ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA–HQ–OAR–2013–0566; FRL–9990–28–OAR]

RIN 2060–AT68

Review of the Primary National Ambient Air Quality Standards for Sulfur Oxides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: Based on the Environmental Protection Agency's (EPA's) review of the air quality criteria addressing human health effects and the primary national ambient air quality standard (NAAQS) for sulfur oxides (SO_X), the EPA is retaining the current standard, without revision.

DATES: This final action is effective on April 17, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2013–0566. Incorporated into this docket is a separate docket established for the Integrated Science Assessment for this review (Docket ID No. EPA–HQ–ORD–2013–0357). All documents in these dockets are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and may be viewed, with prior arrangement, at the EPA Docket Center. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air and Radiation Docket Information Center, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Air and Radiation Docket Information Center is (202) 566–1742.

Availability of Information Related to This Action

A number of the documents that are relevant to this action are available through the EPA's website at *https://www.epa.gov/naaqs/sulfur-dioxide-so2-primary-air-quality-standards.* These documents include the Integrated Review Plan for the Primary National Ambient Air Quality Standard for Sulfur Dioxide (U.S. EPA, 2014a), available at *https://www3.epa.gov/ttn/naaqs/standards/so2/data/20141028so2reviewplan.pdf,* the Integrated Science Assessment for Sulfur Oxides—Health Criteria (ISA [U.S. EPA, 2017a]), available at *https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=338596,* the Risk and Exposure Assessment for the Review of the National Ambient Air Quality Standard for Sulfur Oxides (REA [U.S. EPA, 2018a]), available at *https://www.epa.gov/naaqs/sulfur-dioxide-so2-standards-risk-and-exposure-assessments-current-review* and the Policy Assessment for the Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides (PA [U.S. EPA, 2018b]), available at *https://www.epa.gov/naaqs/sulfur-dioxide-so2-standards-policy-assessments-current-review.* These and other related documents are also available for inspection and copying in the EPA docket identified above.

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SUPPLEMENTARY INFORMATION:

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Executive Summary

The EPA has completed its current review of the primary (health-based) NAAQS for SO_X, a group of closely related gaseous compounds that include sulfur dioxide (SO_2). Of these compounds, SO_2 (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 current primary standard is set at a level of 75 parts per billion (ppb), as the 99th percentile of daily maximum 1-hour SO_2 concentrations, averaged over 3 years. Based on the EPA's review of key aspects of the currently available health effects evidence, quantitative risk and exposure information, advice from the Clean Air Scientific Advisory Committee (CASAC), and public comments, the EPA is retaining the current standard, without revision.

Reviews of the NAAQS are required by the Clean Air Act (CAA) on a periodic basis. The last review of the primary SO_2 NAAQS was completed in 2010 (75 FR 35520, June 22, 2010). In that review, the EPA significantly strengthened the primary standard, establishing a 1-hour standard and revoking the 24-hour and annual standards. The 1-hour standard was established to provide protection from respiratory effects associated with exposures as short as a few minutes based on evidence from health studies that documented respiratory effects in people with asthma exposed to SO_2 for 5 to 10 minutes while breathing at elevated rates. Revisions to the NAAQS in 2010 were accompanied by revisions to the ambient air monitoring and reporting regulations, requiring the reporting of hourly maximum 5-minute SO_2 concentrations, in addition to the hourly concentrations.

Emissions of SO_2 and associated concentrations in ambient air have declined appreciably since 2010 and over the longer term. For example, as summarized in the PA, emissions nationally are estimated to have declined by 82% over the period from 2000 to 2016, with a 64% decline from 2010 to 2016. Such declines in SO_2 emissions are likely related to the implementation of national control programs developed under the Clean Air Act Amendments of 1990, as well as changes in market conditions, *e.g.,* reduction in energy generation by coal. One-hour concentrations of SO_2 in ambient air in the U.S. declined more than 82% from 1980 to 2016 at locations continuously monitored over this period. The decline since 2000 has been 69% at a larger number of locations continuously monitored since that time. Daily maximum 5-minute concentrations have also consistently declined from 2011 to 2016.

In this review, as in past reviews of the primary NAAQS for SO_X, the health effects evidence evaluated in the ISA is focused on SO_2. 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 (PM). Additionally, the welfare effects of SO_X and the ecological effects of particulate atmospheric transformation products are being considered in the review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur, and PM, 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 PM.

The health effects evidence newly available in this review, as critically assessed in the ISA in conjunction with the full body of evidence, reaffirms the conclusions from the last review. The health effects evidence continues to support the conclusion that respiratory effects are causally related to short-term SO_2 exposures, including effects related to asthma exacerbation in people with asthma, particularly children with asthma. The clearest evidence for this conclusion comes from controlled human exposure studies, available at the time of the last review, that show that people with asthma experience respiratory effects following very short (*e.g.,* 5–10 minute) exposures to SO_2 while breathing at elevated rates. Epidemiologic evidence, including that from studies not available in the last review, also supports this conclusion, primarily due to studies reporting positive associations between ambient air concentrations and emergency department visits and hospital admissions, specifically for children.

Quantitative analyses of population exposure and risk also inform the final decision. These analyses expand and improve upon the quantitative analyses available in the last review. Unlike the REA available in the last review, which analyzed single-year air quality scenarios for potential standard levels bracketing the now-current level, the current REA assesses an air quality scenario for 3 years of air quality conditions that just meet the now-current standard, considering all of its elements, including its 3-year form. Other ways in which the current REA analyses are improved and expanded include improvements to models, model inputs and underlying databases, including the vastly expanded ambient air monitoring dataset for 5-minute concentrations, available as a result of changes in the last review to data reporting requirements.

Based on this evidence and quantitative information, as well as CASAC advice and consideration of public comment, the Administrator has concluded that the current primary SO_2 standard is requisite to protect public health, with an adequate margin of safety, from effects of SO_X in ambient air and should be retained, without revision. Therefore, the EPA is retaining the current 1-hour primary SO_2 standard, without revision. This decision is consistent with CASAC recommendations.

I. Background

This review focuses on the presence in ambient air of SO_X, a group of closely related gaseous compounds that includes SO_2 and sulfur trioxide (SO_3) and of which SO_2 (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, as well as visibility, climate, and materials damage-related welfare effects of such particulate sulfur compounds are being addressed in the review of the NAAQS for particulate matter (PM) (U.S. EPA, 2014a, 2016a, 2018c). Additionally, the ecological welfare effects of SO_X and their particulate atmospheric transformation products are being considered in the review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur, and PM (U.S. EPA, 2014a, 2017b).[1]

A. Legislative Requirements

Two sections of the Clean Air Act (CAA or the Act) 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 air pollutants that 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 results from numerous or diverse mobile or stationary sources;" and "for which . . . [the Administrator] plans to issue air quality criteria . . . ." Air quality criteria are intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of 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. Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, [is] requisite to protect the public health." [2] As provided in 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." [3]

[1] Additional information on the review of secondary NAAQS for oxides of nitrogen, oxides of sulfur, and PM with regard to ecological welfare effects is available at: *https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards.* Additional information on the review of the PM NAAQS is available at: *https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards.*

[2] 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). *See also Lead Industries Association* v. *EPA,* 647 F.2d 1130, 1152 (D.C. Cir 1980); *American Lung Association* v. *EPA,* 134 F.3d 388, 389 (D.C. Cir. 1998) ("NAAQS must protect not only average healthy individuals, but also 'sensitive citizens'—children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution.").

[3] As specified in section 302(h) of the CAA (42 U.S.C. 7602(h)) effects on welfare include, but are

Continued

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); *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1186 (D.C. Cir. 1981); *American Farm Bureau Federation* v. *EPA,* 559 F.3d 512, 533 (D.C. Cir. 2009); *Association of Battery Recyclers* v. *EPA,* 604 F.3d 613, 617–18 (D.C. Cir. 2010). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that provide 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. However, the CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentrations, *see Lead Industries Association* v. *EPA,* 647 F.2d at 1156 n.51, 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 sensitive population(s) at risk,[4] and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *See Lead Industries Association* v. *EPA,* 647 F.2d at 1161–62.

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 for these purposes. 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,* 665 F.2d at 1185.

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

B. Related SO_2 Control Programs

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under section 110 of the Act, 42 U.S.C. 7410, and related provisions, states are to submit, for EPA approval, state implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The states, in conjunction with the EPA, also administer the prevention of significant deterioration permitting program that covers these and other air pollutants. *See* 42 U.S.C. 7470–7479. In addition, federal programs provide for nationwide reductions in emissions of these and other air pollutants under Title II of the Act, 42 U.S.C. 7521–7574, which involves controls for automobile, truck, bus, motorcycle, nonroad engine and equipment, and aircraft emissions. Furthermore, the EPA establishes emission standards for stationary sources under other provisions of the CAA; these standards, which include the new source performance standards (under section 111 of the Act, 42 U.S.C. 7411), and the national emission standards for hazardous air pollutants (under section 112 of the Act, 42 U.S.C. 7412) may also contribute to SO_2 emissions controls and reductions, including through controls aimed at reducing other pollutants.

C. Review of the Air Quality Criteria and Standard for Sulfur Oxides

The initial air quality criteria for SO_X were issued in 1967 and reevaluated in 1969 (34 FR 1988, February 11, 1969; U.S. DHEW, 1967, 1969). Based on the 1969 criteria, the EPA, in initially promulgating NAAQS for SO_X in 1971, established the indicator as SO_2. SO_X are a group of closely related gaseous compounds that include SO_2 and SO_3 and of which SO_2 (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 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 (36 FR 8186, April 30, 1971).

The first review of the air quality criteria and primary standards for SO_X was initiated in the early 1980s and concluded in 1996 with the decision to retain the standards without revision (61 FR 25566, May 22, 1996). In reaching this decision, the Administrator considered the evidence newly available since the standards were set that documented asthma-related respiratory effects in people with asthma exposed for very short periods, such as 5 to 10 minutes. Based on his consideration of an exposure analysis using the then-limited monitoring data and early exposure modeling methods, the Administrator judged that revisions to the standards were not needed to provide requisite public health protection from SO_X in ambient air at that time (61 FR 25566, May 22, 1996). This decision was challenged in the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit), which found that the EPA had failed to adequately explain its determination that no revision to the primary SO_2 standards was appropriate and remanded the determination back to the EPA for further explanation. *American Lung Association* v. *EPA,* 134 F.3d 388 (D.C. Cir. 1998).

This remand was addressed in the last review of the air quality criteria and primary standards for SO_X, which was completed in 2010. In that review, the

not limited to, "effects on soils, water, crops, vegetation, manmade 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."

[4] As used here and similarly throughout this document, the term population (or group) refers to persons having a quality or characteristic in common, such as a specific pre-existing illness or a specific age or lifestage. Section II.A.2.b below describes the identification of sensitive groups (called at-risk groups or at-risk populations) in this review.

EPA promulgated a new 1-hour standard and also promulgated provisions for the revocation of the then-existing 24-hour and annual primary standards.[5] The new 1-hour standard was set with a level of 75 parts per billion (ppb), a form of the 3-year average of the annual 99th percentile of daily maximum 1-hour average SO_2 concentrations, and SO_2 as the indicator. The Administrator judged that such a standard would provide the requisite protection for at-risk populations, such as people with asthma, against the array of adverse respiratory health effects related to short-term SO_2 exposures, including those as short as 5 minutes. With regard to longer-term exposures, the new standard was expected to maintain 24-hour and annual concentrations generally well below the levels of the previous standards, and the available evidence did not indicate the need for separate standards designed to protect against longer-term exposures (75 FR 35520, June 22, 2010). The EPA also 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; [6] agencies may report all twelve 5-minute concentrations for each hour, including the maximum, although it is not required (75 FR 35568, June 22, 2010). This rule and the EPA's denial of several petitions for administrative reconsideration were challenged in the D.C. Circuit, and the court denied or dismissed on jurisdictional grounds all the claims in the petitions for review. *National Environmental Development Association's Clean Air Project* v. *EPA,* 686 F.3d 803, 805 (D.C. Cir. 2012) (''*NEDA/CAP*'').

In May 2013, the EPA initiated the current review by issuing a call for information in the **Federal Register** and also announcing a public workshop to inform the review (78 FR 27387, May 10, 2013). As was the case for the prior review, this review is focused on health effects associated with SO_X and the public health protection afforded by the existing standard. Participants in the kickoff workshop included 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, and biology). Workshop discussions focused on key policy-relevant issues around which the Agency would structure the review and the newly available scientific information related to these issues. Based in part on the workshop discussions, the EPA developed the draft Integrated Review Plan (IRP) outlining the schedule, process, and key policy-relevant questions to guide this review of the SO_X air quality criteria and primary standard (U.S. EPA, 2014b). The draft IRP was released for public comment and was reviewed by the CASAC at a public teleconference on April 22, 2014 (79 FR 14035, March 12, 2014; Frey and Diez Roux, 2014). The final IRP was developed with consideration of comments from the CASAC and the public (U.S. EPA, 2014a; 79 FR 16325, March 25, 2014; 79 FR 66721, November 10, 2014).

As an early step in development of the Integrated Science Assessment (ISA) [7] for this review, the EPA's National Center for Environmental Assessment (NCEA) hosted a public workshop at which preliminary drafts of key ISA chapters were reviewed by subject matter experts (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 first draft ISA (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 second draft ISA in December 2016 (U.S. EPA, 2016b; 81 FR 89097, December 9, 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; Diez Roux, 2017a). The final ISA was released in December 2017 (U.S. EPA, 2017a; 82 FR 58600, December 13, 2017).

In considering the need for quantitative exposure and risk analyses in this review, the EPA completed the Risk and Exposure Assessment (REA) Planning Document in February 2017 (U.S. EPA, 2017c; 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; Diez Roux, 2017b). In consideration of the CASAC's comments at that consultation and public comments, the EPA developed the draft REA and draft PA, which were released on August 24, 2017 (U.S. EPA, 2017d, e; 82 FR 43756, September 19, 2017). The draft REA and draft PA were reviewed by the CASAC on September 18–19, 2017 (82 FR 37213, August 9, 2017; Cox and Diez Roux, 2018a, b). The EPA considered the advice and comments from the CASAC on the draft REA and draft PA, as well as public comments, in developing the final REA and final PA, which were released in early May 2018 (U.S. EPA, 2018a, b).

The proposed decision (henceforth ''proposal'') to retain the primary SO_2 NAAQS was signed on May 25, 2018, and published in the **Federal Register** on June 8, 2018 (83 FR 26752). The EPA held a public hearing in Washington, DC on July 10, 2018 (83 FR 28843, June 21, 2018). At the public hearing, the EPA heard testimony from three individuals representing specific interested organizations. The transcript from this hearing and written testimony provided at the hearing are in the docket for this review. The EPA extended the 45-day comment period by 17 days, until August 9, 2018 (83 FR 28843, June 21, 2018), and comments were received from various government, industry, and environmental groups, as well as members of the general public.

The schedule for completion of this review is governed by a consent decree resolving a lawsuit filed in July 2016 that included a claim that the EPA had failed to complete its review of the primary SO_2 NAAQS within 5 years, as required by the CAA.[8] The consent decree, which was entered by the court on April 28, 2017, provides that the EPA will sign, for publication, a notice setting forth the final decision concerning its review of the primary NAAQS for SO_X no later than January

[5] Timing and related requirements for the implementation of the revocation are specified in 40 CFR 50.4(e).

[6] The rationale for this requirement was described as providing additional monitoring data for use in subsequent reviews of the primary standard, particularly for use in considering the extent of protection provided by the 1-hour standard against 5-minute peak SO_2 concentrations of concern (75 FR 35568, June 22, 2010). In establishing this requirement, the EPA described such data as being ''of high value to inform future health studies and, subsequently, future SO_2 NAAQS reviews'' (75 FR 35568, June 22, 2010).

[7] The ISA for this review provides a comprehensive assessment of the current scientific literature useful in indicating the kind of and extent of all identifiable effects on public health associated with the presence of the pollutant in the ambient air, as described in section 108 of the CAA, emphasizing information that has become available since the last air quality criteria review in order to reflect the current state of knowledge. As such, the ISA forms the scientific foundation for this NAAQS review and is intended to provide information useful in forming policy relevant judgments about air quality indicator(s), form(s), averaging time(s) and level(s) for the NAAQS. The ISA functions in the current NAAQS review process as the Air Quality Criteria Document (AQCD) did in reviews completed prior to 2009.

[8] *See* Complaint, *Center for Biological Diversity et al.* v. *Wheeler,* No. 3:16–cv–03796–VC (N.D. Cal., filed July 7, 2016), Doc. No. 1.

28, 2019, with such date to be extended automatically one day for each day of a lapse in appropriations if such a lapse were to occur within 120 days of this deadline.[9] The EPA experienced such a lapse in appropriations in late December 2018 and January 2019, which led to the automatic extension of the January 28, 2019 deadline to February 25, 2019.[10]

D. Air Quality Information

This section presents information on sources and emissions of SO_2 and ambient concentrations, with a focus on information that is most relevant for the review of the primary SO_2 standard. This section is drawn from the more detailed discussion of SO_2 air quality in the PA and the ISA. It presents a summary of SO_X sources and emissions (section I.D.1) and ambient concentrations (section I.D.2).

1. Sources and Emissions of Sulfur Oxides

Sulfur oxides are emitted into air from specific sources (*e.g.,* fuel combustion processes) and are 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.[11] Sulfur oxides known to occur in the troposphere include SO_2 and SO_3 (ISA, section 2.3). 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, 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).[12]

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).[13] 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 electricity generation, and 97% of SO_2 from electricity generation is from coal combustion. Other anthropogenic sources of SO_2 emissions include industrial fuel combustion and process emissions, industrial processing, commercial marine activity, and the use of fire in landscape management and agriculture (ISA, section 2.2.1).

National average SO_2 emissions are estimated to have declined by 82% over the period from 2000 to 2016, with a 64% decline from 2010 to 2016 (PA, Figure 2–2; 2014 National Emissions Inventory (NEI)). Such 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, the Cross-State Air Pollution Rule, and the Mercury Air Toxic Standards,[14] as well as changes in market conditions, *e.g.,* reduction in energy generation by coal (PA, section 2.1, Figure 2–2; U.S. EIA, 2017).[15] Regulations on sulfur content of diesel fuel, both fuel for onroad vehicles and nonroad engines and equipment, may also contribute to declining trends in SO_2 emissions.[16] Declines in emissions from all sources 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).

2. Ambient Concentrations

Ambient air concentrations of SO_2 in the U.S. have declined substantially from 1980 to 2016, more than 82% in terms of the form of the current standard (the 3-year average of annual 99th percentile daily maximum 1-hour concentrations) at locations continuously monitored over this period (PA, Figure 2–4).[17] The decline since 2000 has been 69% at the larger number of locations continuously monitored since that time (PA, Figure 2–5).[18]

As a result of changes to the monitoring data reporting requirements promulgated in 2010 (as summarized in section I.C above) maximum hourly 5-minute concentrations of SO_2 in ambient air are available at SO_2 NAAQS compliance monitoring sites (PA, Figure 2–3; 75 FR 35554, June 22, 2010).[19] These newly available data document reductions in peak 5-minute concentrations across the U.S. For example, over the period from 2011 to 2016, the 99th percentile 5-minute SO_2 concentrations at SO_2 sites continuously monitored during this period declined approximately 53% (PA, Figure 2–6, Appendix B).

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.,* locations influenced by emissions from EGUs). Consistent with the locations of larger SO_2 sources, higher concentrations are primarily

[9] Consent Judgment at 4, *Center for Biological Diversity et al.* v. *Wheeler,* No. 3:16–cv–03796–VC (N.D. Cal., entered April 28, 2017), Doc. No. 37.

[10] Joint Notice of Automatic Deadline Extension in Light of Lapse in Appropriations, *Center for Biological Diversity et al.* v. *Wheeler,* No. 3:16–cv–03796–VC (N.D. Cal., filed February 15, 2019), Doc. No. 39.

[11] Some sulfur compounds formed from or emitted with SO_X are very short-lived (ISA, pp. 2–23 to 2–24). For example, studies in the 1970s and 1980s identified particle-phase sulfur compounds, including inorganic SO_3^{-2} complexed with Fe(III) in the particles emitted by a smelter near Salt Lake City, UT. Subsequent studies reported rapid oxidation of such compounds, ''on the order of seconds to minutes'' and ''further accelerated by low pH'' (ISA, p. 2–24). Thus, ''[t]he highly acidic aqueous conditions that arise once smelter plume particles equilibrate with the ambient atmosphere ensure that S(IV)-Fe(III) complexes have a small probability of persisting and becoming a matter of concern for human exposure'' (ISA, p. 2–24).

[12] The health effects of particulate atmospheric transformation products of SO_X, such as sulfates, are addressed in the review of the NAAQS for PM (U.S. EPA 2014a, 2016a, 2018c).

[13] A modeling analysis estimated annual mean SO_2 concentrations for 2001 in the absence of any U.S. anthropogenic emissions of SO_2 (2008 ISA, section 2.5.3; ISA, section 2.5.5). Such concentrations are referred to as U.S. 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 (ISA, section 2.5.5).

[14] When established, the MATS Rule was estimated to reduce SO_2 emissions from power plants by 41% beyond the reductions expected from the Cross-State Air Pollution Rule (U.S. EPA, 2011).

[15] In 2014, the EPA promulgated Tier 3 Motor Vehicle Emission and Fuel Standards that set emissions standards for new vehicles and lowered the sulfur content of gasoline. Reductions in SO_2 emissions resulting from these standards are expected to be more than 14,000 tons in 2018 (U.S. EPA, 2014c).

[16] See *https://www.epa.gov/diesel-fuel-standards/diesel-fuel-standards-and-rulemakings#nonroad-diesel*.

[17] This decline is the average of observations at 24 monitoring sites that have been continuously operating from 1980–2016.

[18] This decline is the average of observations at 193 monitoring sites that have been continuously operating across 2000–2016.

[19] Such measurements were available for fewer than 10% of monitoring sites at the time of the last review. 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 (PA, section 2.2). The expanded dataset has provided a more robust foundation for the quantitative analyses in the REA for this review.

located in the eastern half of the continental U.S., especially in the Ohio River valley, upper Midwest, and along the Atlantic coast (PA, Figure 2–7). The point source nature of SO_2 emissions contributes to the relatively high spatial variability of SO_2 concentrations compared with pollutants such as ozone (ISA, section 3.2.3). Another factor in the spatial variability is the dispersion and oxidation of SO_2 in the atmosphere, processes that contribute to decreasing concentrations with increasing distance from the source. Point source emissions of sulfur oxides create a plume of appreciably higher concentrations in the air, which may or may not impact large portions of the surrounding populated areas depending on specific source characteristics, meteorological conditions and terrain.

Analyses in the ISA of ambient air monitoring data for 2013–2015 in six areas 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).[20] This seasonal variation as well as month-to-month variations are generally consistent with month-to-month emissions patterns and the expected atmospheric chemistry of SO_2 for a given season. 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 all six areas evaluated 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 sites evaluated in the ISA were likely related to a combination of source emissions and meteorological parameters (ISA, section 2.5.3.3; 2008 ISA [U.S. EPA 2008a], section 2.5.1).

II. Rationale for Decision

This section presents the rationale for the Administrator's decision to retain the existing primary SO_2 standard. This decision is based on a thorough review in the ISA of the latest scientific information, published through August 2016 (ISA, p. xlii), on human health effects associated with SO_X in ambient air. This decision also accounts for analyses in the PA of policy-relevant information from the ISA and the REA, as well as information on air quality; the analyses of human exposure and health risks in the REA; CASAC advice; and consideration of public comments received on the proposal.

Section II.A provides background on the general approach for this review and the basis for the existing standard, and also presents brief summaries of key aspects of the currently available health effects and exposure/risk information. Section II.B summarizes the proposed conclusions and CASAC advice, addresses public comments received on the proposal and presents the Administrator's conclusions on the adequacy of the current standard, drawing on consideration of this information, advice from the CASAC, and comments from the public. Section II.C summarizes the Administrator's decision on the primary standard.

A. Introduction

As in prior reviews, the general approach to reviewing the current primary standard is based, most fundamentally, on using the EPA's assessment of current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding a primary SO_2 standard that protects public health with an adequate margin of safety. In drawing conclusions with regard to the primary standard, the final decision on the adequacy of the current standard is largely a public health policy judgment to be made by the Administrator. The Administrator's final decision draws upon scientific information and analyses about health effects, population exposure and risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and exposure/risk analyses. The approach to informing these judgments, discussed more fully below, is based on the recognition that the available health effects evidence generally reflects a continuum, consisting of 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. This approach is consistent with the requirements of the NAAQS provisions of the Clean Air Act and with how the EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish primary standards that, in his 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 avoids unacceptable risks to public health including the health of sensitive groups.[21] The four basic elements of the NAAQS (indicator, averaging time, level, and form) are considered collectively in evaluating the health protection afforded by a standard.

In evaluating the appropriateness of retaining or revising the current primary SO_2 standard, the EPA has adopted an approach that builds upon the general approach used in the last review and reflects the body of evidence and information now available. As summarized in section II.A.1 below, the Administrator's decisions in the prior review were based on an integration of information on health effects associated with exposure to SO_2 with information on the public health significance of key health effects, as well as on policy judgments as to when the standard is requisite to protect public health with an adequate margin of safety and on consideration of advice from the CASAC and public comments. These decisions were also informed by air quality and related analyses and quantitative exposure and risk information.

Similarly, in this review, as described in the PA, the proposal, and elsewhere in this document, we draw on the current evidence and quantitative assessments of exposure and risk pertaining to the public health risk of SO_2 in ambient air. The past and current approaches are both based, most fundamentally, on the EPA's assessments of the current scientific evidence and associated quantitative analyses. The EPA's assessments are primarily documented in the ISA, REA and PA, all of which have received CASAC review and public comment (80 FR 73183, November 24, 2015; 80 FR 79330, December 21, 2015; 81 FR 89097, December 9, 2016; 82 FR 11356, February 22, 2017; 82 FR 11449, February 23, 2017; 82 FR 23563, May 23, 2017; 82 FR 37123, August 9, 2017; 82 FR 43756, September 19, 2017; 83 FR 14638, April 5, 2018). To bridge the gap between the scientific assessments of the ISA and REA and the judgments required of the Administrator in determining whether the current standard remains requisite to protect

[20] The six "focus areas" evaluated in the ISA are: Cleveland, OH; Pittsburgh, PA; New York City, NY; St. Louis, MO (and neighboring areas in IL); Houston, TX; and Gila County, AZ (ISA, section 2.5.2.2). These six locations were selected 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.

[21] As noted in section I.A above, such protection is specified for the sensitive group of individuals and not to a single person in the sensitive group (see S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 [1970]).

public health with an adequate margin of safety, the PA evaluates the policy implications of the current evidence in the ISA and of the quantitative analyses in the REA.

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 most particularly that which has been critically analyzed and characterized in the current ISA. We additionally consider the quantitative exposure and risk information described in the REA that estimated SO_2-related exposures and lung function decrements associated with air quality conditions just meeting the current standard in simulated at-risk populations in multiple case study areas (REA, chapter 5). The evidence-based discussions presented below (and summarized more fully in the proposal) draw upon evidence from studies evaluating health effects related to exposures to SO_2, as discussed in the ISA. The exposure/risk-based discussions also presented below (and summarized more fully in the proposal) have been drawn from the quantitative analyses for SO_2, as discussed in the REA. Sections II.A.2 and II.A.3 below provide an overview of the current health effects and quantitative exposure and risk information with a focus on the specific policy-relevant questions identified for these categories of information in the PA (PA, chapter 3).

1. Background on the Current Standard

The current primary standard was established in the last review of the primary NAAQS for SO_X, which was completed in 2010 (75 FR 35520, June 22, 2010). The decision in that review to revise the primary standards (establishing a 1-hour standard and providing for revocation of the 24-hour and annual standards) reflected the extensive body of evidence of respiratory effects in people with asthma, which has expanded over the four decades since the first SO_2 standards were established in 1971 (U.S. EPA, 1982, 1986, 1994, 2008a). This evidence was assessed in the 2008 ISA.

A key element of the expanded evidence base was a series of controlled human exposure studies documenting effects on lung function associated with bronchoconstriction in people with asthma exposed while breathing at elevated rates [22] for periods as short as minutes (U.S. EPA, 1982, 1986, 1994, 2008a). Another aspect of the information available in the 2010 review was the air quality database, which had expanded since the previous review (completed in 1996), and which provided data on the pattern of peak 5-minute SO_2 concentrations occurring at that time. The EPA used these data in the 2009 quantitative exposure and risk assessments to provide an up-to-date ambient air quality context for interpreting the health effects evidence. In addition to providing support for decisions in the 2010 review, these aspects of that review provided support to the EPA in addressing the issues raised in the court remand of the Agency's 1996 decision not to revise the standards to specifically address 5-minute exposures with that decision (75 FR 35523, June 22, 2010). Together, the evidence characterized in the 2008 ISA, which included epidemiologic and animal toxicologic studies as well as the extensive set of controlled human exposure studies, and the quantitative assessments in the 2009 REA, as well as advice from the CASAC and public comment, formed the basis for the EPA's 2010 action to strengthen the primary NAAQS for SO_X to provide the requisite protection of public health with an adequate margin of safety, and to provide increased protection for at-risk populations, such as people with asthma (75 FR 35550, June 22, 2010).

Thus, the 2010 decision focused on the effects most pertinent to SO_X in ambient air and recognized the long-standing evidence regarding the sensitivity of some people with asthma to brief SO_2 exposures experienced while breathing at elevated rates. The robust evidence base, comprised of findings from controlled human exposure, epidemiologic, and animal toxicological studies, was judged "sufficient to infer a causal 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 5.3). Supporting evidence was provided by epidemiologic studies of associations of a broader range of health outcomes with ambient air concentrations of SO_2, with uncertainty noted about the magnitude of the study effect estimates, quantification of the concentration-response relationship, potential confounding by copollutants, and other aspects (75 FR 35535–36, June 22, 2010; 2008 ISA, section 5.3).

Accordingly, conclusions reached in the last review were based primarily on consideration of the health effects evidence for short-term exposures, and particularly on interpretation of the evidence from controlled human exposure studies within the context of the quantitative exposure and risk analyses. The epidemiologic evidence also provided support for various aspects of the decision. In making judgments on the public health significance of health effects related to short-term ambient air-related SO_2 exposures, the Administrator considered statements from the American Thoracic Society (ATS) regarding adverse effects of air pollution,[23] the CASAC's written advice and comments,[24] and judgments made by the EPA in considering similar effects in previous NAAQS reviews (75 FR 35526 and 35536, June 22, 2010; ATS, 1985, 2000a). Based on these considerations, the Administrator, in 2010, gave weight to the findings of respiratory effects in exercising people with asthma after 5- to 10-minute exposures as low as 200 ppb, and further recognized that higher exposures (at or above 400 ppb) were associated with respiratory symptoms and with a greater number of study subjects experiencing lung function decrements. Moreover, she took note of the greater severity of the response at and above 400 ppb, recognizing effects associated

[22] The phrase "elevated ventilation" (or "moderate or greater exertion") was used in the 2009 REA and **Federal Register** notifications in the last review to refer to activity levels in adults that 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 (U.S. EPA, 2009, section 4.1.4.4). Accordingly, these phrases are used in the current review when referring to REA analyses from the last review. Otherwise, however, the documents for this review generally use the phrase "elevated breathing rates" in place of those phrases.

[23] The 1999 statement of the ATS (published in 2000) on "What Constitutes an Adverse Health Effect of Air Pollution?" is "intended to provide guidance to policy makers and others who interpret the scientific evidence on the health effects of air pollution for the purpose of risk management" and describes "principles to be used in weighing the evidence" when considering what may be adverse and nonadverse effects on health (ATS, 2000a). For example, the ATS statements recognized a distinction between reversible and irreversible effects, recommending that reversible loss of lung function in combination with the presence of symptoms be considered adverse (ATS 1985, 2000a; 75 FR 35526, June 22, 2010).

[24] For example, 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).

with exposures as low as 200 ppb to be less severe (75 FR 35547, June 22, 2010).

As a result and based on consideration of the entire body of evidence and information available in the review, with particular attention to the exposure and risk estimates from the 2009 REA, as well as the advice from the CASAC and public comments, the Administrator concluded that the then-existing 24-hour standard did not adequately protect public health (75 FR 35536, June 22, 2010). The 2009 REA estimated that substantial percentages of children with asthma might be expected to experience exposures at least once annually that had been associated with moderate or greater lung function decrements[25] in the controlled human exposure studies (75 FR 35536, June 22, 2010). The Administrator judged that such exposures can result in adverse health effects in people with asthma and found that the estimated population frequencies for such exposures (24% of the at-risk population with at least one occurrence per year at or above 400 ppb and 73% with at least one occurrence per year at or above 200 ppb) were significant from a public health perspective and that the then-existing primary standards did not adequately protect public health (75 FR 35536, June 22, 2010).[26] In order to provide the requisite protection to people with asthma from the adverse health effects of 5-minute to 24-hour SO_2 exposures, she replaced the 24-hour standard with a new, 1-hour standard (75 FR 35536, June 22, 2010). Further, upon reviewing the evidence with regard to the potential for effects from long-term exposures,[27] the Administrator revoked the annual standard based on her recognition of the lack of sufficient health evidence to support a long-term standard and on air quality information indicating that the new short-term standard 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 Administrator selected a 1-hour averaging time for the new standard based on available air quality analyses in the REA that indicated that a 1-hour averaging time would be effective in addressing 5-minute peak SO_2 concentrations such 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).[28] The analyses suggested that, compared to a 24-hour averaging time, a 1-hour averaging time would more efficiently and effectively limit 5-minute peak concentrations 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 (2009 REA, section 10.5.2.2; 75 FR 35539, June 22, 2010). The analyses 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 effects, while the longer averaging time was shown to lack effectiveness and efficiency in addressing 5-minute peak SO_2 concentrations, likely over-controlling in some areas while under-controlling in others (75 FR 35539, June 22, 2010; 2009 REA, section 10.5.2.2). The CASAC additionally advised that "a one-hour standard is the preferred averaging time" (Samet, 2009, pp. 15, 16), finding the REA to provide a "convincing rationale" that supported "a one-hour standard as protective of public health" (Samet, 2009, pp. 1, 15 and 16). Thus, in consideration of the available information summarized here and CASAC advice, the Administrator judged that a 1-hour standard (given the appropriate level and form) was the appropriate means for controlling short-term exposures to SO_2 ranging from 5 minutes to 24 hours (75 FR 35539, June 22, 2010).

The statistical form for the 1-hour standard, the 99th percentile daily maximum 1-hour average concentrations averaged over 3 years, is based on consideration of the health effects evidence, stability in the public health protection provided by the programs implementing the standard, and advice from the CASAC, as well as results of the 2009 REA for alternative standard forms (75 FR 35541, June 22, 2010). With regard to stability, the concentration-based form averaged over 3 years was concluded to 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 Administrator's objective in selecting the specific concentration-based form was for the form of the new standard to be especially focused on limiting the upper end of the distribution of ambient SO_2 concentrations (*i.e.,* above 90th percentile SO_2 concentrations) in order to provide protection with an adequate margin of safety against effects observed in controlled human exposure studies and associated with ambient air SO_2 concentrations in epidemiologic studies (75 FR 35541, June 22, 2010). Based on results of air quality and exposure analyses in the REA which indicated the 99th percentile form likely to be appreciably more effective at achieving the desired control of 5-minute peak exposures than a 98th percentile form, the Administrator decided the form should be the 99th percentile of daily maximum 1-hour concentrations averaged over 3 years (75 FR 35541, June 22, 2010).

The level for the new standard was set primarily based on consideration of the findings of the 2009 REA exposure analyses with regard to the varying degrees of protection that different levels of a 1-hour daily maximum SO_2 standard might be expected to provide against 5-minute exposures to concentrations of 200 ppb and 400 ppb.[29] For example, the single-year

[25] In assessments for NAAQS reviews, the magnitude of lung function responses described as indicative of a moderate response include increases in specific airway resistance (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 forced expiratory volume in 1 second (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 was also consistent with the relationship observed between sRaw and FEV_1 responses in the Linn et al. studies (1987, 1990) 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).

[26] In giving particular attention to the exposure and risk estimates from the 2009 REA for air quality just meeting the then-existing standards, the Administrator also noted epidemiologic study findings of associations with respiratory-related health outcomes in studies of locations where maximum 24-hour average SO_2 concentrations were below the level of the then-existing 24-hour standard, while also recognizing uncertainties associated with the epidemiologic evidence (75 FR 35535–36, June 22, 2010).

[27] 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; 2008 ISA, p. 3–1).

[28] The Administrator 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). 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).

[29] The Administrator additionally noted the results of the analysis of the limited available air quality data for 5-minute SO_2 concentrations with regard to prevalence of higher 5-minute concentrations at monitor sites when data were adjusted to just meet a standard level of 100 ppb. This 40-county analysis, which compared 5-minute concentrations estimated to occur in these air quality scenarios to benchmark levels, indicated for a 1-hour standard level of 100 ppb, there would be a maximum annual average of 2 days per year with 5-minute concentrations above 400 ppb and 13 days with 5-minute concentrations above 200 ppb (75 FR 35546, June 22, 2010).

exposure assessment for St. Louis [30] 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 exertion (75 FR 35546–47, June 22, 2010). The St. Louis study area results for the air quality scenario representing a 1-hour standard level of 50 ppb suggested that such a standard would 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, June 22, 2010). In considering the implications of these estimates, and the substantial reduction in 5-minute exposures at or above 200 ppb, the Administrator did not judge that a standard level as low as 50 ppb [31] was warranted (75 FR 35547, June 22, 2010). Before reaching her conclusion with regard to level for the 1-hour standard, the Administrator additionally considered the epidemiologic evidence, placing relatively more weight on those 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 or hospital admissions related to asthma or other respiratory symptoms, and noting a cluster of three studies for which 99th percentile 1-hour daily maximum concentrations were estimated to be between 78–150 ppb and for which the SO_2 effect estimate remained positive and statistically significant in copollutant models with PM (75 FR 35547–48, June 22, 2010).[32]

Based on the above considerations and the comments received on the proposal, advice from the CASAC, the entire body of evidence and information available in that review, and the related uncertainties,[33] the Administrator selected a standard level of 75 ppb. She concluded that such a standard, with a 1-hour averaging time and 99th percentile form, would provide an increase in public health protection compared to the then-existing standards and would be expected to provide the desired degree of protection against the respiratory effects elicited by SO_2 exposures in controlled human exposure studies and associated with ambient air concentrations in epidemiologic studies (75 FR 35548, June 22, 2010).[34] The Administrator emphasized the latter in judging that the level of 75 ppb provided an adequate margin of safety (75 FR 35548, June 22, 2010). Thus, she concluded that a NAAQS for SO_X of 75 ppb, as the 99th percentile of daily maximum 1-hour average SO_2 concentrations averaged over 3 years, would provide the requisite protection of public health with an adequate margin of safety (75 FR 35547–35548, June 22, 2010).

2. Overview of Health Effects Evidence

In this section, we provide an overview of the policy-relevant aspects of the health effects evidence available for consideration in this review. Section II.B of the proposal provides a detailed summary of key information contained in the ISA and in the PA on the health effects associated with SO_2 exposures, and the related public health implications, focusing particularly on the information most relevant to consideration of effects associated with the presence of SO_2 in ambient air (83 FR 26761, June 8, 2018). The subsections below briefly outline this information in the four topic areas addressed in section II.B of the proposal.

a. Nature of Effects

Sulfur dioxide is a highly reactive and water-soluble gas that once inhaled is absorbed almost entirely in the upper respiratory tract [35] (ISA, sections 4.2 and 4.3). Brief exposures to SO_2 can elicit respiratory effects, particularly in individuals with asthma when breathing at elevated rates (ISA, p. 1–17). Under conditions of elevated breathing rates (*e.g.,* while exercising), SO_2 penetrates the upper respiratory tract, entering the tracheobronchial region,[36] where, in sufficient concentration, it results in responses linked to asthma exacerbation in individuals with asthma (ISA, sections 4.2, 4.3, and 5.2). People with asthma have an increased propensity for the airways to narrow in response to certain inhaled stimuli, as compared to people without asthma or allergies (ISA, section 5.2.1.2).[37] This narrowing or constriction of the airways in the respiratory tract, termed bronchoconstriction, is characteristic of an asthma attack and is the most sensitive indicator of SO_2-induced lung function effects (ISA, p. 5–8). Bronchoconstriction causes an increase in airway resistance, often assessed by measurement of specific airway resistance (sRaw). Exercising individuals without asthma have also been found to exhibit increased sRaw or related responses, such as reduced forced expiratory volume in 1 second (FEV_1), but at much higher SO_2

[30] Of the two study areas assessed in the 2009 REA (St. Louis and Greene County, Missouri), the EPA considered the St. Louis results to be more informative to consideration of the adequacy of protection associated with the then-current and alternative standards (75 FR 35528, June 22, 2010; 74 FR 64840, December 8, 2009). The St. Louis study area included several counties and had population size and magnitudes of emissions density (on a spatial scale) similar to other urban areas in the U.S., while the second study area (Greene County, Missouri) was a rural county with much lower population and emissions density.

[31] In the 2009 REA results for the St. Louis single year scenario with a level of 50 ppb (the only level below 100 ppb that was analyzed), 99.9% of children with asthma would be expected to be protected from a day with a 5-minute exposure at or above 200 ppb, and 100% from a day with a 5-minute exposure at or above 400 ppb (2009 REA, Appendix, p. B–62).

[32] 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).

[33] Such uncertainties included both those with regard to the epidemiologic evidence, including potential confounding and exposure measurement error, and also those with regard to the information from controlled human exposure studies for at-risk groups, including the extent to which the results would be expected to be similar for individuals with more severe asthma than that in study subjects (75 FR 35546, June 22, 2010).

[34] For example, such a standard was 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" and also was "expected to substantially limit asthmatics' exposure to 5–10 minute SO_2 concentrations ≥200 ppb, thereby substantially limiting the adverse health effects associated with such exposures" (75 FR 35548, June 22, 2010).

[35] 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).

[36] 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, bronchi, and bronchioles.

[37] The propensity for airways to narrow following inhalation of some stimuli is termed bronchial or airway responsiveness (ISA, section 5.2.1.2, p. 5–8). In clinical situations where airway responsiveness to methacholine or histamine is assessed and the concentration resulting in a specific reduction in lung function (the provocative concentration) meets the ATS criteria for classification of the subject as hyperresponsive, the terms airway hyperresponsiveness (AHR) or bronchial hyperresponsiveness (BHR) are used (ATS, 2000b). Along with symptoms, variable airway obstruction, and airway inflammation, AHR (or BHR) is a primary feature in the clinical definition and characterization of asthma severity (ISA, section 5.2.1.2; Reddel et al., 2009).

exposure concentrations than exercising individuals with asthma (ISA, section 5.2.1.7). For example, the ISA finds that ''healthy adults are relatively insensitive to the respiratory effects of SO_2 below 1 ppm'' (ISA, p. 5–9).

Based on assessment of the currently available evidence, as in the last review, the ISA concludes that there is a causal relationship between short-term SO_2 exposures (as short as a few minutes) and respiratory effects (ISA, section 5.2.1). The clearest evidence comes from the long-standing evidence base of controlled human exposure studies demonstrating effects related to asthma exacerbation including lung function decrements [38] and respiratory symptoms (*e.g.,* cough, shortness of breath, chest tightness and wheeze) in people with asthma exposed to SO_2 for 5 to 10 minutes at elevated breathing rates (U.S. EPA, 1994; 2008 ISA; ISA, section 5.2.1). Bronchoconstriction, evidenced by decrements in lung function, that are sometimes accompanied by respiratory symptoms, occurs in these studies 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). In contrast, respiratory effects are not generally observed in other people with asthma (nonresponders [39]) and healthy adults exposed to SO_2 concentrations below 1000 ppb while exercising (ISA, sections 5.2.1.2 and 5.2.1.7). Across studies, bronchoconstriction in response to SO_2 exposure is seen during respiratory conditions of elevated breathing rates, such as exercise, or with mouthpiece exposures that involve laboratory-facilitated rapid, deep breathing.[40] With these breathing conditions, breathing shifts from nasal breathing to oral (with mouthpiece) or oronasal breathing, which increases the concentrations of SO_2 reaching the tracheobronchial 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 current evidence base of controlled human exposure studies of individuals with asthma,[41] is consistent with the evidence base from the last review, and is summarized in the ISA (ISA, section 5.2.1.2, Tables 5–1 and 5–2). With regard to effects related to asthma exacerbation, 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 recognized in the last review, the results of these studies indicate that among individuals with asthma, some individuals (*e.g.,* responders) 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 just a few minutes) when individuals are exposed while breathing at an elevated rate, and is transient, with recovery occurring with a return to resting breathing rate or cessation of exposure, generally within an hour (ISA, p. 5–14, Table 5–2; Linn et al., 1984; Johns et al., 2010).

The currently available epidemiologic evidence includes studies reporting positive associations with short-term SO_2 exposures for asthma-related hospital admissions of children or emergency department visits by children (ISA, section 5.2.1). These findings provide supporting evidence of the EPA's conclusion of a causal relationship between short-term SO_2 exposures and respiratory effects, for which the controlled human exposure studies are the primary basis (ISA, section 5.2.1.9). Among the epidemiologic studies newly available in this review, there are a limited number that have investigated SO_2 effects related to asthma exacerbation, with the most supportive evidence coming from studies of asthma-related hospital admissions of children or emergency department visits by children (ISA, section 5.2.1.2). As in the last review, areas of uncertainty in the epidemiologic evidence are related to the characterization of exposure based on the use of ambient air concentrations at fixed site monitors 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 [42] 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).

For long-term SO_2 exposure and respiratory effects, the evidence base is somewhat augmented since the last review such that the current ISA 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 epidemiologic 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). 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, sections 1.6.1.2 and 5.2.2.7). Further, there are uncertainties associated with the epidemiologic evidence across the respiratory effects examined for long-term exposure (ISA, section 5.2.2.7).

For effects other than those involving the respiratory system, the current evidence is generally similar to the evidence available in the last review and leads to similar conclusions about the totality of adverse health effects. With regard to a relationship between short-term SO_2 exposure and total mortality, the ISA reaches the same conclusion as 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 the findings of previously and newly available multicity epidemiologic studies that report positive associations, accompanied by uncertainty with respect to the potential for SO_2 to have an independent effect on mortality. While recent studies have analyzed some key uncertainties and addressed data gaps from the previous review, uncertainties still exist. These uncertainties include that: The number of studies that examined copollutant confounding is limited; there is evidence of a reduction in the SO_2-mortality effect estimates (*i.e.,* relative risks) in copollutant models with

[38] The specific responses reported in the evidence base that are described in the ISA as lung function decrements are increased sRaw and FEV_1 (ISA, section 5.2.1.2).

[39] The data from controlled human exposure studies of people with asthma indicate that there are two subpopulations that differ in their airway responsiveness to SO_2, with the second subpopulation (non-responders) being insensitive to SO_2 bronchoconstrictive effects at concentrations as high as 1000 ppb (ISA, pp. 5–14 to 5–21; Johns et al., 2010).

[40] Laboratory-facilitated rapid deep breathing involves rapid, deep breathing through a mouthpiece that provides a mixture of oxygen with enough carbon dioxide to prevent an imbalance of gases in the blood usually resulting from hyperventilation. Breathing in the laboratory with this technique is referred to as eucapnic hypernea (ISA, p. 5–6).

[41] The subjects in these studies have primarily been adults. The exception has been a few studies conducted in adolescents aged 12 to 18 years of age (ISA, pp. 5–22 to 5–23; PA, sections 3.2.1.3 and 3.2.1.4).

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

nitrogen dioxide and PM with mass median aerodynamic diameter nominally below 10 microns (PM_{10}); and a potential biological mechanism for mortality following short-term SO_2 exposures is lacking (ISA, section 1.6.2.4).

For other categories of health effects,[43] the currently available 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, the potential for 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 (ISA, p. xlviii).

Thus, given the strength of the evidence supporting the conclusion of a causal relationship between short-term exposure to SO_2 in ambient air and respiratory effects, in particular, asthma exacerbation in individuals with asthma, the focus in this review, as in prior reviews, is on such effects.

b. At-Risk Populations

In this review, we use the term ''at-risk populations'' to recognize populations with a quality or characteristic in common (*e.g.,* a specific pre-existing illness or specific age or lifestage) that contributes to them having a greater likelihood of experiencing SO_2-related health effects. People with asthma are at increased risk for SO_2-related health effects, specifically for respiratory effects, and specifically asthma exacerbation elicited by 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, as was the case in 2010, is based on the well-established and well-characterized evidence from controlled human exposure studies, supported by the evidence related to mode of action for SO_2 and evidence from epidemiologic studies (ISA, sections 5.2.1.2 and 6.3.1). Further, some individuals with asthma have a greater response to SO_2 than others with similar disease status (ISA, section 5.2.1.2; Horstman et al., 1986; Johns et al., 2010). The ISA also finds the evidence to be suggestive of increased risk for children and older adults, while noting some limitations and inconsistencies (ISA, sections 6.5.1.1 and 6.5.1.2).[44] Children with asthma, however, 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, as summarized in section II.B of the proposal, that may put children with asthma at greater risk of SO_2-related bronchoconstrictive effects than adults with asthma.[45]

The finding that some individuals with asthma have a greater response to SO_2 than others with similar disease status is quantitatively analyzed in a study, newly available in this review, that examined differences in lung function response using individual subject data available from five studies of individuals with asthma exposed to multiple concentrations of SO_2 for 5 to 10 minutes while breathing at elevated rates (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). In analyses focused on the more sensitive subpopulation, the study demonstrated statistically significant increases in bronchoconstriction with exposures as low as 0.3 ppm (Johns et al., 2010). While such information provides documentation that some individuals with asthma have a greater response to SO_2 than others, the factors contributing to this greater susceptibility are not yet known (ISA, pp. 5–14 to 5–21).

c. Exposure 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. These studies in individuals with asthma exposed to SO_2 for 5 to 10 minutes while breathing at elevated rates demonstrate clear and consistent increases in magnitude and occurrence of decrements in lung function (*e.g.,* increased sRaw and reduced FEV_1) and in occurrence of respiratory symptoms with increasing SO_2 exposure (ISA, section 1.6.1.1, Table 5–2 and pp. 5–35, 5–39). Further, the evidence base demonstrates the occurrence of SO_2-related effects resulting from peak exposures on the order of minutes [46] and other short-term exposures have been found to elicit a similar bronchoconstrictive response for somewhat longer (*e.g.,* 30-minute) exposure durations (ISA, p. 5–14; Kehrl et al., 1987).

The controlled human exposure studies of people with asthma further demonstrate [47] that SO_2 concentrations as low as 200 to 300 ppb for 5 to 10 minutes elicited moderate or greater lung function decrements (a decrease in FEV_1 of at least 15% or an increase in sRaw of at least 100%) in a subset of the study subjects (ISA, sections 1.6.1.1 and 5.2.1). The percent of individuals affected, the severity of response, and the accompanying occurrence of respiratory symptoms increased with increasing SO_2 exposure concentrations (ISA, section 5.2.1). At concentrations ranging from 200 to 300 ppb, the lowest levels for which the ISA describes the occurrence of moderate or greater SO_2-related lung function decrements, as many as 33% of exercising study subjects with asthma experienced such decrements in lung function (ISA,

[43] 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 exposures (ISA, section 1.6.2 and Table 1–1).

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

[45] There are few controlled human exposure studies to inform our understanding of any differences in exposure concentrations associated with bronchoconstrictive effects in young children as compared to adults or adolescents as those studies have not included subjects younger than 12 years (ISA, p. 5–22). The ISA does not find the evidence to be adequate to conclude differential risk status for subgroups of children with asthma (ISA, sections 6.5.1.1 and 6.6). In consideration of the limited information regarding factors related to breathing habit, however, the ISA suggests that children with asthma approximately 5 to 11 years of age, 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, pp. 5–36 and 4–7).

[46] While the air quality metrics in the epidemiologic studies are for time periods longer than the 5- to 10-minute exposures eliciting effects in the controlled human exposure studies, these studies may not adequately capture the spatial and temporal variation in SO_2 concentrations and cannot address whether observed associations of asthma-related emergency room visits or hospital admissions with 1-hour to 24-hour ambient air concentration metrics are indicative of a potential response to exposure on the order of hours or much shorter-term exposure to peaks in SO_2 concentration (ISA, pp. 5–49, 5–59, 5–25).

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

section 5.2.1, Table 5–2).[48] At concentrations at or above 400 ppb, moderate or greater decrements in lung function occurred in as many as approximately 30 to 60% of exercising individuals with asthma, and compared to the results for exposures at 200 to 300 ppb, a larger percentage of individuals with asthma experienced the 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) at these higher concentrations (ISA, section 5.2.1.2, p. 5–9 and Table 5–2). Additionally, at concentrations at or above 400 ppb, moderate or greater decrements in lung function were frequently accompanied by respiratory symptoms, such as cough, wheeze, chest tightness, or shortness of breath, with some of these findings reaching statistical significance at the study group level (ISA, Table 5–2 and section 5.2.1).

Two hundred ppb is the lowest exposure concentration for which individual study subject data for percent changes in sRaw and FEV_1 are available from studies that have assessed the SO_2 effect *versus* the effect of exercise in clean air (ISA, Table 5–2 and Figure 5–1). In nearly all of these studies (and all of these studies with such data for concentrations from 200 to 400 ppb), study subjects breathed freely (*e.g.,* without using a mouthpiece).[49] In studies that tested 200 ppb exposures, 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% (ISA, Table 5–2 and Figure 5–2; PA, Table 3–1; Linn et al., 1983a; Linn et al., 1987).

With regard to exposure concentrations below 200 ppb, very limited evidence is available for concentrations as low as 100 ppb. Some differences in methodology and the reporting of results complicate comparison of the studies with 100 ppb exposure to studies using higher exposures. In the studies evaluating the 100 ppb concentration level, 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; ISA, section 5.2.1.2; PA, section 3.2.1.3). Additionally, only a few of these studies included an exposure to clean air while exercising that would have allowed for distinguishing the effect of SO_2 from the effect of exercise in causing bronchoconstriction (Sheppard et al., 1981; Sheppard et al., 1984; Koenig et al., 1989). In those few 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 exposures of 200 ppb or more.[50] [51] Thus, while the studies evaluating 100 ppb exposures are limited and their interpretation is complicated by the use of different reporting of results and exposure methods that differ from those used in studies of higher concentrations, the 100 ppb studies do not indicate that exposure at 100 ppb results in as much as a doubling in sRaw, based on the extremely few adults and adolescents tested (Sheppard et al., 1981; Sheppard et al., 1984; Koenig et al., 1989).

Specific exposure concentrations that may be eliciting respiratory responses are not available from the epidemiologic evidence base, which includes studies that find associations with outcomes such as asthma-related emergency department visits and hospital admissions. For example, in noting limitations of epidemiologic studies with regard to uncertainties in SO_2 exposure estimates, the ISA recognized that "[it] is unclear whether SO_2 concentrations at the available fixed site monitors adequately represent variation in personal exposures especially if peak exposures are as important as indicated by the controlled human exposure studies" (ISA, p. 5–37). This extends the observation of the 2008 ISA that "it is possible that these epidemiologic associations are determined in large part by peak exposures within a 24-h[our] period" (2008 ISA, p. 5–5). Another key uncertainty in the epidemiologic evidence available in this review, as in the last review, is potential confounding by copollutants, particularly PM, given the important role of SO_2 as a precursor to PM in ambient air (ISA, p. 5–5). Among the U.S. epidemiologic studies reporting mostly positive and sometimes statistically significant associations between ambient SO_2 concentrations and emergency department visits or hospital admissions (some conducted in multiple locations), few studies have attempted to address the uncertainty of potential copollutant confounding. 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. No additional such studies have been newly identified in this review that might inform this issue (83 FR 26765, June 8, 2018). Thus, such uncertainties regarding copollutant confounding, as well as exposure measurement error, remain in the currently available epidemiologic evidence base (ISA, p. 5–6).

d. Potential Impacts on Public Health

In general, the magnitude and implications of potential impacts on public health are dependent upon the type and severity of the effect, as well as the size and other features of the population affected (ISA, section 1.7.4; PA, 3.2.1.5). The information discussed in this section indicates the potential for exposures to SO_2 in ambient air to be of 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 provide the requisite public health protection for at-risk populations from short-term exposures of concern.

The potential public health impacts of SO_2 concentrations in ambient air relate to respiratory effects of short-term exposures and particularly those effects

[48] Additionally, analyses of data from the full set of these studies that focused only on the results for the study subjects that are responsive to SO_2 at exposure concentrations below 1000 ppb found there to be statistically significant increases in lung function decrements occurring at 300 ppb (ISA, p. 153; Johns et al., 2010).

[49] 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).

[50] For example, although individual study subject data for SO_2-attributable changes in sRaw in these studies are not available in the terms needed to summarize the responses consistent with the study result summaries in the ISA, Table 5–2 (*e.g.,* percent change), 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 eight study subjects experienced as much as a doubling in sRaw in response to the mouthpiece exposure to 125 ppb while exercising (in Table 2 of Sheppard et al., 1984, concentrations calculated to cause a doubling of sRaw in all subjects are higher than 125 ppb, the lowest exposure concentration). In the study of adolescents (aged 12 to 18 years), among the three individual study subjects for which total respiratory resistance appears to have increased with SO_2 exposure, the magnitude of increase in that metric after consideration of the response to exercise appears to be less than 100% in each subject (Koenig et al., 1989).

[51] 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 the tracheobronchial airways (2008 ISA, p. 3–4; ISA, section 4.1.2.2). This allowance of deeper penetration of SO_2 into the tracheobronchial airways, 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., 1983b).

associated with asthma exacerbation in people with asthma. As summarized above in section II.A.2.a, these effects include bronchoconstriction resulting in decrements in lung function and elicited by short-term exposures during periods of elevated breathing rate. Consistent with these SO_2-related effects, asthma-related health outcomes such as emergency department visits and hospital admissions have been positively associated with ambient air concentrations of SO_2 in epidemiologic studies (ISA, section 5.2.1.9).

As summarized in section II.A.2.b above, people with asthma are the population at risk for SO_2-related effects and children with asthma are considered to be at relatively greater risk than other age groups (ISA, section 6.3.1). The evidence supporting this conclusion comes primarily from studies of individuals with mild to moderate asthma,[52] with very little evidence available for individuals with severe asthma. The evidence base of controlled human exposure studies of exercising people with asthma provides very limited information indicating that there are similar responses (in terms of relative decrements in lung function in response to SO_2 exposures) across individuals with asthma of differing severity.[53] 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). Consideration of such baseline differences among members of at-risk populations and of the relative transience or persistence of these responses (*e.g.,* as noted in section II.A.2.a above), as well as other factors, is important to characterizing implications for public health, as recognized by the ATS in their recent statement on evaluating adverse health effects of air pollution (Thurston et al., 2017).

Multiple statements by the ATS on what constitutes an adverse health effect of air pollution inform the Administrator's judgment on the public health significance of SO_2-related effects, particularly those with the potential to occur under air quality conditions allowed by the current standard. Building on the earlier statement by the ATS that was considered in the last review (ATS, 2000a), the recent policy statement by the ATS provides a general framework for interpreting evidence that proposes 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 could put its members at potentially increased risk of effects from another agent (ATS, 2000a). The consideration of effects on individuals with preexisting diminished lung function continues to be recognized as important in the more recent ATS statement (Thurston et al., 2017). All of these concepts, including the consideration of the magnitude or severity of effects occurring in just a subset of study subjects, as well as the consideration of persistence or transience of effects,[54] are recognized as important considerations in the more recent ATS statement (Thurston et al., 2017) and continue to be relevant to consideration of the evidence base for SO_2.

Such concepts are routinely considered by the Agency in weighing public health implications for decisions on primary NAAQS, as summarized in section I.A above. For example, in deliberations on a standard that provides the requisite public health protection under the Act, the EPA traditionally recognizes the nature and severity of the health effects involved, recognizing the greater public health significance of more severe health effects, including, for example, responses that have been documented to be accompanied by respiratory symptoms, and of the risk of repeated occurrences of effects (76 FR 54308, August 31, 2011; 80 FR 65292, October 26, 2015). Another area of consideration is characterization of the population at risk, including its size and, as pertinent, the exposure/risk estimates in this regard. Such factors related to public health significance, and the kind and degree of associated uncertainties, are considered by the EPA in addressing the CAA requirement that the primary NAAQS be requisite to protect public health, including an adequate margin of safety, as summarized in section I.A above.

Ambient air concentrations of SO_2 vary considerably in areas near sources, but concentrations in the vast majority of the U.S. are well below the current standard (PA, Figure 2–7). Thus, while the population counts discussed below may convey information and context regarding the size of populations living near sizeable sources of SO_2 emissions in some areas, the concentrations in most areas of the U.S. are well below the conditions assessed in the REA.

With regard to the size of the U.S. population at risk of SO_2-related effects, the National Center for Health Statistics data from the 2015 National Health Interview Survey (NHIS)[55] indicate that approximately 8% of the U.S. population has asthma (PA, Table 3–2; CDC, 2017). The estimated prevalence is greater in children (8.4% for children less than 18 years of age) than adults (7.6%) (PA, Table 3–2; CDC, 2017). 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). As noted in the PA, there are more than 24 million people with asthma currently in the U.S., including more than 6 million children (PA, sections 3.2.2.4 and 3.2.4). Among populations of different races or ethnicities, black non-Hispanic and Puerto Rican Hispanic children are estimated to have the highest

[52] These studies categorized 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 their ability to engage in moderate to heavy levels of exercise (ISA, p. 5–22; Johns et al., 2010; Reddel, 2009).

[53] 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). Based on the criteria used in the study by Linn et al. (1987) for placing individuals in the "moderate/severe" group, however, 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).

[54] In speaking of transient effects, the recent statement refers to effects lasting on the order of hours (Thurston et al., 2017).

[55] 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*).

prevalence, at 13.4% and 13.9%, respectively. Asthma prevalence is also increased among populations in poverty, with the prevalence estimated to be 11.1% among people living in households below the poverty level compared to 7.2% of those living above it (CDC, 2017).

With regard to the potential for exposure of the populations at risk from exposures to SO_2 in ambient air, while SO_2 concentrations have generally declined across the U.S. since 2010 when the current standard was set (PA, Figures 2–5 and 2–6), there are numerous areas where SO_2 concentrations still contribute to air quality that is near or above the standard. For example, the PA noted that the air quality monitoring data for the 2014–2016 period indicated there to be 15 core-based statistical areas [56] with air quality exceeding the primary SO_2 standard (design values [57] were above the existing standard level of 75 ppb), of which a number have sizeable populations (PA, section 3.2.2.4). In addition to this evidence of elevated ambient air SO_2 concentrations, there are limitations in the monitoring network with regard to the extent that it might be expected to capture all areas with the potential to exceed the standard (*e.g.,* 75 FR 35551; June 22, 2010). In recognition of these limitations, we also examined the proximity of populations to sizeable SO_2 point sources using the recently available emissions inventory information (2014 NEI), which is also characterized in the ISA (PA, section 3.2.2.4, Appendix F; ISA, section 2.2.2). This information indicates that there are more than 300,000 and 60,000 children living within 1 km of facilities emitting at least 1000 and 2000 tpy of SO_2, respectively (PA, section 3.2.2.4). Within 5 km of such sources, the numbers are approximately 1.4 million and 700,000, respectively (PA, Table 3–5). While information on SO_2 concentrations in locations of maximum impact of such sources is not available for all these areas, and SO_2 concentrations vary appreciably near sources, simply considering the 2015 national estimate of asthma prevalence of approximately 8% (noted above), this information would suggest there may be as many as 24,000 to more than 100,000 children with asthma that live in areas near substantially sized sources of SO_2 emissions to ambient air (PA, section 3.2.1.5; Table 3–5).

3. Overview of Risk and Exposure Information

Our consideration of the scientific evidence available in the current review (summarized in section II.A.2 above), as at the time of the last review, is informed by results from a quantitative analysis of estimated population exposure and associated risk of respiratory effects that the evidence indicates to be elicited in some portion of exercising people with asthma by short-term exposures to elevated SO_2 concentrations, *e.g.,* such as exposures lasting 5 or 10 minutes. This analysis, for the air quality scenario of just meeting the current standard, estimates two types of risk metrics in terms of percentages of the simulated at-risk populations of adults with asthma and children with asthma (REA, section 4.6). The first of the two risk metrics is based on comparison of the estimated 5-minute exposure concentrations for individuals breathing at elevated rates to 5-minute exposure concentrations of potential concern (benchmark concentrations). The second risk metric utilizes exposure-response (E–R) information from studies in which subjects experienced moderate or greater lung function decrements (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 a SO_2-related increase in sRaw of at least 100% (REA, sections 4.6.1 and 4.6.2). Both metrics are used in the REA to characterize health risk associated with 5-minute peak SO_2 exposures among simulated at-risk populations 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 2010 decision that established the current standard (75 FR 35546–35547, June 22, 2010).

The following subsections provide brief overviews of the key aspects of the design and methods of the quantitative assessment in this review (section II.A.3.a) and the important uncertainties associated with these analyses (section II.A.3.b). The results of the analyses are summarized in section II.A.3.c. These overviews are drawn from the summary presented in section II.C of the proposal (83 FR 26767, June 8, 2018).

a. Key Design Aspects

In this section, we provide a brief overview of key aspects of the quantitative exposure and risk assessment conducted for this review and summarized in more detail in section II.C.1 of the proposal (83 FR 26767, June 8, 2018), including the study areas, air quality adjustment approach, modeling tools, at-risk populations simulated, and benchmark concentrations assessed. The assessment is described in detail in the REA and summarized in section 3.2.2 of the PA.

The REA focuses on air quality conditions that just meet the current standard, and 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 related to population exposure to short-term peak concentrations of SO_2 in ambient air, including a range in total population size, different mixtures of SO_2 emissions sources, and three different climate regions of the U.S.: The Northeast, Ohio River Valley (Central), and South (REA, section 3.1; Karl and Koss, 1984).[58] 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 (PA, Figure 2–7 and Appendix F). Accordingly, the three study areas illustrate three different patterns of exposure to SO_2 concentrations in a populated area in the U.S. (REA, section 5.1). While the same air quality scenario is simulated in all three study areas (conditions that just meet the current standard), study-area-specific characteristics related to sources, meteorology, topography and population contribute to variation in the estimated magnitude of exposure and associated risk across study areas.

As indicated by this case study approach to assessing exposure and risk, the analyses in the REA 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 that will be informative to the EPA's consideration of potential

[56] 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 (*https://www.census.gov/geo/reference/gtc/gtc_cbsa.html*). Populations in the 15 CBSAs referred to in the body of the text range from approximately 30,000 to more than a million (based on 2016 U.S. Census Bureau estimates).

[57] A design value is a statistic that describes the air quality status of a given area relative to the level of the standard, taking into account the averaging time and form (as well as indicator). Thus, design values for the SO_2 NAAQS are in terms of 3-year averages of annual 99th percentile 1-hour daily maximum concentrations of SO_2. Design values are typically used to assess whether the NAAQS is violated, to classify nonattainment areas, to track air quality trends and progress toward meeting the NAAQS and to develop control strategies.

[58] Additionally, continuous 5-minute ambient air monitoring data (*i.e.,* all 5-minute values for each hour) are available in all three study areas (REA, section 3.2).

exposures and risks that may be associated with the air quality conditions occurring under the current SO_2 standard. The REA analyses are not designed to provide a comprehensive national assessment of such conditions (REA, section 2.2). The objective of the REA is not to present an exhaustive analysis of exposure and risk in areas of the U.S. that currently just meet the standard or an analysis of exposure and risk associated with air quality adjusted down to just meet the standard in areas that currently do not meet the standard.[59] Rather, 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 current standard was established. Accordingly, capturing an appropriate level of diversity in study areas and air quality conditions (that reflect the current standard scenario) is important to the role of the REA in informing the EPA's understanding of, and conclusions on, the public health protection afforded by the current standard (PA, section 3.2.2.2).

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 as local meteorology. Estimates derived using the particular analytical approaches and methodologies for characterizing the study area-specific air quality provide an indication of this variability in the spatial and temporal patterns of SO_2 concentrations occurring under air quality conditions just meeting the current standard. In light of the uncertainty associated with these concentration estimates, the REA presents results from two different approaches to adjusting air quality to just meet the current standard (described in more detail in sections 3.4 and 6.2.2.2 of the REA).[60]

Consistent with the health effects evidence summarized in section II.A.2 above, the focus of the REA is on short-term (5-minute) exposures of individuals with asthma in the simulated populations during times when they are breathing at an elevated rate. Five-minute concentrations in ambient air were estimated for the current standard scenario using a combination of 1-hour concentrations from the EPA's preferred near-field dispersion model, the American Meteorological Society/EPA regulatory model (AERMOD), with adjustment such that they just meet the current standard, and relationships between 1-hour and 5-minute concentrations occurring in the local ambient air monitoring data. The air quality modeling step was taken to capture the spatial variation in ambient SO_2 concentrations across each urban study area. Such variation can be relatively high in areas affected by large point sources and is unlikely to be captured by the limited number of monitoring locations in each area. The modeling step yields 1-hour concentrations at model receptor sites across the modeling domain across the 3-year modeling period (consistent with the 3-year form of the standard). These concentrations were adjusted such that the air quality modeling receptor location(s) with the highest concentrations just met the current standard. Rather than applying the same adjustment to concentrations at all receptors in a study area, the adjustment was derived by focusing on reducing emissions from the source(s) contributing the most to the standard exceedances (REA, section 3.4 and 6.2.2.1). 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 model receptor locations in each of the three study areas (REA, section 3.5). In this way, available continuous 5-minute ambient air monitoring data (datasets with all twelve 5-minute concentrations in each hour) were used to reflect the fine-scale temporal variation in SO_2 concentrations documented by these data. This approach was used in recognition of the limitations associated with air quality modeling at this fine temporal scale, *e.g.,* limitations in the time steps of currently available model input data such as for emissions estimates.

The estimated 5-minute concentrations in ambient air across each study area were then used together with the Air Pollutants Exposure (APEX) model, a probabilistic human exposure model that simulates the activity of individuals in the population, including their exertion levels and movement through time and space, to estimate concentrations of 5-minute SO_2 exposure events in indoor, outdoor, and in-vehicle microenvironments. The use of APEX for estimating exposures allows for consideration of factors that affect exposures that are not addressed by consideration of ambient air concentrations alone. These factors include: (1) Attenuation in SO_2 concentrations expected to occur in some indoor microenvironments; (2) the influence of human activity patterns on the time series of exposure concentrations; and (3) accounting for human physiology and the occurrence of elevated breathing rates concurrent with SO_2 exposures (REA, section 2.2). These factors are all key to appropriately characterizing exposure and associated health risk for SO_2.[61]

The at-risk populations for which exposure and risk are estimated (children and adults with asthma) ranges from 8.0 to 8.7% of the total populations (ages 5–95) in the exposure modeling domains for the three study areas (REA, section 5.1). The percent of children with asthma in the simulated populations ranges from 9.7 to 11.2% across the three study areas (REA, section 5.1). Within each study area the percent varies with age, sex and whether family income is above or below the poverty level (REA, section 4.1.2, Appendix E).[62] This variation is greatest in the Fall River study area, with census block level, age-specific asthma prevalence estimates ranging from 7.9 to 18.6% for girls and from 10.7 to 21.5% for boys (REA, Table 4–1).

The REA for this review, consistent with the analyses in the last review, uses the APEX model estimates of 5-minute exposure concentrations for simulated individuals with asthma while breathing at elevated rates to

[59] Nor is the objective of the REA to provide a comprehensive assessment of current air quality across the U.S.

[60] The first approach uses the highest design value across all modeled air quality receptors to estimate the amount of SO_2 concentration reduction needed to adjust the air quality concentrations in each area to just meet the standard (REA, section 3.4). In recognition of potential uncertainty in the first approach, the second approach uses the air quality receptor having the 99th percentile of the distribution of design values (instead of the receptor with the maximum design value) to estimate the SO_2 concentration reductions needed to adjust the air quality to just meet the standard, setting all receptors at or above the 99th percentile to just meet the standard (REA, section 6.2.2.2).

[61] The exposure modeling performed for this review, including ways in which it has been updated since the 2009 REA are summarized in section II.C of the proposal and described in detail in the REA (*e.g.,* REA, Chapter 4 and Appendices E through I).

[62] 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 poverty status.

characterize health risk in two ways (REA, section 4.5). The first is the percentage of the simulated at-risk populations expected to experience days with 5-minute exposures, while breathing at elevated rates, that are at or above a range of benchmark levels. The second is the percentage of these populations expected to experience days with an occurrence of a doubling or tripling of sRaw.

The benchmark concentrations used in the comparison-to-benchmarks analysis (400, 300, 200 and 100 ppb) were identified based on consideration of the evidence discussed in section II.A.2 above. In particular, benchmark concentrations of 400 ppb, 300 ppb, and 200 ppb were based on concentrations included in the well-documented controlled human exposure studies summarized in section II.A.2 above, and the 100 ppb benchmark was selected in consideration of uncertainties with regard to lower concentrations and population groups with more limited data (REA, section 4.5.1). 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, with some increases in these symptoms also being statistically significant at the group level (ISA, Section 5.2.1.2 and Table 5–2). At 300 ppb, statistically significant increases in lung function decrements (specifically reductions in 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, pp. 5–85 and 5–153 and Table 5–21; Johns et al., 2010). The 200 ppb benchmark concentration represents the lowest level for which studies are available that have assessed the SO_2 effect *versus* the effect of exercise in clean air and for which individual study subject data are available to summarize percent changes in sRaw and FEV_1; moderate or greater lung function decrements were documented in some of these study subjects (ISA, Table 5–2 and Figure 5–1; PA, Table 3–1; REA, section 4.6.1). With regard to exposure concentrations below 200 ppb, limited data are available for exposures at 100 ppb that, while not directly comparable to the data at higher concentrations because of differences in methodology and metrics reported,[63] do not indicate that study subjects experienced responses of a magnitude as high as a doubling in sRaw. However, in consideration of some study subjects with asthma experiencing moderate or greater decrements in lung function at the 200 ppb exposure concentration (approximately 8 to 9% of the study group) and of the paucity or lack of any specific study data for some groups of individuals with asthma, such as primary-school-age children and those with more severe asthma (described in sections II.B.3 and II.C.1 of the proposal), a benchmark concentration of 100 ppb (one half the 200 ppb exposure concentration) was also included in the analyses.

The E–R function for estimating 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 to as low as 200 ppb (REA, Table 4–11). In addition to the assessment of these studies and their results in past NAAQS reviews, there has been extensive evaluation of the individual subject results, including a data quality review in the 2010 review of the primary SO_2 standard (Johns and Simmons, 2009) and detailed analysis in two subsequent publications (Johns et al., 2010; Johns and Linn, 2011). The E–R function was derived from the sRaw responses reported in the controlled exposure studies as summarized in the ISA in terms of percent of study subjects experiencing responses of a magnitude equal to a doubling or tripling or more (*e.g.,* ISA, Table 5–2; Long and Brown, 2018; REA, section 4.6.2). 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).

b. Key Limitations and Uncertainties

While the general approach and methodology for the exposure-based assessment in this review is similar to that used in the last review, there are a number of ways in which the current analyses are different; some differences reflect improvements and, in some cases, reflect improvements that may address limitations of the 2009 assessment. For example, the number and type of study areas assessed has been expanded since the last review, and input data and modeling approaches have improved in a number of ways, including the availability of continuous 5-minute air monitoring data at monitors within the three study areas. In addition, 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.

In characterizing uncertainty associated with the risk and exposure estimates in this review, the REA used a qualitative uncertainty characterization approach adapted from the World Health Organization (WHO) approach for characterizing uncertainty in exposure assessment (WHO, 2008) accompanied by quantitative sensitivity analyses of key aspects of the assessment approach (REA, chapter 6).[64] The approach used in the REA places 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 estimates of exposure and risk). The evaluation considers the limitations and uncertainties underlying the analysis inputs and approaches and the relative impact that these uncertainties may have on the resultant exposure/risk estimates. Consistent with the WHO (2008) approach, the overall impact of the uncertainty is then characterized by the extent or magnitude of the impact of the uncertainty (*e.g.,* high, moderate, low) 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 and risk estimates (*e.g.,* likely to produce over- or under-estimates).

Several areas of uncertainty are identified as particularly important, with some similarities to those recognized in the last review. Generally, these areas of uncertainty include estimation of the spatial distribution of SO_2 concentrations across each study

[63] As explained in section II.B.3 of the proposal, these studies involved exposures via mouthpiece, and 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 and associated lung function decrements (ISA, section 5.2.1.2; PA, section 3.2.1.3).

[64] The approach used has been applied in REAs for past NAAQS review for nitrogen oxides, carbon monoxide, and ozone (U.S. EPA, 2008b; 2010; 2014d), as well as SO_X (U.S. EPA, 2009).

area under air quality conditions just meeting the current standard, including the fine-scale temporal pattern of 5-minute concentrations. They also include uncertainty with regard to population groups and exposure concentrations for which the health effects evidence base is limited or lacking (PA, section 3.2.2.3).

With regard to the spatial distribution of SO_2 concentrations, there is some uncertainty associated with the ambient air concentration estimates in the air quality scenarios assessed. A more detailed characterization of contributors to this uncertainty is presented in section 6.2 of the REA, with a brief overview provided here. Some aspects of the assessment approach contributing to this uncertainty include estimation of the 1-hour concentrations and the approach employed to adjust the air quality surface to concentrations just meeting the current standard (REA, section 6.2.2.2; PA, section 3.2.2.2), as well as the estimation of 1-hour ambient air concentrations resulting from emissions sources not explicitly modeled. All of these assessment approaches influence the resultant temporal and spatial pattern of concentrations and associated exposure circumstances represented in the study areas (REA, sections 6.2.1 and 6.2.2). There is also uncertainty in the estimates of 5-minute concentrations in ambient air across the modeling receptors in each study area. The ambient air monitoring dataset available to inform the 5-minute estimates, much expanded in this review over the dataset available in the last review, is used to draw on relationships occurring at one location and over one range of concentrations to estimate the fine-scale temporal pattern in concentrations at the other locations. While 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, the approach used to represent fine-scale temporal variability in the three study areas is strongly based in the available information and has been evaluated in the REA (REA, Table 6–3; sections 3.5.2 and 3.5.3).

Another important area of uncertainty in the REA is particular to the lung function risk estimates derived for exposure concentrations below those represented in the evidence base (REA, Table 6–3). The E–R function on which the risk estimates are based generates non-zero predictions of the percentage of the at-risk population expected to experience a day with the occurrence of at least a doubling of sRaw for all 5-minute exposure concentrations each simulated individual encounters while breathing at an elevated rate. The uncertainty in the response estimates increases substantially with decreasing exposure concentrations below those well represented in the data from the controlled human exposure studies (*i.e.,* below 200 ppb).

Additionally, 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 a doubling or tripling of sRaw. Although there is some uncertainty associated with the potential for additional, uncounted events in the same day, the health effects evidence indicates a 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). Further, information is somewhat limited with regard to the length of time after recovery from one exposure by which a repeat exposure would elicit an effect similar to that of the initial exposure event (REA, Table 6–3). In addition, there is uncertainty regarding the potential influence of co-occurring pollutants on the relationship between short-term SO_2 exposures and respiratory effects. For example, 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 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).[65]

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 section II.A.2, the evidence base of controlled human exposure studies does not include studies of children younger than 12 years old and is limited with regard to studies of people with more severe asthma.[66] The limited evidence that informs our understanding of potential risk to these groups indicates the potential for them to experience greater impacts than other population groups with asthma under similar exposure circumstances or, in the case of people with severe asthma, to have a more limited reserve for addressing this risk (ISA, section 5.2.1.2). Further, we note the lack of information on the factors contributing to increased susceptibility to SO_2-induced bronchoconstriction among some people with asthma compared to others (ISA, pp. 5–19 to 5–21). These data limitations contribute uncertainty to the exposure/risk estimates with regard to the extent to which they represent the populations at greatest risk of SO_2-related respiratory effects.

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, several are particularly important. These include uncertainties related to the following: Estimation of 5-minute concentrations in ambient air; the lack of information from controlled human exposure studies for the lower, more prevalent concentrations of SO_2 and limited information regarding multiple exposure episodes within a day; the prevalence of different exposure circumstances represented by the three study areas; and characterization of particular subgroups of people with asthma that may be at greater risk.

c. Summary of Exposure and Risk Estimates

The REA provides estimates for two simulated at-risk populations: Adults with asthma and school-aged children[67]

[65] 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). 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).

[66] We additionally recognize that limitations in the activity pattern information for children younger than 5 years old precluded their inclusion in the populations of children simulated in the REA (REA, section 4.1.2).

[67] The adult population group is comprised of individuals older than 18 years of age and school-aged children are individuals aged 5 to 18 years old. As in other NAAQS reviews, this REA does not estimate exposures and risk for children younger than 5 years old due to the more limited information contributing relatively greater uncertainty in modeling their activity patterns and physiological processes compared to children between the ages of 5 to 18 (REA, p. 2–8).

with asthma (REA, section 2.2). This summary focuses on the population of children with asthma given that the ISA describes children as ''particularly at risk'' and the REA generally yields higher exposure and risk estimates for children than adults (in terms of percentage of the population group). Summarized here are two sets of exposure and 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 experiencing multiple lung function decrements associated with SO_2 exposures (detailed results are presented in chapter 5 of the REA). Both types of estimates are lower for adults with asthma compared to children with asthma, generally due to the lesser amount and frequency of time spent outdoors while breathing at elevated rates (REA, section 5.2). As summarized in section II.A.3.b above, the REA provides results for two different approaches to adjusting air quality. The estimates summarized here are drawn from the results for both approaches, as presented in Tables 1 and 2 of the proposal (83 FR 26772, June 8, 2018).

This summary focuses first on the results for the benchmark-based risk metric in terms of 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 (REA, Tables 6–8 and 6–9). In two of the three study areas, 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 (83 FR 26772 [Table 1], June 8, 2018).[68] With regard to the 200 ppb benchmark concentration, these two study areas' estimates are as high as 0.7%, on average across the 3-year period, and range up to as high as 2.2% in a single year. Less than 0.1% of either area's simulated children with asthma were estimated to experience multiple days with such an exposure at or above 200 ppb (REA, Tables 6–8 and 6–9). Additionally, in the study area with the highest estimates for exposures at or above 200 ppb, approximately a quarter of a percent of simulated children with asthma also were estimated to experience a day with a 5-minute exposure at or above 300 ppb across the 3-year period (the percentage for the 400 ppb benchmark was 0.1% or lower). 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).

With regard to lung function risk, in the two study areas for which the exposure estimates are highest, as many as 1.3% and 1.1%, respectively, of children with asthma, on average across the 3-year period (and as many as 1.9% in a single year), were estimated to experience at least 1 day per year with a SO_2-related doubling in sRaw (83 FR 26772 [Table 2], June 8, 2018; REA, Tables 6–10 and 6–11).[69] 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 (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 (83 FR 26772 [Table 2], June 8, 2018).

B. Conclusions on Standard

In drawing conclusions on the adequacy of the current primary SO_2 standard, in view of the advances in scientific knowledge and additional information now available, the Administrator has considered the evidence base, information, and policy judgments that were the foundation of the last review and reflects upon the body of evidence and information newly available in this review. In so doing, the Administrator has taken into account both evidence-based and exposure- and risk-based considerations, as well as advice from the CASAC and public comments. Evidence-based considerations draw upon the EPA's assessment and integrated synthesis of the scientific evidence from controlled human exposure studies and epidemiologic studies evaluating health effects related to exposures of SO_2 as presented in the ISA, with a focus on policy-relevant considerations as discussed in the PA (summarized in sections II.B and II.D.1 of the proposal and section II.A.2 above). The exposure- and risk-based considerations draw from the results of the quantitative analyses presented in the REA (as summarized in section II.C of the proposal and section II.A.3 above) and consideration of these results in the PA.

Consideration of the evidence and exposure/risk information in the PA and by the Administrator is framed by consideration of a series of key policy-relevant questions. Section II.B.1 below summarizes the rationale for the Administrator's proposed decision, drawing from section II.D.3 of the proposal. The advice and recommendations of the CASAC and public comments on the proposed decision are addressed below in sections II.B.2 and II.B.3, respectively. The Administrator's conclusions in this review regarding the adequacy of the current primary standard and whether any revisions are appropriate are described in section II.B.4.

1. Basis for Proposed Decision

At the time of the proposal, the Administrator carefully considered the assessment of the current evidence and conclusions reached in the ISA; the currently available exposure and risk information, including associated limitations and uncertainties, described in detail in the REA and characterized in the PA; considerations and staff conclusions and associated rationales presented in the PA, including consideration of commonly accepted guidelines or criteria within the public health community, including the ATS, an organization of respiratory disease specialists; the advice and recommendations from the CASAC; and public comments that had been offered up to that point (83 FR 26778, June 8, 2018). In reaching his proposed decision on the primary SO_2 standard, the Administrator first recognized the long-standing evidence that has established the key aspects of the harmful effects of very short SO_2 exposures on people with asthma. This evidence, drawn largely from the controlled human exposure studies, demonstrates that very short exposures (for as short as a few minutes) to less than 1000 ppb SO_2, while breathing at an elevated rate (such as while exercising), induces bronchoconstriction and related

[68] These estimates for the third area (Tulsa) are much lower than those for the other two areas. No individuals of the simulated at-risk population in the third study area were estimated to experience exposures at or above 200 ppb and less than 0.5% are estimated to experience an exposure at or above the 100 ppb benchmark.

[69] As with the comparison-to-benchmark results, the estimates for risk of lung function decrements in terms of a doubling or more in sRaw are also lower in the Tulsa study area than the other two areas (83 FR 26772 [Table 2], June 8, 2018; REA, Tables 6–10 and 6–11).

respiratory effects in people with asthma and provides support for identification of this group as the population at risk from short-term peak concentrations in ambient air (ISA; 2008 ISA; U.S. EPA, 1994).[70] Within this evidence base, there is a relative lack of such information for some subgroups of this population, including young children and people with severe asthma. The evidence base additionally includes epidemiologic evidence that supports the conclusion of a causal relationship between short-term SO_2 exposures and respiratory effects, for which the controlled human exposure studies are the primary evidence.

With regard to the health effects evidence newly available in this review, in the proposal the Administrator noted that, while the health effects evidence, as assessed in the ISA, has been augmented with additional studies since the time of the last review, including more than 200 new health studies, it 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 or additional populations at risk of SO_2-related effects. Thus, the Administrator recognized that the health effects evidence available in this review and addressed in the ISA is consistent with evidence available in the last review when the current standard was established and that this strong evidence base continues to demonstrate a causal relationship between relevant short-term exposures to SO_2 and respiratory effects, particularly with regard to effects related to asthma exacerbation in people with asthma. He also recognized that the ISA conclusion on the respiratory effects caused by short-term exposures is based primarily on the evidence from controlled human exposure studies that reported effects in people with asthma exposed to SO_2 for 5 to 10 minutes while breathing at an elevated rate (ISA, section 5.2.1.9), and that the current 1-hour standard was established to provide protection from effects such as these (75 FR 35520, June 22, 2010; 83 FR 26778, June 8, 2018).

In considering exposure concentrations of interest in this review, the Administrator particularly noted the evidence from controlled human exposure studies, also available in the last review, that demonstrate the occurrence of moderate or greater lung function decrements in some people with asthma exposed to SO_2 concentrations as low as 200 ppb for very short periods of time while breathing at elevated rates (ISA, Table 5–2 [71] and Figure 5–1, summarized in Table 3–1 of the PA).[72] He recognized that the data for the 200 ppb exposures include limited evidence of respiratory symptoms accompanying the lung function effects observed, and that the severity and number of individuals affected is found to increase with increasing exposure levels, as is the frequency of accompaniment by respiratory symptoms, such that, at concentrations at or above 400 ppb, the moderate or greater decrements in lung function were frequently accompanied by respiratory symptoms, with some of these findings reaching statistical significance at the study group level (ISA, Table 5–2 and section 5.2.1; PA, section 3.2.1.3; 83 FR 26779, June 8, 2018).

In considering the potential public health significance of these effects associated with SO_2 exposures, the Administrator's proposed decision recognized both the greater significance of larger lung function decrements, which are more frequently documented at exposures above 200 ppb, and the potential for greater impacts of SO_2-induced decrements in people with more severe asthma, as recognized in the ISA and by the CASAC (as summarized in section II.D.2 of the proposal).[73] Thus, the Administrator recognized that health effects resulting from exposures at and above 400 ppb are appreciably more severe than those elicited by exposure to SO_2 concentrations at 200 ppb, and that health impacts of short-term SO_2 exposures (including those occurring at concentrations below 400 ppb) have the potential to be more significant in the subgroup of people with asthma that have more severe disease and for which the study data are more limited (83 FR 26779, June 8, 2018).

As was the case for the 2010 decision, the Administrator's proposed decision in this review recognized the importance of considering the health effects evidence in the context of the exposure and risk modeling performed for this review. The Administrator recognized that such a context is critical for SO_2, a chemical for which the associated health effects that occur in people with asthma are linked to exposures during periods of elevated breathing rates, such as while exercising. Accordingly, in considering the adequacy of public health protection provided by the current standard, the Administrator considered the evidence in this context. In so doing, he found the PA considerations regarding the REA results and the associated uncertainties, as well as the nature and magnitude of the uncertainties inherent in the scientific evidence upon which the REA is based, to be important to judgments such as the extent to which the exposure and risk estimates for air quality conditions that just meet the current standard in the three study areas indicate exposures and risks that are important from a public health perspective.

Thus, in considering whether the current standard provides the requisite protection of public health in the proposal, the Administrator took note of: (1) The PA consideration of a sizeable number of at-risk individuals living in locations near large SO_2 emissions sources that may contribute to increased concentrations in ambient air, and associated exposures and risk; (2) the REA estimates of children with asthma estimated to experience single or multiple days across the 3-year assessment period, as well as in a single year, with a 5-minute exposure at or above 200 ppb, while breathing at elevated rates; and (3) limitations and associated uncertainties with regard to population groups at potentially greater risk but for which the evidence is lacking, recognizing that the CAA requirement that primary standards provide an adequate margin of safety is intended to address uncertainties associated with inconclusive scientific and technical information, as well as to provide a reasonable degree of protection against hazards that research has not yet identified (83 FR 26780, June 8, 2018). Further, the proposed decision recognized advice received from the CASAC, including its conclusion that the current evidence and exposure/risk information supports retaining the current standard, as well as its statement that it did not

[70] For people without asthma, such effects have only been observed in studies of exposure concentrations at or above 1000 ppb (ISA, section 5.2.1.7).

[71] The availability of individual subject data from these studies allowed for the comparison of results in a consistent manner across studies (ISA, Table 5–2; Long and Brown, 2018).

[72] The Administrator additionally considered the very limited evidence for exposure concentrations below 200 ppb, for which relatively less severe effects are indicated, while noting the limitations of this dataset (83 FR 26781, June 8, 2018).

[73] The ISA notes that while extremely limited evidence for adults with moderate to severe asthma indicates such groups may have similar relative lung function decrements in response to SO_2 as adults with less severe asthma, individuals with severe asthma may have greater absolute decrements that may relate to the role of exercise (ISA, pp. 1–17 and 5–22). The ISA concluded that individuals with severe asthma may have "less reserve capacity to deal with an insult compared with individuals with mild asthma" (ISA, pp. 1–17 and 5–22).

recommend reconsideration of the level of the standard to provide a greater margin of safety (83 FR 26780, June 8, 2018). Based on all of these considerations, the Administrator proposed to conclude that a less stringent standard would not provide the requisite protection of public health, including an adequate margin of safety (83 FR 26780, June 8, 2018).

The Administrator also considered the adequacy of protection provided by the current standard from effects associated with lower short-term exposures, including those at or below 200 ppb. In so doing, he considered the REA estimates for such effects, and the significance of estimates for single (*versus* multiple) occurrences of exposures at or above the lower benchmark concentrations and associated lung function decrements, and the nature and magnitude of the various uncertainties that are inherent in the underlying scientific evidence and REA analyses. Based on these, he placed little weight on the significance of estimates of occurrences of short-term exposures below 200 ppb and focused on the REA results for exposures at and above 200 ppb in light of his considerations, noted above, regarding the health significance of findings from the controlled human exposure studies. He further placed relatively less weight on the significance of infrequent or rare occurrences of exposures at or just above 200 ppb, and more weight on the significance of repeated such occurrences, as well as occurrences of higher exposures. With this weighing of the REA estimates and recognizing the uncertainties associated with such estimates for the scenarios of air quality developed to represent conditions just meeting the current standard, the Administrator considered the current standard to provide a high degree of protection to at-risk populations from SO_2 exposures associated with the more severe health effects, which are more clearly of public health concern, as indicated by the extremely low estimates of occurrences of exposures at or above 400 ppb (and at or above 300 ppb); and to additionally provide a slightly lower, but still high, degree of protection for the appreciably less severe effects associated with lower exposures (*i.e.,* at and below 200 ppb), for which public health implications are less clear. The Administrator further observed that although the CASAC stated that there is uncertainty in the adequacy of the margin of safety provided by the current standard for less well studied yet potentially susceptible population groups, it concluded that ''the CASAC does not recommend reconsideration of the level in order to provide a greater margin of safety'' (Cox and Diez Roux, 2018b, Consensus Responses, p. 5; 83 FR 26780, June 8, 2018). Based on these and all of the above considerations, the Administrator proposed to conclude that a more stringent standard is not needed to provide requisite protection and that the current standard provides the requisite protection of public health under the Act (83 FR 26781, June 8, 2018).

In summary, the Administrator considered the specific elements of the existing standard and proposed to retain the existing standard, in all of its elements. With regard to SO_2 as the indicator, he recognized the support for retaining this indicator in the current evidence base, noting the ISA conclusion that SO_2 is the most abundant of the SO_X in the atmosphere and the one most clearly linked to human health effects. The Administrator additionally recognized the control exerted by the 1-hour averaging time on 5-minute ambient air concentrations of SO_2 and the associated exposures of particular importance for SO_2-related health effects. Lastly, with regard to form and level of the standard, the Administrator noted the REA results and the level of protection that they indicate the elements of the current standard to collectively provide. The Administrator additionally noted CASAC support for retaining the current standard and the CASAC's specific recommendation that all four elements should remain the same.

Thus, based on consideration of the evidence and exposure/risk information available in this review, with its attendant uncertainties and limitations, and information that might inform public health policy judgments, as well as consideration of advice from the CASAC, including their concurrence with the PA conclusions that the current evidence does not support revision of the primary SO_2 standard, the Administrator proposed to conclude that it is appropriate to retain the current standard without revision based on his judgment that the current primary SO_2 standard provides an adequate margin of safety against adverse effects associated with short-term exposures to SO_X in ambient air. For these reasons, and all of the reasons discussed above, and recognizing the CASAC conclusion that the current evidence and REA results provide support for retaining the current standard, the Administrator proposed to conclude that the current primary SO_2 standard is requisite to protect public health with an adequate margin of safety from effects of SO_X in ambient air and should be retained, without revision.

2. CASAC Advice in This Review

In comments on the draft PA, the CASAC concurred with staff's overall preliminary conclusions that ''the current scientific literature does not support revision of the primary NAAQS for SO_2,'' additionally stating the following (Cox and Diez Roux, 2018b, p. 3 of letter):

> The CASAC notes that the new scientific information in the current review does not lead to different conclusions from the previous review. Thus, based on review of the current state of the science, the CASAC supports retaining the current standard, and specifically notes that all four elements (indicator, averaging time, form, and level) should remain the same.

The CASAC further stated the following (Cox and Diez Roux, 2018b, p. 3 of 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. 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 noted that the draft PA ''clearly identifies most of the key uncertainties, including uncertainties in dose-response'' and that ''[t]here are also some additional uncertainties that should be mentioned'' (Cox and Diez Roux, 2018b, pp. 6–7 of Consensus Response to Charge Questions). These are in a variety of areas including risk for various population groups, personal exposures to SO_2, and estimating short-term ambient air concentrations.[74] The CASAC additionally recommended attention to assessment of the impact of relatively lower levels of SO_2 in persons who may be at increased risk, including those referenced above (Cox and Diez Roux, 2018b, p. 3 of letter). The CASAC suggested research and data gathering in these and other areas that would inform the next primary SO_2 standard review (Cox and Diez Roux, 2018b, p. 6 of Consensus Responses to Charge Questions).

3. Comments on the Proposed Decision

During the public comment period for the proposed decision, we received 24 comments.

a. Comments in Support of Proposed Decision

Of the comments addressing the proposed decision, the majority supported the Administrator's proposed decision to retain the current primary standard, without revision. This group includes an association of state and local air agencies, all of the state agencies that submitted comments, more than half of the industry organizations that submitted comments, and a couple of comments from individuals. All of these commenters generally note their agreement with the rationale provided in the proposal and the CASAC concurrence with the PA conclusion that the current evidence does not support revision to the standard. Most also cite the EPA and CASAC statements that information newly available in this review has not substantially altered our previous understanding of effects from exposures lower than what was previously examined or of the at-risk populations and does not call into question the adequacy of the current standard. They all find the proposed decision to retain the current standard to be well supported. The EPA agrees with these comments and with the CASAC advice regarding the adequacy of the current primary standard and the lack of support for revision of the standard.

We additionally note that some of the industry commenters that stated their support for retaining the current standard without revision additionally stated that in their view the current standard provides more public health protection than the EPA has recognized in the proposal. As support for this view, these comments variously state that concentrations in most of the U.S. are well below those evaluated in the REA; that the studies in the ISA do not demonstrate statistically significant response to SO_2 concentrations below 300 ppb; and, that a large percentage of the REA estimates of lung function risk is attributable to exposures below 200 ppb. The commenters also claim that in the 2010 decision that established the current standard (75 FR 33547, June 22, 2010), the EPA had determined that a standard protecting about 97–98% of exposed children with asthma from a doubling of sRaw would be appropriate, but that the estimates in the current REA indicate that over 99% of exercising children with asthma receive such protection from the current NAAQS.

As an initial matter, while we agree with the commenters that most of the U.S. has SO_2 concentrations below those assessed in the REA, we disagree that this indicates the standard is overly protective. Rather, this simply indicates the lack of large SO_2 emissions sources in many parts of the country (although their presence in other parts of the country contributes to ambient air concentrations of SO_2 similar to or higher than those in the REA). As recognized in section II.A.3 above, the REA is designed to inform our understanding of exposure and risk in areas of the U.S. where SO_2 emissions contribute to airborne concentrations such that the current standard is just met because the REA is intended to inform the Agency's decision regarding the public health protection provided by the current standard, rather than to describe exposure and risk in areas with SO_2 concentrations well below the current standard (*e.g.,* such that they that would meet alternative more restrictive standards). This approach is consistent with section 109 of the CAA, which requires the EPA to review whether the current primary standard—not current air quality—is requisite to protect public health with an adequate margin of safety (CAA section 109(b)(1) and 109(d)(1); *see also NEDA/CAP,* 686 F.3d at 813 [rejecting the notion that it would be inappropriate for the EPA to revise a NAAQS if current air quality does not warrant revision, stating ''[n]othing in the CAA requires EPA to give the current air quality such a controlling role in setting NAAQS'']). Thus, the EPA disagrees with the commenters that the public health protection provided by the standard is indicated by exposure and risk associated with air quality in parts of the U.S. with concentrations well below the standard, and finds the REA appropriately designed for purposes of informing consideration of the adequacy of the public health protection provided by the current standard.

With regard to the characterization of risk in the REA, it is true as the commenters state that the lung function risk estimates include estimates of risk based on 5-minute exposures below 200 ppb and that the evidence from controlled human exposure studies is very limited for concentrations below 200 ppb. We recognize this as an uncertainty in the estimates (*e.g.,* PA, section 3.2.2.3).[75] In considering the uncertainties in and any associated implications of these estimates, we also recognize, however, that we lack information for some population groups, including young children with asthma and individuals with severe asthma who might exhibit responses at lower exposures than those already studied. And, as is noted in section II.A.2 above and by the CASAC in their advice (summarized in section II.B.2 above), there is the potential for responses in these populations to exposure concentrations lower than those that have been tested in the controlled human exposure studies. Thus, while we recognize the uncertainty in the estimates noted by the commenters, we have considered the methodology (which derived risk estimates based on

[74] These and other comments from the CASAC on the draft PA and REA were considered in preparing the final PA and REA, as well as in developing the proposed and final decisions in this review.

[75] For example, the PA recognizes the uncertainty in the lung function risk estimates increases substantially with decreasing exposure concentrations below those examined in the controlled human exposure studies (PA, section 3.2.2.3; REA, Table 6–3).

the lower exposure concentrations) to be appropriate in light of the potential for the estimates to inform our consideration of the protection afforded to these unstudied populations. Further, in considering the risk estimates with regard to the level of protection provided to at-risk populations in reaching a conclusion about the adequacy of the current standard, the Administrator has recognized them to be associated with somewhat greater uncertainty than the comparison-to-benchmark estimates (see section II.B.4 below).

Lastly, we do not agree with the comment that the estimates of children protected from exposures of concern by the now-current standard were appreciably lower when the standard was established. While there are a number of differences between the 2009 REA and the quantitative modeling and analyses performed in the current REA (as described in PA, section 3.2.2 and summarized in section II.A.3 above), the percentage of children with asthma that are estimated in the current REA to experience at least a doubling in sRaw ranges up to 98.7% as a 3-year average across the three study areas.[76] Although the REA in the last review did not estimate risk for a 1-hour standard with a level of 75 ppb, the estimate from the current REA falls squarely between the 2009 REA estimates for the two air quality scenarios most similar to a scenario just meeting the current standard: 99.5% for a level of 50 ppb and 97.1% for a level of 100 ppb (PA, section 3.2.2.2; 74 FR 64841, Table 4, December 8, 2009). In making their comment, the commenters claim that the 2010 decision conveyed that the selected standard of 75 ppb would protect 97 to 98 percent of exposed children from a doubling of sRaw. Given the lack of 2009 REA estimates for the level of 75 ppb, it might be presumed that the commenter's two percentages represent the results for the 50 ppb and 100 ppb scenarios, thus providing a range within which results for 75 ppb might be expected to fall. However, that is not the case; rather, the percentages cited by the commenter (97–98%) pertain to the 2009 REA sRaw risk estimates for the air quality scenario with a standard level of 100 ppb (75 FR 35547, June 22, 2010; 74 FR 64841 and Table 4, December 8, 2009). Thus, the comment's statement is not borne out by the risk estimates relevant to the current standard. Further, while we recognize distinctions between the methodology and scenarios for the two REAs, we find the estimates for lung function risk based on sRaw and the similar estimates for exposures at or above the 200 ppb benchmark to be of a magnitude roughly consistent between the two REAs (as summarized in PA, section 3.2.2.2 and 3.1.1.2.4). Accordingly, while we agree there are uncertainties in the evidence and in the exposure and risk estimates, the currently available information indicates a level of protection to be afforded by the current standard that is generally similar to what was indicated by the evidence available when the standard was set in 2010. For these reasons, we disagree that the current standard provides more public health protection than recognized in the proposal.

b. Comments in Disagreement With Proposed Decision

Of the commenters that disagreed with the proposal to retain the current standard, three recommend a tightening of the standard, while five recommend a less stringent standard. The commenters that recommended a tighter standard state their support for revisions to provide greater public health protection, generally claiming that the current standard is inadequate and does not provide an adequate margin of safety for potentially vulnerable groups. Commenters supporting a less stringent standard assert that the current standard is overprotective, with some of these commenters stating that the EPA is inappropriately concerned about respiratory effects from exposures as low as 200 ppb. We address these comments in turn below.

(i) Comments in Disagreement With Proposed Decision and Calling for More Stringent Standard

The commenters advocating for a more stringent standard variously recommend that the level of the existing standard be revised to a value no higher than 50 ppb, the form should be revised to allow the occurrence of fewer hours with average concentrations above 75 ppb, and/or that a new 24-hour standard be established. These three points are addressed below.

With regard to a standard level of 50 ppb, two of the commenters supporting this view note that they also expressed this view in comments they submitted during the 2010 review. In the comment in the current review, these commenters cite asthma prevalence estimates for children and other population groups, noting that asthma attacks may contribute to missed school days, potentially affecting children's education. These commenters additionally suggest that the current standard does not adequately protect all population groups or provide an adequate margin of safety given uncertainties in the health effects evidence base, including those associated with the lack of controlled human exposure studies that have investigated effects in particular at-risk populations, such as young children with asthma, or at concentrations below 100 ppb, as well as their view that available studies did not address multiple exposures in the same day.

One of the commenters quoted from the comment they submitted in the last review which supported revisions to the then-current standards (different from the revisions in the 2009 proposal).[77] The quoted text stated that epidemiologic studies (available in the decade prior to the 2010 decision) include associations of health outcomes with 24-hour SO_2 concentrations that are below the level of the then-current 24-hour standard (140 ppb) and that these studies indicate SO_2 effects at concentrations below the then-current standards. The commenter then expressed the view that the science accumulated in the intervening years has strengthened and reaffirmed this. As the 2010 decision concluded that the then-existing 24-hour standard did not provide adequate public health protection from short-term SO_2 concentrations (and consequently established a new standard expressly for that purpose), we find that the commenter's statements regarding the then-current 24-hour standard do not pertain to the issue at hand in the current review, *i.e.,* the adequacy of protection provided by the current 1-hour standard. Moreover, assessments in the last review supported the Administrator's conclusion at that time that the then-existing 24-hour standard

[76] We note that in claiming that the current REA indicates "over 99%" of exercising asthmatic children to be protected from a doubling of sRaw, the commenter erroneously cites the percentage for multiple occurrences of a doubling of sRaw (83 FR 26781/3, June 8, 2018). In multiple other locations in the proposal, the percentage for one or more occurrences is given as up to 98.7% across the three study areas as a 3-year average (83 FR 26772, Table 2 and text, 26775/2, 26777/1, 26779/3, June 8, 2018).

[77] As part of the comments they submitted in the current review, this commenter incorporated by reference their comments on the 2009 proposal. Given the different framing of the current proposal (to retain the now-existing 1-hour standard) from the proposal in the last review (to significantly revise the then-existing standards including the establishment of a new 1-hour standard) and that this review relies on the current record, which differs in a number of ways from that in the last review (*e.g.,* the updated analyses in the REA), we do not believe that merely incorporating 2009 comments by reference is sufficient to raise a significant comment with reasonable specificity in this review, without further description of why the issues presented in the prior comment are still relevant to the proposal in the current review.

did not provide adequate protection from the short-term concentrations of most concern. As a result, the decision in the last review was to provide for revocation of the 24-hour standard and to establish the now current 1-hour standard to provide the needed protection of at-risk populations with asthma from respiratory effects of SO_2 (75 FR 35550, June 22, 2010). To the extent that these comments on the proposal in the current review are intended to imply that the epidemiologic studies briefly mentioned in the quotation from the comment in the last review or studies that have become available in the intervening years indicate that the current standard is inadequate, the comments do not provide any explanation or analysis to support such an assertion. With regard to the current standard and the epidemiologic evidence, we further note that such evidence was considered by the Administrator in 2010 (as were the comments submitted at that time) in the setting of the now-current standard, and that the EPA has again considered the complete body of evidence in this review and found no newly available studies that might support alternative conclusions (75 FR 35548, June 22, 2010; 83 FR 26765, June 8, 2018). While the pattern of associations across the newly available epidemiologic studies is consistent with the studies available in the last review, key uncertainties remain, including the potential for confounding by PM or other copollutants (as summarized in section II.A.2 above). Among the U.S. epidemiologic studies reporting mostly positive and sometimes statistically significant associations between ambient SO_2 concentrations and emergency department visits or hospital admissions (some conducted in multiple locations), few studies have attempted to address this uncertainty, *e.g.,* through the use of copollutant models (83 FR 26765, June 8, 2018; ISA, section 5.2.1.2). In the last review, there were three U.S. studies for which the SO_2 effect estimate remained positive and statistically significant in copollutant models with PM.[78] As noted in the proposal, no additional such studies have been newly identified in this review (83 FR 26765, June 8, 2018). The conclusions of these studies and the air quality of the study areas were given consideration by the Administrator in 2010 in setting the current standard (83 FR 26761, June 8, 2018), and they do not call into question the adequacy of the current standard in this review.

Another comment in support of revising the standard level to 50 ppb cites information on the impact of asthma and asthma attacks on children and other population groups as a basis for their view that many people are being harmed under the current standard with its level of 75 ppb. While this comment described some of the health effects of SO_2 exposures for people with asthma and opined that SO_2-induced asthma attacks interfere with children's health, school attendance and education, the commenter did not provide evidence that such effects were allowed by and occurring under the current standard. While we agree with the commenter regarding the important impact of asthma on public health in the U.S., including impacts on the health of children and population groups for which asthma prevalence may be higher than the national average, and we agree that people with asthma, and particularly children with asthma, are at greatest risk of SO_2-related effects, we do not find the information currently available in this review to provide evidence of SO_2-induced asthma attacks or other harm to public health in areas of the U.S. that meet the current standard.[79] Thus, we disagree with the comment that the current standard fails to address the need to provide protection from asthma-related effects of SO_X in ambient air.

Commenters in support of a lower level for the standard additionally express concern that populations living in communities near large sources of SO_2 emissions, including children in population groups with relatively higher asthma prevalence, may not be adequately protected by the current standard. In considering this comment, we note that while the REA did not categorize simulated children with asthma with regard to specific demographic subgroups, such as those mentioned by the commenter or discussed in section II.A.2.d above, the estimates are for children with asthma in areas with large sources of SO_2 emissions and with air quality just meeting the current standard. As noted in section II.A.3 above, the asthma prevalence across census tracts in the three REA study areas ranged from 8.0 to 8.7% for all ages (REA, section 5.1) and from 9.7 to 11.2% for children (REA, section 5.1), which reflects some of the higher prevalence rates in the U.S. today (PA, sections 3.2.1.5 and 3.2.2.1). Thus, in considering these results to inform his decision regarding the adequacy of protection provided by the current standard, the Administrator is focused on the patterns of exposure and populations with elevated rates of asthma stated to be the situation of concern to these commenters.

In two of the three REA study areas, each of which include large emissions sources and air quality adjusted to just meet the current standard, no children with asthma were estimated to experience a day with an exposure while breathing at elevated rates to a 5-minute SO_2 concentration at or above 400 ppb, the concentration at which moderate or greater lung function decrements have been documented in 20–60% of study subjects, with decrements frequently accompanied by respiratory symptoms. In the third area the estimate was less than 0.1%, on average across the 3-year period. Further, fewer than 1% of children with asthma, on average across the 3-year assessment period, were estimated to experience any days with exposures at or above 200 ppb in two of the areas, and no children were estimated to experience such days in the third area (PA, Table 3–3; 83 FR 26775, June 8, 2018). Thus, the REA exposure and risk estimates for the current review indicate that the current standard is likely to provide a very high level of protection from SO_2-related effects documented at higher concentrations and a high level of protection from the transient lung-function decrements documented in individuals with asthma in controlled human exposure study concentrations as low as 200 ppb.

The comment claiming that the current standard does not provide an adequate margin of safety emphasized limitations in the evidence base of controlled human exposure studies, noting the very limited available studies that examined 5-minute SO_2 exposures as low as 100 ppb; the lack of studies in young children with asthma and people of any age with severe asthma; and that the studies did not examine the impact of multiple exposures in the same day. While we agree that the

[78] 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 (83 FR 26765, June 8, 2018).

[79] An overview of the evidence available in this review, and the ISA and PA conclusions regarding it, is provided in section II.A.2 above and summarized in the proposal. These conclusions did not find the currently available evidence to indicate that air quality conditions allowed by the current standard allow SO_2-induced asthma attacks that interfere with children's health, school attendance and education. The CASAC has concurred with the ISA conclusions regarding the evidence, which also support the overarching conclusion in the PA that the currently available evidence and exposure/risk information does not call into question the adequacy of public health protection provided by the current standard, a conclusion with which the CASAC also concurred, as summarized in section II.B.2 above.

evidence base is limited with regard to examination of potential effects at lower concentrations and in some population groups, we disagree with the latter statement that the currently available studies have not investigated multiple exposures within the same day. In fact, there are some studies that inform our understanding of responses to repeated occurrences of exposure during exercise within the same day (REA, Table 6–3; ISA, section 5.2.1.2). For example, there are studies that have investigated the magnitude of lung function response from separate exercise events within the same 1-hour or 6-hour exposure, and from exposures with exercise occurring on subsequent days (Linn et al., 1984; Kehrl et al., 1987). As an initial matter, we note that the evidence shows lung function decrements that occur with short SO_2 exposures are resolved with the cessation of either the exposure or exercise, with lung function returning to baseline in either situation (ISA, section 5.2.1.2). Further, responses to repeated exercise events occurring within the same 1-hour or 6-hour exposure are diminished in comparison to the response to the initial event (Kehrl et al., 1987; Linn et al., 1984; Linn et al., 1987). Even responses to exposures while exercising that are separated by a day are still very slightly diminished from the initial response (Linn et al., 1984). Thus, we disagree with the commenter's statement that the available controlled human exposure studies have not examined the impact of multiple exposures in the same day. While the studies involve single continuous exposure periods shorter than a day, the discontinuous nature of the exercise component of the exposure design provides the relevant circumstances for assessing the impact of multiple exposure-with-exercise events in a single day. The evidence from these studies documents the transient nature of the lung function response, even to the high concentrations studied (600 to 1000 ppb), as well as a lessening of decrements in response to subsequent occurrences within a day.

We agree with this comment that the evidence base is limited with regard to examination of potential effects at lower concentrations and in some population groups. As summarized in I.A.2 above, the health effects evidence newly available in this review does not extend our understanding of the range of 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 controlled human exposure studies where study subjects are freely breathing in exposure chambers. The limited information available for exposure concentrations below 200 ppb, including exposure concentrations of 100 ppb, while not amenable to direct quantitative comparisons with information from studies at higher concentrations, generally indicates a lesser response. Further, as discussed in section II.A.2 above, we recognize that evidence for some at-risk population groups, including young children with asthma and individuals with severe asthma, is limited or lacking at any exposure concentration. As discussed in section II.B.4 below, the Administrator has explicitly recognized this in reaching conclusions regarding the adequacy of the public health protection provided by the current standard, including considerations of margin of safety for the health of at-risk populations.

One commenter advocating a more stringent standard additionally notes that evidence from controlled human exposure studies is also lacking for adults older than 75 years, an age group for which the commenter states there is new research placing this age group at increased risk. While some recent epidemiologic studies have examined associations of SO_2 with the occurrence of various health outcomes in older adults (typically ages 65 years and older), such studies have not consistently found stronger associations for this group compared to younger adults (ISA, sections 6.5.1.2 and 6.6). As a result, the ISA concluded that the evidence was only suggestive of the older age group being at increased risk of SO_2-related health effects. Such a characterization indicates that "the evidence is limited due to some inconsistency within a discipline or, where applicable, a lack of coherence across disciplines" (ISA, Table 6–1), and in this case, the ISA indicates that the study results were concluded to be "mixed" or "generally inconsistent" (ISA, Table 6–7). Further, there is no evidence indicating that the individuals in this group would be affected at lower exposure concentrations than other population groups or that they would be inadequately protected by the current standard. As noted by the CASAC more broadly, "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" (Cox and Diez Roux, 2018b, p. 3 of letter).

With that recognition in mind, the CASAC explicitly considered the issue of margin of safety provided by the current standard. While noting that "[i]t is plausible that the current 75 ppb level does not provide an adequate margin of safety in these groups," the CASAC additionally stated that "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 concluded that the 75 ppb level of the standard "is protective" and that the current scientific evidence "does not support revision of the primary NAAQS for SO_2" (Cox and Diez Roux, 2018b, pp. 1 and 3 of letter). In addition, we note that the D.C. Circuit has concluded that the selection of any particular approach for providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment (*Lead Industries Association* v. *EPA,* 647 F.2d at 1161–62; *Mississippi,* 744 F.3d at 1353). In light of such considerations, as discussed in section II.B.4 below, the Administrator does not agree with commenters that the current standard fails to include an adequate margin of safety or otherwise insufficiently protects older adults or other population groups, including those that are recognized as being most at risk of SO_2-related effects in this review, *i.e.,* people with asthma, in particular children with asthma.

As additional support for their view that the standard level should be revised to 50 ppb, one of the commenters states that any new standard would have to be more protective to make up for the lack of progress on implementation of the 2010 standard. Such a rationale lacks a basis in the CAA. The requirements in sections 108 and 109 of the CAA for establishing and reviewing the NAAQS are separate and distinct from the CAA requirements for implementing the NAAQS (*e.g.,* CAA sections 107, 110, and 172), and the time it takes to attain a standard under those requirements is not evidence pertaining to the adequacy of that standard with regard to public health protection under section 109. In setting primary and secondary standards that are "requisite" to protect public health and public 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 for these purposes.[80]

[80] In so doing, the EPA may not consider the costs of implementing the standards. See generally,

Continued

Moreover, section 109(d)(1), the statutory provision that governs the review and revision of the NAAQS, provides that the Administrator shall periodically review the NAAQS and the air quality criteria and "shall make such revisions . . . as may be appropriate in accordance" with sections 108 and 109(b), but does not mention any of the sections of the Act related to NAAQS implementation as relevant to that review. In addition, the Act contains specific provisions addressing the timing of NAAQS implementation, such as promulgating area designations under section 107(d) and adoption of state implementation plans for NAAQS implementation and enforcement under sections 110(a)(1) and 172(c), and these provisions establish their own requirements for timing and substantive decisions that are, likewise, not governed by the deadlines and criteria that govern the EPA's review under section 109. Each of these sections—109, 107, 110 and 172—govern EPA action independently of each other, and the EPA's performance of its duties under each provision is independently and fully reviewable without regard to the timeliness of its actions under the other provisions. Thus, there is no reason to think that Congress intended to require the Agency to address issues of the timing of NAAQS implementation through the NAAQS review process, including in the consideration of whether a specific standard provides the requisite protection.

One of the comments submitted in support of a lower standard level also recommended that the form of the standard be revised to one that would allow fewer daily maximum 1-hour concentrations above 75 ppb. This commenter stated that if the level of the current standard is retained, a more restrictive form of the standard should be adopted. In support of this position, this commenter stated that the current 99th percentile form allows for "multiple days a year of dangerous levels of SO_2." The commenter does not provide a basis for their characterization of any 1-hour SO_2 concentration above 75 ppb as dangerous and does not explain their view of what "dangerous" encompasses with respect to potential exposures and health risk, estimates of which are provided by the REA for air quality scenarios that just meet the current standard and would allow no more than 4 days per year (on average across a 3-year period) with 1-hour concentrations above 75 ppb. We do not consider the exposures allowed by the current standard and characterized in the REA to be dangerous to public health. Thus, we disagree with the commenter's view that the small number of days that may have 1-hour concentrations above 75 ppb under conditions meeting the current standard create "dangerous" circumstances. The evidence base of controlled human exposure studies, which provides the most detailed information about human health effects resulting from exposure to SO_2, does not include exposure concentrations below 100 ppb. While the data are limited at that concentration, they indicate a lesser response than that at the 200 ppb level. The results for exposures at 200 ppb indicate that, which includes less than 10% of study subjects with asthma, exposed while exercising, experiencing a moderate or greater lung function decrement, with the response ceasing with cessation of exposure or exertion. Nor do we agree that a more restrictive form of the standard is necessary to protect at-risk populations from adverse effects associated with short (*e.g.,* 5-minute) peak SO_2 exposures which was an explicit consideration in the establishment of the current standard (75 FR 35539, June 22, 2010). Section II.A.2 above summarizes the current health effects evidence regarding concentrations associated with effects of such exposures and the severity of such effects. As noted there, the current evidence is consistent with that available in the last review when the standard was set. Further, as recognized in sections II.A.1 and II.B.1 above, the protection afforded by the current standard stems from its elements collectively, including the level of 75 ppb, in combination with the averaging time of one hour and the form of the 3-year average of annual 99th percentile daily maximum concentrations. The REA analyses of exposure and risk for air quality conditions just meeting the current standard (in all its elements) indicate a high level of protection of children with asthma from days with an exposure, while exercising, to peak concentrations as low as 200 ppb, the lowest concentration at which moderate or greater lung function decrements have been documented, and a very high level of protection against 400 ppb exposures.[81] We additionally note that analyses of air quality at the 308 monitors across the U.S. at which the current standard was met during the recent 3-year period analyzed in the PA (2014–2016), indicate that peak SO_2 concentrations in ambient air at or above 200 ppb are quite rare (PA, Figure C–5). Lastly, we note that in explicitly considering the elements of the standard the CASAC advised that "all four elements (indicator, averaging time, form, and level) should remain the same" (Cox and Diez Roux, 2018b, p. 3 of letter). Considerations such as these from the CASAC inform the Administrator's conclusion (discussed in section II.B.4 below) that no revisions to the current standard, including its form, are needed.

The commenter that recommended establishment of a 24-hour standard, with a level of 40 ppb, stated that epidemiologic studies support the need for an additional 24-hour standard and note their position in the 2010 review for revision of the level of the then-existing 24-hr standard to 40 ppb, matching the level of California's current 24-hour standard. In terms of support for their advocacy of a 24-hour standard, the commenter cited three epidemiologic studies of associations of short-term SO_2 concentrations with premature death from respiratory causes in Chinese cities and two studies of associations of longer-term SO_2 concentrations with the development of asthma (conducted in the U.S. and Canada). We disagree that these studies indicate an inadequacy of the existing standard or indicate a need for an additional standard. As an initial matter, we note that the ISA for this review has assessed the current evidence regarding SO_2 and mortality, including the evidence provided by the three studies in Chinese cities. We agree with the comment that these three studies include analyses that controlled for some co-occurring pollutants, although we note that those analyses were limited to investigation of just two co-occurring pollutants, PM_{10} and NO_2. We additionally note that while the copollutant analyses found associations with SO_2 that generally remain positive and statistically significant after adjustment for PM_{10}, those after-adjustment associations are somewhat attenuated, indicating potential contributions to the association from PM_{10} (ISA, section 5.2.1.2, p. 5–145).[82] Moreover, these analyses show that after

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,* 665 F.2d at 1185.

[81] Although aspects of the studies of concentrations below 200 ppb complicate comparisons with the studies at 200 ppb, the limited evidence available does not indicate a response in any of the few subjects studied as severe as a doubling in sRaw (83 FR 26764, June 8, 2018).

[82] When adjusted for PM_{10} concentrations in the analyses, the magnitude of effect in the relationship between SO_2 and mortality was lower, compared to when PM_{10} was not controlled for.

adjustment for NO_2, the associations are much more attenuated and lose statistical significance (ISA, section 5.2.1.2, p. 5–145). Further, none of the studies adjusted for $PM_{2.5}$ (PM with mass median aerodynamic diameter nominally below 2.5 microns), a pollutant of particular importance with regard to potential confounding of epidemiologic analyses for SO_2 because of the fact that SO_2 is a precursor of $PM_{2.5}$ (ISA, section 1.6.2.4; PA, section 3.2.1.1). Additionally, these studies are limited in that they were conducted in Asian cities where the air pollution mixture and concentrations are different from the U.S., *e.g.,* SO_2 concentrations are much higher than concentrations in the U.S., which limits generalizability and "complicates the interpretation of independent association for SO_2" (ISA, Table 5–21; section 5.2.1.8) at lower concentrations where there are no studies that have controlled for relevant copollutants. In consideration of the full evidence base in this review, including these studies, the ISA concludes that the evidence regarding short-term SO_2 concentrations and respiratory mortality "is inconsistent within and across disciplines and outcomes, and there is uncertainty related to potential confounding by copollutants" (ISA, p. 5–155). Accordingly, as noted in the ISA, this limited and inconsistent evidence for associations with premature mortality does not substantially contribute to the determination that short-term SO_2 exposure is causally related to respiratory effects, a determination supported primarily by evidence from controlled human exposure studies (ISA, p. 5–153).

Further, with regard to the commenter's suggestion concerning a 24-hour standard and their reference to the current 24-hour standard in the state of California, the commenter simply states that they advocated such a standard in comments on the 2009 proposal in the 2010 review. We first note that as a general matter, we do not believe that merely stating that that was their position in the 2010 review is sufficient to raise a significant comment with reasonable specificity in this review. Moreover, we note that the California 24-hour standard was adopted in 1991, nearly 20 years prior to the EPA's last review of the primary SO_2 NAAQS in which we reviewed the then-currently available health effects evidence.[83] Since that time, the body of evidence has been expanded, including the epidemiologic studies raised by the commenter. As summarized in section II.A above, the 24-hour standard that had existed prior to the last review of the SO_2 NAAQS, was revoked based on the determination in the last review that the new 1-hour daily maximum standard would control SO_2 concentrations and protect public health from the associated short-term exposures (ranging from 5 minutes to 24 hours) with an adequate margin of safety (75 FR 35548, June 22, 2010). As summarized above and in the proposal, the evidence in this review is not substantively changed from that in the last review. Thus, based on the consistency of the currently available epidemiologic evidence (as well as the evidence from controlled human exposure studies) with that available in the last review, we continue to conclude that an additional standard with a 24-hour averaging time is not needed to provide the protection required of the NAAQS. Accordingly, we find the comment regarding a 24-hour standard and the rationale provided by the commenter to lack a foundation in the currently available health effects evidence. Furthermore, as explained in section I.A above, under section 109(b)(1) of the CAA the EPA Administrator is to set primary standards for criteria pollutants that are, in his judgment, requisite to protect public health with an adequate margin of safety, and these standards are to be based on the current air quality criteria for that pollutant. Under this framework, the mere fact that a different agency has previously established a different standard for a pollutant has no bearing on the Administrator's conclusions. As discussed in section II.B.4 below, the Administrator judges the current standard, based on the currently available evidence and exposure/risk information, to protect public health with an adequate margin of safety. Thus, we disagree with the commenter that the existing primary standard provides inadequate public health protection or that a 24-hour standard is needed to provide the appropriate protection.[84]

With regard to the epidemiologic studies of associations between long-term SO_2 concentrations and respiratory effects, including development of asthma, the ISA concluded that, for long-term exposure and respiratory effects, the complete evidence base, including those studies cited by the commenter, was suggestive of, but not sufficient to infer, the presence of a causal relationship (ISA, Section 5.2.2, Table 5–24). While limited animal toxicological evidence suggests biological plausibility for such effects of SO_2, the overall body of evidence across disciplines lacks consistency and there are uncertainties that apply to the epidemiologic evidence, including that newly available in this review, across the respiratory effects examined for long-term exposure (ISA, sections 1.6.1.2 and 5.2.2.7). In this light, the ISA concludes that there is uncertainty remaining regarding potential copollutant confounding and an independent effect of long-term SO_2 exposure, so that chance, confounding, and other biases cannot be ruled out (ISA, Table 1–1). Thus, we disagree with the commenter that the current evidence base supports their concern regarding long-term exposure or a need for longer-term standard. In so doing, we additionally note the conclusion reached in the last review that a standard based on 1-hour daily maximum SO_2 concentrations will afford requisite increased protection for people with asthma and other at-risk populations against an array of adverse respiratory health effects[85] related to short-term SO_2 exposures ranging from 5 minutes to 24 hours. As described in section II.B.4 below, the Administrator also concludes, based on the current review of the available scientific evidence documented in the ISA (which includes the studies cited by the commenter) and the REA estimates, that the current standard continues to provide the requisite protection of public health from health effects of sulfur oxides in ambient air.

(ii) Comments in Disagreement With Proposed Decision and Calling for Less Stringent Standard

Among the five commenters recommending revision to a less stringent standard, most generally expressed the view that the current standard is more stringent than necessary to protect public health. In support of this view some of these commenters claimed that the EPA was

[83] *https://www.arb.ca.gov/research/aaqs/caaqs/hist1/hist1.htm.*

[84] We additionally note that in addition to the 24-hour standard of 40 ppb, the California 1-hour air quality standard for SO_2 is set at a level of 250 ppb, more than three times the level of the current primary SO_2 NAAQS that was set in 2010. The 1-hour NAAQS of 75 ppb was established to protect against short-term exposures of a few minutes up to 24 hours, and was concluded in 2010 to provide the requisite protection of public health with an adequate margin of safety that was lacking under the prior 24-hour and annual standards.

[85] The effects were recognized to include decrements in lung function, increases in respiratory symptoms, and related serious indicators of respiratory morbidity that had been investigated in epidemiologic studies, including emergency department visits and hospital admissions for respiratory causes (75 FR 35550, June 22, 2010).

inappropriately concerned with limiting 5-minute exposures of 200 ppb and higher, rather than focusing only on exposures at or above 300 ppb or 400 ppb. Based on their view that the standard should focus only on limiting population exposures to these higher concentrations, these commenters variously recommended raising the level of the standard to 150 ppb or to just below 110 ppb, or, revising the percentile aspect of the form from a 99th to a 98th percentile. Other commenters stated that even for a focus on limiting 5-minute exposures at and above 200 ppb, the current standard is overly protective. These commenters recommended either revision of the averaging time or of the form, each claiming that such a revision, accompanied by no change to any other element of the standard, would still achieve adequate protection from exposures at or above 200 ppb.

The commenters in whose view the standard did not need to limit 5-minute exposures as low as 200 ppb stated that the studies of this exposure level did not find a statistically significant lung function response across the full group of study subjects and that the EPA should focus on a higher concentration, one at which the study subject group response was statistically significant. These commenters variously state that the controlled human exposure studies do not demonstrate statistically significant responses in lung function at SO_2 exposure concentrations less than 300 ppb or 400 ppb, respectively.

The EPA disagrees with the premise of these comments that the Agency's consideration of the adequacy of protection provided by the current standard is focused solely, and inappropriately, on limiting exposures to peak SO_2 concentrations at or above 200 ppb. Both the proposed decision and the Administrator's final decision, discussed in section II.B.4 below, consider the evidence from controlled human exposure studies and what it indicates regarding the severity and prevalence of lung function decrements in people with asthma exposed to the range of concentrations from 200 ppb through 400 ppb, and above, while breathing at elevated rates. The decision also considers what can be discerned from the extremely limited evidence at 100 ppb and also what the available evidence does not address, such as the concentrations at which a moderate or greater lung function decrement [86] might be expected to be elicited in exposed young children with asthma or people of any age that have severe asthma. Given the more severe response observed in some of the study subjects exposed to 400 ppb, the greater percentage of the study subjects with at least a moderate lung function decrement at this exposure, and the frequent association of these findings with respiratory symptoms, such as cough, wheeze, chest tightness, or shortness of breath, as well as the findings of statistical significance in various studies (ISA, Table 5–2 and section 5.2.1), the Administrator recognizes the importance of the standard providing a high degree of protection from exposures at and above 400 ppb, as discussed in section II.B.4 below. Thus, we agree with commenters that it is important to consider the level of protection provided by the current standard against 5-minute exposures to 400 ppb.

We disagree, however, with commenters who claim that it is not important to also consider the protection afforded by the standard against exposures below 400 ppb (including those at 200 ppb). As discussed in section II.B.4 below, in reaching a judgment on the adequacy of the current standard, the Administrator has considered the evidence of effects from exposures below 400 ppb. In so doing, the Administrator has taken note of the findings of a statistically significant decrement in lung function at 300 ppb at the study group level for a group of more SO_2-responsive study subjects (ISA, p. 5–153; Johns et al., 2010),[87] and of the percentage of subjects (as many as nearly 10%) experiencing a moderate or greater lung function decrement in controlled exposure studies of 200 ppb (ISA, Table 3–2). In considering the public health importance of effects associated with exposure to levels of SO_2 below 400 ppb, the Administrator gives weight to these findings, particularly in light of limitations in the evidence base, as well as to the ATS statement with regard to respiratory effects in people with asthma. Based on the findings, and in light of the fact that the evidence base is lacking or extremely limited for some population groups, including particularly young children with asthma, a group which the ISA concludes to be at greater risk than other individuals with asthma, and individuals of any age with severe asthma, a group for which the ISA suggests a potential for greater sensitivity,[88] the Administrator judges it important that the standard provide appropriate protection from peak SO_2 concentrations as low as 200 ppb, as discussed in section II.B.4 below. We also note that in the decision that established the current standard, weight was given to ensuring the new standard provided some level of protection from short exposures of people with asthma, breathing at elevated rates, to concentrations as low as 200 ppb (75 FR 35546, June 22, 2010). In denying the petitions for review of that decision, the D.C. Circuit concluded that the EPA acted reasonably, and within its discretion, in considering results from the controlled human exposure studies at concentrations as low as 200 ppb (*NEDA/CAP,* 686 F.3d at 812–13). In its conclusion that the standard was neither unreasonable nor unsupported by the record, the D.C. Circuit, noted the EPA's recognition that statistical significance was not reported for lung function decrements at that exposure level, and it also cited the EPA's conclusion that some groups, such as people with severe asthma, were not included among those studied and could suffer more serious health consequences from short-term exposures to 200 ppb SO_2 (*NEDA/CAP,* 686 F.3d at 812–13).

Three of the commenters, in whose views 400 ppb or 300 ppb is the lowest SO_2 exposure level that the standard

[86] As described in section II.A.2.c and consistent with the ISA in the last 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 (ISA, section 5.2.1.2 and Table 5–2).

[87] As discussed in the ISA and summarized in the PA, and recognized in the last review, among individuals with asthma, some individuals have a greater response to SO_2 than other individuals with asthma or a measurable response at lower exposure concentrations (ISA, p. 5–14). Data from a study newly available in this review "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).

[88] Even the study subjects described as having "moderate/severe" asthma would likely be classified as moderate by today's classification standards (83 FR 26765, June 8, 2018; ISA, p. 5–22; Johns et al., 2010; Reddel, 2009). The limited data that are available indicate a similar magnitude of relative lung function decrements in response to SO_2 as that for individuals with less severe asthma, although the individuals with more severe asthma are indicated to have a larger absolute response and a greater response to exercise prior to SO_2 exposure, indicating uncertainty in the role of exercise versus SO_2 and 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 previously, evidence from controlled human exposure studies are not available for children younger than 12 years old, and the ISA indicates that the information regarding breathing habit and methacholine responsiveness for the subset of this age group that is of primary school age (*i.e.,* 5–12 years) indicates a potential for greater response (ISA, pp. 5–22 to 5.25).

should protect against, stated that the standard of 75 ppb is more stringent than necessary and advocate revision of the level to a value no lower than 150 ppb, or a level just below 110 ppb.

The commenters advocating a level no lower than 150 ppb emphasize their view that the current standard is more stringent than necessary because it considers protection against 5-minute SO_2 concentrations of 200 ppb and higher rather than only 400 ppb and higher. They claim that adjusting the focus to one aimed at concentrations of 400 ppb and higher provides support for a revised level of 150 ppb and point, without further elaboration, to their comment submission during the public comment period for the 2010 rulemaking as providing supporting analysis. Similar to the cited submission from the 2010 rulemaking, the core argument of their current comments appears to be that the standard does not need to protect against exposures lower than 400 ppb, and that the EPA should not consider information about exposures as low as 200 ppb, which they claim was EPA's focus in its 2009 proposal to set the level for the new 1-hour standard within the range of 50 to 100 ppb. Rather, the commenters claimed that the EPA should focus only on 400 ppb and that based on results of analyses presented in the 2009 REA, a standard no lower than 150 ppb provides comparable protection for the 400 ppb benchmark as a standard between 50 and 100 ppb was estimated to provide for the 200 ppb benchmark. For example, the cited 2010 comment submission stated that the air quality analyses presented in the 2009 REA (based on air quality data for 40 U.S. counties from the late 1990s through 2007 and an estimated relationship between 1-hour and 5-minute concentrations, and involving the adjustment of the 1-hour concentrations to just meet different 99th percentile daily maximum 1-hour standards) indicates that the range of maximum annual mean number of days estimated to have 5-minute concentrations at or above 400 ppb at monitors adjusted to just meet 99th percentile daily maximum 1-hour standard levels of 150 and 200 ppb (7 to 13 days) was similar to the number of such days estimated to have 5-minute concentrations at or above 200 ppb at monitors adjusted to just meet 99th percentile daily maximum 1-hour standard levels of 50 and 100 ppb (2 to 13 days).

As an initial matter, as noted above, we do not believe that merely pointing to a comment or analysis offered during the last review, on the 2009 proposal, is sufficient to raise a significant comment in this review, without further description of why the issues raised in the 2010 review are still relevant to the proposal in the current review, which the commenter has not provided. Additionally, as explained above, the EPA continues to disagree with the view that the Agency should not consider the amount of protection provided by the primary SO_2 standard against 5-minute exposures to 200 ppb SO_2 in evaluating the current standard. Further we disagree with the commenter that the air quality and exposure analyses for different standard levels presented in the 2009 REA provide an appropriate basis for considering potential exposures allowed by the current standard. This is because the air quality and exposures analyses presented in the 2009 REA are appreciably limited compared to those available in the current review. The exposure analyses for this review are extensively improved and expanded over the 2009 analyses, as summarized in section II.A.3 above, including the fact that they address the full 3-year period of the standard rather than a single year of air quality and that they assess the existing standard rather than standard levels above and below the existing level. Additionally, the air quality data available in this review are appreciably expanded since the dataset used in the 2009 REA, such that the current dataset is much more robust. As just one example of this, the analyses of frequency of 5-minute concentrations above specific benchmarks at monitors meeting the current standard have been able to be conducted with 5-minute measurements rather than 5-minute concentration estimates as was the case in the last review. These analyses of recent air quality data indicate that at monitors with concentrations that meet the current standard, the maximum annual mean number of days with a 5-minute concentration above 400 ppb was seven (PA, section 2.3.2.3, Appendix C), a value falling within the range that the 2010 comment had found acceptable for the what was to be a new 1-hour standard (based on the then-available data). Thus, putting aside the commenter's view that no weight should be given to 5-minute SO_2 concentrations below 400 ppb (a view with which we disagree as discussed above), we note that the air quality analyses available in this review, which provide a more robust characterization of 5-minute concentrations occurring in locations meeting the current standard than that estimated in the 2009 REA, indicate the control of 5-minute 400 ppb concentrations provided by the current standard to be within with the commenter's target range. Thus, even if we accepted the premise that the current standard should be evaluated based solely on the degree of control of 5-minute 400 ppb concentrations, the basis for the commenter's concern that the current standard is overly stringent is not found in the current air quality analyses.

The comment that advocated revision of the level to a value just below 110 ppb provides little explanation for this specific alternative level. Given this commenter's emphasis on 300 ppb as the relevant benchmark from the controlled human exposure studies (and their view that EPA inappropriately considered 200 ppb), we interpret this comment as relating to application of a factor to the existing standard level, with the factor being derived by dividing 300 ppb (the exposure the commenter claims should be the focus for the standard) by 200 ppb (the concentration the commenter claims is the focus of the existing standard).[89] This commenter additionally cites several court decisions in support of EPA standard-setting decisions, two of which related to the EPA's setting of the level for the PM standard (a standard established with primary consideration of epidemiologic rather than controlled human exposure studies) at a concentration which the commenter describes as ''just below'' concentrations in areas and study periods for which epidemiologic studies observed a statistical association with health outcomes.[90] Thus, we interpret the comment to suggest that the standard level should be set slightly below the value resulting from application of the factor of 300 ppb divided by 200 ppb to the existing standard level of 75 ppb, *i.e.,* the level should be revised to just below about 110 ppb.

The EPA disagrees with the implication of the comment that the relevant basis for the primary standard level stems or should stem from a simple proportional relationship between the level of the 1-hour standard and the magnitude of the 5-minute concentration for which protection should be provided. Rather, consistent

[89] Multiplying 75 times 300 and dividing by 200 yields a value of 112.5 which rounds to 110 ppb.

[90] We agree with the comment states that an approach of setting standard levels below concentrations associated with statistically significant associations with negative health effects, such as in prior PM NAAQS reviews, has been upheld on judicial review. We additionally note, however, that caselaw, including that associated with challenges to the current SO_2 standard, makes clear that EPA has discretion in the approach it uses to set standard levels, provided it has presented a reasonable rationale that is supported by the record (*NEDA/CAP,* 686 F.3d at 813).

with the requirements of CAA sections 108 and 109 and the caselaw interpreting these provisions, as discussed in detail in section I.A above, the level of the standard, and the standard itself (as a reflection of its elements collectively), should be firmly based on the evidence in the review and other relevant considerations, such as consideration of the strengths and limitations of the evidence base.[91] The commenter provides no explicit rationale for why they consider such a proportional relationship to be appropriate and have not provided a clear explanation, based on health effects evidence or exposure/risk information, for the value of 110 ppb. Further, even if the commenter intends to imply that if the relevant 5-minute benchmark of concern is increased by a factor (*e.g.,* 150%), then the appropriate level for the 1-hour standard should also be increased by the same factor, the commenter provides no evidence for this assumption and the EPA is aware of none. Thus, the EPA disagrees with these comments that the level of the standard should be raised to 110 (or just below that value) or 150 ppb.

As summarized in section II.A.1 above, the existing standard, with its level of 75 ppb, was established in 2010 based on consideration of the level of protection provided from short exposures to peak concentrations of SO_2, as indicated from the REA results available at that time for standard levels above and below 75 ppb, as well as judgments of an adequate margin of safety in light of concentrations in a set of epidemiologic studies that found statistically significant associations of SO_2 concentrations with respiratory health outcomes when using copollutant models with PM. Review of the current standard is based on the health effects evidence and exposure and risk information now available, including the exposure and risk estimates for air quality scenarios in which the current standard is just met (which were not available at the time the standard was set). Based on all of the currently available information, the Administrator has concluded that the current standard (in all of its elements) remains requisite to protect public health with an adequate margin of safety (as discussed in section II.B.4, below), and that a less stringent standard would not provide adequate protection.

The commenters who stated that the percentile aspect of the form of the standard should be revised to be the 98th percentile rather than the current 99th percentile based their rationale primarily on their views that either 300 ppb or 400 ppb is the lowest exposure level that should be considered in evaluating the protection provided by the standard. These commenters state that the EPA's 2010 selection of the 99th percentile was based on the Agency's conclusion regarding the greater effectiveness of a 99th percentile form than a 98th percentile form with regard to controlling 5-minute concentrations at and above 200 ppb. These commenters generally state that with a change in focus to one that considers only the protection provided from exposures at and above either 300 ppb or 400 ppb (a change that they advocate), a 98th percentile form would provide effective control of the relevant 5-minute concentrations. Additionally, beyond the disagreement with the EPA about the need to protect at-risk populations from exposures below 300 ppb or 400 ppb (addressed above), the commenters variously cite the following reasons for such a revision in form: (1) The view that a 98th percentile would provide greater regulatory stability than a 99th percentile form; and (2) a claim that EPA's choice of a 99th percentile form in 2010 was inappropriately based in part on concentrations in three U.S. epidemiologic studies and in part on EPA's air quality analyses of the effectiveness of control of 5-minute concentrations.[92]

With regard to the first reason, the issue of regulatory stability was considered by the EPA in selecting the 99th percentile form when the standard was established in 2010. As described in the last review, analyses in the 2009 REA indicated that over a 10-year period, there appeared to be little difference in the stability of design values based on a 98th or 99th percentile form, leading the EPA to conclude at that time that there would "not be a substantial difference in stability between 98th and 99th percentile forms" (75 FR 35540, June 22, 2010; 2009 REA, section 10.5.3). Further, the commenter provides no alternative analysis to support their view that the 98th percentile is more stable; nor do they provide any reasoning or analysis that would demonstrate a flaw in the EPA analysis or conclusions. Thus, we are not aware of any basis for the view that a 98th percentile form would offer greater stability.

With regard to the second reason, as an initial matter, we note that the question of whether the 99th percentile form was appropriately adopted in 2010 is a question that the EPA resolved in the last review, and one that is not before us in this review.[93] However, to the extent that the comment is intended to suggest that we should not retain the 99th percentile form in this review based on the objections raised in the comments, we respond as follows. First, we find the commenter to be mistaken in their assertion that the EPA's choice of the 99th percentile for the percentile aspect of the form in setting the current standard relied on specific concentrations in three U.S. epidemiologic studies. In making this assertion, the commenter incompletely paraphrases a statement in the proposal for this review regarding the elements of the 2010 standard and the Administrator's judgment that this standard would provide the requisite protection for at-risk populations against the array of adverse respiratory health effects related to short-term SO_2 exposures, including those as short as 5 minutes (83 FR 26756, June 8, 2018) and then incorrectly relates the EPA's 2010 judgment on form for the standard to a statement in the proposal in the current review that summarized 99th percentile daily maximum 1-hour concentrations[94] in a set of U.S. studies for which the SO_2 effect estimates remain positive and statistically significant in copollutant models with PM (83 FR 26765, June 8, 2018). The disconnected statements cited by the commenter do not refer to the EPA's rationale in setting the form for the current standard or its rationale in the proposal in this review to retain the current standard without revision. Rather, the basis for the form for the current standard, and rationale in this review, is summarized in sections II.A.1 and II.B.3 of the proposal (83 FR 26760, 26782, June 8, 2018)[95] and in sections

[91] For example, in *Mississippi,* 744 F.3d at 1352–53, the D.C. Circuit concluded that EPA had reasonably explained the limitations of the scientific evidence in determining the level of the 2008 ozone NAAQS.

[92] The commenter making this claim additionally states that the EPA has not to date provided an explanation of why a 99th percentile form would be more effective than a 98th percentile form in providing such control.

[93] The EPA has not reopened the last review in this action.

[94] The commenter additionally states their view regarding comparison of 99th and 98th percentiles of daily maximum hourly concentrations in these epidemiologic studies (which variously differed by some 10 to 20%) that there is little if any statistical difference between them, although no statistical analyses were submitted in support of this view.

[95] The relevant section in the **Federal Register** notification of proposed decision for this review begins with the phrase "[w]ith regard to the statistical form for the new 1-hour standard." This section is a summary of the section titled "Conclusions on Form" in the 2010 **Federal Register** notification of final decision (75 FR 35541, June 22, 2010). While the Administrator's conclusion on form for the current standard

II.A.1 and II.B.1 above. Briefly, the statistical form of the current standard is based on consideration of the health effects evidence, stability in the public health protection provided by the programs implementing the standard, and advice from the CASAC, as well as results of air quality analyses in the 2009 REA for alternative standard forms (75 FR 35539–41, June 22, 2010). Because the premise of the comment is mistaken, it does not provide grounds to conclude in this review that the 99th percentile form is inappropriate.

With regard to the comment about the 2009 REA air quality analyses in the 2010 review, the analyses found a 99th percentile form to be appreciably more effective at limiting 5-minute peak SO_2 concentrations than a 98th percentile form (75 FR 35539–40, June 22, 2010; 2009 REA, section 10.5.3, Figures 7–27 and 7–28). To the extent that the commenter intended to assert that it is inappropriate to retain the 99th percentile based on objections to this analysis or its consideration in establishing the form of the standard, we disagree. While the comment notes the findings of these air quality analyses and the fact that a 98th percentile form would allow appreciably more days per year with 5-minute concentrations above 400 ppb and 200 ppb, it claims that the EPA's conclusion in the last review of greater effectiveness was arbitrary and misplaced for four reasons, three of which refer to aspects of epidemiologic studies and one which appears to point to the controlled human exposure studies stating that statistically significant findings at the study group level have not been found for exposures to short-term SO_2 concentrations below 300 ppb. As above, we note that any challenges to whether the EPA reached the appropriate conclusions in the last review are not properly before us in this review, as this is a new review of the current standard based on the current record and the EPA did not reopen the last review in this action. However, to the extent that the comment is intended to suggest that we should not retain the 99th percentile form in this review based on these four reasons, we respond as follows. As the epidemiologic studies were not identified as a factor in the EPA's 2010 decision on the 99th percentile (versus a 98th percentile) form for the standard (75 FR 35541, June 22, 2010),[96] and were not identified as a basis for the proposal in this review to retain the current standard, without revision, we find the commenter's reasons related to epidemiologic studies to have no relevance to our decision here. With regard to statistical significance of study subject responses below 300 ppb, putting aside our disagreement with the comment about the need to protect at-risk populations from exposures *below* 300 ppb (addressed above), we note that the air quality analyses relied on in the 2010 decision also demonstrated greater control of 5-minute concentrations *above* 300 (at 400 ppb) by the 99th percentile. Further, the comment also does not provide any reason for why a 98th percentile would be a more appropriate form. Accordingly, we find the comment lacks a sound basis for any claim that the form of the standard is arbitrary and misplaced or should not be retained. Therefore, we conclude that this comment does not call into question the appropriateness of the form of the current standard.

We also disagree with these commenters that a 98th percentile form would provide effective control of short exposures to peak SO_2 concentrations, for either exposures at and above 200 ppb or exposures to the still higher concentrations on which the commenters prefer to focus (at and above 300 ppb or 400 ppb). In this regard, we note as an initial matter the EPA analysis on which the 2010 conclusion is based (summarized immediately above); that analysis, presented in the 2009 REA "indicated that at a given SO_2 standard level, a 99th percentile form is appreciably more effective at limiting 5-minute peak SO_2 concentrations than a 98th percentile form" (75 FR 35540, June 22, 2010; 2009 REA, section 10.5.3, Figures 7–27 and 7–28). Further, we describe here a set of additional analyses of more recent air quality performed in the current review, the results of which support that conclusion in this review (Solomon et al., 2019). From these analyses of air monitoring data at 337 monitoring sites in the U.S., it can be seen that, compared to the current 99th percentile standard, a standard with an alternative 98th percentile-based form exerts less control of 5-minute peaks. For example, during this recent time period (2014–2016), there were three times as many 5-minute daily maximum concentrations at or above 400 ppb, 24 times as many such concentrations at or above 300 ppb, and more than 25 times as many such concentrations at or above 200 ppb at sites meeting an alternative 98th percentile standard as at sites meeting the current standard with its 99th percentile form (Solomon et al., 2019, Tables 1 and 2).

Thus, together, the stability analyses documented in the 2010 review and the analyses of more recent air quality demonstrate that the 98th and 99th percentile forms have similar stability, and that a standard revised to have a 98th percentile form provides appreciably less control than the current standard, both with regard to 5-minute concentrations above 400 ppb and 300 ppb, and also such concentrations above 200 ppb. The CASAC similarly concluded that the 99th percentile form is preferable to a 98th percentile form to limit the upper end of the distribution of 5-minute concentrations (Cox and Diez Roux, 2018b, p. 3 of letter). Accordingly, a standard with a 98th percentile-based form would provide less protection than that provided by the current standard from peak SO_2 concentrations, even from those at or above 400 ppb or 300 ppb, the concentrations that the commenters state are appropriate for the standard to provide protection from. Additionally, as discussed in section II.B.4 below, the Administrator considers it appropriate for the primary SO_2 standard to control 5-minute concentrations at and above 200 ppb, as well as those at and above 400 ppb, and considers the current standard, with the current form, to provide requisite protection from exposures to such concentrations. Thus, the EPA disagrees with the commenters and, for the reasons described above, finds that a revised standard with a 98th

considered the need to limit the upper end of the distribution of SO_2 concentrations in ambient air to provide protection with an adequate margin of safety against effects reported in both epidemiologic and controlled human exposure studies, the choice of 99th percentile over 98th percentile was not based on specific epidemiologic study concentrations. Rather, in considering the epidemiological evidence in her decision on standard level, the Administrator considered SO_2 concentrations in three specific epidemiologic studies (as summarized in II.A.1 above) in terms of the 99th percentile in light of her selection of that percentile for the standard form (75 FR 35547, June 22, 2010).

[96] The EPA's consideration of epidemiologic studies in its 2010 decision on the specific percentile for the form for the standard was with regard to the appropriateness of a percentile above the 90th, and not, as implied by the commenter, with regard to the selection of the 99th percentile (*e.g.,* as compared to the 98th percentile). Specifically, the Administrator at that time noted that, in line with the controlled human exposure study findings of effects from peak concentrations, some of the epidemiologic studies described in the 2008 ISA reported an increase in SO_2-related respiratory health effects at the upper end of the distribution of ambient air concentrations (*i.e.,* above 90th percentile SO_2 concentrations; see ISA, section 5.3, p. 5–9). Accordingly, 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 90th percentile SO_2 concentrations) in order to provide protection with an adequate margin of safety against effects reported in both epidemiologic and controlled human exposure studies (75 FR 35541, June 22, 2010).

percentile-based form would not provide the desired control of 5-minute concentrations at and above either 200 ppb or 400 ppb, nor the appropriate protection from the exposures associated with such concentrations.

Three commenters that recommended revision of the standard to be less stringent stated that, even when focused on limiting exposures at and above 200 ppb, the current standard is overly protective. These commenters recommended either revision of the averaging time or of the form, each claiming that their recommended revision, accompanied by no change to any other element of the standard, would still achieve adequate protection from exposures at or above 200 ppb. We address these comments in turn below.

The commenter that recommended revising the averaging time of the standard, stated that a standard with an averaging time of 3 hours, 8 hours, or 24 hours, and keeping all other elements of the current standard the same (including the level of 75 ppb, and the form that involves averaging annual 99th percentile daily maximum concentrations across a three consecutive period), would still be protective of a peak 5-minute 200 ppb concentration, and would provide regulatory stability. In support of this position, this commenter submitted a statistical analysis of SO_2 data from a subset of ambient air monitors in the U.S. The commenter's dataset was limited to 16 monitors located within 1 km of SO_2 emissions sources with greater than 4,000 tons per year of reported SO_2 emissions in the 2014 NEI; it included at most only 18 months of data from these monitors, and fewer data from some monitors. From the limited data available for these monitors, most of which do not yet have 3 full years of data from which to calculate a valid design value for the current standard, the commenter identified the 1-hour, 3-hour, 8-hour, and 24-hour periods in which the average concentrations were less than 75 ppb, and counted the number of times a 5-minute concentration within those periods was at or above 200 ppb. The commenter then summarized the results in terms of the percentage of the 1-hour, 3-hour, 8-hour or 24-hour periods with average concentrations less than 75 ppb that included a 5-minute concentration at or above 200 ppb. The commenter, while noting that the percentages were higher for longer periods than for shorter periods, claimed that this limited dataset covering 18 or fewer months demonstrated that even a standard with a 24-hour averaging time would be protective of 5-minute SO_2 concentrations at and above 200 ppb.

We disagree with the commenter that their analysis is adequate to judge the level of control that the existing standard exerts over 5-minute concentrations of potential concern, much less to judge the protection provided by the current standard against exposures associated with respiratory effects in people with asthma or the adequacy of that protection. The commenter's analysis focuses on a dataset that by definition is biased to underestimate the occurrences of 5-minute concentrations at or above 200 ppb. First, by limiting the analysis to 18 months or less, the commenter's analysis did not include 3 years of data that would allow for judgment of whether or not the monitors included met the current standard or any of the suggested alternatives. Over a timeframe longer than that provided by the commenter, there would be opportunity for more peak 5-minute concentrations at or above 200 ppb. Given the lack of three full years of data to determine whether the monitor met the standard at the locations for which the commenter provided data, it is not possible to evaluate the protectiveness of the current standard or the suggested alternatives at these monitoring locations. Further, the commenter focused their statistics only on hours (or 3-hour, 8-hour or 24-hour periods) for which the average concentrations were at or below 75 ppb. Yet given the form for the current standard, a 3-year period at a location that meets the current standard (or the commenter's alternatives) could also include hours (or 3-hour, 8-hour or 24-hour periods) above 75 ppb, along with the associated 5-minute concentrations. Lastly, the commenter's analysis summarizes the occurrences of 5-minute concentrations at or above 200 ppb in terms of percentages (of hours at or below 75 ppb), rather than the number of occurrences during a year or the full 3-year period. This framing of their analysis precludes a consideration of the frequency of such peak concentrations at monitors meeting the standard. The frequency is an appropriate consideration because increasing frequency would directly relate to increasing potential for exposure to such peak concentrations, while percentage of a subset of the hours cannot be interpreted with regard to such a relevant consideration.

Accordingly, in considering the commenter's view that an alternative averaging time would still be protective of exposures to 5-minute concentrations at or above 200 ppb, the EPA conducted an analysis that, like the commenter's analysis, focused on SO_2 monitoring sites located within 1 km of emissions sources with greater than 4,000 tons per year of reported SO_2 emissions according to the 2014 NEI, but that also included three complete years of data for each site, consistent with the form of the current standard (Solomon et al., 2019).[97] Further, the EPA analysis summarizes the frequency of occurrences of 5-minute concentrations at or above 200 ppb and does this for those monitoring locations that meet the current standard, and also at those that would meet an alternative 3-hour, 8-hour, or 24-hour standard (with a level of 75 ppb)[98] (Solomon et al., 2019, Tables 5 through 8). At sites that would meet standards with such alternative averaging times, there were many more 5-minute daily maximum SO_2 concentrations at or above 200 ppb than at sites that meet the current standard, in many instances 20 to 200 times more. (Solomon et al., 2019, Tables 5 through 8). This relates in part to the fact that more sites meet the alternative standards than the current standard due to the lesser stringency of a standard with a longer averaging time that has the same level as the current standard. Additionally, however, when evaluating 5-minute concentrations on a per-monitor basis, it can also be seen that as many as 15, 29, and 144 times more 5-minute daily maximum SO_2 concentrations at or above 200 ppb are allowed to occur at monitors that would meet an alternative standard with a 3-hour, 8-hour or 24-hour averaging time, respectively, compared with only two at the monitor meeting the current standard (Solomon et al., 2019, Table 9). Thus, it can be seen even from this analysis of the small number of sites near very large emissions sources (>4,000 tons per year in 2014 NEI), that a standard with a longer averaging time (and the level of 75 ppb) would provide less public health protection than that provided by the current 1-hour standard. We additionally note that the focus for the commenter analysis on monitors near sources emitting 4,000 or more tons per year as of 2014 yields an analysis focused on a small percentage

[97] The resulting set of 3-year data included six monitoring sites, with five of these also included in the commenter's 1-year dataset (Solomon et al., 2019). Three years of data were not available for any of the other monitors in the commenter's dataset.

[98] The Solomon et al. (2019) analysis derived DVs at each monitoring site based on the three alternative averaging times cited by the commenter. Then it sorted and binned the sites based on whether the design value was above or below a level of 75 ppb (which commenters stated to be the level for their preferred alternative standard).

of all monitors in the U.S. Although this may capture monitors near (within 1 km of) the largest sources in the U.S., it does not necessarily capture areas with the highest SO_2 concentrations that still meet the current (and the commenter's alternative) standard. For example, an analysis in the PA of all the monitors meeting the current standard documents a monitor with as many as 32 days per year having a 5-minute concentration at or above 200 ppb (PA, p. 2–12 and Appendix C, Figure C–2). Thus, we find the commenter's analysis to be insufficient to examine the implications for public health protection of a revised averaging time. Based on the more complete analyses we have conducted with recent air quality data from across the U.S., which is focused on the locations near large sources consistent with the commenter analysis and where peak concentrations would be expected to be more frequent, we find that a longer averaging time, as advocated by the comment, would be appreciably less effective at limiting 5-minute ambient air concentrations at and above 200 ppb, and also at and above 400 ppb, and, consequently, would be expected to provide a lesser level of protection of at-risk populations from exposure to such concentrations.

Three commenters recommended revising the form of the standard to remove the focus on daily maximum 1-hour concentrations. They recommended revising the form of the standard to one based on all 1-hour average concentrations (versus the daily maximum 1-hour average concentrations). They claimed that a standard with such a revised form, yet otherwise identical to the existing standard, would still be protective against short-term SO_2 exposures at or above 200 ppb. These commenters stated that a standard with such a form would be preferable to the current standard as it would consider the concentrations of all hours in a year (including multiple hours in any day) in judging attainment with the standard rather than considering only the highest 1-hour concentrations per day within the year. In supporting materials for this comment, the commenters provide an example in which the fourth highest daily maximum 1-hour concentration [99] in 2 years of the 3-year evaluation period for the standard is above 75 ppb, while this concentration in the third year is well below 75 ppb such that the current standard might be met. In the two high years in the example, the commenters note that if all hours in the 4 days are above 75 ppb, then 96 hours (24 hours in each of the 4 days) would be above 75 ppb. Yet they claim that their example would only allow 88 hours above 75 ppb for their preferred alternative form. As the premise of their example is that there may be much higher concentrations in two of the three years, however, it is unclear why they claim only 88 hours above 75 ppb would be allowed by their preferred alternative. If the 3rd year is suitable low, there could be many more than 88 hours above 75 ppb and still meet their alternative standard. The commenters additionally provided observations related to ambient air monitoring data for 2011–2013 at monitors within the three REA study areas, and observations from a year of ambient air monitoring data at two monitors near aluminum smelters, stating that such observations supported their view regarding the protectiveness of a standard with a 99th percentile hourly form.

We disagree with these commenters' claims. As an initial matter, we find the commenters' example to be incorrect given its dependence on the specific scenario created by the commenter. We note that there are many other distributions of hourly concentrations across 3 years that could meet a design value of 75 ppb in which the total number of hours greater than 75 ppb is greater for the commenter's preferred alternative standard. Given the 3-year average aspect of the current form, the simplest example is one based on the average year. In order to meet the current standard in an average year, only 3 days (and at most the associated 72 hours) can have a daily maximum 1-hour concentration above 75 ppb because the 4th daily maximum 1-hour concentration could be no higher than 75 ppb. If the average year has a 99th percentile equal to 75 ppb (and consequently just meets the current standard), there could be no more than 72 hours above 75 ppb in each of the 3 years (3 days times 24 hours per day). Yet as the 99th percentile of the 8760 hours in a year is 88, an alternative standard with a 99th percentile hourly form could be met with 87 1-hour average concentrations above 75 ppb—15 more hours than that allowed by the current standard. Further, if the hours above 75 ppb in the average year all occurred on separate days, the commenter's alternative standard would allow there to be 87 days with a 1-hour concentration above 75 ppb, while the current standard allows there to be only 3 such days. Thus, a standard with a 99th percentile hourly form (rather than a form based on the 99th percentile of *daily maximum* 1-hour concentrations) would allow there to be many more days with an hour above the level of the standard (87 compared to 3). Given the variability in 1-hour SO_2 concentrations that is common near sources (*e.g.,* 95th percent confidence intervals on mean hourly concentrations at six locations indicate hourly variation can be a factor of two and greater [ISA, Figure 2–23]), such a consideration is relevant. Additionally, the health effects evidence indicates a greater response associated with exposures that are separated in time compared to those that are close in time.[100] Together, these observations based both in the air quality data and in the health effects evidence increase the importance of exposures on separate days versus those in consecutive hours. Further, presentations in the PA of recent air quality data demonstrate the control of peak 5-minute concentrations exerted by a standard based on daily maximum 1-hour concentrations (PA, Appendix B).

In the commenters' analysis of data from monitors in the three REA study areas, they failed to recognize that all but one of these monitors had design values based on the current standard that were at or below 75 ppb (*i.e.,* the data for only one monitor violated the NAAQS). While the commenters emphasized the few 5-minute concentrations above benchmarks across all of these monitors (five occurrences above 200 ppb across these seven monitors), we note that such a low number of elevated peak concentrations would be expected at monitors meeting the current standard. We additionally note that as shown in the commenters' submission there were seven occurrences of 5-minute concentrations above 200 ppb at the single monitor location for which the 2011–2013 data did not meet the standard. Together, we find this dataset, although very limited, documents a degree of control of peak concentrations by the current standard.

In order to more thoroughly assess the commenter's assertion that their preferred alternative hourly form would provide similar protection from 5-minute exposures at or above 200 ppb

[99] When measurements are available for all hours in a year, the 99th percentile of the 8760 hours in a year is 88, while the 99th percentile of 365 days in a year is four (and there are 96 hours in 4 days).

[100] As noted in section II.C.2 of the proposal (83 FR 26771, June 8, 2018) and section II.A.2 above, the health effects evidence indicates a 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). Further, 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 exposure event (REA, Table 6–3).

as the current standard, we performed two analyses, the first focused on the REA study areas and the second involving air quality data at monitors nationwide. As the exposure and risk estimates for the three REA study areas indicate the level of protection in these areas for the air quality scenario just meeting the current standard,[101] we analyzed the estimated concentrations in this scenario for each study area to determine what the design value for a standard with the commenters' preferred alternative form (the 99th percentile of all hours in a year, averaged over 3 years). We found that such a design value in each study area would be below 75 ppb, with variation from 31 ppb to 65 ppb across the three areas related to the different temporal and spatial patterns of concentrations in those areas (Solomon et al., 2019, Table 10). This finding of lower design values (*e.g.,* as low as 31 ppb) for a standard with such an alternative form indicates that such a form is less stringent and that to achieve similar protection against peak SO_2 exposures in the three areas, such an alternative SO_2 standard would require a standard level lower than 75 ppb. Additionally, looking at unadjusted concentrations across all U.S. monitoring sites in 2014–2016, the relationship between design values for the current standard and design values for an alternative standard with an hourly-based form (versus one based on daily maximum 1-hour concentrations) is seen to be approximately two to one, indicating that the SO_2 level associated with U.S. air quality summarized in terms of the commenter's preferred alternative form is one half the level for air quality summarized in terms of the current standard (Solomon et al., 2019, Figure 1). Thus, these additional analyses of adjusted air quality in the REA study areas and of the recent unadjusted ambient air monitoring data indicate that to achieve comparable protection of 5-minute exposures of concern, an alternative standard with a form based on the 99th percentile of all 1-hour concentrations in each year of the 3-year period (rather than the 99th percentile of daily maximum 1-hour concentrations) would need to have a level appreciably lower than 75 ppb (Solomon et al., 2019).

One of these commenters provided an analysis of ambient air monitoring data to demonstrate that an alternative standard that retains the level of 75 ppb yet revises the form to be based on the 99th percentile of all 1-hour concentrations in each year of the 3-year period would be protective of short-term exposures to 200 ppb SO_2. We find the commenter's analysis to be inadequate to support this position. This analysis is limited to just two monitors at the fenceline of an aluminum smelter facility. The NAAQS are national standards and must provide protection across all sites in the U.S. Moreover, the current standard is averaged over 3 years, but the commenter's analysis only includes 1 year of data. Thus, to consider the commenter's position using a more comprehensive dataset, we analyzed ambient air monitoring data for SO_2 at the 337 monitoring sites that met the completeness criteria for the recent 3-year period, 2014–2016. For monitors meeting the current standard and then for monitors meeting an alternative standard with an hourly form, we counted the number of 5-minute daily maximum concentrations at or above 200 ppb in each year. Across the 3-year period, for the 318 monitors meeting the current standard, there were 93 5-minute daily maximum concentrations at or above 200 ppb (Solomon et al., 2019, Table 1). There were more than six times as many such 5-minute concentrations across the same 3-year period at the 335 monitors meeting an alternative hourly standard (Solomon et al., 2019, Table 3). These results demonstrate that revision of the form to establish an alternative hourly standard, contrary to the assertion by the commenter, would result in a substantial reduction in control of 5-minute concentrations at or above 200 ppb and an associated reduction in protection from exposures to such concentrations.

One of the commenters that recommended consideration of a revised standard with a form based on the 99th percentile of all 1-hour concentrations in each year of the 3-year period additionally recommended that, if the EPA does not revise the form of the standard in such a way, the EPA should instead include a second level of evaluation of monitoring data in judging attainment of the standard. The commenter explained that, under this second level of evaluation, the EPA would not judge a monitoring site to exceed the NAAQS if the 5-minute data for that site do not include concentrations at or above 200 ppb. The framework recommended by the commenter provides that only those hours in which there is at least one 5-minute average concentration above 200 ppb (or the subset for which the 1-hour concentration is also above 75 ppb) would be used to determine whether a monitoring site exceeded the NAAQS.[102] The commenter claimed that data for monitors included in the REA study areas, and their limited analysis of 12 months of data at two monitoring locations, provided support for their position by indicating few or no 5-minute concentrations above 200 ppb during hours with average concentrations above 75 ppb. The commenter concluded, based on their analysis, that the current standard "is more stringent than is requisite to protect public health" since their limited dataset includes hours with 1-hour concentrations above 75 ppb and in which there are not any 5-minute concentrations at or above 200 ppb. The commenter further suggests that areas may be found in non-attainment of the 2010 NAAQS even if there is not a single 5-minute concentration at or above 200 ppb.

We disagree with the commenter's assertion that the absence of 5-minute SO_2 concentrations at or above 200 ppb at the two monitoring locations in their 12-month dataset shows that the current standard is more stringent than necessary. Examining a more extensive dataset demonstrates issues in the commenter's premise: Monitors exceeding the current standard also have 5-minute SO_2 concentrations at or above 200 ppb (Solomon et. al, 2019, Table 1). Given the insufficiency of the commenter's dataset for reaching conclusions with regard to air quality nationally under the current standard, we investigated the frequency of 5-minute concentrations at or above 200 ppb at monitoring sites nationally. In this analysis, we reviewed the data for all 337 monitoring sites meeting completeness criteria for a recent three-year period, 2014–2016 (documented in the PA, Appendix A). The data across these 3 years at all 19 monitors that do not meet the current standard include occurrences of 5-minute SO_2 concentrations at or above 200 ppb (Solomon et al., 2019, Table 4). Further

[101] This scenario was developed through adjustments of the hourly air quality data as described in section II.A.3.a above and described in detail in sections 3.4 and 6.2.2.2 of the REA.

[102] This comment submission includes inconsistent criteria for inclusion of data for judging compliance with the standard. In one place, the commenter suggests that only those hours with an average concentration at or above 75 ppb which also have a 5-minute concentration at or above 200 ppb would be included. Elsewhere, the commenter suggests that any hour—regardless of the average 1-hour concentration—that has a 5-minute concentration at or above 200 ppb would be included. Further, the commenter does not then make clear how the data included in this more limited dataset would be evaluated when judging attainment of the standard. For example, the current requirements for deriving design values for judging whether a site violates the standard specify completeness criteria for the dataset (see appendix T to part 50).

we note that these concentrations occur in some 1-hour periods with average concentrations above 75 ppb and also in some 1-hour periods with average concentrations below 75 ppb, while the commenter appears to limit their focus only to hours with average concentrations above 75 ppb. Further, analyses of these data in the PA demonstrate the reduction of 5-minute concentrations above 200 ppb and higher benchmarks achieved by the current standard (PA, section 2.3.2.3 and Figure C–5). These analyses do not indicate overcontrol of 5-minute concentrations; for example, among sites meeting the current standard, as many as 32 days per year were recorded with a 5-minute concentration at or above 200 ppb, and as many as 7 days per year with a 5-minute concentration at or above 400 ppb (PA, section 2.3.2.3 and Figure C–5). Thus, the commenter's position that the current approach to judging attainment (based on a valid design value at or below 75 ppb) is overly stringent in its control of 5-minute concentrations at and above 200 ppb is not supported by a comprehensive analysis of the available data across the U.S.

Although the comments do not make clear the exact inclusion criteria for data or the exact calculations they are advocating be applied in the second level of evaluation for judging attainment, such a second level evaluation would appear to allow the designation of areas as attaining the current standard when the areas do not meet the standard. As specified under the Clean Air Act, primary ambient air quality standards are those the attainment and maintenance of which are judged requisite to protect public health with an adequate margin of safety. The elements of the current standard include the highest daily 1-hour concentrations, not the highest 5-minute concentrations. To apply a second level of data evaluation for purposes of determining attainment that is based on consideration of 5-minute concentrations would have the effect of changing the standard itself rather than evaluating attainment with the existing standard. Thus, we disagree with the commenter that such an evaluation could be adopted for judging attainment without effecting a change to the standard itself.

d. Other Comments

Comments on topics not directly related to consideration of the current primary standard included recommendations for addressing data gaps and uncertainties to inform future reviews. We agree with many of these suggestions and note that the PA highlighted key uncertainties and data gaps associated with reviewing and establishing NAAQS for SO_2 and also areas for future health-related research, model development, and data gathering. We encourage research in these areas, although we note that research planning and priority setting are beyond the scope of this action.

The EPA also received several comments related to implementation of the primary SO_2 NAAQS, including comments concerning the use of AERMOD for estimating 1-hour concentrations versus concentrations over longer time periods, and comments citing facilities' difficulty demonstrating compliance with the 1-hour SO_2 standard. We are not addressing those comments here because, as described in section I.A above, this action is being taken pursuant to CAA section 109(d)(1) and relevant case law. Additionally, consistent with this case law, the EPA has not considered costs associated with attaining the standard as a part of this review, including the costs or economic impacts related to permitting or other implementation concerns, in this action (*Whitman,* 531 U.S. at 471 & n.4). Under CAA section 109(d)(1) the EPA has the obligation to periodically review the air quality criteria and the existing primary NAAQS and make sure revisions as may be appropriate. Accordingly, the scope of this action is to satisfy that obligation; it is not to address concerns related to implementation of the existing standard. State and federal SO_2 control programs, such as those discussed in section I.D, may provide an opportunity for permitting and other implementation concerns to be addressed. For example, in light of public comments suggesting potential unintended consequences for areas with low peak-to-mean SO_2 concentrations, the EPA intends to continue to work closely with the relevant air agencies for these areas in implementing the standard, building upon its 2014 Guidance for 1-Hour SO_2 Nonattainment Area SIP Submissions.[103]

4. Administrator's Conclusions

Having carefully considered the public comments, as discussed above, the Administrator believes that the fundamental scientific conclusions on effects of SO_2 in ambient air that were reached in the ISA and summarized in the PA, the air quality analyses summarized in the PA, and estimates of potential SO_2 exposures and risks described in the REA and PA, and summarized above and in sections II.B and II.C of the proposal, remain valid. Additionally, the Administrator believes the judgments he proposed to reach in the proposal (section II.D) with regard to the evidence and the quantitative exposure/risk information remain appropriate. Thus, as described below, the Administrator concludes that the current primary SO_2 standard provides the requisite protection of public health with an adequate margin of safety, including for at-risk populations, and should be retained.

In considering the adequacy of the current primary SO_2 standard in this review, the Administrator has carefully considered the policy-relevant evidence and conclusions contained in the ISA; the exposure/risk information presented and assessed in the REA; the evaluation of this evidence, the exposure/risk information and air quality analyses, and the rationale and conclusions presented in the PA; the advice and recommendations from the CASAC; and public comments, as addressed in section II.B.3 above. In the discussion below, the Administrator gives weight to the PA conclusions, with which the CASAC has concurred, as summarized in section II.D of the proposal, and takes note of key aspects of the rationale for those conclusions that contribute to his decision in this review.

In considering the PA evaluations and conclusions, the Administrator specifically takes note of the overall conclusions that the health effects evidence and exposure/risk information are generally consistent with what was considered in the last review when the current standard was established (PA, section 3.2.4). In so doing, he additionally notes the CASAC conclusion that, as the new scientific information in the current review does not lead to different conclusions from the last review, the CASAC supports retaining the current standard (Cox and Roux, 2018b, p. 3 of letter). As noted below, the newly available health effects evidence, critically assessed in the ISA as part of the full body of current evidence, reaffirms conclusions on the respiratory effects recognized in the last review, including with regard to key aspects on which the current standard is based. Further, the quantitative exposure and risk estimates for conditions just meeting the current standard indicate a similar level of protection, for at-risk populations, as that described in the last review for the now-current standard. The Administrator also recognizes limitations and uncertainties that

[103] Available at: *https://www.epa.gov/sites/production/files/2016-06/documents/20140423guidance_nonattainment_sip.pdf.*

continue to be associated with the available information.

With regard to the current evidence, as summarized in the PA and discussed in detail in the ISA, the Administrator takes note of the long-standing evidence that has established key health effects associated with short-term exposure to SO_2. This evidence, largely drawn from the controlled human exposure studies, demonstrates that very short exposures (for as short as a few minutes) to less than 1000 ppb SO_2, while breathing at an elevated rate (such as while exercising), induces bronchoconstriction and related respiratory effects in people with asthma and supports identification of people with asthma as the population at risk from short-term peak concentrations in ambient air (ISA; 2008 ISA; U.S. EPA, 1994).[104] The available epidemiologic evidence, generally consistent with that in the last review, provides support for the conclusion of a causal relationship between short-term SO_2 exposures and respiratory effects, for which the controlled human exposure studies are the primary evidence. The epidemiologic studies report positive associations of short-term (*i.e.,* hourly or daily) concentrations of SO_2 in ambient air with asthma-related health outcomes, including hospital admissions and emergency department visits. In considering these epidemiologic studies in the context of the larger evidence base, the Administrator recognizes that, as described in the ISA, while these studies analyze hourly or daily metrics, there is the potential for shorter-term peak concentrations within the study area to be playing a role in such associations. The Administrator further takes note of the associated uncertainties identified in the ISA related to potential confounding from co-occurring pollutants such as PM, a chemical mixture including some components for which SO_2 is a precursor,[105] and also related to the ability of available fixed-site monitors to adequately represent variations in personal SO_2 exposure, particularly with regard to peak exposures (ISA, p. 5–37; PA, section 3.2.1.4; 83 FR 26764, June 8, 2018).

With regard to health effects evidence newly available in this review, the Administrator takes note of the PA finding that, while the health effects evidence, as assessed in the ISA, has been augmented with additional studies since the time of the last review, 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 or additional populations at risk of SO_2-related effects. Thus, the Administrator recognizes that, as in the last review, the health effects evidence continues to demonstrate a causal relationship between relevant short-term exposures to SO_2 and respiratory effects, particularly with regard to effects related to asthma exacerbation in people with asthma. He also recognizes that the ISA conclusion on the respiratory effects caused by short-term exposures is based primarily on evidence from controlled human exposure studies, also available at the time of the last review, that document moderate or greater 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, and that the current 1-hour standard was established to provide protection from effects such as these (ISA, section 5.2.1.9; 75 FR 35520, June 22, 2010).

With regard to exposure concentrations of interest in this review, the Administrator particularly takes note of the evidence assessed in the ISA from controlled human exposure studies that demonstrate the occurrence of moderate or greater lung function decrements, at times accompanied by respiratory symptoms, in subjects with asthma exposed for very short periods of time while breathing at elevated rates, focusing primarily on the ISA analysis of findings from such studies for which respiratory response measurements are available to the EPA for individual study subjects (ISA, Table 5–2 and Figure 5–1; PA, Table 3–1).[106] These data demonstrate respiratory effects in a percentage of people with asthma exposed while exercising to SO_2 concentrations as low as 200 ppb. Nearly 10% of the study subjects experienced moderate or greater lung function decrements at this exposure level and respiratory symptoms were also reported to occur in some subjects in some studies at the study group level (ISA, Table 5–2; Linn et al., 1983; Linn et al., 1987). In weighing this evidence, the Administrator notes the statements from the ATS which continue to emphasize the importance of the consideration of effects on individuals with preexisting diminished lung function (ATS, 2000a; Thurston et al., 2017). Consistent with the ATS characterization of their most recent statement as ''providing a set of considerations that can be applied in forming judgments,'' the Administrator notes the importance of considering whether effects occur in people with diminished reserve, such as people with asthma, as well as consideration of the magnitude or severity of effects, the persistence or transience of the effects, and the potential for repeated occurrences (Thurston et al., 2017). Thus, as in the last review, when the current standard was set, the Administrator judges it appropriate to consider the protection provided by the current standard to the at-risk population of people with asthma from exposures to peak concentrations as low as 200 ppb while breathing at elevated rates, while also recognizing the reduced severity of effects at this exposure level, as was recognized by the Administrator in the last review.

The Administrator recognizes that both the percent of individuals experiencing lung function decrements and the severity of the decrements, as well as the frequency with which they are accompanied by symptoms, increase with increasing SO_2 concentrations across the range of exposure levels studied (ISA, Table 5–2; PA, section 3.2.1.3). For example, while almost 10% of study subjects experienced moderate or greater lung function decrements at 200 ppb, as noted above, at exposures of 300 to 400 ppb, as many as approximately 30% of subjects in some studies experienced moderate or greater decrements (as defined in section II.A above). Also, while less than 5% of study subjects exposed to 200 ppb experienced decrements that were greater than moderate, the percentage experiencing such larger decrements was nearly 15% and higher in some studies of 300 and 400 ppb (ISA, Table 5–2). Further, at concentrations at or above 400 ppb, moderate or greater lung function decrements were frequently accompanied by respiratory symptoms, such as cough, wheeze, chest tightness, or shortness of breath, with some of these findings reaching statistical significance at the study group level (ISA, Table 5–2 and section 5.2.1).

In considering the potential public health significance of these effects associated with SO_2 exposures, and documented in studies of individuals with asthma, the Administrator recognizes there to be greater significance associated with lung

[104] For people without asthma, such effects have only been observed in studies of exposure concentrations at or above 1000 ppb (ISA, section 5.2.1.7).

[105] Sulfur dioxide is a precursor to sulfate, which commonly occurs in particulate form (ISA, section 2.3; U.S. EPA, 2009, section 3.3.2 and Table 3–2).

[106] The availability of individual study subject data allowed for the comparison of results in a consistent manner across studies (ISA, Table-2; Long and Brown, 2018).

function decrements accompanied by respiratory symptoms and with larger decrements, both of which are more frequently documented to occur at exposures above 200 ppb, and also with the potential for greater impacts of SO_2-induced decrements in the much less well studied population of people with more severe asthma or young children with asthma, as recognized by the CASAC and summarized in sections II.A.2.d and II.B.2 above.[107] For example, he recognizes that health effects resulting from exposures at and above 400 ppb are appreciably more severe than those elicited by exposure to SO_2 concentrations of 200 ppb (or lower), and that health impacts of short-term SO_2 exposures (including those occurring at concentrations below 400 ppb) have the potential to be more significant in the subgroup of people with asthma that have more severe disease and for which the study data are more limited. He also notes that controlled human exposure studies may be limited or lacking in other population subgroups identified by the CASAC. Thus, the Administrator finds it important to consider the protection afforded from concentrations as low as 200 ppb, particularly in light of limitations in the evidence base for some population groups, as in the last review when the standard was set, and also judges it particularly important to provide a high degree of protection against exposures at and above 400 ppb given the increased prevalence and severity of effects in study subjects at such exposures.

In judging the level of protection afforded by the current standard, the Administrator turns to the REA, recognizing that health effects in people with asthma are linked to exposures during periods of elevated breathing rates, such as while exercising. Accordingly, the Administrator finds that, as was the case at the time of the last review, population exposure modeling that takes human activity levels into account is integral to consideration of population exposures compared to SO_2 benchmark concentrations and of population lung function risk, and that such consideration is integral to judging whether the protection afforded by the primary SO_2 standard is requisite. He additionally notes that the populations modeled in the REA, children and adults with asthma, are those identified as at risk from SO_2 related effects.

In his consideration of the REA estimates available in this review, the Administrator recognizes a number of improvements of the current REA compared to the REA in the last review, including that the current REA assesses an air quality scenario for 3 years of air quality conditions adjusted to just meet the current standard.[108] The current REA is additionally expanded from the prior one with regard to the number of study areas in that it now includes three urban areas, each with populations of more than 100,000 people.[109] The Administrator also notes that the asthma prevalence across census tracts in the three REA study areas ranged from 8.0 to 8.7% for all ages (REA, section 5.1) and from 9.7 to 11.2% for children (REA, section 5.1), which reflects some of the higher prevalence rates in the U.S. today (PA, sections 3.2.1.5 and 3.2.2.1). The other ways in which the current REA analyses are improved and expanded from those in the REA for the last review relate to improvements that have been made to models, model inputs and underlying databases. These improvements include the database, vastly expanded since the last review, of ambient air monitoring data for 5-minute concentrations, as summarized in section II.A.3 above.[110] While recognizing the differences between the current REA analyses and the 2009 REA analyses, the Administrator notes the PA finding of a rough consistency of the associated estimates when considering the array of study areas in both reviews. He additionally notes the PA findings that the newly available quantitative analyses comport with the conclusions reached in the last review regarding the control expected to be exerted by the now-current 1-hour standard on 5-minute exposures of concern (83 FR 26775–26776, June 8, 2018).

As at the time of proposal, the Administrator finds that when taking the REA estimates of exposure and risk together, and while recognizing the uncertainties associated with developing such estimates for air quality conditions adjusted to just meet the current standard, the current standard provides a very high degree of protection to at-risk populations from SO_2 exposures associated with health effects of more clear public health concern, as indicated by extremely low estimates of occurrences of exposures at or above 400 ppb [111] and of lung function risk for multiple days with moderate or greater decrement as well as for single days with the occurrence of a larger decrement, such as a tripling in sRaw. In reaching this judgment, the Administrator notes that the REA results for the three REA study areas under air quality conditions that just meet the current standard indicate 99.9% or more of children with asthma, on average across the 3 year period, to be protected from experiencing as much as a single day per year with an exposure, while breathing at an elevated rate, that is at or above the benchmark concentration of 400 ppb, an exposure level frequently associated with respiratory symptoms in controlled human exposure studies. In so noting, he recognizes the limitations and uncertainties associated with the REA modeling, including those associated with simulating temporal and spatial patterns of 5-minute concentrations in areas near large sources. Moreover, he finds it important that the REA results do not estimate any children in any of the three study areas to experience more than one such exposure in a year for the assessed conditions of air quality that just meets the current standard. Given the very transient nature of the effects associated with such short SO_2 exposures (as summarized in section II.A.2.a above), the Administrator gives greater attention to such findings regarding the potential for multiple (*versus* single) days with occurrences of such exposures which he considers an additional indication of the strength of protection against the occurrence of the potential for SO_2-related health effects. The Administrator judges these REA estimates for population exposures compared to the 400 ppb benchmark to represent a very high level of protection (at least 99.7% protected from a single occurrence in the highest year and 100% protected from multiple occurrences) from the risk of respiratory effects that have been

[107] The ISA notes that while the extremely limited evidence for adults with moderate to severe asthma indicates such groups may have similar relative lung function decrements in response to SO_2 as adults with less severe asthma, individuals with severe asthma may have greater absolute decrements that may relate to the role of exercise (ISA, p. 1–17 and 5–22). The ISA concluded that individuals with severe asthma may have "less reserve capacity to deal with an insult compared with individuals with mild asthma" (ISA, p. 1–17 and 5–22).

[108] In the 2009 REA, the exposure and risk estimates were analyzed for single-year air quality scenarios for potential standard levels (50 ppb and 100 ppb) bracketing the now current level of 75 ppb.

[109] In the 2009 REA, there was only one urban study area included in the analysis.

[110] Additional 5-minute monitoring data are available in this review as a result of the monitoring data reporting requirement established in the last review to inform subsequent primary NAAQS reviews for SO_X and the associated assessments (75 FR 25567–68, June 22, 2010).

[111] REA estimates are also extremely low for occurrences of exposures at or above 300 ppb, the exposure concentration at which an analysis that is newly available in this review finds statistically significant differences in response among groups of individuals with asthma that are responsive to SO_2 exposures at or below 1000 ppb (PA, Table 3–3; ISA, p. 5–153).

observed to occur in as many as approximately 25% of controlled human exposure study subjects with asthma exposed to 400 ppb while breathing at elevated rates, and that have been accompanied by respiratory symptoms (PA, Table 3–3; ISA, Table 5–2 and section 5.2.1).[112] He additionally notes the similarity of such findings to those considered by the Administrator in establishing the standard in 2010 in the last review (as summarized in section II.D.1. of the proposal).

The Administrator additionally finds the REA estimates for risk of moderate or greater lung function decrements, in terms of doubling and tripling of sRaw, to also indicate the current standard to provide a high level of protection for the simulated at-risk populations, including specifically the population of children with asthma. With regard to a doubling of sRaw, the REA results indicate nearly 99% or more of the at-risk population to be protected from experiencing a single day per year with this estimated magnitude of SO_2-related response, based on average estimates across the 3-year period, and 99% or more of this population to be protected from multiple such days. The REA results indicate still greater protection from a more severe tripling in sRaw, *e.g.,* more than 99.7% of children with asthma protected from experiencing a day per year with a SO_2-related tripling of sRaw, based on average estimates across the 3-year period, and at least 99.8% from experiencing multiple such days per year in areas with air quality just meeting the current standard. As with his consideration of the REA estimates for multiple days with exposures at or above benchmarks and recognizing somewhat lesser uncertainty in the comparison-to-benchmarks estimates,[113] the Administrator finds these lung function risk estimates for multiple occurrences and for occurrences of days with a tripling of sRaw to also be informative to his judgment on the appropriateness of the protection provided by the current standard. Together, the Administrator judges both sets of REA estimates to indicate that the current standard provides an appropriately high level of protection from the more severe and well characterized effects from very short exposures to SO_2, such as those at and above 400 ppb on people with asthma breathing at elevated rates.

In making this judgment, the Administrator also considers whether this level of protection is more than what is requisite and whether a less stringent standard would be appropriate to consider. In so doing, he first recognizes that a less stringent standard would allow the occurrence of higher peak SO_2 concentrations and a greater frequency of concentrations above benchmarks of interest, likely contributing to higher exposures and risks than those estimated by the REA. That is, a less stringent standard, with its lesser control on peak SO_2 concentrations, would be expected to allow a higher frequency of ambient air SO_2 concentrations at or above benchmarks of interest, including the 400 ppb benchmark, at which controlled human exposure studies of exercising people with asthma have reported nearly 25% of study subjects to experience a moderate or greater lung function decrement and nearly 10% of subjects to experience greater than moderate lung function decrements (*e.g.,* a tripling of sRaw). Such air quality patterns would likely contribute to higher exposures and risks than those estimated by the REA, and accordingly relatively lesser protection of people with asthma from exposures at or above benchmarks of interest.

Additionally, in considering potential ramifications of a less stringent standard, the Administrator recognizes that through its control of SO_2 concentrations at or above the lowest benchmark of 200 ppb, the current standard provides a margin of safety for less well studied exposure levels and population groups for which the evidence is limited or lacking. In so doing, he recognizes that our understanding of the relationships between the presence of a pollutant in ambient air and associated health effects is based on a broad body of information encompassing not only more established aspects of the evidence, such as the conclusion that exposure to higher SO_2 concentrations results in more severe lung function decrements, but also aspects with which there may be substantial uncertainty. For example, in the case of this review, he notes there to be increased uncertainty associated with characterization of the risk of lung function decrements (including their magnitude and prevalence, and the associated public health significance) at exposure levels below 400 ppb, and indeed below those represented in the controlled human exposure studies. In this regard, the Administrator notes the uncertainty regarding characterization of the risk of respiratory effects in populations at risk but for which the evidence base is limited or lacking, such as children with asthma or individuals with more severe asthma (PA, section 3.2.2.3; REA, section 5.3). He also takes note of the CASAC comments on these uncertainties, and on consideration of these groups in assuring the standard's adequate margin of safety. Further, he considers the epidemiologic evidence, taking note of the uncertainties associated with exposure measurement error and copollutant confounding in the evidence. In considering the uncertainties in both the controlled human exposure and epidemiologic of studies, he recognizes that collectively, the health effects evidence generally reflects a continuum, consisting of 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. In light of these uncertainties, the Administrator recognizes that the CAA requirement that primary standards provide an adequate margin of safety, as summarized in section I.A above, is intended to address uncertainties associated with inconclusive scientific and technical information, as well as to provide a reasonable degree of protection against hazards that research has not yet identified. Based on all of the considerations noted here, and considering the current body of evidence, including the associated limitations and uncertainties, in combination with the exposure/risk information, the Administrator concludes that a less stringent standard than the current standard would not provide the requisite protection of public health, including an adequate margin of safety.

Having concluded that a less stringent standard would not provide the requisite protection of public health, based in part on his judgment that the evidence and exposure/risk information indicates that the current standard provides an appropriately high level of protection from the more severe and well characterized effects on people with asthma from very short exposures to SO_2 while breathing at elevated rates

[112] The ISA finds controlled human exposure studies of exposures at 400 ppb to include stronger evidence (than at lower concentrations) of the occurrence of respiratory symptoms, with statistical significance (ISA, Table 5–2).

[113] In considering these estimates, the Administrator recognizes the quantitative uncertainty discussed in the REA, noted in section II.A.3.b above and cited in some public comments with regard to risk estimates associated with exposure concentrations below those assessed in the controlled human exposure studies. Accordingly, he recognizes somewhat greater uncertainty associated with the lung function risk estimates than the comparison-to-benchmark estimates, and in considering the lung function risk estimates, places relatively greater weight on the estimates for occurrences of days with larger decrements (associated with relatively higher exposure concentrations).

(*e.g.,* those associated with exposures at or above 400 ppb), and in part on his judgment that a less stringent standard would not provide the appropriate margin of safety in consideration of uncertainties regarding population groups at risk or potentially at risk but for which the evidence is limited or lacking, the Administrator also judges it appropriate to consider whether the level of protection associated with the current standard is less than what is requisite and whether a more stringent standard would be appropriate to consider. In this context, he first takes note of the very high level of protection that the REA results indicate to be provided by the current standard, including 99.9% or more of the simulated at-risk population with asthma, on average across the 3-year period, to be protected from experiencing a single day with an exposure at or above 400 ppb, while breathing at an elevated rate (as well as at least 99.7% with such protection in the highest year and 100% protected from multiple occurrences).[114] He finds such findings to indicate an appropriate level of protection from such exposures.

The Administrator additionally considers, as raised above, the level of protection offered by the current standard from exposures for which public health implications are less clear. In so doing, he again notes that information is lacking on concentrations associated with effects in populations such as young children with asthma and that information is limited for individuals of any age with severe asthma. With this in mind, he first considers the REA results for air quality adjusted to just meet the current standard across the 3-year period analyzed in each of the three study areas that indicate 0.7% or fewer of children with asthma to experience a single day per year (on average across the 3-year period) with a 5-minute exposure at or above 200 ppb in a single year, while breathing at elevated rates. Somewhat less than 0.1% of children with asthma are estimated to experience multiple such days, in any 1 year (see section II.A.3 above and section II.C.3 in the proposal). Based on the information that is available for studied individuals with asthma, summarized in section II.A.2 above, the Administrator recognizes exposures to 200 ppb to be associated with less severe effects than those associated with higher exposures (*i.e.,* at or above 300 or 400 ppb). In recognition of the limitations in the available evidence that contribute uncertainty to our understanding of the magnitude or severity of lung function decrements in young children with asthma and in individuals of any age with severe asthma exposed to SO_2 at such lower levels, the Administrator next considers the findings of the epidemiologic studies that document positive associations of short-term concentrations of SO_2 in ambient air with asthma-related health outcomes for children, including hospital admissions and emergency department visits. Yet, in so doing, he recognizes complications in our ability to discern the exposure concentrations that may be contributing to such outcomes, noting the conclusions of the current ISA and the ISA for the last review regarding the lack of clarity in the evidence regarding the concentrations that may be eliciting the associated outcomes (83 FR 26765, June 8, 2018).[115] [116]

The Administrator additionally considers comments from the CASAC, including those regarding uncertainties that remain in this review (summarized in section II.B.2 above). In these comments, the CASAC noted 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 one example, people with severe asthma, and also citing physiologic and clinical understanding (Cox and Diez Roux, 2018, p. 3 of letter). In considering these comments, in which the CASAC additionally stated that "[i]t is plausible that the current 75 ppb level does not provide an adequate margin of safety in these groups," the Administrator takes note of the CASAC consideration of uncertainty related to this issue and its conclusion that "the CASAC does not recommend reconsideration of the level at this time" (Cox and Diez Roux, 2018, p. 3 of letter). The Administrator further notes the CASAC overall conclusion in this review that the current evidence and exposure/risk information supports retaining the current standard.

Thus, in light of the currently available information, including uncertainties and limitations of the evidence base available to inform his judgments regarding protection for the at-risk population groups, as referenced above, as well as CASAC advice, the Administrator does not find it appropriate to increase the stringency of the standard in order to provide the requisite public health protection. Rather, he judges it appropriate to maintain the high level of protection provided by the current standard for people with asthma of different subgroups that may be exposed to such levels while breathing at elevated rates and he does not judge the available information and the associated uncertainties to indicate the need for a greater level of public health protection.

With regard to the uncertainties raised above, the Administrator notes that his final decision in this review is a public health policy judgment that draws upon scientific information and analyses about health effects and risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the information and analyses. Accordingly, he recognizes that his decision requires judgments based on an interpretation of the evidence and other information that neither overstates nor understates the strength and limitations of the evidence and information nor the appropriate inferences to be drawn. He recognizes, as described in section I.A above, that the Act does not require that primary standards be set at a zero-risk level; rather, the NAAQS must be sufficient but not more stringent than necessary to protect public health, including the health of sensitive groups, with an adequate margin of safety.

Recognizing and building upon all of the above considerations and judgments, the Administrator has reached his conclusions in the current review. As an initial matter, he recognizes the control exerted by the current standard on short-term peak concentrations of SO_2 in ambient air, as indicated by the PA analyses of recent air quality data that examined the occurrence of 5-minute concentrations above benchmarks of interest (PA,

[114] The REA estimates further indicate 99.7% or more of the simulated at-risk population with asthma, on average across the 3-year period, to be protected from experiencing a single day with an exposure at or above 300 ppb, while exercising (as well as at least 99.2% with such protection in the highest year and 100% protected from multiple such occurrences).

[115] The ISA in the current review concluded that "[i]t is unclear whether SO_2 concentrations at the available fixed site monitors adequately represent variation in personal exposures especially if peak exposures are as important as indicated by the controlled human exposure studies" (ISA, p. 5–37). This extends the observation of the 2008 ISA that "it is possible that these epidemiologic associations are determined in large part by peak exposures within a 24-h[our] period" (2008 ISA, p. 5–5).

[116] Notwithstanding such complications, the Administrator notes the lack of newly available epidemiologic studies for these health outcomes for children that include copollutant models for PM, and he also observes that based on data available for specific time periods at some monitors in the areas of the three such U.S. studies that are available from the last review and for which the SO_2 effect estimate remains positive and statistically significant in copollutant models with PM, the 99th percentile 1-hour daily maximum concentrations were estimated in the last review to be between 78 and 150 ppb, *i.e.,* higher than the level of the now-current 1-hour standard (83 FR 26765, June 8, 2018).

chapter 2 and Appendix B). Taking the REA estimates of exposure and risk for air quality conditions just meeting the current standard together (summarized in section II.A.3 above), while recognizing the uncertainties associated with such estimates, the Administrator judges the current standard to provide an appropriately high degree of protection to at-risk populations (and specifically people with asthma) from SO_2 exposures associated with health effects of more clear public health concern, as indicated by the extremely low estimates of occurrences of exposures at or above 400 ppb (and at or above 300 ppb). He further judges the current standard to additionally provide a slightly lower, but still appropriately high degree of protection for the appreciably less severe effects associated with lower exposures (*i.e.,* at or below 200 ppb while breathing at elevated rates), for which public health implications are less clear. In considering the adequacy of protection afforded by the current standard from these lower exposure concentrations, the Administrator recognizes, as noted above, that the effects reported at such concentrations are less severe than at the higher exposure levels. However, considering the array of limitations in the evidence with regard to characterizing the potential response of at-risk individuals to exposures below 200 ppb, as well as the limitations in the evidence for population groups at risk or potentially at risk but for which the evidence is lacking, the Administrator finds it appropriate to provide protection from these exposures in light of the CAA requirements for an adequate margin of safety to address uncertainties generally associated with limitations in the scientific and technical information and hazards that research has not yet identified. In this light, he judges the current standard to provide the appropriate protection from peak SO_2 concentrations in ambient air. Based on these and all of the above considerations, the Administrator concludes that the current primary SO_2 standard provides an adequate margin of safety against adverse effects associated with short-term exposures to SO_X in ambient air, and accordingly concludes that the current standard provides the requisite protection of public health under the Act.

With regard to key aspects of the specific elements of the standard, the Administrator recognizes the support in the current evidence base for SO_2 as the indicator for SO_X, as summarized in section II.B.1 of the proposal. In so doing, he notes the ISA conclusion that SO_2 is the most abundant of the SO_X in the atmosphere and the one most clearly linked to human health effects. He additionally recognizes the control exerted by the 1-hour averaging time on 5-minute ambient air concentrations of SO_2 (including, particularly, concentrations at and above 200 to 400 ppb) and the associated exposures of particular importance for SO_2-related health effects (*e.g.,* as indicated by the REA estimates). After consideration of the public comments advocating revision of the averaging time, as addressed in section II.B.3 above, the Administrator continues to find that the current standard as defined by the existing 1-hour averaging time along with the other elements, is requisite. Similarly, with regard to form and level of the standard, the Administrator takes note of the REA results as discussed above and the level of protection that they indicate the elements of the current standard collectively to provide. He has additionally considered the public comments regarding revisions to these elements of the standard, as addressed in section II.B.3 above, and continues to judge that the existing level and the existing form, in all its aspects, together with the other elements of the existing standard provide the appropriate level of public health protection.

The Administrator additionally takes note of the CASAC support for retaining the current standard and the CASAC's specific recommendation that all four elements should remain the same. Beyond his recognition of this support in the available information and in CASAC advice for the elements of the current standard, the Administrator has considered the elements collectively in evaluating the health protection afforded by the current standard. For all of the reasons discussed above, and recognizing the CASAC conclusion that the current evidence and REA results provide support for retaining the current standard, the Administrator concludes that the current primary SO_2 standard (in all of its elements) is requisite to protect public health with an adequate margin of safety from effects of SO_X in ambient air, including the health of at-risk populations, and should be retained, without revision.

C. Decision on the Primary Standard

For the reasons discussed above and taking into account information and assessments presented in the ISA, REA, and PA, the advice from the CASAC, and consideration of public comments, the Administrator concludes that the current primary standard for SO_X is requisite to protect public health with an adequate margin of safety, including the health of at-risk populations, and is retaining the current standard without revision.

III. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. There are no information collection requirements directly associated with a decision to retain a NAAQS without any revision under section 109 of the CAA. This action retains the current primary SO_2 NAAQS without any revisions.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Rather, this action retains, without revision, the existing national standard for allowable concentrations of SO_2 in ambient air as required by section 109 of the CAA. See also *American Trucking Associations* v. *EPA,* 175 F.3d 1027, 1044–45 (D.C. Cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities), *rev'd in part on other grounds, Whitman* v. *American Trucking Associations,* 531 U.S. 457 (2001).

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in the UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian tribes. This action does not change existing regulations; it retains the current primary SO_2 NAAQS, without revision. The primary NAAQS protects public health, including the health of at-risk or sensitive groups, with an adequate margin of safety. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866. The health effects evidence and risk assessment information for this action, which focuses on children with asthma as a key at-risk population, is summarized in sections II.A.2 and II.A.3 above and described in the ISA and PA, copies of which are in the public docket for this action.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act

This action does not involve technical standards.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation related to this is summarized in section II above and presented in detail in the ISA for the review. The action in this notification is to retain without revision the existing primary SO_2 NAAQS based on the Administrator's conclusion that the existing standard protects public health, including the health of sensitive groups, with an adequate margin of safety. As discussed in section II, the EPA expressly considered the available information regarding health effects among at-risk populations in reaching the decision that the existing standard is requisite.

L. Determination Under Section 307(d)

Section 307(d)(1)(V) of the CAA provides that the provisions of section 307(d) apply to ''such other actions as the Administrator may determine.'' Pursuant to section 307(d)(1)(V), the Administrator determines that this action is subject to the provisions of section 307(d).

M. Congressional Review Act

The EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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List of Subjects in 40 CFR Part 50

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

Dated: February 25, 2019.

Andrew Wheeler,

Acting Administrator.

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Committee will be allowed a maximum of five minutes to present their point of view. Also, written comments should be submitted electronically to *eargle.frances@epa.gov* for the LGAC and to *mercurio.cristina@epa.gov* for the SCAS. Please contact the Designated Federal Officers (DFO) at the numbers listed below to schedule a time on the agenda. Time will be allotted on a first-come first-serve basis, and the total period for comments may be extended if the number of requests for appearances requires it.

ADDRESSES: The Local Government Advisory Committee meetings will be held at the U.S. Environmental Protection Agency, Conference Room 1153, William Jefferson Clinton EPA East Building, 1201 Constitution Avenue NW, Washington, DC 20460. The Small Communities Advisory Subcommittee meetings will be held at the U.S. Environmental Protection Agency, Conference Room 1153, William Jefferson Clinton EPA East Building, 1201 Constitution Avenue NW, Washington, DC 20460. Meeting summaries will be available after the meeting online at *www.epa.gov/ocir/scas_lgac/lgac_index.htm* and can be obtained by written request to the DFO. In the event of cancellation for unforeseen circumstances, please contact the the designated federal officer(s) for reschedule information.

FOR FURTHER INFORMATION CONTACT: Local Government Advisory Committee (LGAC) contact Frances Eargle, Designated Federal Officer, at (202) 564–3115 or email at *eargle.frances@epa.gov.* and Small Communities Advisory Subcommittee (SCAS), contact Cristina Mercurio, Designated Federal Officer, at (202) 564–6481 or email at *mercurio.cristina@epa.gov.*

Information on Services for Those With Disabilities: For information on access or services for individuals with disabilities, please contact Frances Eargle at (202) 564–3115 or email at *eargle.frances@epa.gov* . To request accommodation of a disability, please request it 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: March 11, 2019.

Jack Bowles,

Director, State and Local Relations, Office of Congressional and Intergovernmental Relations.

[FR Doc. 2019–06130 Filed 3–28–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9990–96–ORD]

Ambient Air Monitoring Reference and Equivalent Methods; Designation of One New Equivalent Method

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of the designation of a new equivalent method for monitoring ambient air quality.

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) has designated one new equivalent method for measuring concentrations of ozone (O_3) in ambient air.

FOR FURTHER INFORMATION CONTACT: Robert Vanderpool, Exposure Methods and Measurement Division (MD–D205–03), National Exposure Research Laboratory, U.S. EPA, Research Triangle Park, North Carolina 27711. Phone: 919–541–7877. Email: *Vanderpool.Robert@epa.gov.*

SUPPLEMENTARY INFORMATION: In accordance with regulations at 40 CFR part 53, the EPA evaluates various methods for monitoring the concentrations of those ambient air pollutants for which EPA has established National Ambient Air Quality Standards (NAAQS) as set forth in 40 CFR part 50. Monitoring methods that are determined to meet specific requirements for adequacy are designated by the EPA as either reference or equivalent methods (as applicable), thereby permitting their use under 40 CFR part 58 by States and other agencies for determining compliance with the NAAQS. A list of all reference or equivalent methods that have been previously designated by EPA may be found at *http://www.epa.gov/ttn/amtic/criteria.html.*

The EPA hereby announces the designation of one new equivalent method for measuring concentrations of O_3 in ambient air. This designation is made under the provisions of 40 CFR part 53, as amended on October 26, 2015 (80 FR 65291–65468).

The new equivalent method for O_3 is an automated method (analyzer) utilizing the measurement principle based on UV photometry. This newly designated equivalent method is identified as follows:

EQOA–0219–251, ''KENTEK Inc. Model MEZUS 410 O_3 Analyzer,'' UV photometric analyzer operated in a range of 0–0.5 ppm, with 0.5 µm, 47 mm diameter Teflon® filter installed, operated at temperatures between 20 °C and 30 °C, with temperature and pressure compensation, at a nominal sampling flow rate of 800 cc/min, using a 5 minute averaging time, with either 105VAC–125VAC or 200VAC–240VAC input power options installed, 230-watt power consumption, equipped with 7 inch LCD touch screen display, and operated according to the KENTEK Inc. Model MEZUS 410 Ozone Analyzer User's Instruction Manual.

This application for a reference method determination for this O_3 method was received by the Office of Research and Development on January 29, 2019. This analyzer is commercially available from the applicant, Kentek Inc., Hansin S–MECA 65, Techno 3-ro, Yuseong-gu, Daejeon 34016, Korea.

A representative test analyzer was tested in accordance with the applicable test procedures specified in 40 CFR part 53, as amended on October 26, 2015. After reviewing the results of those tests and other information submitted by the applicant, EPA has determined, in accordance with part 53, that this method should be designated as an equivalent method.

As a designated equivalent method, this method is acceptable for use by states and other air monitoring agencies under the requirements of 40 CFR part 58, Ambient Air Quality Surveillance. For such purposes, this method must be used in strict accordance with the operation or instruction manual associated with the method and subject to any specifications and limitations (*e.g.,* configuration or operational settings) specified in the designated method description (see the identification of the method above).

Use of the method also should be in general accordance with the guidance and recommendations of applicable sections of the ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I,'' EPA/600/R–94/038a and ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Quality Monitoring Program,'' EPA–454/B–13–003, (both available at *http://www.epa.gov/ttn/amtic/qalist.html*). Provisions concerning modification of such methods by users are specified under Section 2.8 (Modifications of Methods by Users) of Appendix C to 40 CFR part 58.

Consistent or repeated noncompliance with any of these conditions should be reported to: Director, Exposure Methods and Measurement Division (MD–E205–01), National Exposure Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

Designation of this equivalent method is intended to assist the States in establishing and operating their air quality surveillance systems under 40 CFR part 58. Questions concerning the commercial availability or technical aspects of the method should be directed to the applicant.

Dated: March 8, 2019.

Timothy Watkins,

Director, National Exposure Research Laboratory.

[FR Doc. 2019–06132 Filed 3–28–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2018–0691, FRL–9990–27–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Standardized Permit for RCRA Hazardous Waste Management Facilities (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Standardized Permit for RCRA Hazardous Waste Management Facilities (EPA ICR Number 1935.06, OMB Control Number 2050–0182) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through March 31, 2019. Public comments were previously requested via the **Federal Register** on October 29, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before April 29, 2019.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OLEM–2018–0691, to (1) EPA, either online using *www.regulations.gov* (our preferred method), or by email to *rcra-docket@epa.gov,* or by mail to: RCRA Docket (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Jeff Gaines, Office of Resource Conservation and Recovery, (5303P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 703–308–8655; fax number: 703–308–8617; email address: *gaines.jeff@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: Under the authority of sections 3004, 3005, 3008 and 3010 of the Resource Conservation and Recovery Act (RCRA), as amended, EPA revised the RCRA hazardous waste permitting program to allow a ''standardized permit.'' The standardized permit is available to facilities that generate hazardous waste and routinely manage the waste on-site in non-thermal units such as tanks, containers, and containment buildings. In addition, the standardized permit is available to facilities that receive hazardous waste generated off-site by a generator under the same ownership as the receiving facility, and then store or non-thermally treat the hazardous waste in containers, tanks, or containment buildings. The RCRA standardized permit consists of two components: A uniform portion that is included in all cases, and a supplemental portion that the Director of a regulatory agency includes at his or her discretion. The uniform portion consists of terms and conditions, relevant to the unit(s) at the permitted facility, and is established on a national basis. The Director, at his or her discretion, may also issue a supplemental portion on a case-by-case basis. The supplemental portion imposes site-specific permit terms and conditions that the Director determines necessary to institute corrective action under section 264.101 (or state equivalent), or otherwise necessary to protect human health and the environment. Owners and operators have to comply with the terms and conditions in the supplemental portion, in addition to those in the uniform portion.

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this action are business or other for-profit.

Respondent's obligation to respond: Voluntary (40 CFR 270.275).

Estimated number of respondents: 1.

Frequency of response: One time.

Total estimated burden: 218 hours per year. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $11,612 (per year), includes $525 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is a decrease of 13,730 hours for this renewal. This decrease is based on the decrease from the estimated number of respondents from 86 to 1. In the 13 years since the Standardized Permit Rule was finalized, there has only been one such permit issued.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–06027 Filed 3–28–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0466]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the

"PPDC Membership 2019" in the subject line, using one of the following methods:

- *Electronically (preferred):* By email to *jewell.shannon@epa.gov.*
- *Mail:* By mail to: Shannon Jewell, PPDC Designated Federal Officer, Office of Pesticide Programs (7501P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Shannon Jewell, Designated Federal Officer for the PPDC, telephone number: (703) 3347–0109; email address: *jewell.shannon@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of particular interest to persons who work in agricultural settings or persons who are concerned about implementation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.;* the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.;* the amendments to both of these major pesticide laws by the Food Quality Protection Act (FQPA) of 1996, Public Law 104–170 (1996); and the series of Pesticide Registration Improvement Act (PRIA) amendments, including PRIA4, Public Law 116–8 (2019). Potentially affected entities may include, but are not limited to: Agricultural workers and farmers; pesticide industry and trade associations; environmental, consumer, and farmworker groups; pesticide users and growers; animal rights groups; pest consultants; State, local and Tribal governments; academia; public health organizations; and the public. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0058, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. Background

The PPDC is a federal advisory committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix 2. EPA established the PPDC in September 1995 to provide policy advice, information and recommendations to the EPA Administrator through the Director of the Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention. The PPDC provides a public forum to discuss a wide variety of pesticide regulatory developments and reform initiatives, evolving public policy and program implementation issues associated with evaluating and reducing risks from the use of pesticides. The EPA will consider candidates from the following sectors: Environmental/public interest and animal rights groups; farm worker organizations; pesticide industry and trade associations; pesticide user, grower, and commodity groups; federal and state/local/tribal governments; the general public; academia; and public health organizations.

The PPDC usually meets face-to-face twice a year, generally in the spring and the fall. Additionally, members may be asked to serve on work groups to develop recommendations to address specific policy issues. The average workload for members is approximately 4 to 6 hours per month. PPDC members may receive travel and per diem allowances where appropriate and according to applicable federal travel regulations.

III. Nominations

The EPA values and welcomes diversity. In an effort to obtain nominations of diverse candidates, the agency encourages nominations of women and men of all racial and ethnic groups. All nominations will be fully considered, but applicants need to be aware of the specific representation sought as outlined in the Summary above. Any interested person or organization may nominate qualified persons to be considered for appointment to this advisory committee. Individuals may self-nominate. Nominations may be submitted in electronic format (preferred) or mailed in accordance with the instructions under **ADDRESSES.**

To be considered, all nominations should include the following information:

- Current contact information for the nominee, including the nominee's name, organization (and position within that organization), current business address, email address, and daytime telephone number;
- Brief Statement describing the nominee's interest and availability in serving on the PPDC;
- Résumé and a short biography (no more than 2 paragraphs) describing the professional and educational qualifications of the nominee, including a list of relevant activities, or any current or previous experience on advisory committees; and
- Letter[s] of recommendation from a third party supporting the nomination. The letter should describe how the nominee's experience and knowledge will bring value to the work of the PPDC.

Other sources, in addition to this **Federal Register** notice, may also be utilized in the solicitation of nominees.

Authority: 5 U.S.C. Appendix 2.

Dated: May 20, 2019.

Richard Keigwin,

Director, Office of Pesticide Programs.

[FR Doc. 2019–11010 Filed 5–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9994–03–ORD]

Ambient Air Monitoring Reference and Equivalent Methods; Designation of One New Reference Method

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of the designation of a new reference method for monitoring ambient air quality.

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) has designated one new reference method for measuring concentrations of carbon monoxide (CO) in ambient air.

FOR FURTHER INFORMATION CONTACT: Robert Vanderpool, Exposure Methods and Measurement Division (MD–D205–03), National Exposure Research Laboratory, U.S. EPA, Research Triangle Park, North Carolina 27711. Phone: 919–541–7877. Email: *Vanderpool.Robert@epa.gov.*

SUPPLEMENTARY INFORMATION: In accordance with regulations at 40 CFR part 53, the EPA evaluates various methods for monitoring the concentrations of those ambient air

pollutants for which EPA has established National Ambient Air Quality Standards (NAAQS) as set forth in 40 CFR part 50. Monitoring methods that are determined to meet specific requirements for adequacy are designated by the EPA as either reference or equivalent methods (as applicable), thereby permitting their use under 40 CFR part 58 by States and other agencies for determining compliance with the NAAQS. A list of all reference or equivalent methods that have been previously designated by EPA may be found at *http://www.epa.gov/ttn/amtic/criteria.html.*

The EPA hereby announces the designation of one new reference method for measuring concentrations of CO in ambient air. This designation is made under the provisions of 40 CFR part 53, as amended on October 26, 2015(80 FR 65291–65468).

The new reference method for CO is an automated method (analyzer) utilizing the measurement principle based on non-dispersive infrared (NDIR) spectroscopy. This newly designated reference method is identified as follows:

RFCA–0419–252, ''Focused Photonics Inc. AQMS–400 CO Analyzer'' non-dispersive infrared (NDIR) analyzer operated in the range of 0–50 ppm, with 5 μm, 47 mm diameter Teflon®(PTFE) filter installed, operated at temperatures between 20 °C and 30 °C, at nominal input line voltage of 220±10% VAC and frequency of 50 Hz, at a nominal sampling flow rate of 800±80 cc/min, and operated according to the FPI AQMS–400 User Manual.''

This application for a reference method determination for this CO method was received by the Office of Research and Development on April 10, 2017. This analyzer is commercially available from the applicant, Focused Photonics Inc. (FPI), 760 Bin'an Road, Binjiang District, Hangzhou, Zhejiang, China.

A representative test analyzer was tested in accordance with the applicable test procedures specified in 40 CFR part 53, as amended on October 26, 2015. After reviewing the results of those tests and other information submitted by the applicant, EPA has determined, in accordance with part 53, that this method should be designated as a reference method.

As a designated reference method, this method is acceptable for use by states and other air monitoring agencies under the requirements of 40 CFR part 58, Ambient Air Quality Surveillance. For such purposes, this method must be used in strict accordance with the operation or instruction manual associated with the method and subject to any specifications and limitations (*e.g.,* configuration or operational settings) specified in the designated method description (see the identification of the method above).

Use of the method also should be in general accordance with the guidance and recommendations of applicable sections of the ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I,'' EPA/600/R–94/038a and ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Quality Monitoring Program,'' EPA–454/B–13–003, (both available at *http://www.epa.gov/ttn/amtic/qalist.html*). Provisions concerning modification of such methods by users are specified under Section 2.8 (Modifications of Methods by Users) of Appendix C to 40 CFR part 58.

Consistent or repeated noncompliance with any of these conditions should be reported to: Director, Exposure Methods and Measurement Division (MD–E205–01), National Exposure Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

Designation of this reference method is intended to assist the States in establishing and operating their air quality surveillance systems under 40 CFR part 58. Questions concerning the commercial availability or technical aspects of the method should be directed to the applicant.

Dated: May 10, 2019.

Timothy Watkins,

Director, National Exposure Research Laboratory.

[FR Doc. 2019–11073 Filed 5–24–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0405, OMB 3060–XXXX]

Information Collections Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before June 27, 2019. If you anticipate that you will be submitting comments but find it difficult to do so with the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@OMB.eop.gov;* and to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary

Issued in Washington, DC, on May 25, 2018.

Sean Oehlbert,

Acting Policy Director, Office of Nonproliferation and Arms Control, Department of Energy's National Nuclear Security Administration.

[FR Doc. 2018–11787 Filed 5–31–18; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9978–77–ORD]

Ambient Air Monitoring Reference and Equivalent Methods; Designation of One New Reference Method

AGENCY: Office of Research and Development; Environmental Protection Agency.

ACTION: Notice of the designation of a new reference method for monitoring ambient air quality.

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) has designated one new reference method for measuring concentrations of nitrogen dioxide (NO_2) in ambient air.

FOR FURTHER INFORMATION CONTACT: Robert Vanderpool, Exposure Methods and Measurement Division (MD–D205–03), National Exposure Research Laboratory, U.S. EPA, Research Triangle Park, North Carolina 27711. Phone: 919–541–7877. Email: *Vanderpool.Robert@epa.gov.*

SUPPLEMENTARY INFORMATION: In accordance with regulations at 40 CFR part 53, the EPA evaluates various methods for monitoring the concentrations of those ambient air pollutants for which EPA has established National Ambient Air Quality Standards (NAAQS) as set forth in 40 CFR part 50. Monitoring methods that are determined to meet specific requirements for adequacy are designated by the EPA as either reference or equivalent methods (as applicable), thereby permitting their use under 40 CFR part 58 by States and other agencies for determining compliance with the NAAQS. A list of all reference or equivalent methods that have been previously designated by EPA may be found at *http://www.epa.gov/ttn/amtic/criteria.html.*

The EPA hereby announces the designation of one new reference method for measuring concentrations of NO_2 in ambient air. This designation is made under the provisions of 40 CFR part 53, as amended on October 26, 2015(80 FR 65291–65468).

The new reference method for NO_2 is an automated method (analyzer) utilizing the measurement principle based on gas phase chemiluminescence. This newly designated reference method is identified as follows:

RFNA–0418–250, ''Sabio Model 6040 Ambient $NO/NO_2/NO_X$ Analyzer'', operated in the measurement range of 0–0.5 PPM, an any ambient temperature in the range of 5–40 °C, within a line voltage range determined by the selected optional pump [115 VAC external pump: 105–125 VAC (60 Hz); 230 VAC external pump: 210–250 VAC (50–60 Hz); 24 VDC internal pump: 90–260 VAC (50–60 Hz)], at any sample flow rate in the range of 0.50–0.75 L/min, in accordance with the ''Sabio Model 6040 Ambient $NO/NO_2/NO_X$ Analyzer Instruction Manual'', with or without optional zero/span ports for external calibration, and with or without an optional inlet filter.

This application for a reference method determination for this NO_2 method was received by the Office of Research and Development on March 28, 2018. This analyzer is commercially available from the applicant, Sutron Corporation, 21 Cypress Blvd., Suite 1130, Round Rock, TX 78665.

A representative test analyzer was tested in accordance with the applicable test procedures specified in 40 CFR part 53, as amended on October 26, 2015. After reviewing the results of those tests and other information submitted by the applicant, EPA has determined, in accordance with part 53, that this method should be designated as a reference method.

As a designated reference method, this method is acceptable for use by states and other air monitoring agencies under the requirements of 40 CFR part 58, Ambient Air Quality Surveillance. For such purposes, this method must be used in strict accordance with the operation or instruction manual associated with the method and subject to any specifications and limitations (*e.g.,* configuration or operational settings) specified in the designated method description (see the identification of the method above).

Use of the method also should be in general accordance with the guidance and recommendations of applicable sections of the ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I,'' EPA/600/R–94/038a and ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Quality Monitoring Program,'' EPA–454/B–13–003, (both available at *http://www.epa.gov/ttn/amtic/qalist.html*). Provisions concerning modification of such methods by users are specified under Section 2.8 (Modifications of Methods by Users) of Appendix C to 40 CFR part 58.

Consistent or repeated noncompliance with any of these conditions should be reported to: Director, Exposure Methods and Measurement Division (MD–E205–01), National Exposure Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

Designation of this reference method is intended to assist the States in establishing and operating their air quality surveillance systems under 40 CFR part 58. Questions concerning the commercial availability or technical aspects of the method should be directed to the applicant.

Dated: May 21, 2018.

Timothy Watkins,

Director, National Exposure Research Laboratory.

[FR Doc. 2018–11832 Filed 5–31–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9039–6]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7156 or *https://www2.epa.gov/nepa/.*

Weekly receipt of Environmental Impact Statements
Filed 05/21/2018 Through 05/25/2018
Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20180111, Draft, NMFS, NAT, Draft Environmental Impact Statement for Issuing Annual Catch Limits to the Alaska Eskimo Whaling Commission for a Subsistence Hunt on Bowhead Whales for the Years 2019 and Beyond, Comment Period Ends: 07/24/2018, Contact: John Henderschedt, 301–427–8385.

EIS No. 20180112, Draft, FHWA, NY, Hunts Point Interstate Access Improvement Project, Comment Period Ends: 07/16/2018, Contact: Erik Koester, 718–482–4683.

EIS No. 20180113, Draft, CBP, ID, Bog Creek Road Project, Comment Period