uncertainty relates to whether and to what extent some population groups, including young children or people with severe asthma, are more responsive to peak SO_2 exposures (or responsive to lower concentrations), while breathing at elevated rates, than the groups that have been studied.
  - Additional information that might improve our understanding of the effects (severity and occurrence) and the shape of the exposure-response relationship expected at lower 5-minute exposure concentrations (i.e., below 200 ppb) would help to reduce uncertainty in the estimates of lung function effects and, accordingly, in characterizing SO_2-related health effects.
  - A better understanding of the demographic characteristics of people with asthma would facilitate greater detail in our characterization of SO_2 exposure and risk for at-risk populations with asthma. For example, the CASAC has identified people with asthma who are obese and/or African American, as well as young children and those with severe asthma as population groups for which such information is needed.
  - Little information is available on the factors contributing to the susceptibility to lower concentrations of SO_2 of a subgroup of people with asthma, termed "responders" in the ISA (ISA, section 5.2.1.2, Table 5-21; Johns and Linn, 2011). New and innovative studies focused on characterizing this subgroup would contribute to improved characterization of SO_2-related risk.
  - There is also only very limited evidence regarding the potential influence of history of exposure and potential for enhanced effects associated with co-occurring exposure to other air pollutants, such as particulate matter, including particulate sulfur compounds (as recognized in section 3.2.1.4 above). Further research is needed in this area to better inform our characterization of health risk related to SO_2.

- Characterization of the fine-scale spatial and temporal gradients of ambient air SO_2 concentrations in residential areas, as well as near sources of SO_2 emissions in areas with air quality that just meets the current standard, is a key element in our assessment of exposure and risk. Additional information in this area is needed to address current limitations that contribute to uncertainty in characterization of ambient air SO_2 levels in the risk assessment and the resulting exposure and risk estimates.
    - Ambient air monitoring data that provides more detailed characterization of the fine-scale spatial and temporal variation in ambient air SO_2 concentrations in different environments and related to different sources would help reduce this uncertainty and might support further evaluation of air quality model performance in describing fine-scale spatial variation.
    - Additional fine-scale temporal monitoring data (e.g., reporting of all 12 5-minute concentrations for each hour at all ambient air monitors) would help to reduce uncertainty in our estimation of fine-scale temporal variation.
- Uncertainties with regard to other aspects of the health effects evidence include that regarding what may be indicated with regard to exposure concentrations eliciting effects by the epidemiologic studies that show an association between short-term SO_2 exposures and asthma-related hospital admission and emergency department visits. Uncertainty remains regarding the extent of copollutant confounding in these studies, particularly by PM. Additionally, there is uncertainty related to the representation of exposure through fixed site monitors and capturing peak SO_2 concentrations that limits the informativeness of the ambient air concentrations analyzed in the studies to standard reviews.
- National surveys provide information that supports national and regional estimates of asthma prevalence. Additional clarity in this survey information regarding asthma prevalence in additional population subgroups, such as those with obesity, as well as clarity with regard to the extent of the potential for underestimation related to people with undiagnosed asthma, would address some uncertainties noted in this review.
- While the CHAD is much expanded over the last review, limited information and associated uncertainty remain in several aspects of the available human activity data. Additional information would reduce uncertainty in these aspects of our exposure and risk estimates.
    - Collection and analysis of multiday activity patterns that consider the attributes most influential to determining long-term activity patterns, as well as related research, would improve our ability to better evaluate and improve on existing approaches used to generate longitudinal activity profiles (as discussed in the REA, section 4.3.4).
    - Activity data for some population subgroups, such as people with severe asthma and very young children with asthma, as well as people with asthma of different ethnic backgrounds, including African Americans, and also people with asthma who are obese, would address limitations in the information needed to address questions related to the potential for activity patterns and, accordingly, exposures to differ for such groups.

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APPENDIX A

PREPARATION OF DATA FILES FOR GENERATION OF FIGURES IN CHAPTER 2

The raw data came from pre-generated AQS extract files. Files are located at https://aqs.epa.gov/aqsweb/airdata/download_files.html. Documentation of files is located at http://aqsdr1.epa.gov/aqsweb/aqstmp/airdata/FileFormats.html. Hourly Data Files were used. A separate Hourly Data File for each parameter and year combination was run. The type of SO_2 data is determined by the parameter code and duration code and is coded as follows:

- 1-hour values data - parameter code = 42401 and duration code = 1
- 5-minute data (12 observations per hour) - parameter code = 42401 and duration code = H
- 5-minute data (hourly max) – parameter code = 42406 and duration code = 1

For the 1-hour data at a Site/POC to be used, it must have met the following completeness criteria:

- 75% or more of the hourly observations in a day (18 or more) must be present.
- 75% or more of the days in a quarter must be present and complete:
- 1st Quarter – 68 observations or 69 observations in leap year
  - 2nd Quarter – 69 observations
  - 3rd Quarter – 69 observations
  - 4th Quarter – 69 observations
- 4 quarters for each of at least 3 of the 5 years (2011-2016) must be present and complete. For this analytical purpose, the three years do not have to be consecutive. This dataset was prepared in February 2018.

After completeness criteria were applied, the following data screens were also performed to account for some outliers in the 5-minute data:

- Only 5 minute data with a corresponding hourly value in AQS (parameter 42401 and duration code 1) were kept.
- Only 5 minute values with an hourly mean value under 120% of the hourly value in AQS (parameter 42401 and duration code 1) were kept.
- Only hours where a 5-minute max hourly value (AQS parameter 42406 and duration code 1) was reported and fell between 1 and 12 times the AQS hourly value (parameter 42401 and duration code 1) were kept.

APPENDIX B

ADDITIONAL INFORMATION ON DATASETS PRESENTED IN FIGURE 2-8

Table B-1. Summary statistics (in ppb) for distributions of daily maximum 5-minute SO_2 concentrations on days with differing daily maximum 1-hour SO_2 concentrations for 2014-2016.

Bin	Daily Maximum 1-hour Concentration (ppb)			
	<=25	>25-50	>50-75	>75
N	339471	4732	1338	1272
25th percentile	0.8	47.2	95.8	170.1
Median	1.2	62.8	122.6	218.0
Mean	4.4	73.7	137.4	259.5
75th percentile	4.2	88.0	164.2	293.6
95th percentile	19.0	150.0	254.5	512.4
99th percentile	40.5	213.2	352.4	829.6

When the three data sets for sites with DVs at or below 75 ppb are combined, the 99th percentile is 53.3 ppb and the 99.9th percentile is 131 ppb.

Table B-2. Summary statistics (in ppb) for distributions of daily maximum 5-minute SO_2 concentrations at sites with differing design values for 2014-2016.

Bin	Design Value (ppb)			
	<=25	>25-50	>50-75	>75
N	259617	48951	19634	18611
25th percentile	0.6	1.5	2.0	2.0
Median	1.5	4.0	6.0	6.0
Mean	3.1	9.8	18.5	38.3
75th percentile	3.1	11.3	23.0	35.7
95th percentile	11.0	36.3	75.0	192.0
99th percentile	26.0	72	130.3	359.3

Figure B-1. Monitoring data for sites meeting the current standard: Frequency of daily maximum 5-minute values on days with differing daily maximum 1-hour concentrations (2014-2016).

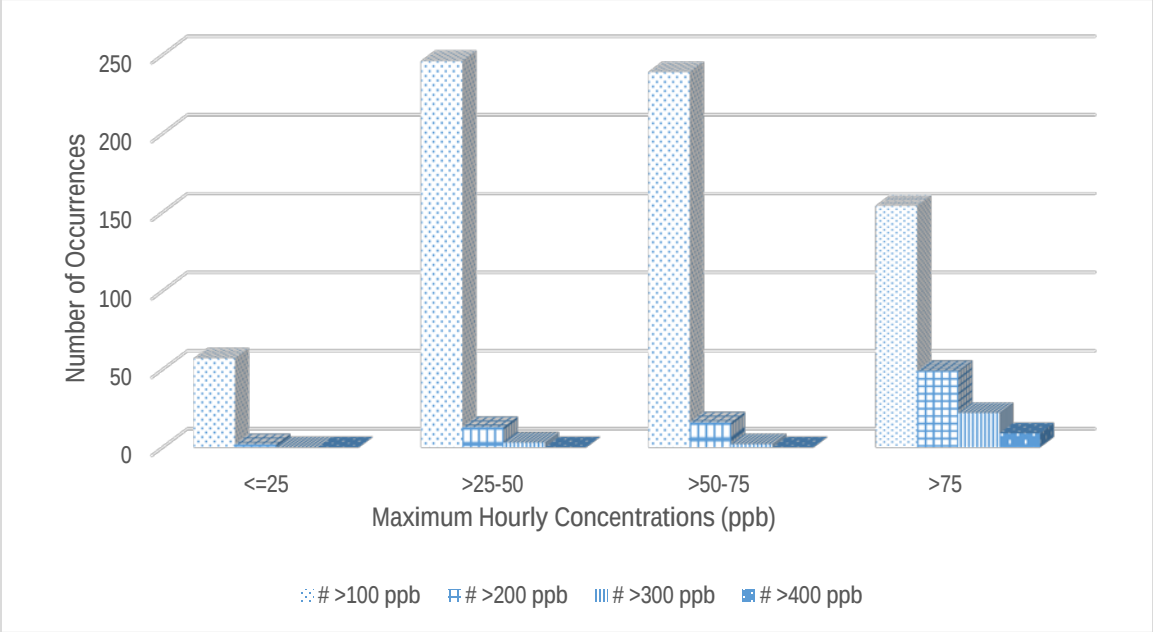
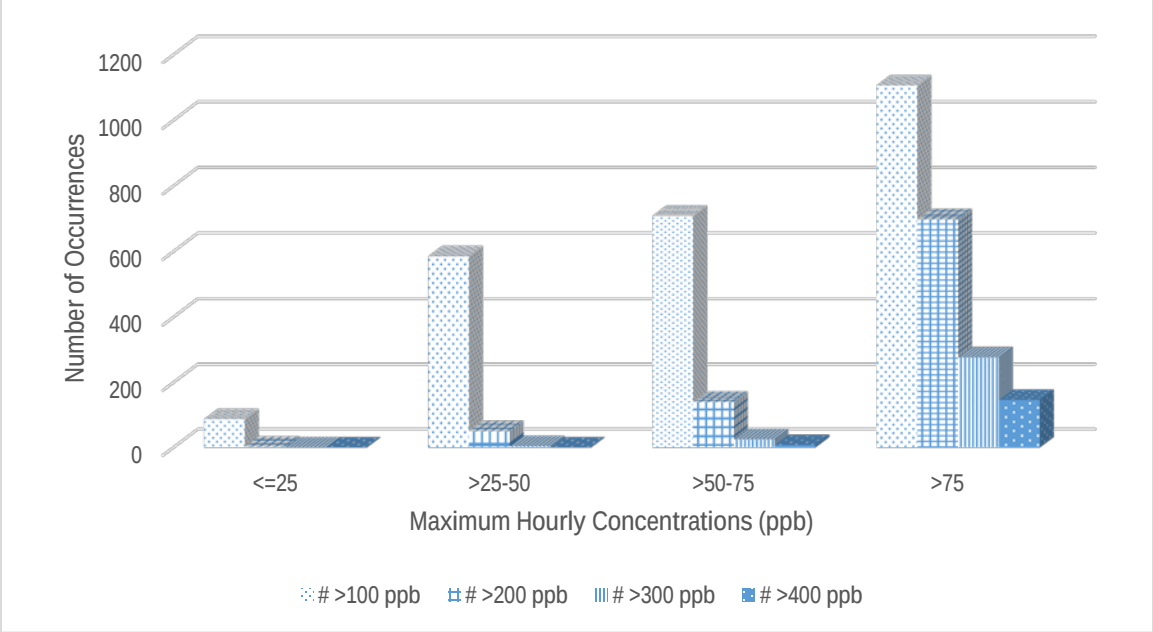


Figure B-2. Monitoring data for sites <u>not</u> <u>meeting</u> the current standard: Frequency of daily maximum 5-minute values on days with differing daily maximum 1-hour concentrations (2014-2016).



APPENDIX C

OCCURRENCES OF 5-MINUTE SO_2 CONCENTRATIONS OF INTEREST IN THE RECENT AMBIENT AIR MONITORING DATA (2014-2016)

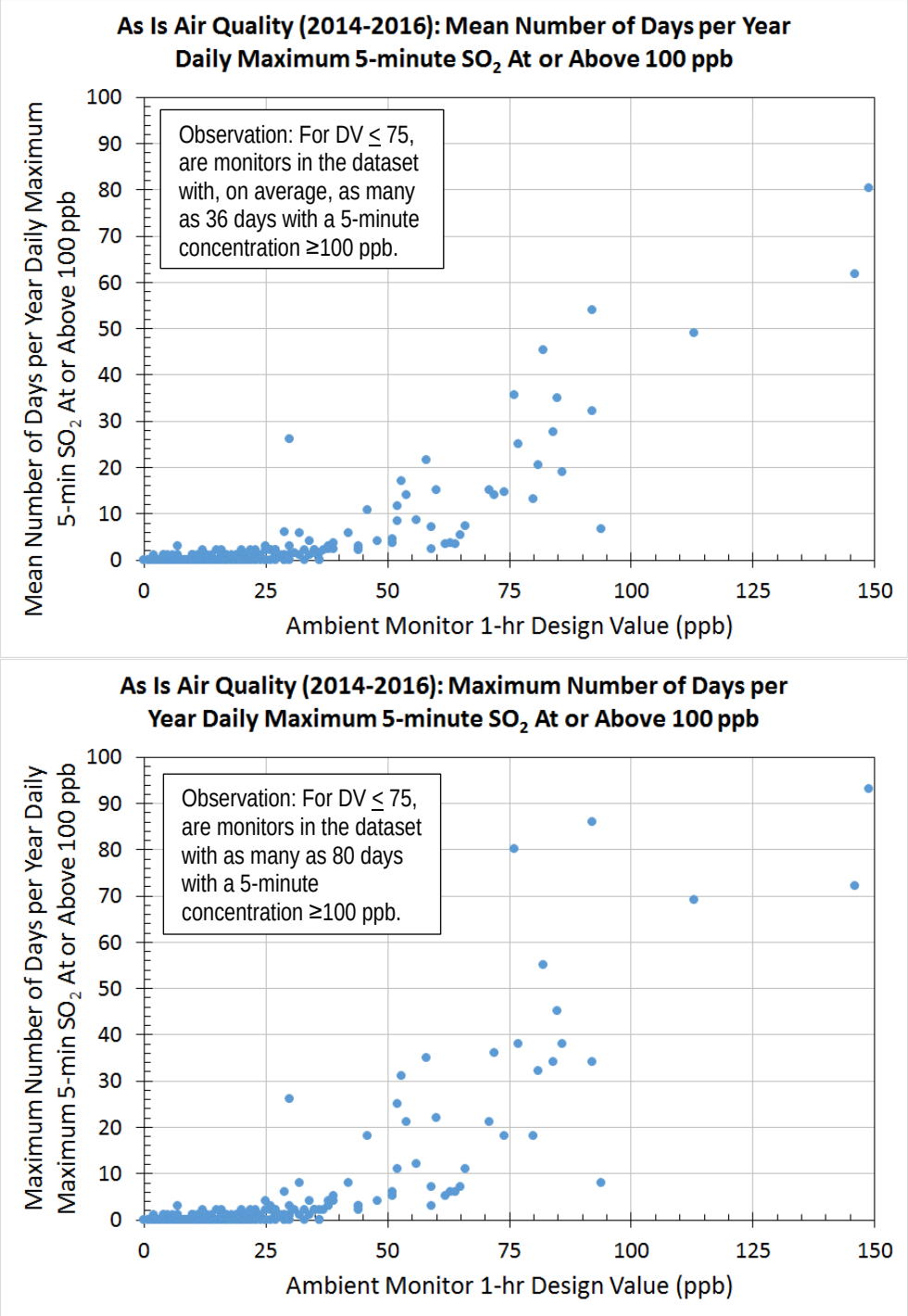


Figure C-1. As is (unadjusted) SO_2 monitoring data (2014-2016). Mean number of days/year (top panel) and maximum number of days/year (bottom panel) with daily maximum 5-minute concentrations of SO_2 at or above 100 ppb.

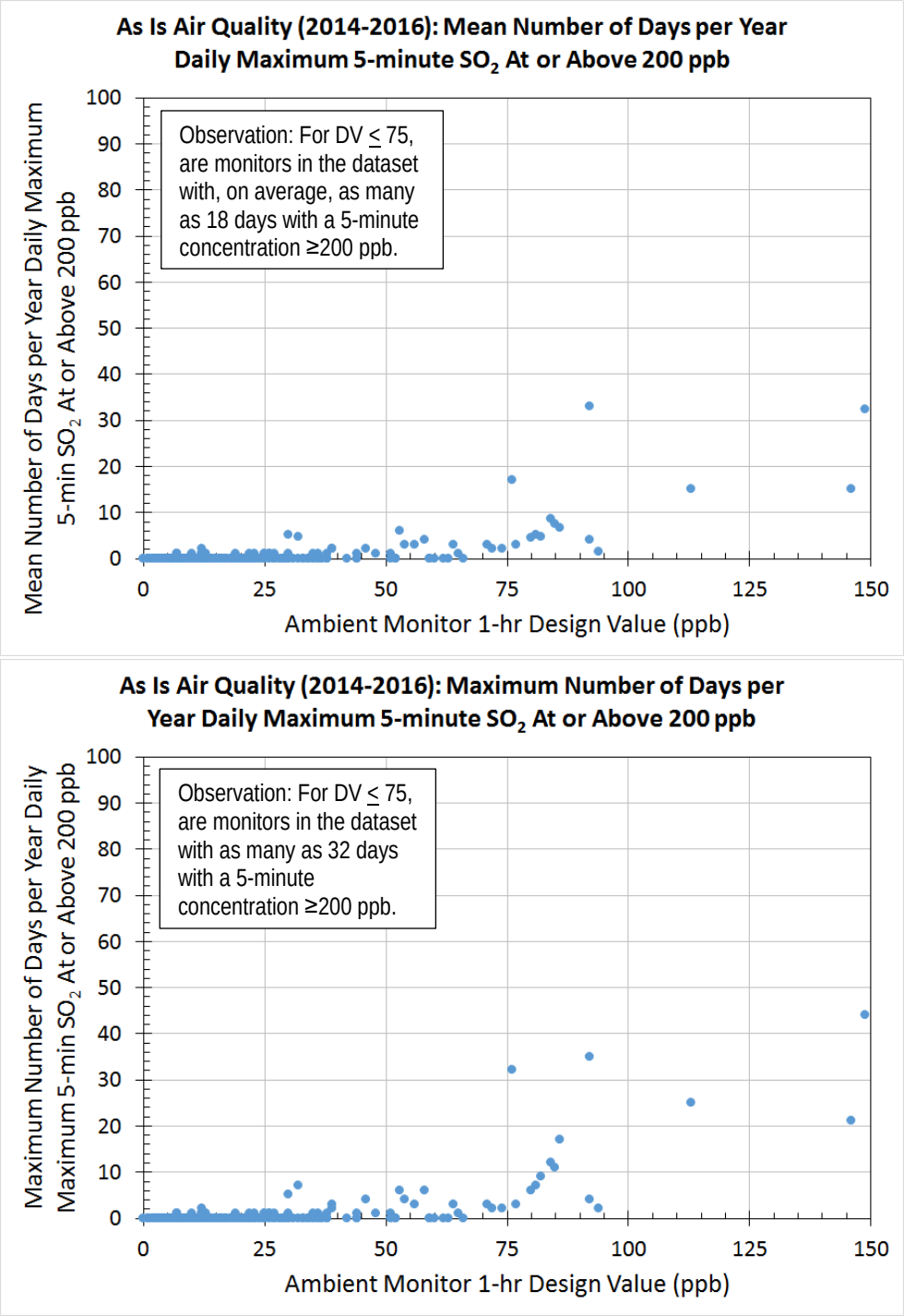


Figure C-2. As is (unadjusted) SO_2 monitoring data (2014-2016). Mean number of days/year (top panel) and maximum number of days/year (bottom panel) with daily maximum 5-minute concentrations of SO_2 at or above 200 ppb.

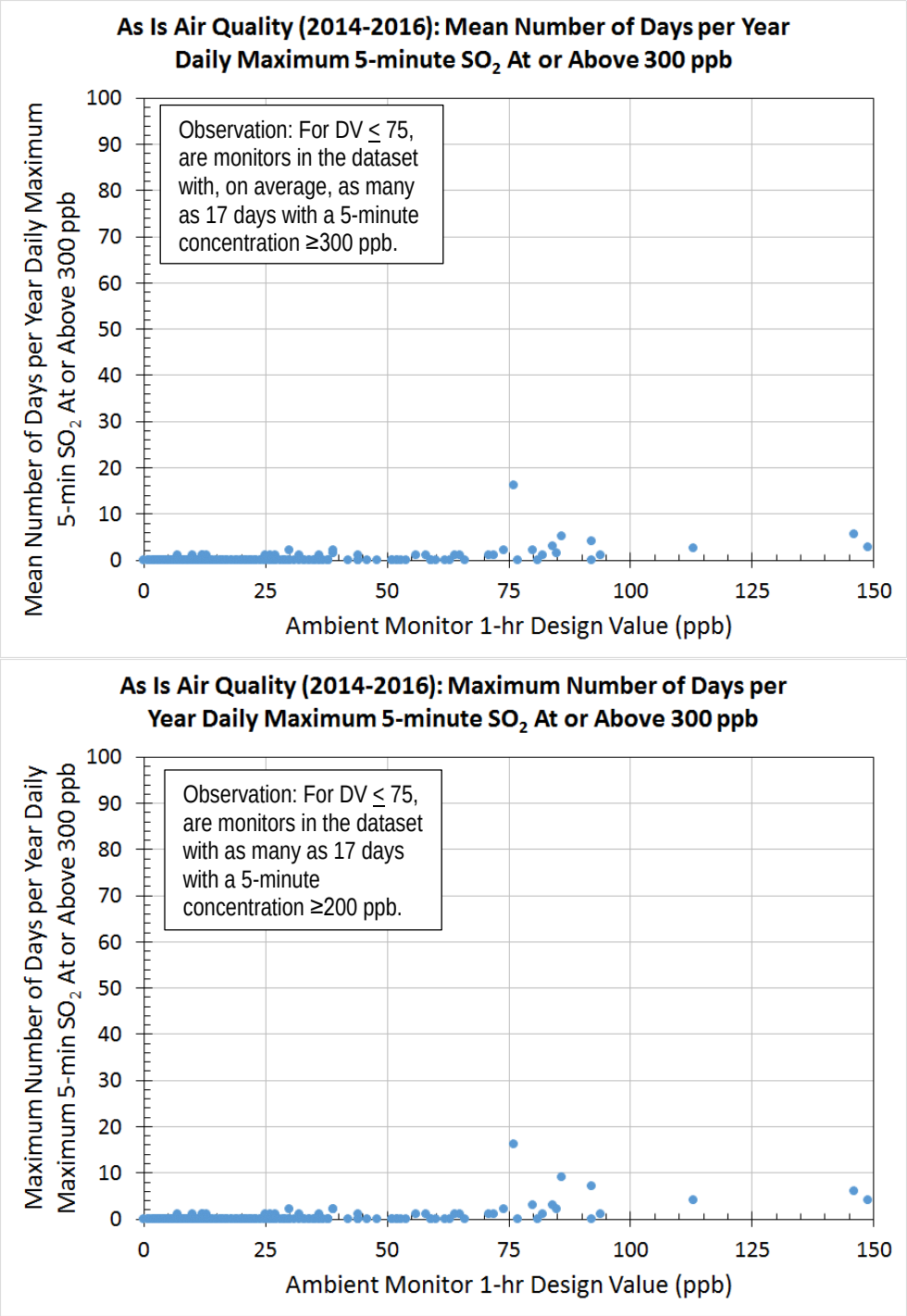


Figure C-3. As is (unadjusted) SO_2 monitoring data (2014-2016). Mean number of days/year (top panel) and maximum number of days/year (bottom panel) with daily maximum 5-minute concentrations of SO_2 at or above 300 ppb.

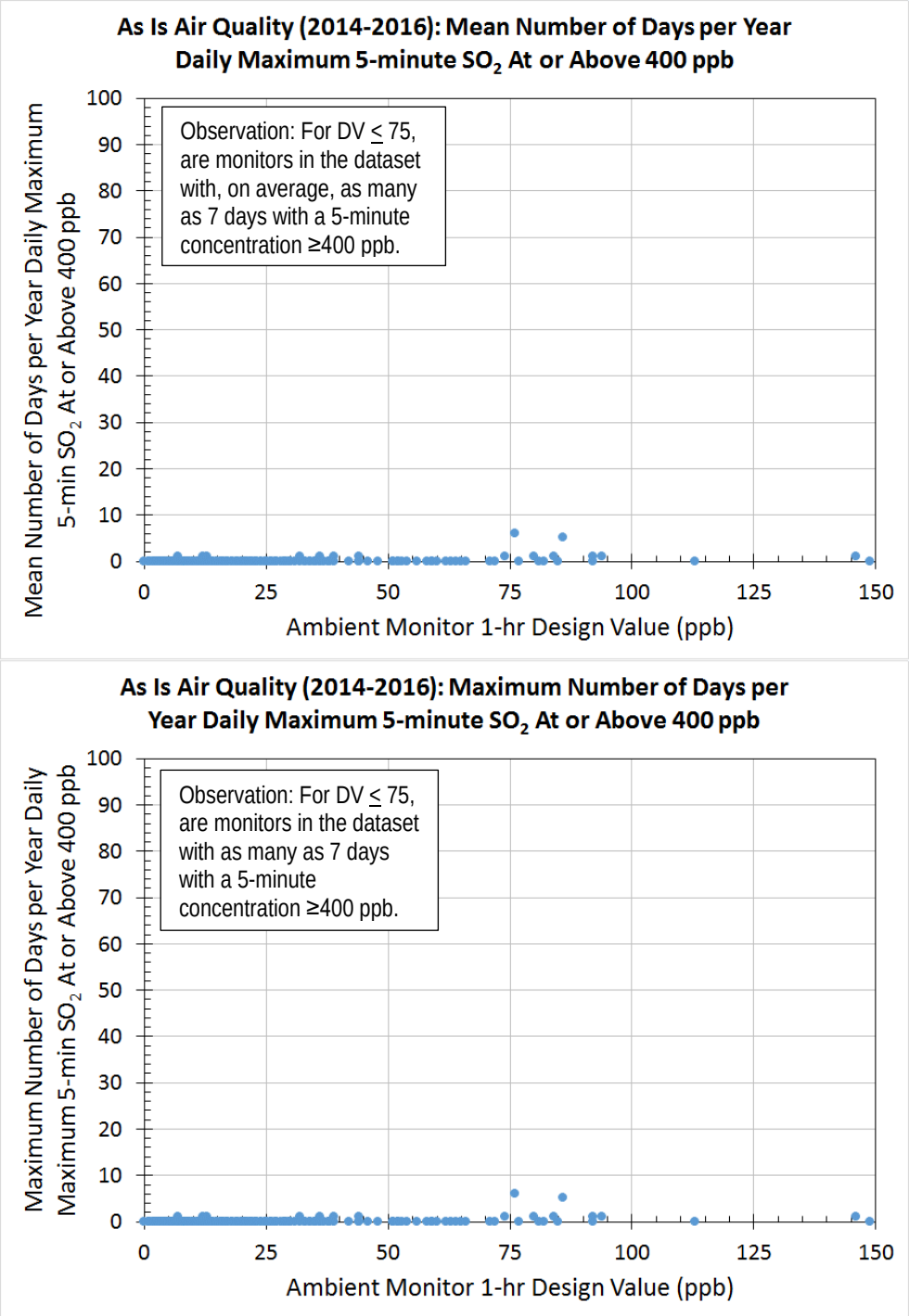


Figure C-4. As is (unadjusted) SO_2 monitoring data (2014-2016). Mean number of days/year (top panel) and maximum number of days/year (bottom panel) with daily maximum 5-minute concentrations of SO_2 at or above 400 ppb.

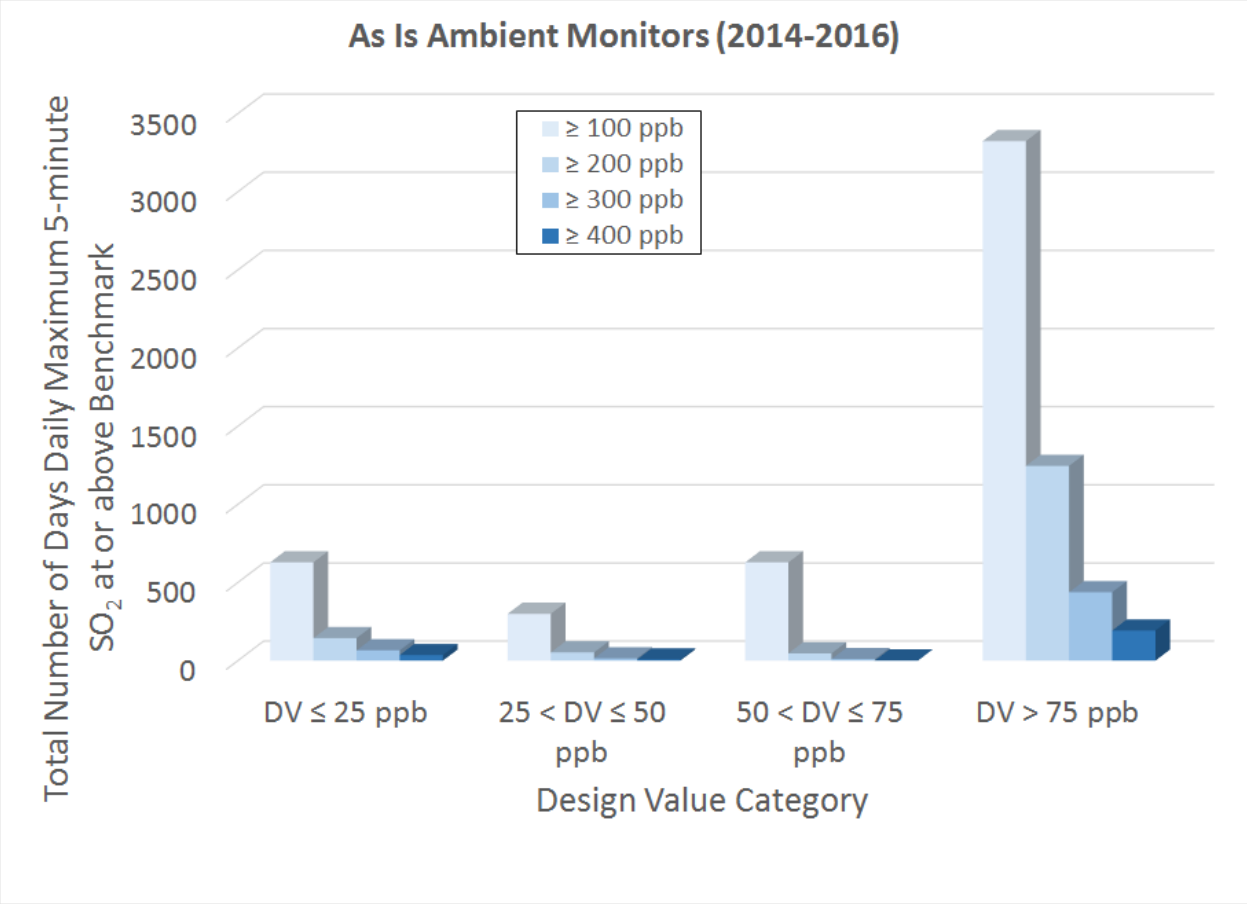


Figure C-5. Monitoring data (2014-2016), unadjusted. Total number of days across 3-year period with daily maximum 5-minute concentrations of SO_2 above 100, 200, 300 and 400 ppb across monitors grouped by design value.

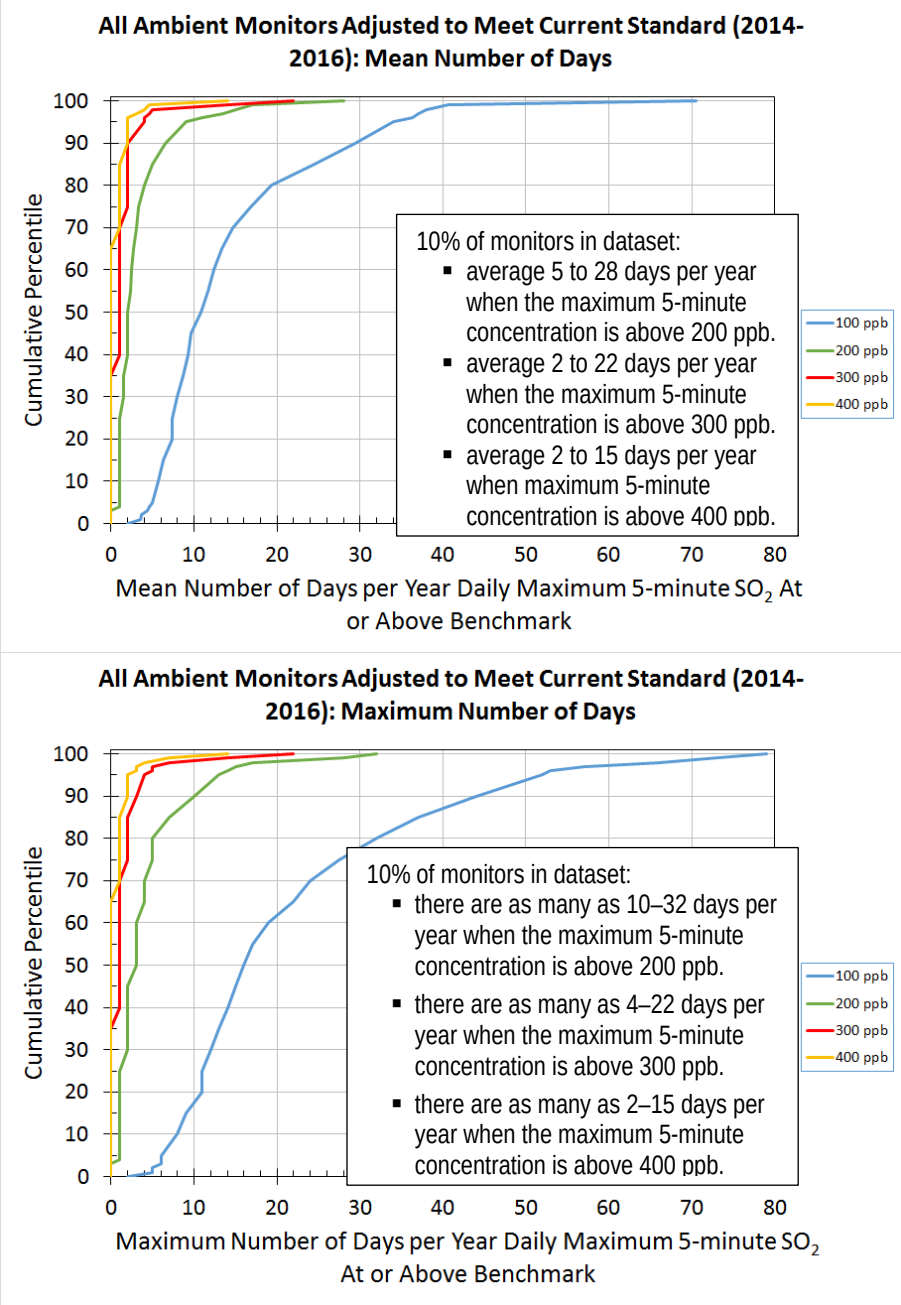


Figure C-6. Monitoring data (2014-2016) adjusted[1] to just meet the current standard (75 ppb as a 3-year average of annual 99th percentile 1-hour daily maximum concentrations). Mean number of days/year (top panel) and maximum number of days/year (bottom panel) with daily maximum 5-minute concentrations of SO_2 at or above 100, 200, 300 and 400 ppb.

[1] Based on 2014-2016 design values, a single adjustment factor was derived for each monitor by dividing 75 by the DV. Ambient concentrations for each year in the averaging period were then multiplied by this adjustment factor to have the three-year averaging period of ambient concentrations just meet the current standard. The data were limited to those with DVs within a factor of 5 (15 ppb < DV < 325 ppb), to limit instances where uncertainties associated with the adjustment would be greatest.

APPENDIX D

AIR QUALITY INFORMATION FOR GEOGRAPHICAL AREAS
OF THREE SELECTED U.S. EPIDEMIOLOGICAL STUDIES

Table D-1. Air quality information for geographical areas of the three U.S. epidemiological studies for which the SO_2 effect estimates for hospital admissions or emergency department visits (for asthma or other respiratory disease) and areawide 24-hour average SO_2 concentrations remained positive and statistically significant in copollutant models with particulate matter.

Study Information								Ambient Air Quality [A]			
Study Area	Study Time Period	Study Reference	SO_2 Concentration Metric Associated with Health Outcome	Assignment of Monitors to Study Subjects for Study Analyses	Study-reported SO_2 Concentrations, [B] 24-hour average (ppm)		99th percentile of daily maximum 1-hour concentrations across study period at highest monitor in study dataset (ppb)	Annual 99th percentile of daily maximum 1-hour concentrations at monitor yielding highest design value (ppb)		Design Value for Current NAAQS (3-year average of annual 99th percentile daily maximum 1-hour concentrations), ppm (monitor ID)	
					Mean	Upper Percentiles					
Bronx County, NY	Jan 1999-Dec 2000	ATSDR 2006 [C]	24-hr ave	2 monitors collecting data in series	12	-	78 [D]	1999	-	[E]	
								2000			
New York City, NY	Jan 1999-Dec 2002	Ito et al 2007	24-hr ave	Average across all (19) monitors	7.8	75th=10 95th=17	82 [F]	1999	78	1999-2001	73 (36-061-0056)
								2000	71		
								2001	71	2000-2002	69 (36-061-0056)
								2002	65		
New Haven, CT	Jan 1988-Dec 1990	Schwartz, 1995	24-hr ave	Average across all (6) monitors	29.8	75th =38.2 90th=60.7	150 [G]	1988	159	1988-1990	147 (09-009-1123)
								1989	167		
								1990	116		

A Air quality information provided here is drawn from monitors reporting to AQS, as documented in Appendix E). Design values are SO_2 concentrations for the study area in the statistical form of the standard, derived in accordance with 40 CFR, Part 50, Appendix T. Presented is the highest valid design value at a monitor reporting to AQS for specified 3-year period.

B Ambient SO_2 concentrations in terms of study metric that are reported in the second draft ISA Table 5-9 (for ATSDR, 2006 and Ito et al., 2007) and Table 5-14 (for Schwartz, 1995). Where multiple monitors contribute data, these are the arithmetic mean and percentiles of the dataset of daily multi-monitor average concentrations for the full study period.

C This study was cited as NY DOH, 2006 in the 2008 ISA.

D This statistic is for combined dataset of 2 monitoring sites due to construction at the initial site (Thompson and Stewart, 2009). Data are from the first monitor (36-005-0073) for the period Jan 1 to July 14, 1999. Data are from the second monitor (36-005-0110), approximately ½ mile northeast of first, for the period Sept 2, 1999 to Nov 22, 2000.

E Due to incomplete quarters or years, there is not a valid design value for a monitor in the Bronx any of the 3-year periods that include the study period.

F This statistic is based on monitor 36-061-0080 (Thompson and Stewart, 2009), for which five quarters of data are available during the study period (from 1999 through first quarter of 2000).

G This statistic is based on monitor 09-009-1123 (Thompson and Stewart, 2009), for which 12 quarters of data are available during the study period (1988 through 1990).

REFERENCES

ATSDR (Agency for Toxic Substances and Disease Registry). (2006). A study of ambient air contaminants and asthma in New York City: Part A and B. Atlanta, GA: U.S. Department of Health and Human Services. http://permanent.access.gpo.gov/lps88357/ASTHMA_BRONX_FINAL_REPORT.pdf

Ito, K; Thurston, GD; Silverman, RA. (2007). Characterization of PM2.5, gaseous pollutants, and meteorological interactions in the context of time-series health effects models. J Expo Sci Environ Epidemiol 17: S45-S60. http://dx.doi.org/10.1038/sj.jes.7500627

Schwartz, J; Morris, R. (1995). Air pollution and hospital admissions for cardiovascular disease in Detroit, Michigan. Am J Epidemiol 142: 23-35.

Thompson, R; Stewart, MJ. (2009). Memorandum to Sulfur Dioxide Review Docket (EPA-HQ-OAR-2007-0352). Air Quality Statistics for Cities Referenced in Key U.S. and Canadian Hospital Admission and Emergency Department Visits for All Respiratory Causes and Asthma. Docket ID No. EPA-HQ-OAR-2007-352-0018.

APPENDIX E

DERIVATION OF DESIGN VALUES PRESENTED IN APPENDIX D

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

User ID: DST

DESIGN VALUE REPORT

Report Request ID: 1565153 Report Code: AMP480 Jun. 20, 2017

GEOGRAPHIC SELECTIONS

Tribal Code	State	County	Site	Parameter	POC	City	AQCR	UAR	CBSA	CSA	EPA Region
	09	009									

PROTOCOL SELECTIONS

Parameter Classification	Parameter	Method	Duration
DESIGN VALUE	42401		

SELECTED OPTIONS

Option Type	Option Value
SINGLE EVENT PROCESSING	EXCLUDE REGIONALLY CONCURRED EVENTS
WORKFILE DELIMITER	,
USER SITE METADATA	STREET ADDRESS
MERGE PDF FILES	YES
QUARTERLY DATA IN WORKFILE	NO
AGENCY ROLE	PQAO

DATE CRITERIA

Start Date	End Date
1990	1990

APPLICABLE STANDARDS

Standard Description
SO2 1-hour 2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
AIR QUALITY SYSTEM
PRELIMINARY DESIGN VALUE REPORT

Report Date: Jun. 20, 2017

Notes:
1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

Pollutant: Sulfur dioxide(42401)
Standard Units: Parts per billion(008)
NAAQS Standard: SO2 1-hour 2010
Statistic: Annual 99th Percentile **Level:** 75

Design Value Year: 1990
REPORT EXCLUDES MEASUREMENTS WITH REGIONALLY CONCURRED EVENT FLAGS.
State Name: Connecticut

		1990			1989			1988			3-Year	
Site ID	STREET ADDRESS	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Design Value	Valid Ind.
09-009-0010	EGAN CENTER, MATHEW ST	3	114 *	Y	4	113		3	118 *		115	N
09-009-0017	LOMBARD STREET				3	112 *		4	113		113	N
09-009-1003	ANIMAL SHELTER, COMMERCE ST	4	68	Y	4	99		4	95		87	Y
09-009-1123	715 STATE STREET	4	116	Y	4	167		4	159		147	Y
09-009-2123	Bank St at Meadow St (see c	4	83	Y	4	97		4	85		88	Y
09-009-3008	LYDIA STREET EXTENTION	3	93 *	Y	4	110		4	100		101	Y

Notes: 1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

CERTIFICATION EVALUATION AND CONCURRENCE FLAG MEANINGS

FLAG	MEANING
M	The monitoring organization has revised data from this monitor since the most recent certification letter received from the state.
N	The certifying agency has submitted the certification letter and required summary reports, but the certifying agency and/or EPA has determined that issues regarding the quality of the ambient concentration data cannot be resolved due to data completeness, the lack of performed quality assurance checks or the results of uncertainty statistics shown in the AMP255 report or the certification and quality assurance report.
S	The certifying agency has submitted the certification letter and required summary reports. A value of "S" conveys no Regional assessment regarding data quality per se. This flag will remain until the Region provides an "N" or "Y" concurrence flag.
U	Uncertified. The certifying agency did not submit a required certification letter and summary reports for this monitor even though the due date has passed, or the state's certification letter specifically did not apply the certification to this monitor.
X	Certification is not required by 40 CFR 58.15 and no conditions apply to be the basis for assigning another flag value
Y	The certifying agency has submitted a certification letter, and EPA has no unresolved reservations about data quality (after reviewing the letter, the attached summary reports, the amount of quality assurance data submitted to AQS, the quality statistics, and the highest reported concentrations).

Notes:
1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

User ID: DST

DESIGN VALUE REPORT

Report Request ID: 1565370 Report Code: AMP480 Jun. 21, 2017

GEOGRAPHIC SELECTIONS

Tribal Code	State	County	Site	Parameter	POC	City	AQCR	UAR	CBSA	CSA	EPA Region
	36	005									
	36	047									
	36	061									
	36	081									
	36	085									

PROTOCOL SELECTIONS

Parameter Classification	Parameter	Method	Duration
DESIGN VALUE	42401		

SELECTED OPTIONS

Option Type	Option Value
SINGLE EVENT PROCESSING	EXCLUDE REGIONALLY CONCURRED EVENTS
WORKFILE DELIMITER	,
USER SITE METADATA	STREET ADDRESS
MERGE PDF FILES	YES
QUARTERLY DATA IN WORKFILE	NO
AGENCY ROLE	PQAO

DATE CRITERIA

Start Date	End Date
2000	2002

APPLICABLE STANDARDS

Standard Description
SO2 1-hour 2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
AIR QUALITY SYSTEM
PRELIMINARY DESIGN VALUE REPORT

Report Date: Jun. 21, 2017

Notes: 1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

Pollutant: Sulfur dioxide(42401)
Standard Units: Parts per billion(008)
NAAQS Standard: SO2 1-hour 2010
Statistic: Annual 99th Percentile **Level:** 75

Design Value Year: 2000
REPORT EXCLUDES MEASUREMENTS WITH REGIONALLY CONCURRED EVENT FLAGS.
State Name: New York

		2000			1999			1998			3-Year	
Site ID	STREET ADDRESS	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Design Value	Valid Ind.
36-005-0073	IS 155, 470 JACKSON AV.				2	68 *	Y	4	70	Y	69	N
36-005-0080	MORRISANIA CENTER, 1225-57	1	94 *		4	77	Y	4	69	Y	80	N
36-005-0083	200TH STREET AND SOUTHERN B	2	62 *								62	N
36-005-0110	IS 52 681 KELLY ST	4	86		1	98 *	Y				92	N
36-047-0011	301 GREENPOINT AVENUE				3	51 *	Y	4	42	Y	47	N
36-047-0076	PS 321 180 7TH AV,	0	36 *		4	54	Y	3	59 *	Y	50	N
36-061-0010	MABEL DEAN HIGH SCH.ANNEX,	3	72 *		4	79	Y	3	64 *	Y	72	N
36-061-0056	PS 59, 228 E. 57TH STREET,	4	71		4	78	Y	4	69	Y	73	Y
36-081-0097	56TH AVE AT SPRINGFIELD BLV	4	50		4	53	Y	2	52 *	Y	52	N
36-085-0067	SUSAN WAGNER HS, 1200 MAN	1	54 *		4	46	Y	4	46	Y	49	N

Notes: 1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

Pollutant: Sulfur dioxide(42401)
Standard Units: Parts per billion(008)
NAAQS Standard: SO2 1-hour 2010
Statistic: Annual 99th Percentile **Level:** 75

Design Value Year: 2001
REPORT EXCLUDES MEASUREMENTS WITH REGIONALLY CONCURRED EVENT FLAGS.
State Name: New York

		2001			2000			1999			3-Year	
Site ID	STREET ADDRESS	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Design Value	Valid Ind.
36-005-0073	IS 155, 470 JACKSON AV.							2	68 *	Y	68	N
36-005-0080	MORRISANIA CENTER, 1225-57				1	94 *		4	77	Y	86	N
36-005-0083	200TH STREET AND SOUTHERN B	4	71	Y	2	62 *					67	N
36-005-0110	IS 52 681 KELLY ST	3	81 *	Y	4	86		1	98 *	Y	88	N
36-047-0011	301 GREENPOINT AVENUE							3	51 *	Y	51	N
36-047-0076	PS 321 180 7TH AV,				0	36 *		4	54	Y	45	N
36-061-0010	MABEL DEAN HIGH SCH.ANNEX,	2	69 *	Y	3	72 *		4	79	Y	73	N
36-061-0056	PS 59, 228 E. 57TH STREET,	4	71	Y	4	71		4	78	Y	73	Y
36-081-0097	56TH AVE AT SPRINGFIELD BLV	4	50	Y	4	50		4	53	Y	51	Y
36-081-0124	Queens College 65-30 Kiss	1	57 *	Y							57	N
36-085-0067	SUSAN WAGNER HS, 1200 MAN				1	54 *		4	46	Y	50	N

Notes: 1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
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Pollutant: Sulfur dioxide(42401)
Standard Units: Parts per billion(008)
NAAQS Standard: SO2 1-hour 2010
Statistic: Annual 99th Percentile **Level:** 75

Design Value Year: 2002
REPORT EXCLUDES MEASUREMENTS WITH REGIONALLY CONCURRED EVENT FLAGS.
State Name: New York

		2002			2001			2000			3-Year	
Site ID	STREET ADDRESS	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Comp. Qrtrs	99th Percentile	Cert& Eval	Design Value	Valid Ind.
36-005-0080	MORRISANIA CENTER, 1225-57							1	94 *		94	N
36-005-0083	200TH STREET AND SOUTHERN B	4	62	Y	4	71	Y	2	62 *		65	N
36-005-0110	IS 52 681 KELLY ST	4	67	Y	3	81 *	Y	4	86		78	N
36-047-0076	PS 321 180 7TH AV,							0	36 *		36	N
36-061-0010	MABEL DEAN HIGH SCH.ANNEX,				2	69 *	Y	3	72 *		71	N
36-061-0056	PS 59, 228 E. 57TH STREET,	4	65	Y	4	71	Y	4	71		69	Y
36-081-0097	56TH AVE AT SPRINGFIELD BLV				4	50	Y	4	50		50	N
36-081-0124	Queens College 65-30 Kiss	4	57	Y	1	57 *	Y				57	N
36-085-0067	SUSAN WAGNER HS, 1200 MAN							1	54 *		54	N

Notes: 1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

CERTIFICATION EVALUATION AND CONCURRENCE FLAG MEANINGS

FLAG	MEANING
M	The monitoring organization has revised data from this monitor since the most recent certification letter received from the state.
N	The certifying agency has submitted the certification letter and required summary reports, but the certifying agency and/or EPA has determined that issues regarding the quality of the ambient concentration data cannot be resolved due to data completeness, the lack of performed quality assurance checks or the results of uncertainty statistics shown in the AMP255 report or the certification and quality assurance report.
S	The certifying agency has submitted the certification letter and required summary reports. A value of "S" conveys no Regional assessment regarding data quality per se. This flag will remain until the Region provides an "N" or "Y" concurrence flag.
U	Uncertified. The certifying agency did not submit a required certification letter and summary reports for this monitor even though the due date has passed, or the state's certification letter specifically did not apply the certification to this monitor.
X	Certification is not required by 40 CFR 58.15 and no conditions apply to be the basis for assigning another flag value
Y	The certifying agency has submitted a certification letter, and EPA has no unresolved reservations about data quality (after reviewing the letter, the attached summary reports, the amount of quality assurance data submitted to AQS, the quality statistics, and the highest reported concentrations).

Notes:
1. Computed design values are a snapshot of the data at the time the report was run (may not be all data for year).
2. Some PM2.5 24-hour DVs for incomplete data that are marked invalid here may be marked valid in the Official report due to additional analysis.
3. Annual Values not meeting completeness criteria are marked with an asterisk ('*').

APPENDIX F

GEOGRAPHIC DISTRIBUTION OF CONTINENTAL
U.S. FACILITIES EMITTING MORE THAN 1,000 TPY SO_2
AND POPULATION DENSITY BASED ON U.S. CENSUS TRACTS

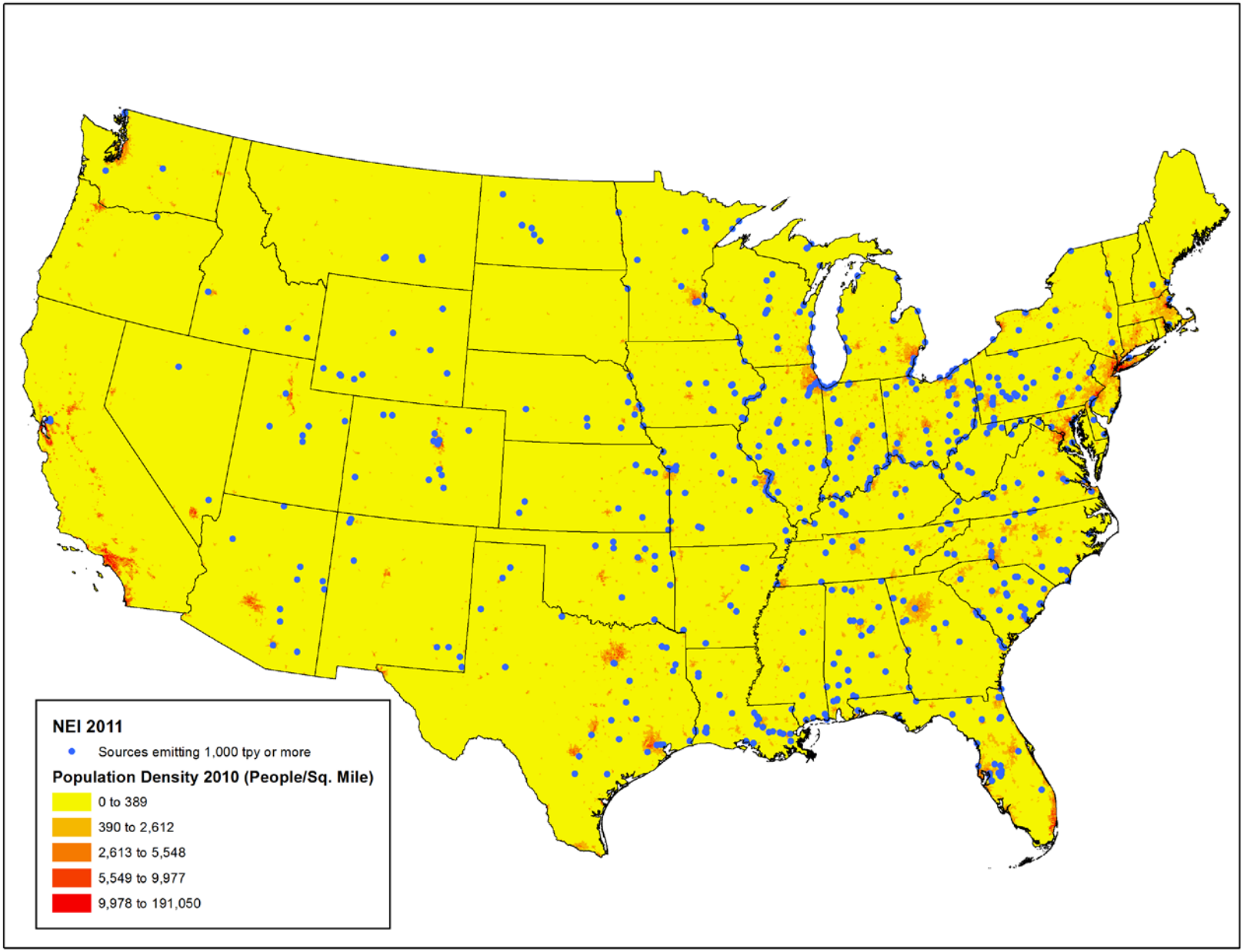

Figure F-1. Continental U.S.: Facilities emitting more than 1,000 tpy SO_2 (n=619 in 2011 NEI) and population density.

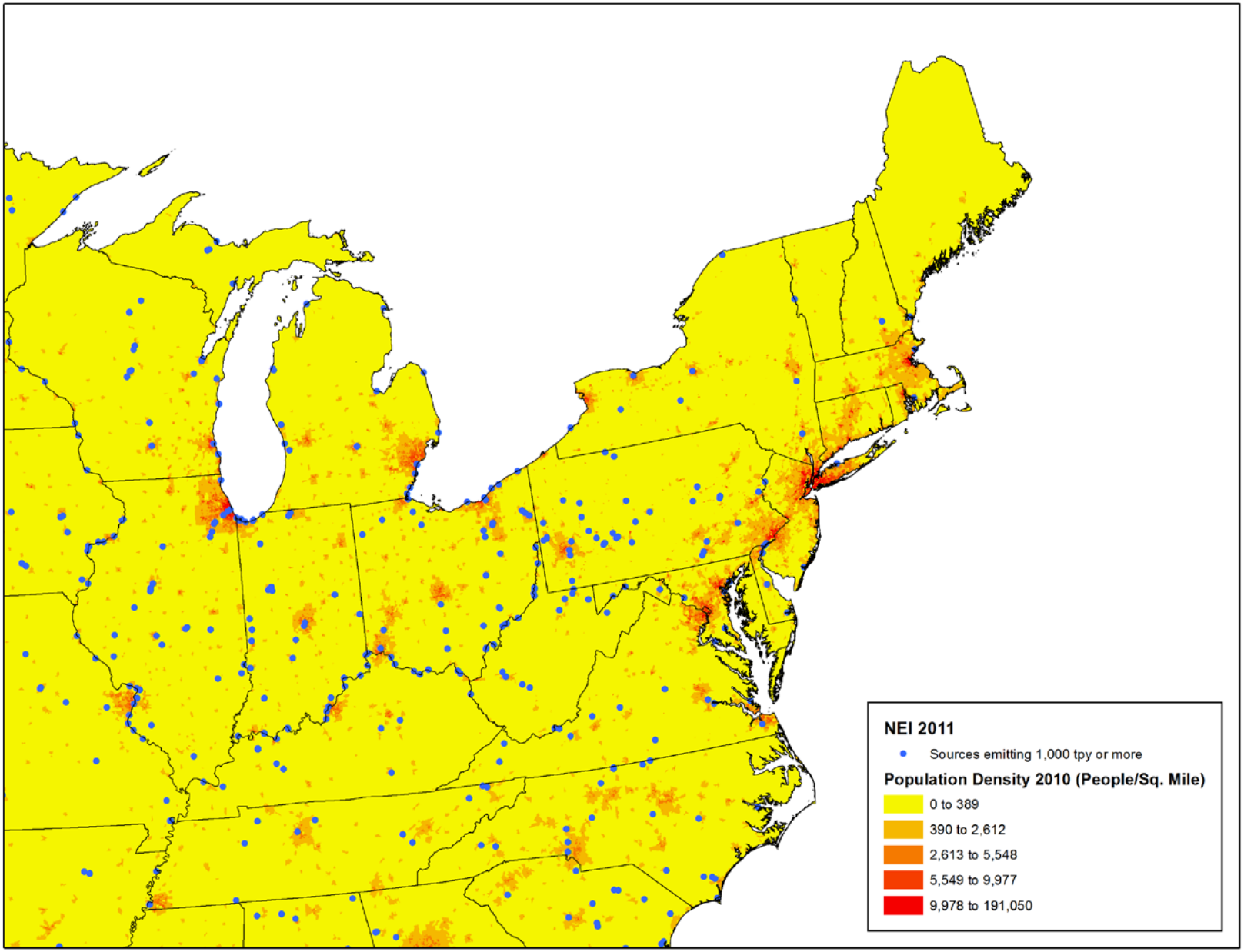

Figure F-2. Northeast U.S.: Facilities emitting more than 1,000 tpy SO_2 and population density.

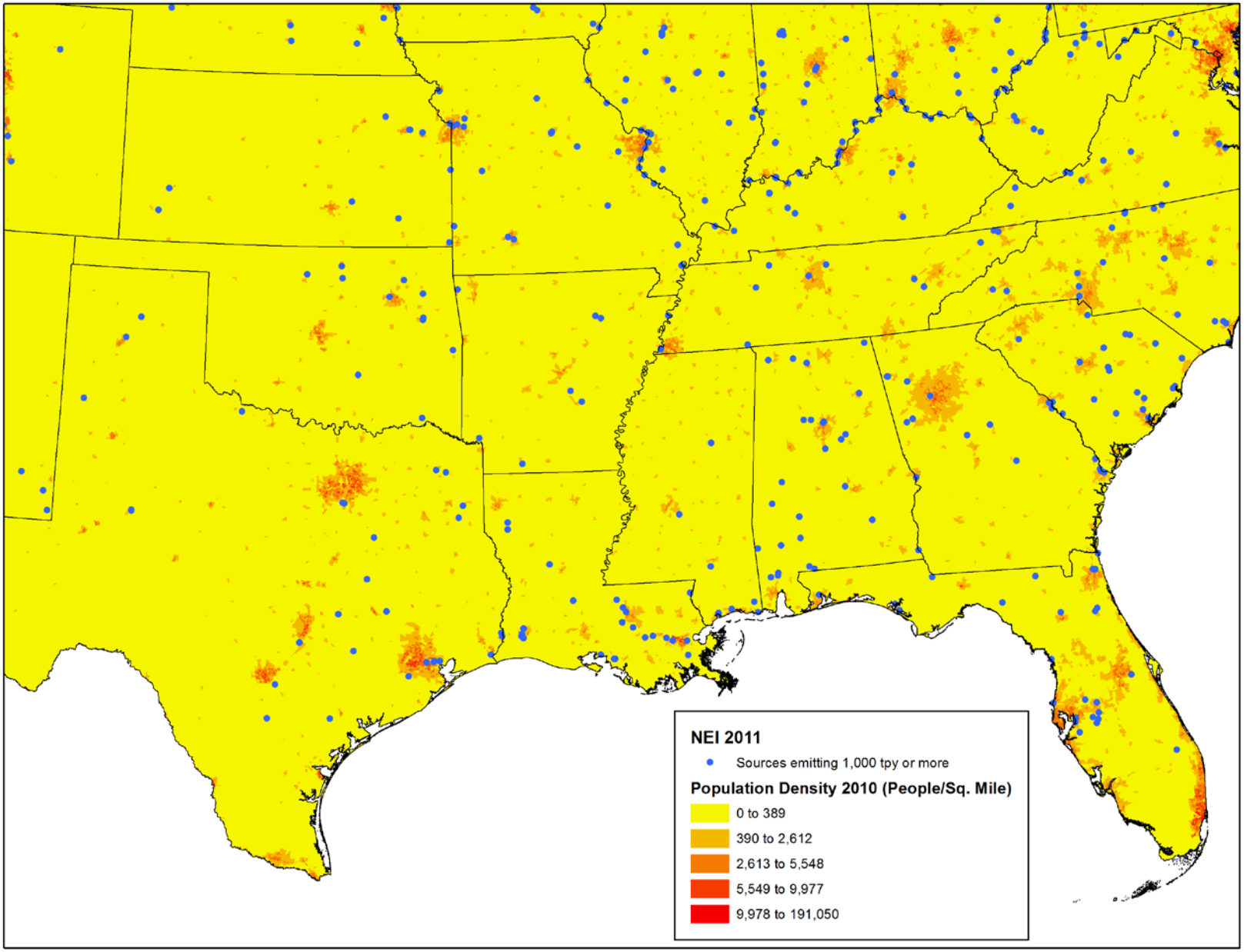

Figure F-3. Southeast U.S.: Facilities emitting more than 1,000 tpy SO_2 and population density.

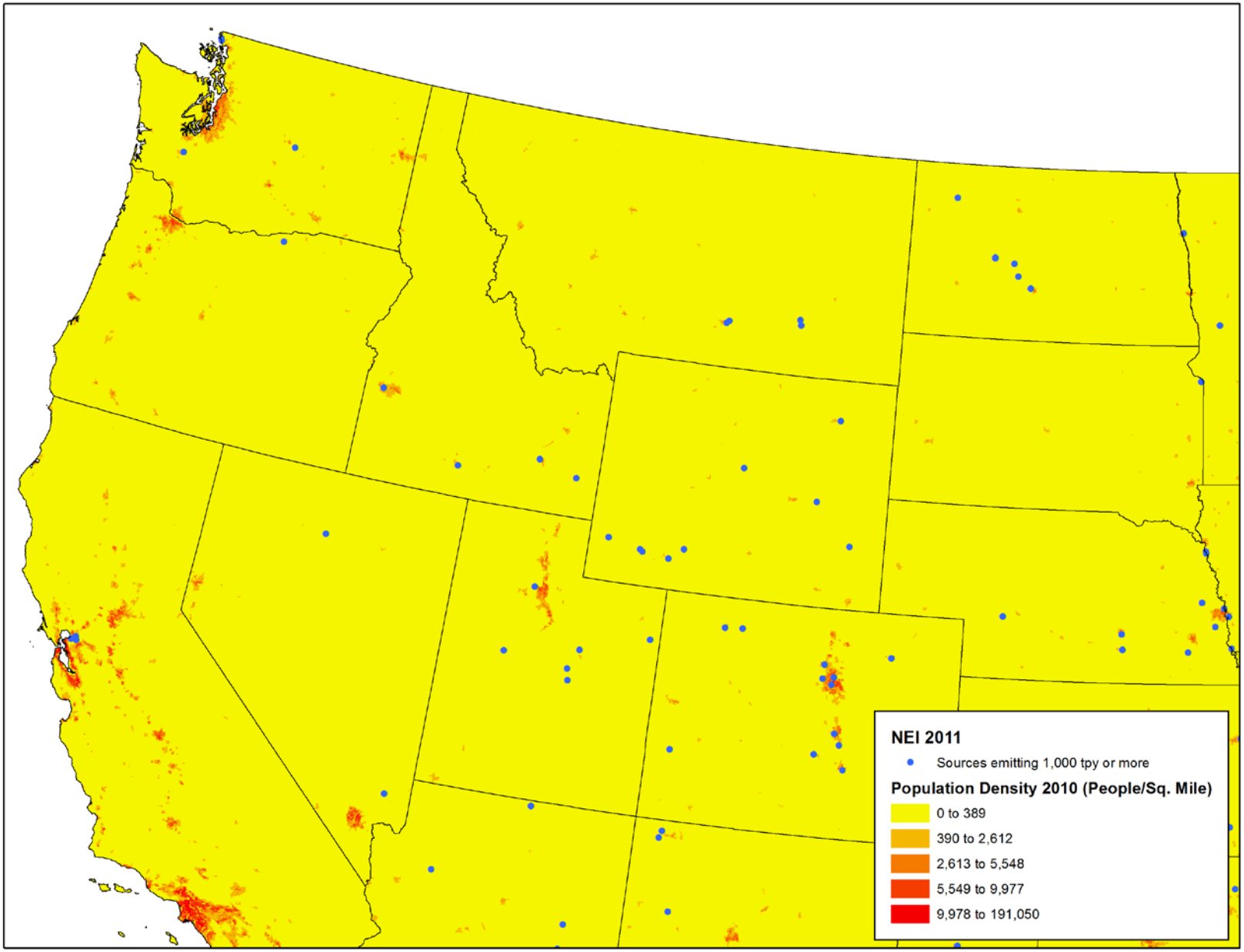

Figure F-4. Northwest U.S.: Facilities emitting more than 1,000 tpy SO_2 and population density.

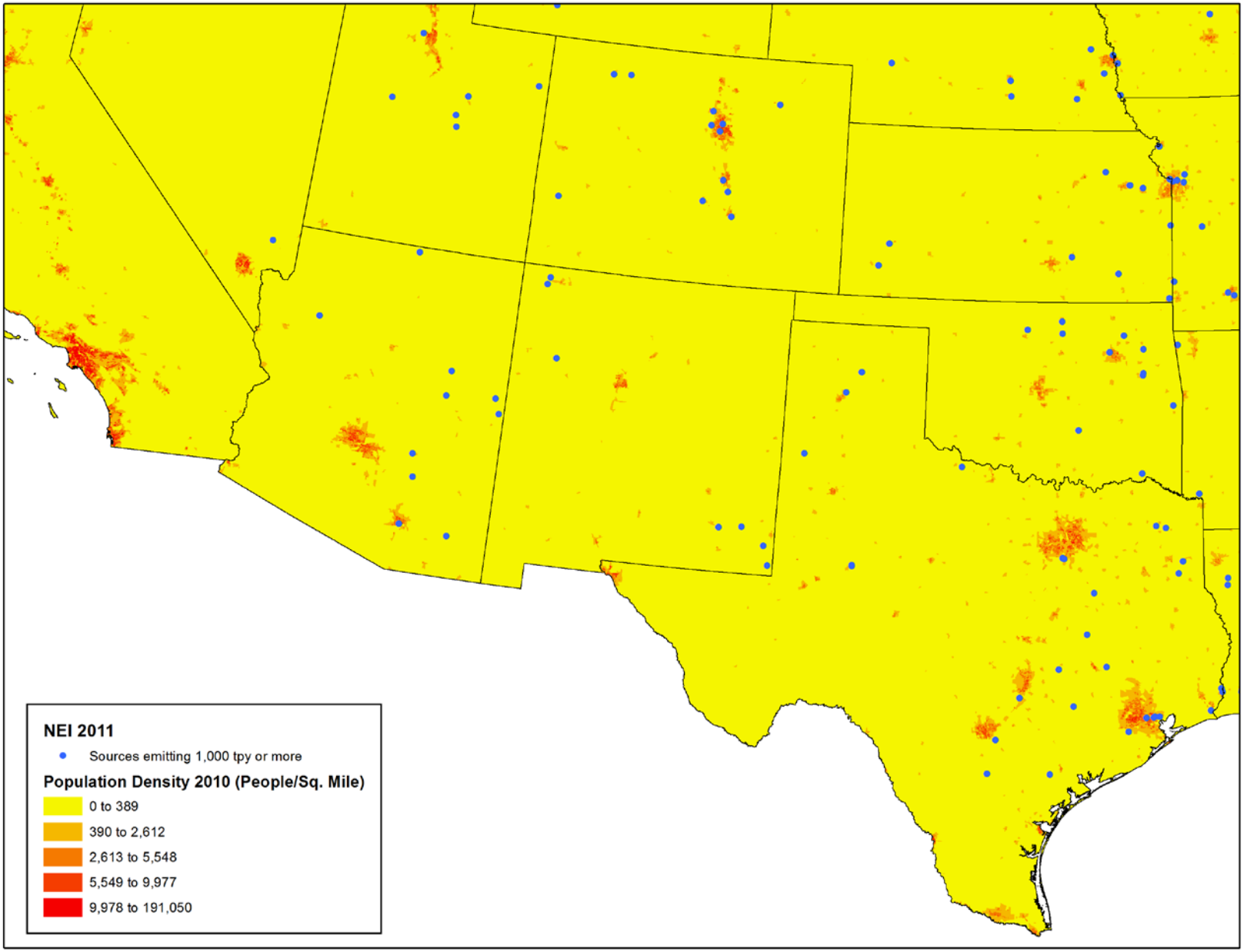

Figure F-5. Southwest U.S.: Facilities emitting more than 1,000 tpy SO_2 and population density.

United States
Environmental Protection
Agency

Office of Air Quality Planning and Standards
Health and Environmental Impacts Division
Research Triangle Park, NC

Publication No. EPA-452/R-18-002
May 2018