## ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50 and 53 [AD-FDL-5103-1]

RIN 2060-AA61

National Ambient Air Quality Standards for Sulfur Oxides (Sulfur Dioxide)—Reproposal

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

**ACTION:** Proposed rule.

**SUMMARY** The EPA today is proposing not to revise the current 24-hour and annual primary standards but is also soliciting comment on the possible need to adopt additional regulatory measures to address short-term peak (SO<sub>2</sub>) exposures and thereby further reduce the health risk to exercising asthmatic individuals. The alternatives under consideration include: revising the existing national ambient air quality standards (NAAQS) by adding a new 5minute standard of 0.60 ppm, 1 expected exceedance; establishing a new regulatory program under section 303 of the Clean Air Act to supplement the protection provided by the existing NAAQS; and augmenting implementation of the existing standards by focusing on those sources or source types likely to produce high 5-minute peak SO<sub>2</sub> concentrations.

Included in this document are proposals to incorporate certain associated technical changes to the requirements for Ambient Air Monitoring Reference and Equivalent Methods (40 CFR part 53) and other minor technical changes regarding the

40 CFR part 50 regulations.

A related document will be published shortly in the **Federal Register** that proposes for comment the requirements for implementing the alternative regulatory measures. Included in that document are technical revisions to 40 CFR parts 51 and 58.

DATES: Written comments on this proposal must be received by February 13, 1995. The EPA will hold a public hearing on this notice in approximately 30 days. The time and place will be announced in a subsequent Federal Register document.

ADDRESSES: Submit comments on the proposed action on the NAAQS (40 CFR part 50) (duplicate copies are preferred) to: Air & Radiation Docket Information Genter (6102), Room M-1500, Environmental Protection Agency Attn: Docket No. A-84-25, 401 M Street, SW., Washington, DC 20460. Comments on the proposed revisions to the Ambient

Air Monitoring Reference and Equivalent Methods (40 CFR part 53) should be separated from those pertaining to the standards and sent to the same address, Attn: Docket No. A-94-42. These dockets are located in the Central Docket Section of the U.S. **Environmental Protection Agency** South Conference Center, Room M-1500, 401 M St., SW., Washington, DC. The docket may be inspected between 8 a.m. and 5:30 p.m. on weekdays, and a reasonable fee may be charged for copying. For the availability of related information, see the SUPPLEMENTARY **INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Part 50 Notice—Mr. John H. Haines, Air Quality Strategies and Standards Division (MD–12), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, telephone (919) 541–5533. Part 53 Notice—Mr. Frank McElroy Atmospheric Research and Exposure Assessment Laboratory (MD–77), U.S. Environmental Protection Agency Research Triangle Park, NC 27711, telephone (919) 541–2622.

## SUPPLEMENTARY INFORMATION:

## Background

In 1971, the EPA promulgated primary and secondary NAAQS for sulfur oxides (measured as SO<sub>2</sub>). The primary standards were set at 365 micrograms per cubic meter (µg/m³) (0.14 part per million (ppm)), averaged over a 24-hour period and not to be exceeded more than once per year, and 80 μg/m³ (0.030 ppm) annual arithmetic mean. The secondary standard was set at 1300 µg/m3 (0.5 ppm) averaged over a period of 3 hours and not to be exceeded more than once per year. In accordance with sections 108 and 109 of the Act, EPA reviewed and revised the health and welfare criteria upon which these primary and secondary SO<sub>2</sub> standards were based.

On April 26, 1988 (53 FR 14926), the EPA announced its proposed decision not to revise these standards. In that notice, the Administrator also solicited comment on an alternative of adding a 1-hour primary standard of 0.4 ppm. The EPA also sought comment on additional revisions in the event a 1hour standard was promulgated. At that time, the EPA also proposed to revise the significant harm levels, associated episode contingency plan guidance (40 CFR part 51), and the Pollutant Standard Index for SO<sub>2</sub> (40 CFR part 58). The EPA also proposed revisions to certain monitoring and reporting requirements (40 CFR part 58).

On April 21, 1993, the EPA announced its final decision that

revision of the secondary standard was not appropriate (58 FR 21351).

## **Availability of Related Information**

The revised criteria document, Air Quality Criteria for Particulate Matter and Sulfur Oxides (three volumes, EPA-600/8-82-029af-cf. December 1982: Volume I, NTIS # PB-84-120401, \$36.50 paper copy and \$9.00 microfiche; Volume II, NTIS # PB-84-120419, \$77.00 paper copy and \$9.00 microfiche; Volume III, NTIS # PB-84-120427 \$77.00 paper copy and \$20.50 microfiche); the criteria document addendum, Second Addendum to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982): Assessment of Newly Available Health Effects Information (EPA/600/8-86-020-F NTIS # PB-87-176574, \$36.50 paper copy and \$9.00 microfiche); the criteria document supplement, Supplement to the Second Addendum (1986) to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982): Assessment of New Findings on Sulfur Dioxide Acute Exposure Health Effects in Asthmatic Individuals (1994) (EPA-600/FP-93/ 002); the 1982 staff paper, Review of the National Ambient Air Quality Standards for Sulfur Oxides: Assessment of Scientific and Technical Information (EPA-450/5-82-007 November 1982; NTIS # PB-84-102920, \$36.50 paper copy and \$9.00 microfiche); the staff paper addendum, Review of the National Ambient Air Quality Standards for Sulfur Oxides: Updated Assessment of Scientific and Technical Information (EPA-450/05-86-013, December 1986; NTIS # PB-87-200259, \$19.50 paper copy and \$9.00 microfiche) and the staff paper supplement, Review of the National Ambient Air Quality Standards For Sulfur Oxides: Updated Assessment of Scientific and Technical Information. Supplement to the 1986 OAQPS Staff Paper Addendum (1994) (EPA-452/R-94-013) are available from: U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161, or call 1-800-553-NTIS. (Add \$3.00 handling charge per order.) A limited number of copies of other documents generated in connection with this standard review, such as the control techniques document, can be obtained from: U.S. Environmental Protection Agency Library (MD-35), Research Triangle Park, NC 27711, telephone (919) 541-2777 These and other related documents are also available in the EPA dockets identified above.

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#### I. Background

A. Legislative Requirements Affecting This Rule

#### 1. The Primary Standards

Two sections of the Act govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify pollutants which "may reasonably be anticipated to endanger public health or welfare" and to issue air quality criteria for them. These air quality criteria are to "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.

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" NAAOS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which, in the judgment of the Administrator, based on the criteria and allowing an adequate margin of safety, (is) requisite to protect the public health.'

The U.S. Court of Appeals for the D.C. Circuit has held that the requirement for an adequate margin of safety for primary standards 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. Lead Industries Association v. EPA, 647 F.2d 1130, 1154 (D.C. Cir. 1980), cert. denied, 101 S. Ct. 621 (1980); American Petroleum Institute v Costle, 665 F.2d 1176, 1177 (D.C. Cir. 1981), cert. denied, 102 S. Ct. 1737 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty Thus, by 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 she finds pose an unacceptable risk of harm, even if that risk is not precisely identified as to nature or degree.

In selecting a margin of safety, the EPA has considered such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. Given that the "margin of safety" requirement by definition only comes into play where no conclusive showing of harm exists, such factors. which involve unknown or only partially quantified risks, have their inherent limits as guides to action. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. Lead Industries Association v. EPA, supra,

647 F.2d at 1161-62.

Section 109(d) of the Act (42 U.S.C. 7409(d)) requires periodic review and, if appropriate, revision of existing criteria

and standards. The process by which the EPA has reviewed the original criteria and standards for sulfur oxides under section 109(d) is described in a later section of this notice.

## 2. Related Control Requirements

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under section 110 (42 U.S.C. 7410) and part D of title I of the Act (42 U.S.C. 7501-7515), States are to submit, for EPA approval, State implementation plans (SIP's) 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 program (42 U.S.C. 7470-7479) for these pollutants. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants through the Federal motor vehicle control program under title II of the Act (42 U.S.C. 7521-7574), which involves controls for automobile, truck, bus, motorcycle, and aircraft emissions; new source performance standards under section 111 (42 U.S.C. 7411); National Emission Standards for Hazardous Air Pollutants under section 112 (42 U.S.C. 7412); and title IV of the Clean Air Act Amendments of 1990 (42 U.S.C. 7651-76510), which specifically provides for major reductions in SO2 emissions.

## B. Sulfur Oxides and Existing Standards for SO<sub>2</sub>

The principal focus of this standard review is on the health effects of SO2, alone and in combination with other pollutants. Other sulfur oxide (SOx) vapors (e.g., sulfur trioxide, SO<sub>3</sub>) are not commonly found in the atmosphere. Information on the effects of the principal atmospheric transformation products of SO<sub>2</sub> (i.e., sulfuric acid and sulfates) was considered in the review of the particulate matter standards and addressed in the revisions to these standards promulgated on July 1, 1987 (52 FR 24634); it will be considered again in the next review of the particulate matter standards, the commencement of which was announced on April 12, 1994 (59 FR 17375).

Sulfur dioxide is a rapidly diffusing reactive gas that is very soluble in water. It is emitted principally from combustion or processing of sulfurcontaining fossil fuels and ores. Sulfur dioxide occurs in the atmosphere with a variety of particles and other gases, and undergoes chemical and physical

interactions with them forming sulfates and other transformation products. At elevated concentrations, 50, can adversely affect human health. Annual average SO<sub>2</sub> levels range from less than 0.004 ppm in remote rural sites to over 0.03 ppm in the most polluted urban industrial areas. The highest short-term values are found in the vicinity (<20 km) of major point sources. In the absence of adequate controls, maximum levels at such sites for 24-hour, 3-hour, and 1-hour averages can reach or exceed 0.4 ppm, 1.4 ppm, and 2.3 ppm, respectively. The origins, relevant concentrations and potential effects of SO<sub>2</sub> are discussed in more detail in the revised criteria document (EPA, 1982a), in the staff paper (EPA, 1982b), in the criteria document addendum (EPA, 1986a), and the staff paper addendum (EPA, 1986b).

On April 30, 1971, the EPA promulgated the primary NAAQS, for SO<sub>2</sub> under section 109 of the Act (36 FR 8186). The existing primary standards for sulfur oxides, measured as SO2, are 365 µg/m³ (0.14 ppm), averaged over a period of 24 hours and not to be exceeded more than once per year, and 80 μg/m³ (0.030 ppm) annual arithmetic mean. The scientific and technical bases for the current standards are contained in the original criteria document, Air Quality Criteria for Sulfur Oxides (DHEW 1970).

Implementation of SO<sub>2</sub> air quality standards by the States and the EPA, together with fuel use shifts and siting decisions motivated by changing economic conditions, have resulted in substantial improvements in ground level air quality. Annual emissions decreased significantly between 1975 and 1982, from 25.7 to 21.4 million metric tons/year. During the mid to late eighties and early nineties, however, annual emissions of SO<sub>2</sub> have remained basically the same, at approximately 20.6 million metric tons/year (EPA,

Title IV of the Act, the acid rain program, requires that electric utilities reduce annual SO<sub>2</sub> emissions by 10 million short tons (9 million metric tons) per year from the 1980 baseline of 23.3 million metric tons. This reduction will be implemented in two phases. The phase 1 reductions are to be accomplished by 1995, and the bulk of the phase 2 reductions are to be accomplished by the year 2000, with an expected annual emission rate of 16.38 million metric tons that year. Total expected reductions from title IV will result in an annual emission rate of 14.22 metric tons in the year 2015.

Ambient air SO<sub>2</sub> trends over the decade from 1983 to 1992 show a

definite downward trend, though the rate of decline has slowed over the last few years. Annual mean SO2 decreased at a median rate of approximately 2 percent per year, resulting in a total drop of 23 percent. The annual second highest 24-hour values over this same time period decreased 31 percent, at an average rate of 4 percent per year (EPA, 1993a). The most recent trends of SO<sub>2</sub> measured in the ambient air have continued to show improvement. Annual mean concentrations decreased a total of 11 percent between 1990 to 1992. Over the last 2 years, the average annual mean SO2 decrease was 7 percent. Second maximum 24-hour SO<sub>2</sub> concentrations declined 12 percent between 1990 and 1992 and 4 percent between 1991 and 1992 (EPA, 1993a).

C. Development of Revised Air Quality Criteria for Sulfur Oxides and Review of the Standards: Development of the Staff

On October 2, 1979, the EPA announced it was revising the original criteria document for sulfur oxides concurrently with that for particulate matter to produce a combined particulate matter/sulfur oxides (PM/ SOx) criteria document (44 FR 56731). A more complete history of the revisions and addenda to the criteria document and staff paper, as well as the text of all CASAC closure letters, is presented in the 1988 proposal (53 FR 14926, April 26, 1988). A brief synopsis appears below.

The EPA provided a number of opportunities for review and comment on the revised criteria document by organizations and individuals outside the Agency. Three drafts of the revised criteria document, prepared by the EPA's Environmental Criteria and

Assessment Office (ECAO), were made available for external review (45 FR 24913, April 11, 1980; 46 FR 9746, Jan. 29, 1981, 46 FR 53210, Oct. 28, 1981). The EPA received and considered numerous and often extensive comments on each of these drafts, and CASAC has held three public meetings (August 20-22, 1980; July 7-9, 1981, November 16-18, 1981) to review successive drafts of the document. Transcripts of these meetings have been placed in the docket for the criteria document (ECAO CD 79-1), In addition, five public workshops were held at which the EPA, its consulting authors and reviewers, and other scientifically and technically qualified experts selected by the EPA discussed the various chapters of the draft document and suggested ways of resolving outstanding issues (45 FR 74047 Nov. 7

1980; 45 FR 76790, Nov. 20, 1980; 45 FR

78224, Nov 26, 1980; 45 FR 80350, Dec. 4, 1980; 46 FR 1775, Jan. 7 1981). The comments received were considered in the preparation of the final document. A CAŜAĈ "closure" memorandum indicating the Committee's satisfaction with the final draft of the criteria document and outlining key issues and recommendations was issued in December 1981.

Following closure, a number of scientific articles were published, or accepted for publication, that appeared to be of sufficient importance to the development of criteria for the primary standards for SO<sub>2</sub> to necessitate an addendum to the criteria document. Two drafts of the addendum were reviewed by CASAC and members of the public in two public meetings (April 26-27 1982; August 30-31, 1982), and transcripts of the meetings have been placed in the docket. The addendum was included as Appendix A to Volume I of the criteria document (EPA, 1982a) when the document was issued on March 20, 1984 with the proposed revisions to the ambient air quality standards for particulate matter (49 FR

10408, Mar. 20, 1984).

As part of this process, the EPA s Office of Air Quality Planning and Standards (OAQPS) in the spring of 1982 prepared the first draft of a staff paper, "Review of the National Ambient Air Quality Standards for Sulfur Oxides: Assessment of Scientific and Technical Information-OAQPS Staff Paper." The first draft and a second draft of the staff paper were reviewed at CASAC meetings on April 26-27 1982 (47 FR 16885, April 20, 1982), and August 30-31, 1982 (47 FR 34855, Aug. 10, 1982), respectively and transcripts of these meetings have been placed in the docket (Docket No. A-79-28). Numerous written and oral comments were received on the drafts from CASAC, representatives of organizations, individual scientists, and other interested members of the public, and some revisions engendered by these comments are discussed in an August 5. 1982 letter to CASAC (Padgett, 1982), as well as the executive summary of the staff paper. The EPA released the final OAQPS staff paper (EPA, 1982b), upon receipt of the formal CASAC closure letter in August 1983 (Goldstein, 1983), accompanied by a minority statement by one member (Higgins, 1983).

In 1984, the Administrator reviewed the standards in light of the above information and decided, at that time, not to propose any revision of the

standards.

In 1986, in response to the publication in the scientific literature of a number of additional studies on the

health effects of SO<sub>2</sub> (as well as some new particulate matter studies), ECAO commenced a second addendum to the PM/SO<sub>x</sub> criteria document (51 FR 11058, Apr. 1, 1986). An external review draft was made available for public comment (51 FR 24392, Jul. 3, 1986) and CASAC held a public meeting on October 15-16, 1986 to review the criteria document addendum (transcript in public docket No. A-82-37). When development of a second addendum of the criteria document was initiated in 1986, OAQPS decided to simultaneously commence an addendum to the staff paper as well (51 FR 24392, Jul. 3, 1986). An external review draft of the addendum to the staff paper was also issued; and the staff paper was reviewed at the same public CASAC meeting at which the second addendum to the criteria document was considered.

The CASAC sent a closure letter on the criteria document addendum to the Administrator dated December 15, 1986, and another on the staff paper, dated February 1987 The closure letter on the staff paper addendum, which also discusses major issues addressed by the CASAC and the Committee's recommendations, is reprinted in Appendix 1 to this notice. The final addenda to the criteria document (EPA, 1986a) and the staff paper (EPA, 1986b), are available from the address listed above. Where there are differences between the 1982 criteria document and staff paper and the more recent addenda, the addenda supersede the earlier documents.

## D. Rulemaking Docket

The EPA established a standard review docket for the sulfur oxides review in July 1979. The EPA also established a rulemaking docket (Docket No. A–84–25) for the April 26, 1988 proposal as required by section 307(d) of the Act. The standard review docket (Docket No. A–79–28) and a separate docket established for criteria document revision (Docket No. ECAO–CD–79–1) have been incorporated into the rulemaking docket.

# II. Summary of the 1988 Proposed Decision Not To Revise the Current Standards

On April 26, 1988 (53 FR 14926), the EPA announced its proposed decision not to revise the existing primary and secondary SO<sub>x</sub> standards (measured as SO<sub>2</sub>). In reaching the provisional conclusion that the current standards provided adequate protection against the health and welfare effects associated with SO<sub>2</sub>, the EPA was mindful of uncertainties in the available evidence

concerning the risk that elevated shortterm (<1-hour) SO<sub>2</sub> concentrations pose to asthmatic individuals exercising in ambient air. Therefore, the EPA specifically requested broad public comment on the alternative of revising the current standards and adding a new 1-hour primary standard of 0.4 ppm. The notice also announced that if a 1hour primary standard were adopted. consideration would be given to replacing the current 3-hour secondary standard (1,300 µg/m<sup>3</sup> (0.5 ppm)) with a 1-hour secondary standard set equal to the primary standard, and adopting an expected-exceedance form for all of the standards.

The EPA also concluded in the April 26, 1988 notice, based upon the thencurrent scientific understanding of the acidic deposition problem, that it would not be appropriate, at that time, to propose a separate secondary SO<sub>X</sub> standard to provide increased protection against the acidic deposition-related effects of SO<sub>X</sub>. The notice added that when the fundamental scientific uncertainties had been reduced through ongoing research activities, the EPA would draft and support an appropriate set of control measures.

The EPA also proposed minor technical revisions to the standards, including restating the levels for the primary and secondary standards in terms of ppm rather than µg/m<sup>3</sup> adding explicit rounding conventions, and specifying data completeness and handling conventions. The EPA also announced its intention to retain the block averaging convention for the 24hour, annual, and 3-hour standards and proposed to eliminate any future questions in this regard by adding clarifying language to 40 CFR 50.4 and 50.5. Based on its assessment of the SO<sub>2</sub> health effects information, the EPA also proposed to revise the significant harm levels for SO<sub>2</sub> and the associated example air pollution episode levels (40 CFR part 51). Finally the EPA proposed some minor modifications to the ambient air quality surveillance requirements (40 ČFR part 58).

The April 26, 1988 (53 FR 14926) notice sets forth in detail the rationale for the proposals discussed above and provides other background information.

## III. Post-Proposal Developments

## A. Opportunities for Public Comment

Following the publication of the proposal, the EPA held a public meeting in Washington on June 10, 1988 to receive comment on the April 26, 1988 proposal. A transcript of the meeting has been placed in the public docket (Docket No. A-84-25). On July 20, 1988,

the EPA announced an extension of the public comment period from July 25, 1988 to September 23, 1988 (53 FR 27362). The EPA issued a second notice on September 21, 1988 (53 FR 36587) to clarify that issues concerning block versus running averaging conventions should be fully aired in the sulfur dioxide rulemaking initiated by the April 26, 1988 notice (53 FR 14926): At the same time, the EPA extended the comment period until November 22, 1988 to provide ample opportunity for the public to comment.

## B. Legislative Activity

In July 1989, legislative proposals for amending the Act were submitted to Congress. This initiative included a comprehensive program to address the acidic deposition problem. After extensive deliberation, the 1990 Amendments, including the title IV acid rain provisions, were passed by Congress and signed into law by the President on November 15, 1990. As discussed earlier in section I.B., and below title IV of the 1990 Amendments was developed specifically to address the acidic deposition problem but will have an attendant benefit of reducing SO<sub>2</sub>-related health effects.

## C. Litigation on Secondary Standard

Prior to the 1988 proposal, the Environmental Defense Fund and other plaintiffs had sued the EPA under section 304 of the Act to compel review and revision of the NAAQS for SOx under section 109(d)(1) of the Act, Environmental Defense Fund v Reilly No. 85 C.V 9507 (S.D.N.Y.). In response to a decision of the U.S. Court of Appeals for the Second Circuit in 1989, Environmental Defense Fund v Thomas, 870 F.2d 892 (2d Cir. 1989). the EPA and the plaintiffs ultimately entered into a consent decree as an alternative to further litigation. The decree required the EPA to take final action by April 15, 1993 on the secondary standard portion of the 1988 proposed rulemaking.

### D. Decision on Secondary Standard

A final decision under section 109(d)(1) of the Act that revision of the secondary standard was not appropriate was signed on April 15, 1993 and was published in the Federal Register on April 21, 1993 (58 FR 21351). The rationale for the decision is set forth in the April 21, 1993 notice. At that time it was also announced that when action was completed on the primary standards portion of the 1988 proposal, the EPA would decide whether to adopt minor technical changes discussed in the 1988 proposal.

## E. Litigation on Primary Standard

In 1992, the American Lung Association sued the EPA to compel review and, if appropriate, revision of the primary standards for SO<sub>X</sub>, American Lung Association v Browner, No. 92–CV–5316 (ERK) (E.D.N.Y.). The U.S. District Court for the Eastern District of New York subsequently issued an order requiring that the EPA by November 1, 1994: take final action on the 1988 proposed decision not to revise the primary standards, or repropose and take final action on the reproposal within 1 year after the close of the public comment period.

## F Supplementation of the Criteria Document and the Staff Paper

In response to the more recent publication of controlled human studies on the health effects of short-term peaks of SO<sub>2</sub> on asthmatic individuals, the ECAO commenced preparation of a supplement to the second addendum to the PM/SO<sub>2</sub> criteria document in 1992. The OAQPS prepared a draft of a supplement to the staff paper addendum to update its assessment of the new information contained in the Criteria Document Supplement and to take into account more recent air quality and exposure information. Initial drafts of these documents were completed in June, 1993. The EPA announced the availability of an external review draft of both documents for public comment on July 30, 1993 (58 FR 40818), and the documents were reviewed by the CASAC at a public meeting on August 19, 1993. Recommended changes were made, and revised drafts of both documents were made available for public comment (59 FR 11985, March 15, 1994). Both documents were reviewed at a public CASAC meeting on April 12, 1994. The CASAC provided its advice and recommendations to the Administrator in a letter dated June 1. 1994 that is reprinted in Appendix 2.

## IV Summary of Public Comments as to Primary Standards and Associated Technical Changes

The following discussion summarizes in general terms the comments received from the public regarding the key aspects of the April 26, 1988 notice as they pertain to the primary standards and associated technical changes. The individual comments have been entered into the public docket (Docket No. A–84–25). For a summary of public comments on the secondary standard, see 58 FR 21354, Apr. 21, 1993.

Extensive written comments were received on the 1988 proposal. Of some 90 written submissions, 33 were

provided by individual industrial concerns or industry groups, 14 by State, local and Federal government agencies and organizations, 14 by environmental and public interest groups, and 29 by individual private citizens. The comments on the key aspects of the April 26, 1988 notice pertaining to the primary standard and associated part 50 technical changes are summarized below.

## A. Current 24-Hour and Annual Standards

Virtually all of the comments that specifically addressed the adequacy of the current standards supported the Administrator's 1988 finding that the current primary SO2 standards are adequate to protect the public health from the effects associated with 24-hour and annual average SO<sub>2</sub> concentrations in the atmosphere. As discussed below the principal exceptions were the comments submitted on the issue of the averaging convention of the standards. These commenters maintained that the current primary standards would not provide adequate protection against adverse health effects if measurements of the currently prescribed concentration levels were restricted to the block averaging convention.

## B. Averaging Convention for the Current Standards

Comments on the Administrator's decision to retain the block averaging convention for the 3-hour, 24-hour, and annual standards were sharply divided. The industry comments on this issue strongly supported the proposed decision to retain the block averaging convention as the appropriate method for determining compliance with the current standards. In support of this position, these commenters typically took note of the text of the 1971 promulgation notice, the Air Quality Criteria for Sulfur Oxides (DHEW 1970), contemporaneous papers that discussed how the measurements were to be collected and analyzed, and the fact that implementation of the standards for the most part has been based on block averaging. The environmental groups maintained. however, that the wording of the original standards clearly did not preclude the use of the running averaging convention; that the EPA's

monitoring capabilities, guidance, and implementation practice demonstrated that the standards were not restricted to block averaging; and accordingly that the use of running averaging would not represent a tightening of the standards. Several State agencies supported the adoption of a running interpretation or requested that the EPA remain silent so as not to undercut the States' use of running averages, while other States and municipalities supported the EPA's proposed decision.

#### C. 1-Hour Standard Alternative

Discussion on this subject was highly polarized. Industry groups and their representatives uniformly opposed a short-term standard, while environmental groups, private citizens, and most State and local agencies that commented strongly favored the adoption of such a standard. Industry maintained that the clinical studies of asthmatics used to support the possible need for a short-term standard failed to show effects that were of such medical significance as to be considered "adverse" under the Act. Environmental groups argued that the effects seen were medically significant and "adverse" at concentrations below 0.5 ppm and called for a standard to be set at levels considerably below the 0.4 ppm, 1-hour alternative that was presented for comment. The nature of the comments were such that there was virtually no consensus over the significance of effects among industry environmental groups, and the different medical experts that commented on the issue.

In support of their position that a short-term standard was not needed, industry groups placed great weight on the results of the exposure analysis presented in the April 26, 1988 notice. They maintained that the analysis demonstrated that the current standards provided considerable protection against short-term peak exposures and that the remaining risk did not pose a significant public health problem. Some environmental groups took exception to the EPA s use of the exposure analysis. They maintained that a large undercounting of exposures occurred because the analysis did not address potential exposures from nonutility sources such as nonferrous smelters, paper mills, and petroleum refineries. Some also argued that the EPA's reliance on the exposure analysis as a basis for retaining the existing standards was without legal authority. These commenters were also critical of the Agency's use of typical activity patterns and maintained that other aspects of the analysis were deficient. Industry groups generally supported the use of exposure analyses

<sup>&</sup>lt;sup>1</sup> The numerical distribution of comments in each category should be viewed with caution. Industry groups typically submit comments on behalf of their member companies in lieu of having each of their member companies sending separate comments. Similarly, comments from environmental or other interest groups represent the views of a number of individuals.

in the standard setting process and maintained that the EPA's focus on utilities was appropriate given that they are the largest emitters of SO<sub>2</sub>.

Environmental groups and private citizens also expressed concern that the significance of asthma episodes were being downplayed and raised concerns about exposures of children, who were dependent on adults for medication and care. They were also highly critical of the EPA's characterization of the number of asthmatics (up to 100,000) potentially at risk to SO<sub>2</sub> peak exposures as small.

State and local agencies that commented mostly supported the adoption of a short-term 1-hour standard.

Finally environmental groups maintained that the 1-hour alternative would not protect against short-term 2 to 10-minute peak SO<sub>2</sub> concentrations. In support of their position, data were submitted showing that certain types of SO<sub>2</sub> sources may have very high 5minute peaks (>1 ppm) and still have hourly averages below 0.4 ppm even when the current standards are being attained. One of the industry commenters also noted that an averaging time shorter than 1 hour would be needed to protect against very high 3- to 5-minute peak SO<sub>2</sub> levels and cited an instance where a 3- to 5-minute peak of 3.7 ppm SO<sub>2</sub> occurred, yet the 1-hour average was only 0.29 ppm. This commenter went on to suggest, however, that such problems would be better addressed through a properly designed program under the authority of section 303 of the Act rather than through the adoption of a new shortterm ambient air quality standard.

## D. Other Changes to Standards

While a number of commenters favored the adoption of a new 1-hour standard, little, if any support was voiced for the associated revisions that the EPA indicated it was considering if a 1-hour standard was adopted. Few, if any, commenters supported the adoption of an expected exceedance form for all of the standards. While several commenters recognized that a statistical form had certain technical advantages, they expressed concern that its adoption would reduce the protection afforded by the current 3-hour, 24-hour and annual standards.

## E. Technical Revisions to 40 CFR 50.4 and 50.5

There was general support for the EPA's proposal to restate the levels of the standards in terms of ppm rather than µg/m³ and for adding explicit rounding conventions and data

completeness and handling conventions Addendum" ("Staff Paper to the regulations.

Addendum" ("Staff Paper Supplement") (EPA, 1994)

## V Rationale for Proposed Decisions

### A. Basis for the Current 24-Hour and Annual Standards

The rationale for retaining the current 24-hour and annual primary standards was presented in some detail in the 1988 proposal (53 FR 14930, Apr. 26, 1988) and remains unchanged. At that time, the EPA concluded that the current 24-hour and annual standards appeared to be both necessary and adequate to protect human health against SO<sub>2</sub> concentrations associated with those averaging periods. The EPA also concluded that retaining the current 24-hour and annual standards was consistent with the scientific data assessed in the criteria document and staff paper and their addenda and with the advice and recommendations of the staff and the CASAC.

The EPA again provisionally concludes, based on the information assessed in the criteria document and staff paper and their addenda, that the current 24-hour and annual primary standards provide adequate health protection against the effects associated with those averaging periods. In reaching this proposed decision, the EPA takes note that the health effects information on 24-hour and annual SO2 exposures remains largely unchanged since 1988. When newer information becomes available and has undergone the rigorous and comprehensive assessment, including CASAC review necessary for incorporation into a new criteria document, it will provide the basis for the next periodic review of the 24-hour and annual primary standards.

## B. Consideration of Short-Term Peak SO<sub>2</sub> Exposures

A number of new studies have become available since 1988 that examine the potential health effects on asthmatic individuals associated with short-term (≤1-hour) exposures to SO<sub>2</sub>. In view of these new studies and other relevant new information, the EPA prepared a "Supplement to the Second Addendum (1986) to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982): Assessment of New Findings on Sulfur-Dioxide Acute Exposure Health Effects in Asthmatic Individuals" ("Criteria Document Supplement") (EPA, 1994a) and an associated staff paper supplement "Review of the National Ambient Air Quality Standards for Sulfur Oxides: Updated Assessment of Scientific and Technical Information—Supplement to: the 1986 OAQPS Staff Paper

Addendum" ("Staff Paper Supplement") (EPA, 1994b). These two documents, together with the 1986 addenda, provide the primary basis for the EPA s present assessment of the health effects and related information on short-term SO<sub>2</sub> exposures and the Administrator's consideration of appropriate regulatory responses. The discussion below summarizes the basis for considering alternative regulatory responses to address the potential effects associated with short-term peak SO<sub>2</sub> exposures.

### 1. Assessment of Health Effects Associated With Short-Term SO<sub>2</sub> Exposures

a. Sensitive Populations. It is clear that healthy nonasthmatic individuals are essentially unaffected by acute exposures to  $SO_2$  at concentrations below 2 ppm and do not constitute a population of concern for short-term, acute  $SO_2$  exposure effects.

Based on the assessment in the Criteria Document Supplement (EPA, 1994a), the EPA concludes that mild and moderate asthmatic children, adolescents, and adults that are physically active outdoors represent the population segments at most risk for acute SO2 induced respiratory effects. Individuals with more severe asthmatic conditions have poor exercise tolerances; as a result, they are very unlikely to engage in sufficiently intense outdoor activity to achieve the requisite breathing rates for SO2induced respiratory effects to occur and therefore maybe at somewhat lower risk. While current studies are suggestive of greater SO<sub>2</sub> responsiveness among those asthmatic patients with more severe disease, this issue cannot be unequivocally resolved. However, because of the lower baseline function in moderate and severe asthmatic persons, especially those lacking optimal medication, any effect of SO<sub>2</sub> would further reduce their lung function toward levels that may become cause for medical concern (EPA, 1994a, p. 44).

While it has been suggested that nonasthmatic atopic individuals may also represent a broader population group at increased risk (White, 1994; 53 FR 14931–14932, Apr. 26, 1988), other assessments have not found evidence establishing the atopic group to be particularly responsive to SO<sub>2</sub> (EPA, 1994a, p. 52; EPA, 1994b, p. 10; Linn et

al., 1987).

b. Asthma. About 10 million people or 4 percent of the population of the United States are estimated to have asthma (NIH, 1991). The true prevalence may be as high as 7 to 10 percent of the

population (Evans et al., 1987), because some individuals with mild asthma may be unaware that they have the disease and thus go unreported. The prevalence is higher among African-Americans. older (8- to 11-year-old) children, and urban residents (Schwartz et al., 1990).

The Expert Panel Report from the National Asthma Education Program of the National Heart, Lung and Blood Institute (NIH, 1991) has recently defined asthma as "a lung disease with the following characteristics: (1) Airway obstruction that is reversible (but not completely so in some patients) either spontaneously or with treatment, (2) airway inflammation, and (3) increased airway responsiveness to a variety of stimuli. Common symptoms include cough, wheezing, shortness of breath. chest tightness, and sputum production. Asthma is characterized by an exaggerated bronchoconstrictor response to many physical challenges (e.g., cold or dry air, exercise) and chemical and pharmacologic agents (e.g., histamine or methacholine).

Ďaily variability in lung function measurements is a typical feature of asthma, with the poorest function (i.e., lowest forced expiratory volume in 1 second (FEV<sub>1</sub>) and highest specific airway resistance (SRaw) being experienced in the early morning hours and the best function (i.e., highest FEV1 and lowest SRaw) occurring in the mid-

afternoon.

The degree of exercise tolerance varies with the severity of disease. Mild asthmatic individuals have good exercise tolerance but may not tolerate vigorous exercise such as prolonged running. Moderate asthmatic individuals have diminished exercise tolerance and individuals with severe disease have very poor exercise tolerance that markedly limits physical activity.

Exercise-induced bronchoconstriction is followed by a refractory period of several hours during which an asthmatic individual is less susceptible to bronchoconstriction (Edmunds et al., 1978). This refractory period may alter an asthmatic individual's responsiveness to SO<sub>2</sub> or other inhaled substances.

Data from the United Kingdom and United States suggest an incidence rate of asthma attacks requiring medical attention of <1 asthmatic patient-year. It is estimated that the incidence rate of hospitalization due to asthma for all asthmatic individuals in the United States is about 45 per 1,000 asthmatics per year (NIH, 1991). Death due to asthma is a rare event: about one per 10,000 asthmatic individuals per year. Mortality rates are higher among males

and about 100 percent higher among nonwhites (EPA, 1994a).

In assessing the results from the controlled human exposure studies, it should be noted that the individuals who participate in such studies typically have mild allergic asthma and can go without medication altogether or can discontinue medication for brief periods of time if exposures are conducted outside their normal allergy season. In addition, African-American and Hispanic adolescents and young adults have not been studied systematically. Finally subjects who participate in controlled exposure studies are also generally self-selected and this may introduce some bias. Thus, the extent to which the participants in the studies reflect the characteristics of the asthmatic population at large is not known. Nevertheless, the high degree of consistency among studies suggests that the subjects are generally representative of the population at risk or that any selection bias is consistently present across a diverse group of laboratories

(EPA, 1994a).

c. Short-Term Health Effects. The basis for considering whether additional regulatory measures are needed to reduce the occurrence of short-term peaks of SO<sub>2</sub> rests primarily on the extensive literature involving brief (2- to 10-min) controlled exposures of persons with mild (and in some cases more moderate) asthma to concentrations of SO<sub>2</sub> in the range of 0.1 ppm to 2 ppm while at elevated ventilation. The major effect of SO<sub>2</sub> on sensitive asthmatic individuals is bronchoconstriction, usually evidenced in these studies by increased specific airway resistance (SRaw) or decreased forced expiratory volume (FEV<sub>1</sub>), and the occurrence of clinical symptoms such as wheezing, chest tightness, and shortness of breath. The magnitude of the response and likely occurrence of symptoms increase at higher SO<sub>2</sub> concentrations and ventilation levels and are relatively brief ın duration. Numerous studies have shown that lung function typically returns to normal for most subjects within an hour of exposure. No substantial "late phase" responses have been noted for SO<sub>2</sub>, unlike the case for more specific stimuli (e.g., pollen, dust mites, or other allergens) in which "late phase" inflammatory responses often occur 4-8 hours after exposure and are often much more severe and dangerous than earlier immediate responses.

In a summary of the literature up to 1986 in the Staff Paper Addendum (EPA, 1986b), the staff concluded that changes in lung function (A SRaw 70 percent) accompanied by symptoms could be observed in some free-

breathing asthmatics at 0.4 ppm at "moderate-heavy exercise." At 0.5 ppm, slightly larger functional changes on individual and group basis were seen at moderate exercise (Δ SRaw 50—100 percent), while at 0.6-0.75 ppm SO<sub>2</sub> functional changes and symptoms could be observed at light-moderate exercise ( $\Delta$  SRaw 120-260 percent), with the effects being judged "indicative of clinical significance." Effects at 1-2 ppm SO<sub>2</sub> were seen as even more pronounced, ranging from "moderate" to "incapacitating" for some individuals (53 FR 14948, April 26, 1988). As the concentration increases within the range studied, effects are more pronounced and the fraction of asthmatic subjects who respond increases (53 FR 14947

April 26, 1988).

Since 1986 several new studies have been published providing pertinent information on: (1) The response of individuals with more moderate asthma to  $SO_2$ , (2) the duration of exposure necessary to provoke a response to SO<sub>2</sub>, and (3) the effects of medication on the SO<sub>2</sub> response. Much of these data also provide a more thorough picture of the magnitude of responses in the range of 0.4 to 1.0 ppm, the range previously identified as being of interest (53 FR 14948, April 26, 1988). Data from several of these recent large-scale chamber studies were reexamined to provide a better understanding of the response observed in more sensitive subjects. Forced expiratory volume in one second was used as a measure of lung function, in addition to specific airway resistance, and other endpoints examined included symptoms, alteration of workload, and medication usage occurring as a consequence of these exposures.

Table B–1 of the Criteria Document Supplement (EPA, 1994a) summarizes the lung function changes in response to SO<sub>2</sub> concentrations in the range of 0.6-1.0 ppm from controlled human exposure studies. Because different studies used different measures of lung function (FEV<sub>1</sub> or SRaw), and different concentrations of SO<sub>2</sub>, the discussion that follows will describe group mean changes first for the studies that used the measure SRaw, then group mean changes for studies that used FEV1, and then finally the individual responses.

The data indicate that, in terms of group mean changes, total SRaw changes 2 were approximately twice as

<sup>&</sup>lt;sup>2</sup> Since elevated ventilation sufficient for oronasal breathing to occur is a requirement for most asthmatic persons to respond to SO2, and because many asthmatic individuals experience bronchoconstriction responses to exercise alone, it is useful to distinguish between the two different effects. Any measure of lung function such as FEV

great at 0.6 ppm and above as at 0.5 ppm is in agreement with the conclusions and below. The differences were even more pronounced when the changes in airway resistance due to SO<sub>2</sub> alone (i.e., after correction for the effects of exercise) were considered.

For FEV1, the difference in responses between 0.4 ppm and 0.6 ppm SO<sub>2</sub> were not as pronounced. At 0.6 ppm SO<sub>2</sub>, group mean decreases in total FEV, of approximately 20 percent were observed in the mild and moderate asthmatics studied. The changes in FEV, due to SO<sub>2</sub> alone resulted in decreases in FEV<sub>1</sub> of approximately 15 percent (EPA, 1994a, Table B-1).

In addition, at 0.6 ppm SO<sub>2</sub>, 25 percent or more of the subjects had pronounced individual responses (either a 200 percent or greater increase in SRaw or a 20 percent or greater decrease in FEV1) due to SO2 alone (total changes in lung function for these individuals would be expected to be even greater). In contrast, at ≤0.5 ppm SO<sub>2</sub> these more pronounced individual responses were less frequent, occurring in fewer than 25 percent of the subjects for both measures of lung function for all but one group studied (EPA, 1994a, p. B-2).

While not examined in as much detail as lung function, other indicators of severity also tend to increase with increasing SO<sub>2</sub> concentration. For instance, in one study, four of 24 moderate/severe asthmatic subjects were required to reduce their exercise level because of asthma symptoms at 0.6 ppm SO<sub>2</sub>. This occurred only once at each of the lower concentrations (EPA. 1994a). Two recent studies which considered medication used to mitigate the effects of SO<sub>2</sub> as a health endpoint and which followed the subjects medication use in detail, found approximately twice as many subjects took medication immediately after exposure to 0.6 ppm SO<sub>2</sub> than after exposure to 0.3 ppm SO<sub>2</sub> (EPA, 1994a,

Table 7 p. 40).

Considering the variety of endpoints for which information is available, clearly the effects beginning at 0.6 ppm and up to 1.0 ppm are more pronounced than those at lower concentrations. This

or SRaw can be expressed as the "Total FEV, or SRaw, which is the total change in lung function experienced by the subject as a result of an exposure to SO<sub>2</sub> while at exercise, or broken down to "the effect of changes due to  $SO_2$  alone, which represents the total lung function change observed minus the change seen for that subject from a control exposure at exercise in clean air. Both measures have their utility: total FEV, or SRaw indicates the magnitude of overall lung function change actually experienced by the subject, while the change due to SO2 alone indicates how much of this total change is attributable to the pollutant itself.

reached in the Staff Paper Addendum (EPA, 1986b), which stated that there were "clearer indications of clinically or physiologically significant effects at 0.6 to 0.75 ppm SO2 and above" (53 FR 14947 Apr. 26, 1988)

d. Significance of Effects. Opinions on the significance of the effect expressed by CASAC and others have been widely divergent. Some CASAC members and outside commenters feel that the responses reported in the range of 0.6 to 1.0 ppm SO<sub>2</sub> are not significant, especially when viewed in the context of the frequency with which asthmatics ordinarily experience similar effects in the course of their daily lives. Other CASAC members and commenters strongly felt that bronchoconstriction of the degree reported in this range of exposure is of medical significance and likely to place an exposed asthmatic at

an unacceptable risk of harm. The frequency of SO<sub>2</sub> induced asthmatic episodes relative to those provided by other stimuli (such as cold/ dry air or moderate exercise) would be expected to vary from one asthmatic ındivıdual to another and from one location to another. As such, the relative contribution of SO<sub>2</sub> to acute episodes of asthma cannot be precisely assessed. However, staff did compare the effects of SO<sub>2</sub> observed in the recent controlled human exposure studies to the effects of moderate exercise, typical daily variation in lung function, and the severity of frequently experienced asthma symptoms. The effects of 0.6 ppm SO<sub>2</sub> exposure at moderate exercise, as measured by FEV1, exceeded either the typical effect of exercise alone or typical daily variations in FEV1 (EPA, 1994a, sections 4.3 and 5.3). For symptomatic responses, two to eight times as many subjects after exposure at exercise to 0.6 ppm SO<sub>2</sub> experienced symptoms of at least moderate severity (13-62 percent of subjects) than after exercise in clean air alone (4-19 percent of subjects) (EPA, 1994a, p. B-12). In addition, a significant portion of subjects (approximately 15 to 60 percent, depending on asthma status) participating in certain controlled human exposure studies seemed to experience symptoms more frequently in response to 0.6 ppm SO<sub>2</sub> than reported at any other time during the majority of the weeks during which they participated in the study (EPA, 1994a, p. B-12).

Furthermore, the response seen in the most sensitive 25 percent of responders at 0.6 ppm equaled or exceeded approximately a 30 percent decline in FEV<sub>1</sub> for mild asthmatic subjects and approximately a 40 percent decline for

moderate asthmatic individuals. By comparison, during clinical bronchoprovocation testing changes are not usually induced beyond a 20 percent decrease in FEV<sub>1</sub>.

In addition, while at least some subjects can experience such a 20 percent decline without experiencing symptoms, in recent studies focusing on effects at 0.6 ppm SO<sub>2</sub>, from 33 percent to 43 percent of moderate asthmatics and from 6 percent to 35 percent of mild asthmatics experienced at least a 20 percent decrease in total FEV, in conjunction with symptoms rated as being of moderate severity or worse. Also deserving consideration is the fact that moderate/severe asthmatic subjects start an exposure with compromised lung function compared to mild asthmatic subjects. Thus, it is not clear that similar functional declines beginning from a different baseline have the same biological importance (EPA,

1994a, pp. 21–25). In the Staff Paper Addendum, "bronchoconstriction accompanied by at least noticeable symptoms, was seen as an appropriate measure of concern (EPA, 1986b, p. 37). However, a substantial proportion of the subjects in these more recent studies are experiencing greater effects, bronchoconstriction with at least moderate symptoms, beginning at 0.6

ppm SO<sub>2</sub> (EPA, 1994a). Considering the recent body of evidence along with previous studies, the Criteria Document Supplement (EPA, 1994a) concluded that substantial percentages (≥25 percent) of mild or moderate asthmatic individuals exposed to 0.6 to 1.0 ppm SO<sub>2</sub> during moderate exercise would be expected to have respiratory function changes and severity of symptoms that distinctly exceed those experienced as typical daily variation in lung function or in response to other stimuli, such as moderate exercise. The severity of effects for many of the responders is likely to be of sufficient concern to cause disruption of ongoing activities. use of bronchodilator medication, and/ or possible seeking of medical attention. At most, only 10 to 20 percent of mild or moderate asthmatic individuals are likely to exhibit lung function decrements in response to SO<sub>2</sub> exposures of 0.2 to 0.5 ppm that would be of distinctly larger magnitude than typical diurnal variation in lung function or changes in lung function experienced by them in response to other often encountered stimuli. Furthermore, it appears likely that only the most sensitive responders might experience sufficiently large lung function changes and/or respiratory

symptoms of such severity as to be of potential health concern, that is leading to the disruption of ongoing activities, the need for bronchodilator medication, or seeking of medical attention.

Based on the staff's assessment, a number of additional factors are important in assessing the significance of effects resulting from SO<sub>2</sub> exposures and determining appropriate concentrations of concern.

Time Course of Response. If an asthmatic individual is at elevated ventilation and encounters a brief SO<sub>2</sub> peak concentration, the onset of the effect can be very rapid although the response does not typically approach maximal levels until 5 minutes of exposure. For example, the total lung function response from a 2-minute exposure was reported to be only 50 percent of that observed after 5 minutes of exposure (Horstman et al., 1988). Balmes (1987) reported (in a mouthpiece exposure study) the response after 3 minutes of exposure was 67 percent of that observed after 5 minutes. After 5 minutes of exposure the magnitude of the response does not appear to significantly increase based on comparisons of lung function changes after 5-minute and 10-minute exposures

(Linn, 1983b; EPA, 1986b, p. A-1). The response is also generally brief in duration; numerous studies have shown that lung function typically returns to normal for most subjects within an hour of exposure. This duration is similar to that experienced in response to exercise and somewhat less than experienced in response to allergens (EPA, 1994b, p. 18). Even if exposure continues beyond the initial 5-10 minutes, lung function may still return to normal as long as the subject ceases to exercise and their ventilation rate decreases to resting levels (Hackney et al., 1984; Schachter et al., 1984).

Effect of Varying Temperature and Humidity. Broncho-constriction in response to SO<sub>2</sub> and exercise is: (a) Reduced by warm or humid conditions, and (b) exacerbated by cold or dry conditions. Thus, the observed effects such as those described above could be either more pronounced, less pronounced, or similar depending on the ambient conditions present during exposure at elevated ventilation.

Effect of Varying Ventilation Rate and Breathing Mode. Another factor that can affect the magnitude of the SO2 induced response is ventilation rate. At higher ventilation rates the responses are likely to be more pronounced at any given SO<sub>2</sub> concentration than those observed at lower ventilation rates. The effects of SO - increase with both increased overall ventilation rates and an

increased proportion of oral ventilation in relation to total ventilation (EPA, 1986a, p. 11). Oral ventilation is thought to accentuate the response because the scrubbing of SO<sub>2</sub> by the nasal passageways is bypassed. Based on its assessment of the available data, the staff concluded that the ventilation rates of concern begin at 35-50 L/min, when most individuals generally switch to oronasal breathing.

Ventilation rates in the range of 35— 40 L/min are comparable to ventilation rates induced by climbing three flights of stairs, light cycling; shoveling snow, light jogging, or playing tennis, and can be induced in a laboratory by walking at 3.5 mph up a 4 percent grade. Ventilation rates in the range of 45-50 L/min are equivalent to moderate cycling, chopping wood, light uphill running, and can be induced by walking at 3.5 mph up an 8 percent grade (EPA,

1994b, p. 20). While the SO 2 effects reported for mild or moderate asthmatic individual are likely to be more pronounced if an individual asthmatic is at a ventilation rate higher than 35-50 L/min (EPA, 1994b, p. 19), the available activity and ventilation data indicate that individuals engage in outdoor activities that induce ventilation rates of 35-50 L/ min only a small percentage of the time (EPA, 1994b, p. 20). Thus, it is unlikely that asthmatic individuals in general would attain sufficiently high ventilation rates (i.e., greater than 35-50 L/min) frequently enough to markedly increase the health risk posed by peak SO<sub>2</sub> exposures.

Use of Medication. The extent to which an asthmatic individual is already medicated for protection against other bronchoconstriction inducing stimuli (e.g., cold dry air, allergens, etc.) and thus would be protected against SO<sub>2</sub>, has been considered relevant in assessing (a) the likelihood of experiencing a bronchoconstriction response to SO<sub>2</sub> and, by extension, (b) the significance of these effects (53 FR 14932, Apr. 26, 1988). The available data now indicate that most types of regularly administered asthma medications are not very effective in blocking the SO<sub>2</sub> response. The exception, however, is the most commonly used class of asthma medications, the β-sympathomimetic drugs (beta-agonist bronchodilator), which are usually highly effective in preventing the SO 2 response from developing if taken shortly before

Prophylactic use of beta-agonist bronchodilators to prevent the effects of SO<sub>2</sub> requires either anticipation of exposure or routine use prior to

engaging in vigorous outdoor activities. While some asthmatic persons do premedicate before exercise, available published data suggest infrequent bronchodilator use in general among mild asthmatic persons and a wide range of compliance rates (from very low to full) among regularly medicated asthmatic persons as a whole (EPA, 1994a, section 2.2). The staff's assessment of this also found low use of beta-agonist bronchodilators among asthmatic subjects participating in some of the clinical studies evaluating SO effects, as well as the relative absence of routine medication use before exercise among such subjects (EPA, 1994a). Given the infrequent use of medication by many mild asthmatic individuals and the poor medication compliance of 30 to 50 percent of the "regularly medicated" asthmatic patients, it appears that a substantial proportion of asthmatic subjects would not likely be "protected" by medication use from impacts of environmental factors on their respiratory health. However, the frequency of use of medication (bronchodilators) specifically prior to engaging in outdoor activity cannot be confidently extrapolated from epidemiologic data on medication compliance. Thus, the relative number of persons who may be protected by medication prior to exercise is unclear (EPA, 1994a, pp. 9-10).

It also should be noted that betaagonist bronchodilators are effective in ameliorating SO 2-induced bronchoconstriction if an asthmatic individual has immediate access to such medication after exposure.

Effect of Other Pollutants. It has been suggested by one study (Koenig et al., 1990) that prior exposure to ozone may result in greater SO2 effects, at any given SO<sub>2</sub> concentration, than those reported in the controlled human exposure studies that examined the effects of SO<sub>2</sub> alone. In the ambient situation, however, potential ozone (O<sub>3</sub>)-induced increases in SO<sub>2</sub> effects may be at least partially attenuated by the hot humid weather that is often associated with elevated O<sub>3</sub> concentrations.

Data on whether prior nitrogen dioxide exposure produces an increased response to SO<sub>2</sub> are unclear, with a mouthpiece study showing positive effects (Jörres et al., 1990), while a chamber study of younger subjects showed no effects of NO2 on responsiveness to SO<sub>2</sub> (Rubenstein et al., 1990). It appears that a pollutant that increases nonspecific bronchial responsiveness may also increase airway responses to SO<sub>2</sub> (EPA, 1994a, p.

Epidemiological Evidence, Available epidemiological studies show no evidence of significant associations between either 24-hour or 1-hour average ambient air SO<sub>2</sub> concentrations above 0.1 ppm and increased visits to hospital emergency rooms for asthma (EPA, 1994a, p. 52). However, it is not clear to what extent epidemiologic studies could detect possible associations between very brief (≤10minute), geographically localized, peak SO<sub>2</sub> exposures and respiratory effects in asthmatic individuals. In the absence of such data, it is not possible to associate peak ambient SO<sub>2</sub> concentrations with excess asthma mortality rates reported to be observed among nonwhite population groups in large urban areas.

Frequency of Exposure Considerations. Based on this assessment of the available health effects information, the authors of the Criteria Document Supplement (EPA, 1994a) concluded that an important consideration in determining the public health significance of the reported SO<sub>2</sub> induced effects is the likely frequency that an asthmatic individual would be exposed to a 5-minute peak SO<sub>2</sub> concentration ≥0.6 ppm. Because asthmatic individuals must be at elevated ventilation in order to experience significant bronchoconstriction in response to peak SO<sub>2</sub> concentrations, any analysis undertaken to estimate the size of the asthmatic population potentially at risk from such exposures must account for both the likelihood that an asthmatic individual will be outdoors at sufficient ventilation and the likelihood that he or she will encounter an SO<sub>2</sub> concentration of concern.

## 2. Air Quality and Exposure Considerations

A central issue raised during the comment period on the 1988 proposal concerned whether a 1-hour standard of 0.4 ppm, based on a typical peak-tomean ratio of approximately 2 to 1, would provide adequate protection from high 5-minute peak SO<sub>2</sub> levels near all sources. Based on examination of more recent data, the staff concluded (EPA, 1994b) that no typical peak-to-mean ratio exists that can be used to determine a uniformly-applicable hourly standard. Given the broad range of hourly values associated with 5minute peaks of SO2 (EPA, 1994b, Table 3-2), it was concluded that reliance on any hourly peak-to-mean ratio would risk over-controlling some sources (if a high peak-to-mean ratio is assumed and a low hourly standard chosen) or undercontrolling other sources (if a low peakto-mean ratio is assumed and a high hourly standard chosen).

The available 5-minute SO2 data examined in the staff paper supplement (EPA, 1994b, pp. 34-37) clearly indicate that high 5-minute peak SO<sub>2</sub> concentrations can occur with some frequency near some sources. Absent comprehensive data on 5-minute peak SO2 levels, the staff used hourly data to estimate the likely nationwide prevalence of high short-term SO2 peaks. The staff examined all hourly averages reported in the AIRS database for the year 1992 and applied different peak-to-mean ratios to produce upper and lower bound estimates of 5-minute peaks ≥0.25 ppm. The method used for calculating the incidence of short-term peaks is given in the Staff Paper Supplement (EPA, 1994b). The lower bound estimate of the number of 5minute peaks ≥0.75 ppm SO<sub>2</sub> indicated that 50 monitors, in 38 counties which contained 18 urban areas, would register at least one 5-minute peak of  $SO_2 \ge 0.75$ ppm. The upper bound estimate was that 132 monitors, in 91 counties with 65 urban areas might experience a shortterm peak of  $SO_2 \ge 0.75$  ppm. The same analysis indicated that 132 monitors, in 91 counties containing 65 urban areas. would be the lower bound estimate of the occurrence of at least one 5-minute peak of SO<sub>2</sub> ≥0.50 ppm. The upper bound estimate was that 247 monitors in 148 counties with 124 urban areas might record at least one 5-minute peak of SO<sub>2</sub> ≥0.50 ppm. This analysis also suggests that the number of monitoring sites likely to record multiple high 5minute peaks in a single year, or over several years, can vary considerably (EPA, 1994b, pgs. 41-42).

The use of existing hourly data to assess the potential prevalence of 5minute peak SO<sub>2</sub> levels has other limitations beyond those introduced by the use of peak-to-mean ratios. The existing monitoring network is designed to accurately characterize ambient air quality associated with 3-hour, 24-hour, and annual SO<sub>2</sub> concentrations rather than to detect short-term peaks SO<sub>2</sub> levels. As a result, the EPA's monitoring guidance on siting criteria, the spanning of SO<sub>2</sub> instruments, and instrument response time could lead to underestimates of high 5-minute peaks and thus the 1-hour averages for hours containing those peaks. Of these factors, monitoring siting may be the largest potential source of underestimation of SO<sub>2</sub> peaks and therefore changes in monitoring siting and density near SO2 sources most likely to produce high 5minute peaks should increase the number of high 5-minute peaks and associated 1-hour averages recorded.

In addition to estimating the occurrence of peak SO2 levels in the ambient air, an important consideration in assessing the public health significance of SO<sub>2</sub>-induced effects is determining the likely frequency that an asthmatic individual will be exposed (EPA, 1994a, p. 51). To address this issue, exposure analyses have been conducted that predict both the frequency of high SO<sub>2</sub> peaks (through air quality modeling) and the probability that an asthmatic individual will be outdoors at sufficient ventilation (>35 L/min) to experience an SO<sub>2</sub>induced effect. The methodologies employed in these analyses, together with the associated uncertainties, are discussed in some detail in the Staff Paper Supplement (EPA, 1994b, pp. 46-47 appendix B).

These analyses indicate that 68,000 to 166,000 asthmatic individuals (or 0.7 to 1.8 percent of the total asthmatic population) potentially could be exposed one or more times, while outdoors at exercise, to 5 minute peaks of SO<sub>2</sub> ≥0.5 ppm. Fewer asthmatic individuals are likely to be exposed to ≥0.6 ppm SO<sub>2</sub> under the same conditions. The estimated number of asthmatic individuals exposed one or more times results in an estimate of 180,000 to 395,000 total exposure events of which the utility sector accounts for about 68,000. After full implementation of the title IV program of the Act, in the year 2015, the number of exposure events at ≥0.5 ppm SO<sub>2</sub> attributable to the utility sector is estimated to drop to 40,000, contingent on trading decisions.

Based on the available air quality and exposure data assessed in the Staff Paper Supplement (EPA, 1994b) and summarized above, the Administrator concurs with the staff and CASAC's views that the likelihood that asthmatic ındivıduals will be exposed to 5- to 10minute peak SO<sub>2</sub> concentration of concern, while outdoors and at exercise, is relatively low when viewed from a national perspective. The Administrator takes note, however, as did the staff, that the data also indicate high peak SO<sub>2</sub> concentrations can occur around certain sources or source types (EPA, 1994b, p. 37) with some frequency suggesting that asthmatic individuals who reside in the vicinity of such sources or source types may be at greater health risk than indicated for the asthmatic population as a whole.

## C. Regulatory Considerations

Taking into account the staff's assessments and the advice and recommendations of the CASAC, the Administrator has considered whether additional regulatory measures are

needed to protect asthmatic individuals against short-term (5- to 10-minute) peak SO2 exposures. In her judgment, the current 3-hour, 24-hour, and annual standards appear to provide substantial protection against the health effects associated with short-term SO2 exposures. As indicated by the air quality analyses described above, the current standards, together with implementation of title IV of the Act, markedly limit the frequency and extent of short-term concentrations of concern. The exposure analyses that take into account normal day-to-day activity patterns further suggest that the risk is relatively low that individuals with mild or moderate asthma will experience exposure conditions approximating those that produced effects of concern in controlled human studies. In view of those analyses, the nature of the reported effects, the effectiveness of bronchodilator medication to prevent or ameliorate SO<sub>2</sub> effects if available and properly used. and the fact that similar events can be provoked more frequently by other stimuli, the Administrator concurs with the staff's and the CASAC's assessment that the public health risk posed by short-term peak SO<sub>2</sub> levels is limited when viewed from a national perspective and does not constitute a broad national public health problem.

The Administrator is mindful, however, that the available data indicate that those asthmatic individuals who reside in proximity to certain individual sources or source types will be at higher risk of being exposed to short-term peak SO<sub>2</sub> levels than the asthmatic population as a whole. While some asthma specialists question the health significance of the reported health effects, the Administrator notes that others believe the effects are significant and that additional protection is warranted. This information, combined with uncertainties regarding the use of bronchodilator medication prior to exercise, particularly among asthmatic children and asthmatic individuals who may not perceive a need to medicate regularly prior to engaging in outdoor activities, suggests to the Administrator that additional regulatory measures may be needed.

In their assessment of the available scientific and technical information, the EPA staff recommended a range of concern for the Administrator's consideration when examining the potential need for new regulatory measures to provide additional public health protection beyond that provided by the existing set of standards (EPA, 1994b). This range, based on the most recent assessments presented in the

criteria document and staff paper supplements and summarized above, is 0.6 to 1.0 ppm SO2. The staff's assessment concluded that a substantial percentage (20 percent or more) of mild to moderate asthmatic individuals exposed to 0.6 to 1.0 ppm SO<sub>2</sub> for 5 to 10 minutes during moderate exercise would be expected to have respiratory function changes and severity of respiratory symptoms that clearly exceed those experienced from typical daily variation in lung function or in response to other stimuli (e.g., moderate exercise or cold/dry air). For many of the responders the effects are likely to be both perceptible and thought to be of some immediate health concern, i.e., to cause disruption of ongoing activities, use of bronchodilator medication, and/ or possibly seeking of medical attention. At SO<sub>2</sub> concentrations at or below 0.5 ppm, the staff concluded that at most only 10 to 20 percent of mild and moderate asthmatic individuals exposed to 0.2 to 0.5 ppm SO<sub>2</sub> during moderate exercise are likely to experience lung function changes distinctly larger than those typically experienced and that, compared to the response at 0.6 to 1.0 ppm SO<sub>2</sub>, the response at or below 0.5 ppm SO<sub>2</sub> is less likely to be perceptible and of immediate health concern.

In considering the staff's most recent assessment of the available health information, the Administrator found it to be generally consistent with the staff's 1986 review. During both reviews there has been divergent opinion as to the appropriate level for the lower bound for the range of concern. Both assessments, however, concluded that 1.0 ppm SO<sub>2</sub> is the appropriate upper bound. At that level there is clear concern that if an asthmatic individual is exposed while at exercise to 1.0 ppm SO<sub>2</sub> for 5 minutes the risk of significant functional and symptomatic responses will be high. This finding in 1986 led several CASAC members to recommend a 1-hour standard level that would restrict the concentration of 5-minute SO<sub>2</sub> peaks to 0.6 to 0.8 ppm in order to preclude 5-minute peaks of 1.0 ppm SO<sub>2</sub> (Lippmann, 1987). The Administrator finds the staff's present recommendations consistent with that point of view.

The Administrator also took note that the current CASAC review panel, while acknowledging the existence of a wide spectrum of views among asthma specialists regarding the clinical and public health significance of the reported effects, did not comment on the range of concern or present the individual panel members' views as to the significance of the reported effects in its "closure" letter. At the April 12,

1994 closure" meeting, however, the panel found that the range recommended by the staff was consistent with the available scientific information. Three members of the panel who addressed the public health significance of the reported effects in their written comments concluded that segments of the asthmatic population exposed to peak SO<sub>2</sub> concentrations while at elevated ventilation were at risk of incurring clinically significant effects if not properly medicated. While the basis for their judgments differed, their views as to the 5-minute concentrations of concern overlapped (0.4 to 0.8 ppm SO<sub>2</sub>; above 0.6 ppm SO<sub>2</sub>, and 0.6 to 1.0 ppm SO<sub>2</sub>) and are in general agreement with both the 1986 and 1994 staff assessments. On the other hand, another panel member who addressed the general issue, while recognizing that SO2 can cause bronchoconstriction, questioned the public health significance of short-term peak SO<sub>2</sub> exposures, based in part on his judgment that the likelihood of an asthmatic individual being exposed while at exercise is exceedingly low given the protection afforded by the existing standards. In its closure letter the CASAC expressed the view that such exposures are rare events and that the likelihood of such exposures should be considered in selecting an appropriate regulatory response.

Based on its assessment of the available data, the staff recommended consideration of three regulatory alternatives: (1) Revising the existing NAAQS by adding a new 5-minute standard implemented through a risk based targeted strategy, (2) establishing a new regulatory program under section 303 of the Act, or (3) augmenting the implementation of current NAAQS by focusing on those sources likely to cause high 5-minute peaks. In considering these alternatives, the Administrator has taken into account the divergent views expressed by the public, asthma specialists, and the CASAC with respect to the public health significance of short-term SO<sub>2</sub> exposures and the appropriate degree of protection needed. In doing so she is mindful that in the absence of conclusive scientific and technical information, the Act requires that the A'dministrator make a judgmental determination as to whether the reported effects endanger public health and pose an unacceptable risk of harm. At the April 12, 1994 CASAC meeting and in written comment. individual members of the 1994 CASAC panel recognized that choosing among the regulatory alternatives presented in the staff paper supplement must be

guided by legal and policy considerations, given the nature of the available scientific and technical information and the divergent views as to the health significance of the reported effect and the pollution level of concern.

The Administrator therefore is proposing for public comment three alternative regulatory approaches for supplementing the protection provided by the current standards if additional protection is judged to be necessary. In so doing, the Administrator has carefully considered the 1994 CASAC review panel's strong recommendation that any additional regulatory measures be implemented through a risk-based. targeted strategy. Consistent with this recommendation, all three regulatory alternatives under consideration, as described below, are based upon such a strategy. The Administrator believes it is important to air the key issues and uncertainties fully and specifically requests broad public comment and deliberation on these alternatives.

## 1. 5-Minute NAAQS Alternative

After considering the staff's recommendations and the views of the 1986 and 1994 CASAC review panels, the Administrator believes that it is both appropriate and necessary to solicit public comment on a 5-minute NAAQS of 0.60 ppm SO<sub>2</sub>. Based on the staff's assessments of the available scientific and technical information, the Administrator is concerned that 5minute peak SO<sub>2</sub> levels beginning at 0.60 ppm and above may present an unacceptable risk of harm to asthmatic individuals who have not premedicated with beta-agonist bronchodilators and are exposed at elevated ventilation. In proposing a 5-minute NAAQS, the Administrator is particularly concerned that asthmatic individuals in the proximity of sources with a high potential to cause or contribute to a 5minute peak SO<sub>2</sub> concentration greater than 0.60 ppm may be at substantially greater risk of experiencing an exposure event, which triggers bronchoconstriction, than the asthmatic population as a whole. Adoption and implementation of a 5-minute NAAQS of 0.60 ppm SO<sub>2</sub> would prevent such exposures and further reduce the likelihood that an asthmatic individual would be exposed at elevated ventilation to lesser concentrations. Therefore, it is the Administrator's provisional judgment that a 5-minute NAAQS of 0.60 ppm SO<sub>2</sub> would

adequately protect the public health. In assessing the possible need for additional protection against peak SO<sub>2</sub> exposures, the Administrator has considered the specific issue of

medication usage. While it is clear from the available data that the use of betaagonist bronchodilators to prevent the effects of other stimuli (e.g., exercise, cold/dry air) will also prevent or ameliorate the effects of SO2, there is considerable debate as to compliance rates and therefore the degree of protection provided. As one CASAC panel member noted, "many moderate asthmatics, particularly those from urban areas and lower economic status. may have less than ideal medical follow-up and are prone to irregular medication use and frequent deterioration" (Schachter, 1994). In public comment on the 1988 proposal, a number of individuals made the point that asthmatic children, who are dependent on adults for their medication and care, are more likely to be unprotected and therefore at particular risk from SO<sub>2</sub> exposures of concern. Other commenters on the criteria document and staff paper supplements noted that asthmatic ındividuals who do not perceive the need to medicate prior to engaging in strenuous outdoor activities would also be at increased risk from SO<sub>2</sub> exposures. While the Administrator believes these are important considerations, the overriding issue is whether the availability of, and reliance on. prophylactic medications should be viewed as an alternative to further regulatory action to reduce the risk posed by high peak SO2 concentrations in the ambient air. In this regard, the Administrator is concerned whether reliance on medications, even if taken to prevent the effects caused by other stimuli, as an alternative to environmental controls would be an appropriate public policy choice, particularly given the potential environmental equity issues involved.

In seeking comment on a possible 5minute NAAQS of 0.60 ppm SO<sub>2</sub>, to further reduce the risk posed by high peak SO<sub>2</sub> concentrations, the Administrator concurs with the staff's recommendation that such a standard be implemented through a risk-based targeted approach. By focusing on those sources or source types that are most likely to cause or contribute to high 5minute SO<sub>2</sub> concentrations and thus pose the greatest risk to asthmatic individuals, such a program would be effective in reducing peak SO<sub>2</sub> concentrations of concern. In response to questions raised by the 1994 CASAC review panel, the Agency continues to believe that such a program would be enforceable, based on its longstanding enforcement experience.

The Administrator recognizes, however, as did the 1994 CASAC review

panel,3 that the adoption of a 5-minute NAAQS might not be appropriate given the nature of the problem or the most efficient means of achieving the desired reductions. Under sections 108 through 110 of the Act, NAAOS and State plans to implement them are designed to address air pollution problems that emanate from numerous and diverse sources whose collective emissions contribute to unacceptable pollution levels, rather than from a limited number of discrete point sources that cause only very localized pollution problems. Moreover, the implementation process for a 5-minute NAAOS (described in detail in the 40 CFR part 51 document to be published shortly in the Federal Register) could impose significant planning and other requirements on the States and the regulated community that are neither very efficient nor necessary for addressing the limited number of point sources that the EPA believes may produce high 5-minute peak SO2 levels. While the targeting strategy presented in the part 51 notice is designed to reduce such burdens to the extent practicable under the Act, the implementation process includes a number of timeconsuming steps (e.g., area designations) that are not particularly germane, given the nature of the problem, and could significantly delay effective remediation. With these factors in mind and in view of her desire to provide such additional protection (beyond the existing NAAQS) as may be appropriate in the most efficient manner, the Administrator is also advancing for public comment the alternative of establishing a new control program

"To the extent CASAC comments about enforcement of a short-term NAAQS.took into account such factors as cost and technological feasibility, the courts have held that such factors are not appropriate considerations in the establishment or revision of NAAQS. The extent to which these factors influenced the CASAC recommendation regarding a 5-minute NAAQS is unclear.

<sup>3</sup> In its "closure letter" the 1994 CASAC panel stated, "It was the consensus of CASAC that any regulatory strategy to ameliorate such exposure be risk-based-targeted on the most likely sources of short-term sulfur dioxide spikes rather than imposing short-term standards on all sources. All of the nine CASAC Panel members recommended that Option 1, the establishment of a new 5-minutes standard, not be adopted. Reasons cited for this recommendation included: the clinical experiences of many ozone experts which suggest that the effects are short-term, readily reversible, and typical of response seen with other stimuli. Further, the committee viewed such exposures as rare events which will even become rarer as sulfur dioxide emissions are further reduced as the 1990 amendments are implemented. In addition, the committee pointed out that enforcement of a shortterm NAAQS would require substantial technical resources. Furthermore, the committee did not think that such a standard would be enforceable

based on sections 303, 110(a)(2)(G), and 301(a) of the Act.

#### 2. Section 303 Program

As an alternative to a new 5-minute. NAAQS, the staff recommended in the staff paper supplement that consideration be given to establishing a new regulatory program under section 303 to supplement the protection provided by the existing NAAQS. The staff recommended that the new program establish a target level for control in the range of 0.60 to 1.0 ppm SO<sub>2</sub>, expressed as the maximum 5minute block average in 1 hour, and that the program be implemented through a risk-based, targeted strategy. This approach would supplement the existing NAAQS by, in effect, placing a cap on ambient short-term peak SO<sub>2</sub> levels. Exceedance of this cap would lead to source-specific control efforts designed to prevent recurrence of such peak levels, thus providing additional protection to asthmatic individuals in proximity to the source(s) involved.

Section 303 authorizes the Administrator to bring suits for injunctive relief or to issue appropriate administrative orders if air pollution levels in an area pose "an imminent and substantial endangerment to public health or welfare, or the environment. Although section 303 is probably best known in connection with EPA regulations for the prevention of "emergency episodes" involving high concentrations of criteria pollutants (40 CFR part 51, subpart H), the Agency interprets it as providing authority to act in a variety of circumstances, including situations involving pollution concentrations lower than "emergency levels and incidents involving industrial accidents or malfunctions (EPA, 1983b, pp. 1-2, 5).4 Section 110(a)(2)(G) of the Act requires State implementation plans (SIP's) to contain authority comparable to section 303 and adequate contingency plans to implement that authority. As indicated above, the program proposed in this notice would be based on both of these provisions, as well as section 301(a) of the Act, which grants general authority to prescribe regulations necessary to carry out the functions of the Administrator.

Although the proposed program would differ in some respects from the approach adopted in the Agency's "emergency episodes" program, it

would be based on some of the same fundamental concepts. The emergency episodes program was designed to supplement the NAAQS by providing additional protection in situations not effectively addressed by them, i.e., in periods of air stagnation when air pollution levels can build up to levels well in excess of the NAAQS. Under the program, SIP's are required to include contingency plans that specify two or more stages of episode criteria-such as the alert, warning, and emergency levels specified in example regulations issued by the EPA-and progressively more stringent abatement actions, including shutting down entire industries to the extent necessary as pollution levels advance from one stage to another (see 40 CFR part 51, subpart H and appendix L). The episode criteria and associated abatement actions are preventive measures designed to ensure that certain pollution concentrations-referred to as significant harm levels (SHL s)-are never achieved.5

Although the Agency established SHL's for these purposes at concentrations associated with relatively severe health effects, the use of section 303 to protect public health is not limited to situations involving such extreme conditions. By design, the SHL's are levels that should never be reached, and relatively drastic measures to prevent their occurrence, including court actions for injunctive relief, are authorized at a lower level, usually the "emergency" level (EPA, 1993b, pp. 4-5). Indeed, abatement measures may be required at even lower levels (id.), both to prevent air quality levels from deteriorating further (36 FR 20513, Oct. 23, 1971), and to avoid less serious health effects that can occur at those levels (39 FR 9672, 9673, Mar. 13, 1974).

Even where there is uncertainty about a threafened harm, the EPA interprets section 303 as authorizing action where there is a "reasonable medical concern' about public health (EPA, 1983b, p. 4). More generally, the courts have construed similar provisions in other EPA statutes liberally indicating that action under them is not limited to extreme, extraordinary or "crisis" situations but may be based on circumstances posing a "reasonable cause for concern that someone or something may be exposed to a risk of harm" if remedial action is not taken. (see, e.g., U.S. versus Conservation Chemical Co., 619 F Supp. 162, 194 (W.D.Mo. 1985); EPA, 1993b, pp. 10-13

(CWA section 504); EPA, 1991, pp. 5–7 (SDWA section 1431); EPA, 1983b, pp. 2–5 (CAA section 303); EPA, 1983a, pp. 8–9 (CERCLA section 106(a))). For these and other reasons, the Agency believes that its authority to address threats to public health or welfare or the environment under section 303 is not limited to situations involving pollutant concentrations associated with severe effects.6

Like the emergency episodes program, the new section 303 program would attempt to avoid the need for ad hoc court actions by establishing a framework for remedial efforts in advance through the Agency's rulemaking authority. However, because 5-minute peak SO<sub>2</sub> concentrations of concern can occur rapidly with little or no prior build-up of SO<sub>2</sub> levels, and because such peak concentrations are relatively quickly dispersed, the Agency believes that a section 303 program modeled closely on the emergency episodes program would not provide an effective response. Instead, the Administrator concurs with the staff recommendation that a health-based, ambient-air target or trigger level be established if this alternative is selected, and that sources that cause or contribute to exceedances of the trigger level be identified and regulated on a case-bycase, source-specific basis to prevent 5minute peaks of concern from recurring. Given the nature of the problem being addressed, the trigger level would need to be preventive in nature; that is, it would need to be set at a level designed to ensure that pollution levels that might pose a significant risk to the public health would not occur in the ambient air.

If this alternative is selected, it is the Administrator's provisional judgment, based on her assessment of available health information and for the reasons discussed above, that the appropriate trigger level for the section 303 program would be 0.60 ppm SO<sub>2</sub> as measured in the ambient air, so as to provide the same level and degree of protection as would be afforded by a possible new 5-minute NAAQS. As discussed earlier,

<sup>&</sup>lt;sup>4</sup> Similar provisions in other EPA statutes have been similarly construed (see, e.g., EPA 1993b (section 504 of the Clean Water Act); EPA 1991 (section 1431 of the Safe Drinking Water Act); EPA 1983a (section 106(a) of the Comprehensive Environmental Response; Compensation, and Liability Act)).

<sup>&</sup>lt;sup>5</sup> This preventive approach—combining elements of rulemaking and advance planning—helps to avoid some of the practical problems associated with attempting to address emergency episodes by seeking injunctive relief on an ad hoc basis.

<sup>&</sup>lt;sup>6</sup> This conclusion is consistent with the legislative history of section 303, as well as that of similar provisions in other EPA statutes (see, e.g., S. Rep. No. 91–1196, 91st Cong., 2d Sess. 35–36 (1970) (section 303 authority applies not only in situations involving incapacitating body damage, irreversible body damage, and increases in mortality but also "whenever air pollution agents reach levels of concentration that are associated with the production of significant health

effects in any significant portion of the general population"). It is also consistent with the steady pattern of broadening and strengthening of section 303 evident in all amendments to the Act since 1967 see, e.g., S. Rep. No. 101–228, 101st Cong., 1st Sess. 370–71 (1989)).

the Administrator is concerned that 5-minute peak SO<sub>2</sub> concentrations of 0.60 ppm and above may present an unacceptable risk of harm to asthmatic individuals who have not premedicated with beta- agonist bronchodilators and are exposed at elevated ventilation.

The details of the proposed section 303 program will be described in the Federal Register in the document concerning implementation issues. Like the emergency episodes program, the proposed program would require States to adopt SIP provisions containing necessary legal authority and contingency plans. Once a violation of the trigger level proposed in today's notice was detected, the State and the pertinent emission source(s) would need to take steps to determine the cause of the violation, and the source(s) would need to implement appropriate remedial actions to prevent recurrences of such emissions. The EPA would also be able to take action, either by enforcing the SIP provisions or directly under its section 303 authority.

The proposed section 303 program would offer several distinct advantages. It would provide an enforceable, healthbased target to guide the actions of the regulated community, and it could be focused specifically on those sources most likely to cause or contribute to high 5-minute peak SO<sub>2</sub> exposures. Once information became available that a source had caused or contributed to an exceedance of the trigger level, appropriate actions could be initiated quickly. While some SIP revisions would be necessary for States to implement this program, more timeconsuming aspects of the SIP process such as designations could be avoided. The EPA would also be able to take action directly if necessary. The likelihood that this program could bring about prompt and effective remediation of problems causing high 5-minute peak SO<sub>2</sub> levels is a factor of considerable importance to the Administrator.

## 3. Retain Current Standards

The Administrator has also considered the staff's third alternative of retaining the current set of standards but augmenting their implementation by focusing on those sources that are most likely to produce high 5-minute peak SO<sub>2</sub> levels. The targeting strategy and implementation plan will be discussed more specifically in the Federal Register document on implementation issues. This approach would be aimed at assuring that the existing standards were met through more targeted monitoring, including the routine collection and reporting of 5-minute data, and more vigorous enforcement of

existing regulatory provisions governing good operating practices, upsets, and malfunctions. The Administrator believes that additional risk reductions can be achieved by these means, and the EPA is presently taking steps to initiate such activities. In summary the EPA is requesting public comment on three alternative approaches for supplementing the protection provided by the current standards against the health risk posed by short-term peak SO<sub>2</sub> levels if additional protection is judged to be necessary. Given the available scientific and analytical data, the final selection of the most appropriate course of action will be based in large part on policy and legal considerations. To better inform the Administrator's final determination, the EPA specifically requests public comment in several key areas. First, the EPA requests the submittal of additional factual information on the frequency of occurrence of 5-minute peak SO<sub>2</sub> levels in the ambient air, as well as information on the source or source types and the nature of the events that are most likely to give rise to such peak SO<sub>2</sub> levels. Such information would assist in determining the most effective regulatory response. Second, throughout the review there has been considerable debate as to the adequacy of the available exposure analyses. In light of the uncertainties in these analyses, the EPA requests the submission of data that would allow for better characterization of the asthmatic population at risk and of the frequency that an asthmatic ındivıdual would likely be exposed to peak SO<sub>2</sub> concentrations, particularly at levels of 0.60 ppm and above, while at elevated ventilation. Third, of particular interest to the Administrator is the issue of the medical significance of the reported SO<sub>2</sub> induced effects. Given the broad diversity of opinion of the asthma specialists that have participated in the review to date, the EPA specifically requests other members of the medical community who are experts in this area to submit their views on this important issue. Finally the EPA requests comment on the appropriateness of the 0.60 ppm level for 5-minute NAAQS and the section 303 program, and whether a numerical value below or above 0.60 ppm would be more appropriate to protect asthmatic ındividuals.

## D. Averaging Convention for the Standards

The averaging convention specifies the interpretation of standards for a particular averaging time (in this case, 3-hour, 24-hour, annual) with respect to

when (time and day) the averaging period(s) begins and ends. The two major alternative averaging conventions are known as "block" and "running. Under the block convention, periods such as 24 hours and 3 hours are measured sequentially and do not overlap; when one averaging period ends, the next begins. For example, one 24-hour measurement would be taken from midnight on day one to midnight on day two; the next would begin at midnight on day two. Under the running convention, measurements are allowed to overlap. Thus, if one 24-hour period were measured from midnight to midnight, the next might be measured from 1 a.m. to 1 a.m. or from 12:01 a.m. to 12:01 a.m. Given a fixed standard level, running averages would produce a somewhat more restrictive standard (Faoro, 1983; Possiel, 1985)

Although the wording of the original 24-hour, 3-hour, and annual SO<sub>2</sub> standards was ambiguous on the matter, the earliest actions of the EPA signify that the block averaging convention was intended for these standards (OAQPS 1986), and block averages have generally been used in implementing the standards.7 The use of running averages would therefore represent a tightening of the standards. Because the Administrator has determined, for the reasons explained in this notice and in the April 21, 1993 notice on the secondary NAAQS (58 FR 21351), that protection of the public health and welfare does not require tightening the existing standards, the Administrator proposes to retain the block averaging convention for the 24-hour, 3-hour, and annual standards. To eliminate any future questions on this aspect of the standards, clarifying language is being proposed in the regulation (40 CFR 50.4 and 50.5).

## E. Form of the Current Standards

In revising the standards for ozone and particulate matter, the EPA concluded that it would be appropriate to make technical improvements to the form in which the standards were expressed (44 FR 8202, Feb. 8, 1979; 52 FR 24653, July 1, 1987). These improvements were embodied in a revised statistical form for the

Although EPA generally does not specify use of a running average in evaluating SO<sub>2</sub> SIP's for attainment and maintenance of the NAAQS, running averages have been used in a limited number of instances. In the enforcement context, in cases where supplementary control systems (SCS) were used as an interim measure to protect the NAAQS at primary copper smelters, consent decrees for such facilities specified running average requirements see, e.g., U.S. v. Phelps Dodge Corp. Civil No. 81–088–TUC-MAR (D. Ariz. filed October 20, 1986)].

standards, which was intended to maintain desired liealth protection while improving ease of implementation. The decisions on the statistical form were made in conjunction with decisions on the level of the standard. The EPA has also considered the alternative of expressing the SO<sub>2</sub> standards in a similar statistical form, with one expected exceedance per year for the 24-hour and 3-hour standards and expressing the annual standard as an expected annual mean. The EPA examined the relative protection afforded by the current standards if they were expressed in statistical form (EPA, 1984a; Frank, 1987). These analyses found that the standards expressed in a statistical form would afford reduced protection against the 24-hour, annual, and 3-hour health and welfare effects associated with these averaging periods and, in addition, would significantly reduce the degree of protection, the existing set of standards provides against 5-minute peak SO2 exposures. Thus, adopting a statistical form would necessitate revisions to the levels of the existing 24-hour, 3-hour, and annual standards to maintain the requisite level of protection needed. In the judgment of the Administrator, the limited technical advantages of adopting a statistical form for these standards are not sufficient to warrant the administrative burden associated with such a change.

In advancing the new alternatives of a 5-minute NAAQS and a section 303 program for public comment, however, the Administrator believes it is appropriate to propose that they take a statistical form as recommended by the staff. In reaching a judgment that a new 5-minute NAAQS of 0.60 ppm SO<sub>2</sub> or a new section 303 trigger level of 0.60 ppm SO<sub>2</sub> may be needed to provide additional public health protection, the Administrator was cognizant of and took into account that these measures would be expressed in the statistical form when determining the level to be proposed for each alternative. The EPA is, however, requesting comment on whether more than one expected exceedance should be allowed as suggested by the staff (EPA 1994b, pp. 60-62). In seeking comment on this question, the EPA is concerned that a single upset or malfunction during a day could cause multiple exceedances of the proposed 5-minute standard level or the alternative section 303 trigger level despite a source operator's good faith and willingness to take prompt and effective abatement action.

### F Other Technical Changes

The EPA is proposing to make some minor technical changes in the part 50 regulations concerning the SO<sub>2</sub> standards (Frank, 1988). First, the levels for the primary and secondary NAAQS would be restated in ppm rather than μg/m<sup>3</sup> (40 CFR 50.4 and 50.5). This would be done to make the SO<sub>2</sub> NAAQS consistent with other pollutants and to improve understanding by the public. The levels would be restated as follows: (a) The level of the annual standard is 0.030 parts per million (ppm) (approximately 80 μg/m<sup>3</sup>), (b) the level of the 24-hour standard is 0.14 ppm (approximately 365 µg/m<sup>3</sup>), and (c) the level of the 3-hour standard is 0.5 ppm (approximately 1300 µg/m³). Secondly explicit rounding conventions would be added (40 CFR 50.4 and 50.5). This would aid State and local air pollution control agencies in interpreting the standard. Finally, data completeness and handling conventions would be specified (40 CFR 50.4 and 50.5). These conventions would be consistent with the definitions used with ozone and would ensure that omission or deletion of some hourly or 5-minute data will not negate obvious exceedances (see 40 CFR part 50, appendix H for the equivalent ozone language).

## VI. Federal Reference Methods and Equivalent Methods

The Federal Reference Method for measuring ambient concentrations of SO<sub>2</sub> set forth in appendix A of part 50 is not capable of providing 5-minute average concentration measurements. Even if it could, such a manual method would not be practical for 5-minute measurements because of the large number of individual samples that would have to be obtained and analyzed. Clearly an automated, continuous monitoring method (equivalent method) is required for 5minute monitoring. This requirement is innocuous, however, since the reference method is now rarely used for routine field monitoring, even for 3-hour or 24hour measurements, having already been replaced with use of continuous, instrumental equivalent methods. Thus, no revisions are proposed to the reference method.

Although most of these instrumental equivalent methods provide nominally continuous SO<sub>2</sub> concentration measurements, these measurements are almost universally reduced to standardized hourly averages (block averages, by convention, as opposed to running or overlapping averages) for purposes of recording, validation, storage, interpretation, and use. (Longer-

term averages are computed from the hourly averages.) Accordingly, the performance of the instruments is usually optimized by the manufacturer toward production of hourly averages. Specifically, the response of the analyzers may be intentionally slowed to provide concentration measurements that change more slowly than the actual input concentration. This "smoothing" filters random fluctuations (noise), provides more stable readings for instrument operators, aids calibration accuracy, and facilitates more accurate integration of the readings into hourly averages.

When such instruments are used to obtain 5-minute average concentration measurements, however, the slowed response often causes the measurements to underestimate the actual peak concentration of short-duration concentration peaks (Eaton et al., 1991; Eaton et al., 1993). The degree of error is estimated to be from a few percent to as much as 20 or 25 percent, depending on the response time of the instrument and the sharpness (height to duration ratio) of the concentration peak. (The smoothed measurements correspondingly overestimate the duration of the peak such that the peak is correctly integrated for longer averaging periods such as 1 hour.)

Fortunately, more accurate 5-minute average concentration measurements can be obtained from most of the equivalent method analyzers available currently by relatively minor modifications to increase their response times. These modifications may include minor electronic adjustments, substitution of modified circuit cards or software programs, or increased flow rates, and the modifications could also likely be made available for existing analyzers through either user or manufacturer retrofitting. Prior to promulgation of one of the regulatory. alternatives, SO<sub>2</sub> analyzer manufacturers would be informed of the new requirements for faster response time for both new and existing analyzers as may be appropriate.

Based on this assessment, the EPA is proposing to establish special, supplemental performance specifications that would be applicable to equivalent method analyzers used for 5-minute SO<sub>2</sub> monitoring. These new performance specifications would be added to 40 CFR part 53, which sets forth the provisions under which the EPA designates reference and equivalent methods for air monitoring to determine attainment of the NAAQS. Part 53 gives the quantitative performance specifications and other requirements that a candidate method must meet to be

designated as a reference or equivalent method, as well as the detailed test procedures by which the various performance parameters are to be measured.

Capability for accurate 5-minute monitoring requires more stringent specifications for certain performance parameters than are required for 1-hour average measurements. The primary performance specifications that must be changed are those having to do with the response time of the analyzer. These are the "rise time" and "fall time" specifications of part 53, which describe the time required for the output measurement or signal of the analyzer to respond to increases or decreases, respectively in the input concentration. More specifically, these times are defined as the time required for the instrument measurement to reach 95 percent of the final, stable reading after a step increase or decrease (respectively) in the input concentration. For 1-hour average SO<sub>2</sub> measurements, analyzer response can be relatively slow the specifications in part 53 for rise and fall time are both 15 minutes. Typical rise and fall times of several widely used designated SO<sub>2</sub> equivalent method analyzers are between 2 and 5 minutes.

However, as noted previously such an analyzer may underestimate the actual 5-minute average concentration of a short-term concentration peak by as much as 20 or 25 percent, depending on the response time of the instrument and the nature (shape) of the concentration peak. To provide more accurate 5minute measurements, the maximum rise and fall time specifications must be reduced to 2 minutes or less. Accordingly part 53 is proposed to be amended by adding supplemental maximum rise and fall time specifications of 2 minutes to be applicable to designated equivalent methods for SO<sub>2</sub> that would be used for 5-minute monitoring.

Another performance parameter that is associated with rise and fall time (and sometimes included in the generic term "response time") is "lag time, which describes the time between the presentation of a step change in the input concentration and the first indication of the change in the measurement readings. Although the lag time represents a delay in the presentation of concentration measurement readings by the analyzer, technically it does not affect the ultimate accuracy or precision of 5minute measurements relative to the accuracy or precision of 1-hour measurements. Therefore, no supplemental lag time specification is needed for 5-minute monitoring.

The only other performance specification that is of special concern for 5-minute monitoring is the measurement range of the analyzer. Measurements of 5-minute SO<sub>2</sub> concentrations in source-targeted areas where high short-term concentrations may occur would likely require a higher measurement range than for monitoring in other areas. It is expected that a 1.0 ppm measurement range would be adequate for most 5-minute monitoring sites. However, accurate measurements require that the measured concentration not exceed the measurement range during any portion of the 5-minute averaging period. Therefore, measurement ranges higher than 1.0 ppm may be needed at some monitoring sites.

Part 53 specifies a base measurement range of 0.5 ppm and permits alternative ranges up to 1.0 ppm. All designated equivalent methods for SO<sub>2</sub> in wide use today have 1.0 ppm measurement ranges that are approved for use under their equivalent method designations. Further, if a higher range is needed at a particular monitoring site, provisions ın 40 CFR part 58, appendix C, section 2.6 allow individual approval of ranges higher than 1.0 ppm at sites where such a higher range is justified. Accordingly only a minor change is proposed to part 53-to require a 1.0 ppm range for equivalent methods for SO<sub>2</sub> that would be used for 5-minute monitoring.

The currently existing rise and fall time and range specifications in 40 CFR part 53 (for 1-hour average measurements) are not proposed to be changed. Hence, there would be no change in the base requirements in 40 CFR part 53 for designation of equivalent methods for SO<sub>2</sub>. The new supplemental rise and fall time and range specifications being proposed would be applicable only to designated equivalent methods used for 5-minute monitoring and would create a subset of SO<sub>2</sub> equivalent methods that would be additionally approved for 5-minute monitoring. Methods that meet all of the existing performance specifications but not the supplemental specifications for rise and fall time and range would be acceptable for all NAAQS monitoring other than 5-minute monitoring. This situation would be similar to that for other performance parameters where, for example, some designated equivalent methods are approved for use on multiple measurement ranges or over a wider operating temperature range than the minimum range specified. In all such cases, the additional performance qualifications, over the minimum requirements of 40 CFR part 53, are clearly identified and

indicated in the equivalent method description. This description appears in both the notice of designation published in the Federal Register and in the List of Reference and Equivalent Methods maintained in accordance with § 53.8(c) and distributed to the EPA Regional Offices and to others upon request.

Manufacturers of new SO<sub>2</sub> analyzers may redesign their analyzers to provide for additional ranges, faster response, or capability for user-selection of these parameters. The test procedures to show that an analyzer meets the new supplemental range and rise and fall time specifications for 5-minute monitoring are the same range and rise and fall time test procedures currently described in 40 CFR part 53. Test results from these tests would be submitted along with the results from the other tests in an application for an equivalent method determination under 40 CFR part 53. A manufacturer of an existing analyzer that is currently designated as an equivalent method for SO<sub>2</sub> but does not meet the new supplemental specifications for range and rise and fall time would be encouraged to develop modifications to the analyzer that would allow it to meet the new specifications. The manufacturer should then carry out appropriate tests to demonstrate that the modified analyzer meets the new specifications and apply for approval of the modifications under § 53.14 (modification of a reference or equivalent method). Manufacturers should note, however, that tests other than the range and rise and fall time tests may have to be carried out, since increasing the range or response time could have a possible adverse effect on other performance parameters, such as noise and lower detectable limit. Ideally such analyzer modifications should be made available to users in the form of a retrofit kit for user installation, if possible. Alternatively the analyzer may have to be returned to the factory for the modifications to meet the new 5minute monitoring specifications.

No other changes to 40 CFR part 53 are deemed necessary to support the 5-minute monitoring requirement.

### VII. Regulatory Impacts

A. Regulatory Impacts Administrative Requirements

Under Executive Order 12866 (58 FR 51713, Oct. 4, 1993), the EPA must determine whether a regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines a "significant regulatory action" as one that is likely to result in a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a maternal way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;
- (3) Materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this notice is a significant regulatory action because of its potential to have an annual effect on the economy of \$100 million or more. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

## **Summary of Regulatory Impacts**

The EPA has prepared and entered into the docket a draft regulatory impact analysis (RIA) entitled "Regulatory Impact Analysis for the Proposed Regulatory Options to Address Short-Term Peak Sulfur Dioxide Exposures (June 1994)." This draft RIA includes estimates of costs, economic impacts, and net benefits associated with implementation of the regulatory alternatives discussed above. The proposed regulatory action is intended to be implemented through a risk-based, targeted monitoring strategy given the localized nature of the short-term SO<sub>2</sub> problem. Absent specific information on which sources would be impacted under this implementation strategy, modeling is used to identify SO2 sources likely to cause exceedances of either the 0.60 ppm SO<sub>2</sub>, 1 or 5 expected exceedance forms of the standard. Although there are large uncertainties associated with the modeling analysis, such analyses are currently the only available tools for predicting sources of short-term SO<sub>2</sub> peaks and estimating associated control costs for reducing peak, ambient concentrations. Given the modeling uncertainties, as well as that the modeling analyses are not reflective of the specific sources to be targeted by States under a risk-based, targeted implementation strategy, the following estimated impacts should be viewed with caution.

Short-term SO₂ NAAQS Regulatory Alternative

The cost estimates for the short-term SO<sub>2</sub> NAAQS regulatory alternative represent a snapshot of the estimated total industry costs that could be incurred at some unspecified time in the future following full implementation of a short-term SO<sub>2</sub> NAAQS. The costs are based on the use of add-on control devices and fuel switching to lowersulfur fuels. Given that EPA believes that many sources will be able to reduce their peaks through other. nontechnological means, this assumption may result in overstating costs. With this caveat in mind, nonutility annualized costs are estimated to be approximately \$250 million for an ambient SO<sub>2</sub> concentration level of 0.60 ppm, 1 expected exceedance. Annualized costs for a 0.60 ppm, 5 annual exceedance concentration level are estimated to be approximately \$160 million. It is estimated that SO2 will be reduced by approximately 910 thousand tons, and 560 thousand tons for the 1 and 5 exceedance cases, respectively. Incremental to the title IV requirements and attainment of the existing SO2 NAAQS, total utility annualized costs in 2005 are estimated to be an additional \$1.5 billion for the 0.60 ppm, 1 expected exceedance case, and \$400 million for the 5 expected exceedance case. Estimated total utility SO<sub>2</sub> emissions in 2005 are not expected to change given the title IV emissions trading program.

Administrative costs are estimated to be approximately \$18 million for the short-term NAAQS regulatory alternative. Monitoring costs are estimated to be minimal.

#### Section 303 Regulatory Alternative

The section 303 regulatory alternative may provide for lower control costs at the national level relative to the cost estimates for the short-term SO<sub>2</sub> NAAQS. First, under the section 303 program, sources would be allowed to use intermittent controls and other practices normally barred by section 123 of the Act (e.g., supplemental control systems, stack height in excess of GEP) to prevent exceedances of a 5-minute trigger level. These types of controls are generally less costly to employ relative to add-on controls. Secondly, given the timetables in the Act regarding SIP development and attainment of the NAAQS, it is probable that emission reductions from a section 303 program could be achieved in a more timely fashion. While some SIP revisions would be necessary for States to implement the section 303 program,

more time-consuming aspects of the SIP process such as designations could be avoided. There is a greater likelihood that the section 303 program could bring about more prompt and effective remediation of high 5-minute SOconcentration relative to the short-term NAAOS alternative. In respect to total annual emission reductions, it is likely that the section 303 program would achieve less emission reductions than a short-term NAAQS program. Administrative costs are expected to be minimal as some resource-intensive components of the SIP process could be bypassed under a section 303 program. Likewise, monitoring costs are estimated to be minimal.

## Analysis of Potential Benefits

A quantitative analysis of the benefits of reducing short-term SO2 peaks through implementation of the regulatory options under consideration in this RIA is not possible at this time. Results of a staff paper exposure analysis conducted on a subset of SO2 sources potentially affected by this rulemaking indicate that as many as 180,000-395,000 exposure events above 0.5 ppm SO<sub>2</sub> may occur among 68,000-166,000 exercising asthmatics nationally every year. Moreover, this analysis shows that there is a clustering of risk of exposure around a subset of those SO<sub>2</sub> sources analyzed. It is expected that reductions in short-term SO<sub>2</sub> peaks resulting from this rulemaking could reduce potential risks of adverse respiratory effects (e.g., bronchoconstriction, wheezing, chest tightness, shortness of breath) among exercising asthmatic individuals that are potentially exposed to these high 5minute SO<sub>2</sub> ambient concentrations. Additionally, reductions in adverse welfare effects due to SO2 such as improvements in visual air quality and reductions in ecosystem impacts, odors, and materials damage, and reductions in adverse health and welfare effects due to particulate matter may be achieved as a result of implementing the regulatory alternatives considered in this document today.

A final RIA will be issued at the time of promulgation of final standards. This draft RIA has not been considered in issuing this proposal. In accordance with Executive Order 12866, this proposed rule was submitted to OMB for review. Written comments from OMB and the EPA written responses to these comments are available for public inspection at the EPA's Central Docket Section (Docket No. A-84-25), South Conference Center, Room 4, Waterside Mall, 401 M Street, SW., Washington, DC

DC.

## B. Impact on Small Entities

Pursuant to the EPA guidelines issued in response to the Regulatory Flexibility Act, 5 U.S.C., 600 et seq., a regulatory flexibility analysis has been prepared and is discussed in the draft RIA cited above. The analysis examined industrywide cost and economic impacts for nonutility and utility sources of SO2 emissions likely to be impacted by the regulatory alternatives discussed in this notice. The EPA also analyzed various industries for the existence of small entities. Given data limitations and because the regulatory alternatives would be implemented through a riskbased targeted strategy described in the Federal Register document on implementation issues, it was not feasible to quantitatively ascertain whether small entities within a given industry category would be differentially impacted when compared to the industry category as a whole.

### C. Reduction of Governmental Burden

Executive Order 12875 ("Enhancing the Intergovernmental Partnership") is designed to reduce the burden to State, local, and tribal governments of the cumulative effect of unfunded Federal mandates, and recognizes the need for these entities to be free from unnecessary Federal regulation to enhance their ability to address problems they face and provides for Federal agencies to grant waivers to these entities from discretionary Federal requirements. In accordance with the purposes of Executive Order 12875, the EPA will consult with representatives of State, local, and tribal governments to inform them of the requirements for implementing the alternative regulatory measures being proposed to address short-term peak SO2 exposures. The EPA will summarize the concerns of the governmental entities and respond to their comments prior to taking final action.

#### D. Environmental Justice

Executive Order 12898 requires that each Federal Agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. The requirements of Executive Order 12898 have been addressed in the draft RIA cited above.

On average, approximately 25 percent of the total population and 14 percent of total households residing in geographic areas that are potentially

impacted by short-term SO2 peaks of 0.60 ppm or greater are nonwhite and below the poverty level, respectively. These estimates exceed the national averages of 19.7 percent and 12.7 percent, respectively. It also follows that, on average, 25 percent of the asthmatics potentially exposed to shortterm SO<sub>2</sub> peaks of 0.60 ppm or greater are nonwhite. Upon closer examination, 44 percent of these potentially SO2impacted areas have a nonwhite population greater than the national average with 24 percent between 1 and 2 times greater, 10 percent between 2 and 3 times greater, 7 percent between 3 and 4 times greater, and 3 percent between 4 and 5 times greater.

## E. Impact on Reporting Requirements

Air quality monitoring activities that would occur as a result of this proposed rule would increase the costs and manhour burdens to State and local agencies for conducting ambient SO2 surveillance required by 40 CFR part 58 and currently approved under OMB Control Number 2060-0084. Increased costs would result from the relocation of some monitors currently operated as part of the State and Local Air Monitoring Stations (SLAMS) networks and from the purchase and operation of additional monitors in a small number of agencies (see the related document to be published shortly in the Federal Register revising 40 CFR parts 51 and 58 for information on compliance with Paperwork Reduction Act requirements).

#### References

- Ayres, S.M., (1994), Comments on the NAAQS for Sulfur Dioxide from Stephen M. Ayres, M.D., Professor of Internal Medicine, Dean Emeritus, Medical College of VA., Virginia Commonwealth University, May 16, 1994, Docket No. A– 84–25, V–D–34.
- Balmes, J.R., Fine, J.M., Sheppard, D. (1987), Symptomatic bronchoconstruction after short-term inhalation of sulfur dioxide, Am. Rev. Respir. Dis. 136: 1117-1121.
- DHEW (U.S. Department of Health, Education, and Welfare) (1970), Air Quality Criteria for Sulfur Oxides, U.S. Government Printing Office, Washington, DC, AP-50.
- Eaton, W.C., Parker, C.D., Rickman, E.E. (1991), Evaluation of the Adequacy of Current SO<sub>2</sub> Measurement Methods to Measure 5-Minute Average Concentrations, Final Report, Research Triangle Institute, EPA Contract 68-02-4550, Work Assignment 234B.
- Eaton, W.C., Parker, C.D., Rickman, E.E., McElroy, F.F. (1993), Performance of Automated Ambient Sulfur Dioxide Analyzers with Respect to a Proposed 5minute Ambient Air Quality Standard, Appl. Occup. Environ. Hyg. 8(4):279– 282.

- Edmunds, A.T., Tooley, M.; Godfrey, S. (1978), The refractory period after exercise-induced asthma: its duration and relation to the severity of exercise, Am. Rev. Resp. Dis. 117:247-254.
- EPA (1978). The Guideline for Public Reporting of Daily Air Quality— Pollutant Standards Index (PSI), Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA-450/2-76-013.
- EPA (1982a), Air Quality Criteria for Particulate Matter and Sulfur Oxides, Environmental Criteria and Assessment Office, Research Triangle Park, NC, EPA– 600/8–82–029a–c.
- EPA (1982b), Review of the National
  Ambient Air Quality Standards for
  Sulfur Oxides: Assessment of Scientific
  and Technical Information—OAQPS
  Staff Paper, Office of Air Quality
  Planning and Standards, Research
  Triangle Park, NC, EPA-450/5-82-007
- EPA (1983a), Gudance Memorandum from Lee M. Thomas and Courtney M. Price to Regional Administrators, Regional Counsels, Air and Waste Management Division Directors, Regional Superfund Coordinators, Directors, Office of Waste Programs Enforcement and Office of Emergency and Remedial Response, and Associate Enforcement Counsel, Subject: Guidance Memorandum on Use and Issuance of Administrative Orders Under § 106(a) of CERCLA, September 8, 1983, Docket No. A-84-25, IV-K-9.
- EPA (1983b), Guidance Memorandum from Edward E. Reich and Michael S. Alushin to Directors, Air Management and Air and Waste Management Divisions, and Regional Counsels, Subject: Guidance on Use of Section 303 of the Clean Air Act, September 15, 1983, Docket No. A-84– 25, IV-K-10.
- EPA (1984), Estimation of Short-Term Sulfur Dioxide Population Exposures, Office of Air Quality Planning and Standards, Research Triangle Park, NC, Docket No. A-79-28, II-A-9.
- EPA (1986a), Second Addendum to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982): Assessment of Newly Available Health Effects Information, Environmental Criteria and Assessment Office, Research Triangle Park, NC, EPA-450/5-86-012.
- EPA (1986b), Review of the National Ambient Atr Quality Standards for Sulfur Oxides: Updated Assessment of Scientific and Technical Information, Addendum to the 1982 OAQPS Staff Paper, Office of Air Quality Planning and Standards, Research Triangle Park, NC EPA-450/05-86-013.
- EPA (1991), Guidance Memorandum from James R. Elder and Frederick F Stiehl to Water Management Division Directors and Regional Counsels, Subject: Final Guidance on Emergency Authority under Section 1431 of the Safe Drinking Water Act, September 27 1991, Docket No. A— 84-25, IV-K-11.

- EPA (1993a), National Air Quality and Emissions Trends Report, 1992. Office of Air Quality Planning and Standards, Research Triangle Park, NC, EPA-454/R-93-031.
- EPA (1993b), Guidance Memorandum from Frederick F Stiehl and Richard G. Kozlowski to Regional Counsels and Water Division Directors, Subject: Guidance on Use of Section 504, the Emergency Powers Provision of the Clean Water Act, July 30, 1993, Docket No A-84-25, IV-K-13.
- EPA (1994a), Supplement to the Second Addendum (1986) to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982): Assessment of New Findings on Sulfur Dioxide Acute Exposure Health Effects in Asthmatic Individuals, Environmental Criteria and Assessment Office, Research Triangle Park, NC, EPA/600/FP-93/002.
- EPA (1994b), Review of the Ambient Air Quality Standards for Sulfur Oxides: Updated Assessment of Scientific and Technical Information, Supplement to the 1986 OAQPS Staff Paper Addendum, Office of Air Quality Planning and Standards, Research Triangle Park, NC, EPA/452/R-94-013.
- Evans, R., III; Mullally, D.I., Wilson, R.W., Gergen, P.J., Rosenberg, H.M., Grauman, J.S., Chevarley, F.M., Feinleib, M. (1987), National trends in the morbidity and mortality of asthma in the US. Prevalence, hospitalization and death from asthma over two decades: 1965– 1984, Chest 91(suppl.): 65S-74S.
- Faoro, B., U.S. EPA, Data Analysis Section (1983), Comparison of Second Max Non-Overlapping and Midnight-to-Midnight (Block) Average, Memorandum to William F Hunt Jr., Chief, Data Analysis Section, August 15, 1983, Docket No. 1 A-79-28, II-B-11.
- Frank, N., U.S.-EPA, Monitoring and Data Analyses Division (1987), Memorandum to John Bachmann, Strategies and Air Standards Division, February 18, 1987 Docket No. 1 A−84−25, II−B−1.
- Frank, N. U.S. EPA, Technical Support Division (1988), Memorandum to John Haines, Air Quality Management Division, January 5, 1988, Docket No. 1 A-84-25, II-B-3.
- Goldstein, B.G. (1983), CASAC Review and Closure of the OAQPS Staff Paper for Sulfur Oxides, Closure Letter to William D. Ruckelshaus, August 1983, Docket No. 1 A-792-28, II-B-3.
- Hackney, J.D., Linn, W.S., Bailey, R.M., Spier, C.E., Valencia, L.M. (1984) Time course of exercise-induced bronchoconstriction in asthmatics exposed to sulfur dioxide. Environ. Res. 34: 321–327
- Higgins, I.T., University of Michigan, School of Public Health, (1983) Minority Statement, Letter to Terry F Yosie, Executive Director, Clean Air Scientific Advisory Committee, October 6, 1983, Docket No. 1 A-79-28, II-D-51.

- Horstman, D.H., Seal, E., Jr., Folinsbee, L.J., Ives, P. Roger, L.J. (1988), The relationship between exposure duration and sulfur dioxide-induced bronchoconstriction in asthmatic subjects, Am. Ind. Hyg. Assoc. J. 49: 38–47
- Jörres, R., Magnussen, H. (1990), Airways response of asthmatics after a 30 min exposure, at resting ventilation, to 0.25 ppm NO<sub>2</sub> or 0.5 ppm SO<sub>2</sub>. Eur. Respir. J. 3: 132–137
- Koenig, J.Q., Covert, D.S., Hanley, Q.S., Van Belle, G., Pierson, W.E. (1990), Prior exposure to ozone potentiates subsequent response to sulfur dioxide in adolescent asthmatic subjects, Am. Rev. Respir. Dis. 141: 377–380.
- Linn, W.S., Venet, T.G., Shamoo, D.A., Valencia, L.M., Anzar, U.T., Spier, C.E., Hackney, J.D. (1983), Respiratory effects of sulfur dioxide in heavily exercising asthmatics: a dose-response study, Am. Rev. Respir. Dis. 127. 278–283.
- Linn, W.S., Avol, E.L., Peng, R.-C., Shamoo, D.A., Hackney, J.D. (1987), Replicated dose-response study of sulfur dioxide effects in normal, atopic, and asthmatic volunteers, Am. Rev. Respir. Dis. 136: 1127–1134.
- Lippmann, M. (1987), Letter from Morton Lippmann, CASAC Chairman, to EPA Administrator Lee M. Thomas, February 19, 1987 Docket No. 1 A-79-28, II-D-83.
- National Institutes of Health (1991),
  Guidelines for the diagnosis and
  management of asthma, Bethesda, MD:
  U.S. Départment of Health and Human
  Services, National Heart, Lung, and
  Blood Institute, National Asthma
  Education Program; publication no. 91–
  3042.
- OAQPS [Office of Air Quality Planning and Standards] (1986), Proper Interpretation of the Averaging Convention for the National Ambient Air Quality Standards for Sulfur Oxides, OAQPS Staff Position Paper, March 1986, Docket No. 1 A-79-28, II-A-15.
- Padgett, J., U.S. EPA, Strategies and Air Standards Division (1982), Letter to Dr. Sheldon Friedlander, Chairman, Clean Air Scientific Advisory Committee, August 5, 1982, Docket No. 1 A-79-28, II-C-3.
- Possiel, N.C., U.S. EPA, Model Applications Section (1985), Analysis of Running Versus Block SO<sub>2</sub> Model Estimates, Memorandum to Henry C. Thomas, Standards Development Section, August 27 1985, Docket No. 1 A-79-28, II-B-
- Rubinstein, I., Bigby, B.G., Reiss, T.F., Boushey, H.A., Jr. (1990), Short-term exposure to 0.3 ppm nitrogen dioxide does not potentiate airway responsiveness to sulfur dioxide in asthmatic subjects, Am. Rev. Respir. Dis. 141: 381–385.
- Schachter, E.N. (1994), Letter to Randall C. Bond, U.S. EPA from E. Neil Schachter, M.D., CASAC Member, re: comments on SO<sub>2</sub> NAAQS Staff Paper Addendum, May 2, 1994, Docket No. A-84-25, V-D-30.

- Schachter, E.N., Witek, T.J., Jr., Beck, G.J., Hosein, H.R., Colice, G., Leaderer, B.P Cain, W. (1984) Airway effects of low concentrations of sulfur dioxide: doseresponse characteristics. Arch. Environ. Health 39: 34–42.
- Schwartz, J., Gold, D., Dockery, D.W., Weiss, S.T., Speizer, F.E. (1990), Predictors of asthma and persistent wheeze in a national sample of children in the United States: association with social class, perinatal events, and race, Am. Rev. Resnit. 40is. 142: 555-562.
- Rev. Respir. Dis. 142: 555-562.
  White, R.H. (1994), Letter to John Haines,
  U.S. EPA from Ronald H. White,
  American Lung Association, re:
  comments on SO<sub>2</sub> NAAQS Staff Paper
  Addendum Supplement, July 1, 1994,
  Docket No. A-84-25, V-D-37

## Appendix I to the Preamble

February 19, 1987

The Honorable Lee M. Thomas, Administrator, U.S. Environmental Protection Agency, Washington, DC 20460.

Dear Mr. Thomas: The Clean Air Scientific Advisory Committee (CASAC) has completed its review of the 1986 Addendum to the 1982 Staff Paper on Sulfur Oxides (Review of the National Ambient Air Quality Standards for Sulfur Oxides: Updated Assessment of Scientific and Technical Information) prepared by the Agency's Office of Air Quality Planning and Standards (OAQPS).

The Committee unanimously concludes that this document is consistent in all significant respects with the scientific evidence presented and interpreted in the. combined Air Quality Criteria Document for Particulate Matter/Sulfur Oxides (1982) and its 1986 Addendum, on which CASAC issued its closure letter on December 15, 1986. The Committee believes that the 1986 Addendum to the 1982 Staff Paper on Sulfur Oxides provides you with the kind and amount of technical guidance that will be needed to make appropriate decisions with respect to the standards. The Committee's major findings and conclusions concerning the various scientific issues and studies discussed in the Staff Paper Addendum are contained in the attached report.

Thank you for the opportunity to present the Committee's views on this important public health and welfare issue. Sincerely,

Morton Lippmann, Ph.D.,

Chairman, Clean Air Scientific Advisory Committee.

cc: A. James Barnes
Gerald Emison
Lester Grant
Vaun Newill
John O'Connor
Craig Potter
Terry Yosie

Summary of Major Scientific Issues and CASAC Conclusions on the 1986 Draft Addendum to the 1982 Sulfur Oxides Staff Paper

The Committee found the technical discussions contained in the Staff Paper Addendum to be scientifically thorough

and acceptable, subject to minor editorial revisions. This document is consistent in all significant respects with the scientific evidence presented in the 1982 combined Air Quality Criteria Document for Particulate Matter/Sulfur Oxides and its 1986 Addendum, on which the Committee issued its closure letter on December 15, 1986.

## Scientific Basis for Primary Standards

The Committee addressed the scientific basis for a 1-hour, 24-hour, and annual primary standards at some length in its August 26, 1983 closure letter on the 1982 Sulfur Oxides Staff Paper. That letter was based on the scientific literature which had been published up to 1982. The present review has examined the more recently published studies.

It is clear that no single study of SO<sub>2</sub> can fully address the range of public health issues that arise during the standard setting process. The Agency has completed a thorough analysis of the strengths and weaknesses of various studies and has derived its recommended ranges of interest by evaluating the weight of the evidence. The Committee endorses this approach.

The Committee wishes to comment on several major issues concerning the scientific data that are available. These issues include:

 Recent studies more clearly implicate particulate matter than SO<sub>2</sub> as a longer-term public health concern at low exposure levels.

• A majority of Committee members believe that the effects reported in the clinical studies of asthmatics represent effects of significant public health

• The exposure uncertainties associated with a 1-hour standard are quite large. The relationship between the frequency of short-term peak exposures and various scenarios of asthmatic responses is not well understood. Both EPA and the electric power industry are conducting further analyses of a series of exposure assessment issues. Such analyses have the potential to increase the collective understanding of the relationship between SO<sub>2</sub> exposures and responses observed in subgroups of the general population.

The number of asthmatics vulnerable to peak exposures near electric power plants, given the protection afforded by the current standards, represents a small number of people. Although the Clean Air Act requires that sensitive population groups receive protection, the size of such groups has not been defined.

CASAC believes that this issue represents a legal/policy matter and has no specific scientific advice to provide on it.

CASAC's advice on primary standards for three averaging times is presented below:

1-Hour Standard-It is our conclusion that a large, consistent data base exists to document the bronchoconstrictive response in mild to moderate asthmatics subjected in clinical chambers to shortterm, low levels of sulfur dioxide while exercising. There is, however, no scientific basis at present to support or dispute the hypothesis that individuals participating in the SO<sub>2</sub> clinical studies are surrogates for more sensitive asthmatics. Estimates of the size of the asthmatic population that experience exposures to short-term peaks of SO2 (0.2-0.5 parts per million (ppm) SO<sub>2</sub> for 5-10 minutes) during light to moderate exercise, and that can be expected to exhibit a bronchoconstrictive response, varies from 5,000 to 50,000.

The majority of the Committee believes that the scientific evidence supporting the establishment of a new 1-hour standard is stronger than it was in 1983. As a result, and in view of the significance of the effects reported in these clinical studies, there is strong, but not unanimous support for the recommendation that the Administrator consider establishing a new 1-hour standard for SO<sub>2</sub> exposures. The Committee agrees that the range suggested by EPA staff (0.2-0.5 ppm) is appropriate, with several members of the Committee suggesting a standard from the middle of this range. The Committee concludes that there is not a scientifically demonstrated need for a wide margin of safety for a 1-hour standärd.

24-Hour Standard—The more recent studies presented and analyzed in the 1986 Staff Paper Addendum, in particular, the episodic lung function studies in children (Dockery et al., and Dassen et al.) serve to strengthen our previous conclusion that the rationale for reaffirming the 24-hour standard is appropriate.

Annual Standard—The Committee reaffirms its conclusion, voiced in its 1983 closure letter, that there is no quantitative basis for retaining the current annual standard. However, a decision to abolish the annual standard must be considered in the light of the total protection that is to be offered by the suite of standards that will be established.

The above recommendations reflect the consensus position of CASAC. Not all CASAC reviewers agree with each position adopted because of the uncertainties associated with the existing scientific data. However, a strong majority supports each of the specific recommendations presented above, and the entire Committee agrees that this letter represents the consensus position.

### Secondary Standards

The 3-hour secondary standard was not addressed at this review.

## APPENDIX II to the Preamble

June 1, 1994.

Honorable Carol M. Browner, Administrator, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460.

Subject: Clean Air Scientific Advisory
Committee Closure on the Supplements
to Criteria Document and Staff Position
Papers for SO<sub>2</sub>

Dear Ms. Browner: The Clean Air Scientific Advisory Committee (CASAC) at a meeting on April 12, 1994, completed its review of the documents: Supplement to the Second Addendum (1986) to Air Quality Criteria for Particulate Matter and Sulfur Oxides; Assessment of New Findings on Sulfur Dioxide and Acute Exposure Health Effects in Asthmatics; and Review of the National Ambient Air Quality Standards for Sulfur Oxides: Updated Assessment of Scientific and Technical Information, Supplement to the 1986 OAQPS Staff Paper Addendum. The Committee notes, with satisfaction, the improvements made in the scientific quality and completeness of the documents.

With the changes recommended at our March 12 session, written comments submitted to the Agency subsequent to the meeting, and the major points provided below, the documents are consistent with the scientific evidence available for sulfur dioxide. They have been organized in a logical fashion and should provide an adequate basis for a regulatory decision. Nevertheless, there are four major points which should be called to your attention while reviewing these materials:

1. A wide spectrum of views exists among the asthma specialists regarding the clinical and public health significance of the effects of 5 to 10 minute concentrations of sulfur dioxide on asthmatics engaged in exercise. On one end of the spectrum is the view that spirometric test responses can be observed following such short-term exposures and they are a surrogate for significant health effects. Also, there is some concern that the effects are underestimated because moderate asthmatics, not severe asthmatics, were used in the clinical tests.

At the other end of the spectrum, the significance of the spirometric test results are questioned because the response is similar to that evoked by other commonly encountered, non-specific stimuli such as exercise alone, cold, dry air inhalation, vigorous coughing, psychological stress, or even fatigue. Typically, the bronchoconstriction reverses itself within one or two hours, is not accompanied by a late-phase response (often more severe and potentially dangerous than the immediate response), and shows no

evidence of cumulative or long-term effects. Instead, it is characterized by a short-term period of bronchoconstriction, and can be prevented or ameliorated by beta-agonist

aerosol inhalation.

2. It was the consensus of CASAC that the exposure scenario of concern is a rare event. The sensitive population in this case is an unmedicated asthmatic engaged in moderate exercise who happens to be near one of the several hundred sulfur dioxide sources that have the potential to produce high groundlevel sulfur dioxide concentrations over a small geographical area under rare adverse meteorological conditions. In addition, CASAC pointed out that sulfur dioxide emissions have been significantly reduced since EPA conducted its exposure analysis and emissions will be further reduced as the 1990 Clean Air Act Amendments are implemented. Consequently, such exposures will become even rarer in the future.

- 3. It was the consensus of CASAC that any regulatory strategy to ameliorate such exposures be risk-based-targeted on the most likely sources of short-term sulfur dioxide spikes rather than imposing shortterm standards on all sources. All of the nine CASAC Panel members recommended that Option 1, the establishment of a new 5minutes standard, not be adopted. Reasons cited for this recommendation included: the clinical experiences of many ozone experts which suggest that the effects are short-term, readily reversible, and typical of response seen with other stimuli. Further, the committee viewed such exposures as rare events which will even become rarer as sulfur dioxide emissions are further reduced as the 1990 amendments are implemented. In addition, the committee pointed out that enforcement of a short-term NAAQS would require substantial technical resources. Furthermore, the committee did not think that such a standard would be enforceable (see below)
- 4. CASAC questioned the enforceability of a 5-minute NAAQS or "target level. Although the Agency has not proposed an air monitoring strategy, to ensure that such a standard or "target level" would not be exceeded, we infer that potential sources would have to be surrounded by concentric circles of monitors. The operation and maintenance of such monitoring networks would be extremely resource intensive. Furthermore, current instrumentation used to routinely monitor sulfur dioxide does not respond quickly enough to accurately characterize 5-minute spikes.

The Committee appreciates the opportunity to participate in this review and looks forward to receiving notice of your decision on the standard. Please do not hesitate to contact me if CASAC can be of further assistance on this matter.

Sincerely,

George T. Wolff, Ph.D.,

Chair, Clean Air Scientific Advisory

## **List of Subjects**

#### 40 CFR Part 50

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

#### 40 CFR Part 53

Environmental protection, Administrative practice and procedure, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

Dated: November 1, 1994.

#### Carol M. Browner.

Administrator

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

## PART 50-NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY **STANDARDS**

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

Authority: Secs. 109 and 301(a), Clean Air Act; as amended (42 U.S.C. 7409, 7601(a)).

2. Section 50.4 is revised to read as

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

(a) The level of the annual standard is 0.030 parts per million (ppm), not to be exceeded in a calendar year. The annual arithmetic mean shall be rounded to three decimal places (fractional parts equal to or greater than 0.0005 ppm

must be rounded up).

(b) The level of the 24-hour standard is 0.14 parts per million (ppm), not to be exceeded more than once per calendar year. The 24-hour averages shall be determined from successive nonoverlapping 24-hour blocks starting at midnight each calendar day and shall be rounded to two decimal places (fractional parts equal to or greater than 0.005 ppm must be rounded up).

(c) The level of the 5-minute standard is 0.60 parts per million (ppm), not to be exceeded more than once per calendar year, as determined in accordance with appendix I of this part.

(d) Sulfur oxides shall be measured in the ambient air as sulfur dioxide by the reference method described in appendix A of this part or by an equivalent method designated in accordance with part 53 of this chapter.

(e) To demonstrate attainment, the annual arithmetic mean and the secondhighest 24-hour averages must be based upon hourly data that are at least 75 percent complete in each calendar quarter. A 24-hour block average shall be considered valid if at least 75 percent of the hourly averages for the 24-hour period are available. In the event that

only 18, 19, 20, 21, 22, or 23 hourly averages are available, the 24-hour block average shall be computed as the sum of the available hourly averages using 18, 19, etc. as the divisor. If less than 18 hourly averages are available, but the 24-hour average would exceed the level of the standard when zeros are substituted for the missing values, subject to the rounding rule of paragraph (b) of this section, then this shall be considered a valid 24-hour average. In this case, the 24-hour block average shall be computed as the sum of the available hourly averages divided by

3. Section 50.5 is revised to read as follows:

#### § 50.5 National secondary ambient air quality standard for sulfur oxides (sulfur dioxide).

(a) The level of the 3-hour standard is 0.5 parts per million (ppm), not to be exceeded more than once per calendar year. The 3-hour averages shall be determined from successive nonoverlapping 3-hour blocks starting at midnight each calendar day and shall be rounded to 1 decimal place (fractional parts equal to or greater than 0.05 ppm must be rounded up).

(b) Sulfur oxides shall be measured in the ambient air as sulfur dioxide by the reference method described in appendix A of this part or by an equivalent method designated in accordance with

Part 53 of this chapter.

- (c) To demonstrate attainment, the second-highest 3-hour average must be based upon hourly data that are at least 75 percent complete in each calendar quarter. A 3-hour block average shall be considered valid only if all three hourly averages for the 3-hour period are available. If only one or two hourly averages are available, but the 3-hour average would exceed the level of the standard when zeros are substituted for the missing values, subject to the rounding rule of paragraph (a) of this section, then this shall be considered a valid 3-hour average. In all cases, the 3hour block average shall be computed as the sum of the hourly averages divided by 3.
- 4. Appendix I is added to part 50 to read as follows:

#### Appendix I to Part 50—Interpretation of the 5-Minute National Ambient Air Quality Standard for Sulfur Dioxide

General.

1.1 This appendix explains the computations necessary for analyzing sulfur dioxide data to determine attainment of the 5-minute standard specified in 40 CFR 50.4. Sulfur dioxide is measured in the ambient air by the reference method specified in Appendix A of this part or an equivalent

method designated in accordance with part 53 of this chapter.

- 1.2 Several terms used in this appendix must be defined. A "5-minute hourly maximum" for SO2 refers to the highest of the 12 possible nonoverlapping 5-minute SO<sub>2</sub> averages calculated or measured during a clock hour. The term "exceedance" of the 5minute standard means a 5-minute hourly maximum that is greater than the level of the 5-minute standard after rounding to the nearest hundredth ppm (i.e. values ending in or greater than 0.005 ppm are rounded up; e.g., a value of 0.605 would be rounded to 0.61, which is the smallest value for an exceedance). The term "year" refers to a calendar year. The term "quarter" refers to a calendar quarter. The 5-minute SO<sub>2</sub> standard is expressed in terms of the number of exceedances per year after adjusting for missing data (if required) and after averaging over a two year period.
  - 2.0 Attainment Determination.
- Under 40 CFR 50.4(c) the 5-minute standard is attained when the number of exceedances per year is less than or equal to one. In general, this determination is to be made by recording the number of 5-minute hourly maximum exceedances at a monitoring site for each year, using the calculations in section 3.2 to compensate for missing data (if required), averaging the number of exceedances over a two year period, and comparing the number of exceedances (rounded to the nearest integer) to the number of allowable exceedances.
- 2.2 There are less stringent requirements for showing that a monitor has failed an attainment test and thus has recorded a violation of the sulfur dioxide standards. Although it is necessary to meet the minimum data completeness requirements to use the computational formula described in section 3.2, this criterion does not apply when there are obvious nonattainment situations. For example, when a site fails to meet the completeness criteria, nonattainment of the 5-minute standard can still be established on the basis of the observed number of exceedances in a year (e.g. three observed exceedances in a single year).
- 3.0 Calculations for the 5-Minute Standard
- 3.1 Calculating a 5-Minute hourly maximum. A 5-minute hourly maximum value for SO<sub>2</sub> is the highest of the 5-minute averages from the twelve possible nonoverlapping periods during a clock hour. These 5-minute values shall be rounded to the nearest hundredth ppm (fractional values equal to or greater than 0.005 ppm are rounded up). A 5-minute maximum shall be considered valid if (1) 5-minute averages were available for at least 9 of the twelve five-minute periods during the clock hour or (2) the value of the 5-minute average exceeds the level of the 5-minute standard.

- 3.2 Calculating estimated exceedances for a year.
- 3.2 Because of practical considerations, a 5-minute maximum SO2 value may not be available for each hour of the year. To account for the possible effect of incomplete data, an adjustment must be made to the data collected at a particular monitoring location to estimate the number of exceedances in a year. The adjustment is made on a quarterly basis to ensure that the entire year is adequately represented. In this adjustment, the assumption is made that the fraction of missing values that would have exceeded the standard level is identical to the fraction of measured values above this level.
- 3.2.2 The computation for incomplete data is to be made for all NAMS and SLAMS sites with 50 percent to 90 percent complete data in each quarter. If a site has more than 90 percent complete data in a quarter, no adjustment for missing data is required. If a site has less than 50 percent complete data in a quarter, no adjustment for missing data is required and the observed exceedances are used. To demonstrate attainment, a site must have at least 75 percent complete data in each quarter.
- 3.2.3 The estimate of the expected number of exceedances for the quarter is equal to the observed number of exceedances plus an increment associated with the missing data. The following formula must be used for these computations:

 $e_q = v_q + [(v_q/n_q) \times (N_q - n_q) = v_q \times N_q/n_q$  [1] where

eq=the estimated number of exceedances for

quarter q,  $v_q$ =the observed number of exceedances for quarter q,

N<sub>q</sub>=the number of hours in quarter q, and nq=the number of hours in the quarter with

valid 5-minute hourly SO<sub>2</sub> maximums q=the index for each quarter, q=1, 2, 3 or 4. The estimated number of exceedances for the quarter must be rounded to the nearest hundredth (fractional values equal to or greater than 0.005 are rounded up).

3.2.4 The estimated number of exceedances for the year, e, is the sum of the estimates for each quarter.

$$e = \sum_{q=1}^{4} e_q \quad [2]$$

The estimated number of exceedances for a single year must be rounded to one decimal place (fractional values equal to or greater than 0.05 are rounded up).

3.2.5 The number of exceedances is then estimated by averaging the individual annual estimates over a two year period, rounding to the nearest integer, and comparing with the allowable exceedance rate of one per year (fractional values equal to or greater than 0.5 are rounded up; e.g., an estimated number of

exceedances of 1.5 would be rounded to 2, which is the lowest value for nonattainment).

3.2.6 Example.

- 1. During the most recent quarter, 1210 out of a possible 2208 5-minute hourly maximums were recorded, with one observed exceedance of the 5-minute standard. Using formula [1], the estimated number of exceedances for the quarter is e=1×2208/1210=1.825 or 1.83
- 11. If the estimated exceedances for the other four quarters were 0.0, then using formula [2], the estimated number of exceedances for the year is
- 1.83+0.0+0.0+0.0=1.83 or 1.8

iii. If the estimated number of exceedances for the previous year was 0.0, then the expected number of exceedances is estimated

(1.8+0.0)/2=0.9 or 1

iv. Since 1 does not exceed the allowable number of exceedances, this monitoring site would not fail the attainment test.

## PART 53—AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT **METHODS**

1. The authority citation for part 53 continues to read as follows:

Authority: Sec. 301(a) of the Clean Air Act (42 U.S.C. sec. 1857g(a)), as amended by sec. 15(c)(2) of Pub. L. 91-604, 84 Stat. 1713, unless otherwise noted.

2. Section 53.20 is amended by adding two sentences to the end of paragraph (b) and by revising the table to paragraph (c) to read as follows:

#### § 53.20 General provisions.

Candidate methods for sulfur dioxide may be additionally approved for use in obtaining 5-minute average concentration measurements by meeting all of the specified requirements for both the 0 to 0.5 ppm and 0 to 1.0 ppm ranges and meeting the supplemental specifications for use and fall time given in Table B-1. Such additional approval for 5-minute monitoring shall be included in any equivalent method designation determination for the method and shall be identified in the Federal Register notice of designation required under § 53.8(a), the notice to the applicant required under § 53.8(b), and the list of designated methods required under § 53.8(c).

(c)

TABLE B-1 -- PERFORMANCE SPECIFICATIONS FOR AUTOMATED METHODS

Performance parameter	Units	Sulfur di- oxide	Photo- chemical oxidants	Carbon monoxide	Nitrogen dioxide	Definitions and test pro- cedures
1. Range Supplemental, 5-minute <sup>2</sup>	ppm 1	0-0.5 0-1.0	0-0.5	0–50	0-0.5	Sec. 53.23(a).
2. Noise	ppm	0.005	0.005	0.50	0.005	Sec. 53.23(b).
Lower detectable limit	ppm	0.01	0.01	1.0	0.01	Sec. 53.23(c).
Each interferant	ppm	±0.02	±0.02	±1.0	> ±0.02	Sec. 53.23(d).
Total interferant	ppm	±0.06	±0.06	±1.5	±0.04	
5. Zero drift, 12 and 24 hour	ppm	±0.02	±0.02	· ±1.0	±0.02	Sec. 53.23(e).
20 percent of upper range limit	Percent	±20.0	±20.0	±10.0	±20.0	Sec. 53.23(e).
80 percent of upper range limit	Percent	±5.0	±5.0	±2.5	±5.0	
7 Lag time	Minutes	20	20	.10	20	Sec. 53.23(e):
8. Rise time Supplemental, 5-minute <sup>2</sup>	Minutes	15	15	5	15	Sec. 53.23(e).
	Minutes	2				
9. Fall time Supplemental, 5-minute <sup>2</sup>	Minutes	15	15	5	15	Sec. 53.23(e).
	Minutes	2				
10. Precision:	1					
20 percent of upper range limit	ppm	0.010	0.010	0.5	0.020	Sec.53.23(e)
80 percent of upper range limit	ppm	0.015	0.010	0:5	0.030	

Parts per million by volume. To convert from parts per million to µg/m³ at 25 °C and 760 mm Hg, multiply by M/0.02447 where M is the molecular weight of the gas.

2 Supplemental specifications applicable to sulfur dioxide equivalent methods to be additionally approved for use for 5-minute monitoring.

[FR Doc. 94-27646 Filed 11-14-94; 8:45 am] BILLING CODE 6560-60-P