and computer output products' or 'manual, maintained in paper files' or 'hybrid, maintained in paper files and in computers') should be stated. Storage does not refer to the container or facility in which the records are kept.

14. *Retrievability:* How records are retrieved from the system (e.g., 'by name,' 'by SSN,' or 'by name and SSN') should be indicated.

15. *Safeguards:* The categories of agency personnel who use the records and those responsible for protecting the records from unauthorized access should be stated. Generally the methods used to protect the records, such as safes, vaults, locked cabinets or rooms, guards, visitor registers, personnel screening, or computer 'fail-safe' systems software should be identified. Safeguards should not be described in such detail as to compromise system security.

16. *Retention and disposal:* Describe how long records are maintained. When appropriate, the length of time records are maintained by the agency in an active status, when they are transferred to a Federal Records Center, how long they are kept at the Federal Records Center, and when they are transferred to the National Archives or destroyed should be stated. If records eventually are destroyed, the method of destruction (e.g., shredding, burning, pulping, etc.) should be stated. If the agency rule is cited, the applicable disposition schedule shall also be identified.

17. *System manager(s) and address.* The title (not the name) and address of the official or officials responsible for managing the system of records should be listed. If the title of the specific official is unknown, such as with a local system, the local director or office head as the system manager should be indicated. For geographically separated or organizationally decentralized activities with which individuals may correspond directly when exercising their rights, the position or title of each category of officials responsible for the system or portion thereof should be listed. Addresses that already are listed in the agency address directory or simply refer to the directory should not be included.

18. *Notification procedures.* (1) Notification procedures describe how an individual can determine if a record in the system pertains to him/her. If the record system has been exempted from the notification requirements of subsection (f)(l) or subsection (e)(4)(G) of the Privacy Act, it should be so stated. If the system has not been exempted, the notice must provide sufficient information to enable an individual to request notification of whether a record in the system pertains to him/her. Merely referring to a DFAS regulation is not sufficient. This section should also include the title (not the name) and address of the official (usually the Program Manager) to whom the request must be directed; any specific information the individual must provide in order for DFAS to respond to the request (e.g., name, SSN, date of birth, etc.); and any description of proof of identity for verification purposes required for personal visits by the requester.

19. *Record access procedures.* This section describes how an individual can review the record and obtain a copy of it. If the system has been exempted from access and publishing access procedures under subsections (d)(1) and (e)(4)(H), respectively, of the Privacy Act, it should be so indicated. If the system has not been exempted, describe the procedures an individual must follow in order to review the record and obtain a copy of it, including any requirements for identity verification. If appropriate, the individual may be referred to the system manager or another DFAS official who shall provide a detailed description of the access procedures. Any addresses already listed in the address directory should not be repeated.

20. *Contesting records procedures.* This section describes how an individual may challenge the denial of access or the contents of a record that pertains to him or her. If the system of record has been exempted from allowing amendments to records or publishing amendment procedures under subsections (d)(1) and (e)(4)(H), respectively, of the Privacy Act, it should be so stated. If the system has not been exempted, this caption describes the procedures an individual must follow in order to challenge the content of a record pertaining to him/her, or explain how he/she can obtain a copy of the procedures (e.g., by contacting the Program Manager or the appropriate DFAS Privacy Act Officer).

21. *Record source categories:* If the system has been exempted from publishing record source categories under subsection (e)(4)(I) of the Privacy Act, it should be so stated. If the system has not been exempted, this caption must describe where DFAS obtained the information maintained in the system. Describing the record sources in general terms is sufficient; specific individuals, organizations, or institutions need not be identified.

22. *Exemptions claimed for the system.* If no exemption has been established for the system, indicate 'None.' If an exemption has been established, state under which provision of the Privacy Act it is established (e.g., 'Portions of this system of records may be exempt under the provisions of 5 U.S.C. 552a(k)(2).')

Dated: May 15, 1996.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96–12856 Filed 5–21–96; 8:45 am]

BILLING CODE 5000–04–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[AD–FRL–5508–5]

RIN 2060–AA61

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final decision.

SUMMARY: In accordance with sections 108 and 109 of the Clean Air Act (Act), EPA has reviewed and revised the air quality criteria upon which the existing national ambient air quality standards (NAAQS) for sulfur oxides are based. Based on that review, this document announces EPA's final decision under section 109(d)(1) that revisions of the NAAQS for sulfur oxides are not appropriate at this time, aside from several minor technical changes.

In lieu of the two alternatives to short-term NAAQS proposed on November 15, 1994, EPA will shortly propose revisions to 40 CFR part 51 to establish concern and intervention levels under section 303 of the Act and associated guidance to assist States in addressing short-term peaks of sulfur dioxide (SO_2). Final action will be taken on proposed changes to 40 CFR parts 53 and 58 when final action is taken on the 40 CFR part 51 proposal and associated guidance.

EFFECTIVE DATE: May 22, 1996.

ADDRESSES: A docket containing information relating to EPA's review of the SO_2 NAAQS (Docket No. A–84–25) is available for public inspection in the Air & Radiation Docket Information Center, U.S. Environmental Protection Agency, South Conference Center, Room M–1500, 401 M Street, SW, Washington, DC, telephone (202) 260–7548. 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 **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Ms. Susan Lyon Stone, Air Quality Strategies and Standards Division (MD–15), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, telephone (919) 541-1146.

SUPPLEMENTARY INFORMATION:

Availability of Related Information

The *1982 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 1986 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 *1994 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 *1986 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 *1994 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, September 1994; NTIS # PB–95–124160, $27.00 paper copy and $12.50 microfiche) 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.) Other documents generated in connection with this standard review are also available in the EPA docket identified above.

Table of Contents

I. Background

A. Legislative Requirements Affecting This Decision

1. Primary Standards

Two sections of the Act govern the establishment and revision of 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'' NAAQS 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.'' For a discussion of the margin of safety requirement, see the November 15, 1994 proposed rule (59 FR 58958).

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 EPA has reviewed the 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 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 Act Amendments of 1990 (42 U.S.C. 7651–76510), which specifically provides for major reductions in SO_2 emissions.

B. Sulfur Oxides and Existing Standards for SO_2

The focus of this standard review is on the health effects of SO_2, alone and in combination with other pollutants. Other sulfur oxide (SO_x) vapors (e.g., sulfur trioxide, SO_3) are not commonly found in the atmosphere. Sulfur dioxide is a rapidly-diffusing reactive gas that is very soluble in water. It is emitted principally from combustion or processing of sulfur-containing fossil fuels and ores. At elevated concentrations, SO_2 can adversely affect human health.

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. Information on the effects of the principal atmospheric transformation products of SO_2 (i.e., sulfuric acid and sulfates) was

considered in the review of the particulate matter standards that culminated in revision of the standards 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).

On April 30, 1971, EPA promulgated primary and secondary NAAQS for sulfur oxides, measured as SO_2, under section 109 of the Act (36 FR 8186). The existing primary standards for SO_2 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 secondary standard was set at 1300 μg/m³ (0.50 ppm) averaged over a period of 3 hours and not to be exceeded more than once per year. The scientific and technical bases for the current standards are contained in the original criteria document, Air Quality Criteria for Sulfur Oxides (DHEW, 1970). For a history of the effects of SO_2 regulations on trends in SO_2 emissions and ambient concentrations, see the November 15, 1994 proposed rule (59 FR 58958).

Annual average SO_2 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_2 are discussed in greater detail in the revised criteria document (EPA, 1982a), in the staff paper (EPA, 1982b), in the criteria document addendum (EPA, 1986a), the staff paper addendum (EPA, 1986b), the criteria document supplement (EPA, 1994a), and the staff paper supplement (EPA, 1994b).

C. 1988 Proposal

Based on reviews of the original air quality criteria and standards for sulfur oxides, EPA published a proposed decision not to revise the existing primary and secondary standards on April 26, 1988 (53 FR 14926).[1] In reaching the provisional conclusion that the current standards provided adequate protection against the health and welfare effects associated with SO_2, EPA was mindful of uncertainties in the available evidence concerning the risk that elevated short-term (< 1-hour) SO_2 concentrations might pose to asthmatic individuals exercising in ambient air. 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 1-hour primary standard were adopted, consideration would be given to replacing the current 3-hour secondary standard (1,300 μg/m³ (0.50 ppm)) with a 1-hour secondary standard set equal to the primary standard, and adopting an expected-exceedance form for all of the standards.[2]

In the same notice, 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/m³, adding explicit rounding conventions, and specifying data completeness and handling conventions. In addition, EPA announced its intention to retain the block averaging convention for the 24-hour, 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_2 health effects information, EPA also proposed to revise the significant harm levels for SO_2 and the associated example air pollution episode levels (40 CFR part 51). Finally, EPA proposed some minor modifications to the ambient air quality surveillance requirements (40 CFR part 58).

D. 1994 Reproposal

As a result of public comments on the 1988 proposal and other post-proposal developments, EPA published a second proposal regarding revision of the primary standards for sulfur oxides on November 15, 1994 (59 FR 58958).[3] The 1994 reproposal was based in part on supplements to the criteria document (EPA, 1994a) and staff paper (EPA, 1994b) that were prepared to take into account recent health studies. Drafts of these documents were made available for review by the public and by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board, which provided its advice and recommendations in a letter dated June 1, 1994 (reprinted as Appendix II to this preamble). These and other aspects of the administrative process leading to the 1994 reproposal are described more fully in the reproposal notice.

As in the 1988 proposal, EPA proposed to retain the existing 24-hour and annual standards. The EPA also solicited comment on three regulatory alternatives to further reduce the health risk posed by exposure to high 5-minute peaks of SO_2 if additional protection were judged to be necessary. The three alternatives included: 1) Revising the existing primary SO_2 NAAQS by adding a new 5-minute standard of 0.60 ppm SO_2, 1 expected exceedance; 2) establishing a new regulatory program under section 303 of the Act to supplement protection provided by the existing NAAQS, with a trigger level of 0.60 ppm SO_2, 1 expected exceedance; and 3) augmenting implementation of existing standards by focusing on those sources or source types likely to produce high 5-minute peak concentrations of SO_2.[4]

In the reproposal notice, EPA specifically requested public comment in several key areas. First, EPA requested the submittal of factual information on the frequency of occurrence of 5-minute peak SO_2 levels in the ambient air, as well as information on the source or source types and the nature of events that are most likely to give rise to such peak SO_2 levels. Second, EPA requested the submission of data that would allow better characterization of the asthmatic population at risk and the frequency that an asthmatic individual would likely be exposed to peak concentrations of 0.60 ppm SO_2 and above, while at elevated ventilation rates. Third, EPA requested that asthma specialists in the medical community submit their views on the medical significance of the reported SO_2 effects, and on whether a numerical value below or above 0.60 ppm SO_2 would be more appropriate to protect asthmatic individuals.

The technical changes to the SO_2 NAAQS that were first proposed in 1988, including formally adopting the block averaging convention, stating the standards in ppm rather than μg/m³, adopting explicit rounding and data completeness conventions and other technical changes, were reproposed in this notice. Comments on this reproposal were to be received by February 13, 1995.

On December 29, 1994 (59 FR 67255), EPA announced that a public hearing on the reproposal would be held on February 8, 1995, and that the public

[1] The proposal notice contains a detailed history of the process leading to the 1988 proposal.

[2] EPA also concluded that it was not appropriate at that time to propose a separate secondary SOx standard to provide increased protection against acidic deposition-related effects of SO_x.

[3] A final decision that revision of the secondary standard was not appropriate was signed on April 15, 1993 and published in the Federal Register on April 21, 1993 (58 FR 21351).

[4] In a subsequent notice, EPA solicited comment on proposed requirements for implementing each of the alternatives (59 FR 12492, March 7, 1995).

comment period was being extended to March 15, 1995. The public hearing was held at the U.S. Environmental Protection Agency's Environmental Research Center Auditorium in Research Triangle Park, NC.

On March 14, 1995 (60 FR 13663), the public comment period was extended again, to April 14, 1995, to allow additional time for commenters to review the proposed requirements for implementing the three regulatory alternatives (59 FR 12492, March 7, 1995) before submitting comments on the 1994 reproposal.

E. Rulemaking Docket

The EPA established a standard review docket (Docket No. A–79–28) for the sulfur oxides review in July 1979. The EPA also established a rulemaking docket (Docket No. A–84–25) for the 1988 proposal as required by section 307(d) of the Act. The standard review docket 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 Public Comments

There were 95 written comments received prior to the end of the comment period on April 14, 1995. An additional 10 written comments were received after the close of the comment period. Of the 105 submissions, 53 were provided by individual industrial companies or industrial associations, 16 by Federal, State and local government agencies, 7 by environmental and public interest groups, and 5 by interested individuals, including one neighborhood association. Comments also were received from physicians and other independent experts knowledgeable about the health effects described in the reproposal. Along with its written comments, one environmental group submitted videotaped testimony.

In addition, 14 persons presented testimony at the February 8, 1995 public hearing. The written text of the comments presented, as well as a transcript of the hearing, may be found in Docket No. A–84–25, Category VIII–F, located in the Air and Radiation Docket Information Center (see the Addresses section above).

A general summary of the public comments follows. Some of the most significant comments are addressed, explicitly or implicitly, in other sections of this preamble. A more detailed summary of the comments received and EPA's responses to them has been placed in Docket No. A–84–25, Category IX–C.

A. Current 24-hour and Annual Standards

Most commenters concurred with EPA's conclusion that the existing 24-hour and annual standards provide adequate protection against SO_2-induced health effects associated with those averaging periods.

B. Regulatory Alternatives To Address Short-term Peak SO_2 Exposures

Almost all commenters agreed on the basic nature of the health effects associated with short-term exposure to SO_2 in controlled human exposure studies; that is, that brief (5-minute) exposures to 0.5 to 1.0 ppm SO_2 caused a proportion of asthmatic subjects at elevated ventilation rates to develop measurable and statistically significant bronchoconstriction, producing a range of symptoms from barely perceptible to severe enough to cause cessation of activity and medication use. In contrast, the comments were sharply divided on whether the existing standards should be supplemented by one of the three regulatory alternatives identified in the 1994 reproposal.

In general, industry commenters and affiliated physicians argued that additional regulatory protection from health effects associated with exposure to short-term peaks of SO_2 was unnecessary. Two broad arguments were made for this position. First, these commenters typically argued that the health effects associated with 5-minute peaks in the range of 0.6 to 1.0 ppm SO_2 are not significant because the effects are transient, subsiding within 1 to 2 hours without medication, do not include a late-phase inflammatory response, can be avoided or ameliorated with medication, and are similar qualitatively and quantitatively to the kinds of effects that asthmatic individuals experience on an almost daily basis as a result of exposure to common stimuli. Second, these commenters argued that exposures to 5-minute peaks of SO_2 are currently rare and, with the advent of title IV reductions in SO_2 emissions, likely to become even rarer. In this regard, some commenters agreed with EPA's conclusion that the existing standards markedly limit the occurrence of short-term peaks of SO_2.

Conversely, environmental and public interest groups and affiliated physicians, citizens and physicians living in SO_2-impacted areas, and independent experts argued that health effects that cause cessation of activity and medication use are adverse health effects, even if transient and preventable or reversible with medication. Citizens and physicians living in SO_2-impacted areas also argued that asthmatic individuals living around industrial sources of SO_2 are repeatedly exposed to short-term peaks of SO_2, and that such repeated exposures affect their health adversely through exacerbation of their asthma and reduction in their quality of life. Some of these commenters disagreed with EPA's conclusion that the existing standards limit the occurrence of short-term peaks of SO_2.

In general, Federal, State and local government agencies focused on the same two broad issues as the other commenters (significance of the health effects and likelihood of exposure) as a basis for supporting or not supporting adoption of one of the three proposed regulatory alternatives to address short-term peaks of SO_2. In addition, most governmental agencies submitted comments on implementation of the alternatives and tended to favor one or another based on the anticipated efficiency and effectiveness of implementing them. Of the 11 State agencies that commented, four favored adopting either the proposed 5-minute NAAQS or the section 303 program. One State agency recommended that EPA not adopt any of the proposed alternatives at this time but continue to study the problem, adding that the proposed level of the standard, 0.60 ppm SO_2, might not be low enough to include an adequate margin of safety. Another State agency was not in favor of adopting any of the proposed regulatory alternatives because it already had adequate authority to eliminate short-term peaks of SO_2 in problem areas. The remaining five State agencies opposed adoption of any of the three proposed regulatory alternatives. Of the two local agencies that commented, one opposed any new regulations. The other did not comment on the need for new SO_2 regulations but provided 5-minute SO_2 data from the local SO_2 surveillance network and relevant information about the causes and temporal distribution of 5-minute peaks $\geq$0.60 ppm SO_2. Of the three Federal agencies that commented, all supported adoption of a 5-minute NAAQS or the section 303 program alternative.

III. Rationale for Final Decision

A. Current 24-hour and Annual Standards

In the 1994 reproposal, EPA proposed to determine that revisions to the 24-hour and annual standards were not appropriate. As in the 1988 proposal, EPA provisionally concluded that the current 24-hour and annual standards

were both necessary and adequate to protect public health against effects associated with those averaging periods. The EPA also provisionally 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 CASAC (Appendix I).

Most comments on the 1994 reproposal focused on whether or not there was a need to adopt one of the regulatory alternatives to limit short-term peaks of SO_2. Virtually every commenter that mentioned the existing primary standards agreed with EPA's conclusion that these standards were necessary and adequate to protect the public health against effects associated with those averaging periods. No commenter argued that the concentrations of these standards should be changed.

After taking into account the public comments, the Administrator again concludes, based on the scientific data assessed in the criteria document and staff paper and their addenda, and consistent with the advice and recommendations of the staff and CASAC, that the 24-hour and annual standards provide adequate protection against the health effects associated with 24-hour and annual SO_2 concentrations. Accordingly, the Administrator concludes that revisions to the 24-hour and annual standards are not appropriate at this time. In reaching this decision, the Administrator notes that the health effects information on 24-hour and annual SO_2 exposures has remained largely unchanged since 1988. As newer information becomes available and is incorporated into new criteria documents, it will provide the basis for future reviews of the 24-hour and annual standards.

B. Short-Term Peak SO_2 Exposures

As reflected in the 1994 reproposal and in public comments on the reproposal, the question of whether revision of the existing NAAQS is appropriate to address risks that may be posed by short-term peaks of SO_2 depends upon two factors: (1) The nature and significance of the health effects per se, and (2) the number of people likely to be exposed under conditions likely to produce such effects. The next two sections address these factors in turn, and the Administrator's overall conclusions are discussed in section III.B.3.

1. Assessment of Health Effects Associated With Short-term SO_2 Exposures

This section focuses on the nature and significance of health effects that have been observed in controlled human exposure studies, putting aside temporarily, questions about the likelihood of such effects occurring under real-life conditions. Subsections a.–c. are adopted from the summary discussion in the 1994 reproposal of several important aspects of the health effects associated with short-term peak concentrations of SO_2. Additional references on these subjects are provided in the reproposal notice. Public comments on the most important and controversial aspects of the short-term SO_2 health effects are discussed in subsection d., with some indication of the Administrator's conclusions on particular issues. The last subsection contains the Administrator's overall conclusions regarding the significance of health effects associated with exposure to short-term peaks of SO_2.

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 that the population of concern for the effects of short-term SO_2 exposure consists of mild and moderate asthmatic children, adolescents and adults that are physically active outdoors. This is a subset of the approximately 10 million people or 4 percent of the population of the United States that 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).

b. Asthma. The Expert Panel Report from the National Asthma Education Program of the National Heart, Lung and Blood Institute (NIH, 1991) has 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).

Daily 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_1) and highest specific airway resistance (SR_{aw})) being experienced in the early morning hours and the best function (i.e., highest FEV_1 and lowest SR_{aw}) 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. Many asthmatic individuals experience bronchoconstriction when exercising, even in clean air. This response, called exercise-induced bronchoconstriction, is made worse by cold, dry air. 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_2 or other inhaled substances.

c. Short-term SO_2 Health Effects. The EPA's concern about the potential public health consequences of exposures to short-term peaks of SO_2 arose from 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_2 in the range of 0.1 ppm to 2 ppm while at elevated ventilation rates. The major effect of SO_2 on sensitive asthmatic individuals is bronchoconstriction, usually evidenced in these studies by increased SR_{aw} or decreased FEV_1, and the occurrence of clinical symptoms such as wheezing, chest tightness, and shortness of breath. The proportion of asthmatic individuals who respond, the magnitude of the response and the occurrence of symptoms increase as SO_2 concentrations and ventilation rates increase. The health effects are relatively transient. 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_2, 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.

The available data also indicate that most types of regularly administered asthma medications are not very effective in blocking the SO_2 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 exposure, or ameliorating the effect, if taken after symptoms develop.

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, the responses of African-American and Hispanic adolescents and young adults to short-term SO_2 exposures 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).

The criteria document supplement (EPA, 1994a) contains a summary of the literature on the health effects associated with brief exposures to SO_2. Recent studies have provided useful information about the magnitude of responses in the range of 0.4 to 1.0 ppm SO_2, the range of interest identified in the 1988 proposal (53 FR 14948, April 26, 1988). Data from several of these recent large-scale chamber studies were reexamined in Appendix B of the criteria document supplement (EPA, 1994a) to provide a better understanding of the responses observed in more sensitive subjects. Forced expiratory volume in 1 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_2 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_1 or SR_{aw}), and different concentrations of SO_2, the discussion that follows describes group mean changes first for the studies that used the measure SR_{aw}, then group mean changes for studies that used FEV_1, and then finally the individual responses.

The data indicate that, in terms of group mean changes, total SR_{aw} changes[5] were approximately twice as great at 0.6 ppm and above as at 0.5 ppm and below. The differences were even more pronounced when the changes in SR_{aw} due to SO_2 alone (i.e., after correction for the effects of exercise) were considered.

For FEV_1, the differences in responses between 0.4 ppm and 0.6 ppm SO_2 were not as pronounced. At 0.6 ppm SO_2, group mean decreases in total FEV_1 of approximately 20 percent were observed in the mild and moderate asthmatics studied. The changes in FEV_1 due to SO_2 alone resulted in decreases in FEV_1 of approximately 15 percent (EPA, 1994a, Table B–1).

In addition, at 0.6 ppm SO_2, 25 percent or more of the subjects had pronounced individual responses (either a 200 percent or greater increase in SR_{aw} or a 20 percent or greater decrease in FEV_1) due to SO_2 alone (total changes in lung function for these individuals would be expected to be even greater). In contrast, at ≤0.5 ppm SO_2, 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_2 concentration. In one study, for example, four of 24 moderate/severe asthmatic subjects were required to reduce their exercise level because of asthma symptoms at 0.6 ppm SO_2. 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_2 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_2 than after exposure to 0.3 ppm SO_2 (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 is in agreement with the conclusions 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 SO_2 and above.''

The staff also compared the effects of SO_2 observed in these 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_2 exposure at moderate exercise, as measured by FEV_1, exceeded either the typical effect of exercise alone or typical daily variations in FEV_1 (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_2, 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_2 than at any other time during their participation in the studies (EPA, 1994a, p. B–12).

Furthermore, the response seen in the most sensitive 25 percent of responders at 0.6 ppm equalled or exceeded approximately a 30 percent decline in FEV_1 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_1.

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_2, from 33–43 percent of moderate asthmatics and from 6–35 percent of mild asthmatics experienced at least a 20 percent

[5] Since elevated ventilation sufficient for oronasal breathing to occur is a requirement for most asthmatic persons to respond to SO_2, and because many asthmatic individuals experience bronchoconstriction responses to exercise alone, it is useful to distinguish between the two different effects. In this discussion, ''total FEV_1 (or SR_{aw})'' refers to the total change in lung function experienced by a subject as a result of an exposure to SO_2 while at exercise, while ''the effect of changes due to SO_2 alone'' refers to 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_1 or SR_{aw} indicates the magnitude of overall lung function change actually experienced by the subject, while the change due to SO_2 alone indicates how much of this total change is attributable to the pollutant itself.

decrease in total FEV_1 in conjunction with symptoms rated as being of moderate severity or worse. It should be noted that the asthmatic subjects with moderate/severe disease started an exposure with compromised lung function compared to mild asthmatic subjects. While the response to SO_2 was similar in the mild versus the moderate/severe asthmatic subjects, similar functional declines beginning from a different baseline may have different 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 experienced greater effects, bronchoconstriction with at least moderate symptoms, beginning at 0.6 ppm SO_2 (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_2 during moderate exercise would be expected to have respiratory function changes and severity of symptoms distinctly exceeding 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_2 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.

d. Public Comments on Significance of Health Effects. In regard to the measured changes in lung function (expressed as FEV_1 or SR_{aw}), commenters did not disagree with the EPA's summary of the available literature contained in the November 15, 1994 (59 FR 58958) reproposal. Where there continues to be a real divergence of opinion among asthma specialists and others is on interpretation of the results, or on the medical significance of the lung function changes that have been measured in exercising asthmatic subjects and summarized in the various EPA documents. At issue are not the published data about SO_2-induced bronchoconstriction, but how they are interpreted.

As noted in the 1994 reproposal, bronchoconstriction caused by brief exposure to 0.6 to 1.0 ppm SO_2 is transient. Measurements of lung function start to improve when the exposure ceases, or when the subject ceases to exercise and the ventilation rate decreases to resting levels; after 5 minutes of exposure, the magnitude of the response does not worsen even if exposure and elevated ventilation rate continue. Most often, lung function returns to preexposure levels within 1 hour, occasionally taking up to 2 hours to return to normal. A dose of one of the most commonly used classes of medication, inhaled $beta_2$-agonists, rapidly attenuates or prevents the response. The transient nature of the response led some commenters to argue that the health effects are not significant. These commenters stated that although they would advise an asthmatic individual to take medication, cease activity or avoid the stimulus, this behavior was an everyday part of an asthmatic individual's life and not cause for medical concern. Other commenters argued that any effect which may entail bronchoconstriction severe enough to limit activity or cause medication use is a significant health effect.

Many commenters argued that the documented effects are not medically significant because, as one commenter put it, ''changes in lung function are not meaningful endpoints in themselves, but must be placed in the context of asthmatics' typical respiratory function, which is both highly variable and reactive to many stimuli and conditions'' (see Docket No. A–84–25, VIII–D–71). In general, these commenters argued that the responses to short-term peaks of SO_2 in the range of 0.6 to 1.0 ppm are similar in nature and magnitude to the well-tolerated responses to a variety of non-specific stimuli (cold, dry air, exercise, irritants such as perfume) encountered on a daily basis by most asthmatic individuals and are not in themselves deleterious to the asthmatic individual's health. Other commenters argued that this fact does not justify the neglect of potential ambient air SO_2 effects, and that unusual susceptibility to an inhaled pollutant does not simply constitute a problem for the susceptible individual.

Despite these opposing points of view, there was some agreement that frequency of occurrence of SO_2-induced health effects could make a difference in the concern that a physician feels. That is, some physicians felt that the documented SO_2-induced health effects were well tolerated by asthmatic individuals; however, if the effects occurred frequently enough, then they would be cause for medical concern (public hearing transcript, 1995, p. 155). Other physicians felt that such effects are a cause for concern despite their transient and reversible nature; if exposures occurred rarely enough, however, these physicians would be less concerned (public hearing transcript, 1995, p. 89–90). Several commenters also noted that cold air appears to act at least additively with SO_2, and that the bronchoconstrictive effect of cold air which contains SO_2 is larger than that of either exposure condition alone.

Some commenters took issue with EPA's assessment of the proportion of asthmatic individuals who would experience meaningful symptoms or have any disruption of daily activities. Based on personal experience, one commenter stated that most asthmatics do not begin to perceive bronchoconstriction until FEV1 falls to about 50 percent of its normal value and SR_{aw} increases about 400 percent (see Docket No. A–84–25, VIII–D–71). Other commenters agreed that the kinds of symptomatic responses experienced by asthmatic subjects exposed to SO_2 in the reviewed chamber studies are no more than brief, perceptible reactions that might temporarily disrupt activities, but are well tolerated and do not endanger the individuals' health or cause them to seek medical attention. On the other hand, commenters who believed the effects were significant argued that transient and reversible decrements in lung function are adverse if they cause physical discomfort, interfere with normal activity or impair the performance of daily activities, or aggravate chronic respiratory disease by increasing the frequency or severity of asthma attacks. Several commenters argued that measurable effects have occurred after brief exposures, with elevated ventilation rates, to concentrations as low as 0.25 to 0.28 ppm SO_2, and thus that the proposed 5-minute standard of 0.60 ppm SO_2 leaves no margin of safety. However, as stated above, considering a 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 at lower concentrations.

As noted in the criteria document supplement (EPA, 1994a), the staff paper supplement (EPA, 1994b) and the November 15, 1994 reproposal (59 FR 58958), unlike the effects of allergens and viral infections, there is no evidence that short-term exposure to SO_2 while at an elevated ventilation rate leads to any ''late phase'' response. ''Late-phase'' bronchoconstriction is indicative of a more serious inflammatory reaction which takes much longer to resolve and which can lead to emergency room visits and/or hospitalization. The ''late phase'' inflammatory response can also cause the airways to become more sensitive to other stimuli. Since this type of response has not been observed with brief exposures in the range of 0.6 to 1.0 ppm SO_2, many commenters argued that the health of asthmatic individuals is not affected by such exposures.

The ability of inhaled $beta_2$-agonists, the most commonly prescribed class of asthma medications, to prevent or ameliorate the effects of SO_2 exposure was frequently cited as one reason why most asthmatic individuals are unlikely to experience bronchoconstriction due to exposure to short-term peaks of SO_2. These commenters argued that since most asthmatic individuals experience exercise-induced bronchoconstriction, they are highly likely to premedicate with an inhaled $beta_2$-agonist medication prior to exercise and therefore be protected from SO_2-induced health effects. Further, these commenters stated that the highly variable compliance rates for medicine usage cited by EPA in the criteria document supplement (EPA, 1994a), staff paper supplement (EPA, 1994b) and November 15, 1994 reproposal (59 FR 58958) do not apply to physically active asthmatic individuals, for whom medication compliance rates are significantly better.

Conversely, many other commenters agreed with EPA that medication compliance rates can be very poor, even for individuals who are physically active, like children, and that many asthmatic individuals use medication only after symptoms occur. These individuals would be at risk for experiencing SO_2-induced bronchoconstriction. Some commenters, including one from a State's Office of Environmental Health Hazard Assessment, which recently reviewed that State's 1-hour SO_2 standard (see Docket No. A–84–25, VIII–D–65), commented that an optimal medication regimen from the standpoint of reducing SO_2-induced bronchoconstriction may result in undesirable side effects. Some of these commenters also noted that SO_2 exposure could cause asymptomatic, exercise-induced bronchoconstriction to become symptomatic, thereby causing an asthmatic individual to take medicine that would normally not be needed. Several commenters argued that relying on medication use instead of regulation was poor public policy. Some of these commenters also argued that asthmatic individuals of lower socioeconomic status may not be able to afford medication or have limited access to health care. In the Administrator's judgment, these concerns about accessibility of medication and health care, and the variability of medication compliance rates, are legitimate ones. Although the use of medication may substantially reduce the incidence and/or severity of SO_2-induced bronchoconstriction, the mere availability of medication does not necessarily mean that all asthmatic individuals will necessarily be protected from this effect. The Administrator therefore concludes that this factor should not be regarded as dispositive in assessing the appropriateness of regulatory action to provide additional protection against short-term SO_2 peaks.

Many commenters argued that there are no epidemiological studies which show an association between short-term peaks of SO_2 and adverse health effects such as asthma symptoms or increased visits to physicians or hospital emergency rooms. Some of these commenters argued that the changes in lung function and symptoms found in some subjects in controlled human exposure studies may not be indicative of what would occur in real-world situations. The reason that there are no epidemiological studies showing an association between short-term (5- to 10-minute) peaks of SO_2 and real-world health effects is that apparently no studies have been conducted to examine the association or lack thereof of short-term SO_2 peaks and adverse health effects. This is most likely because it would be difficult to design and conduct an epidemiological study that could detect possible associations between very brief (5- to 10-minute), geographically localized, peak SO_2 exposures and respiratory effects in asthmatic individuals. Furthermore, the responses of naturally-breathing asthmatics exposed to SO_2 under controlled conditions in an environmental chamber presumably reflect responses that would be observed in the ambient (''real-world'') environment under similar conditions of activity level, air temperature, and humidity. Although there is evidence that other inhaled materials that modify airway responsiveness can influence the response to SO_2, there is no reason, at the present time, to suggest that the ambient pollutant mixture would cause either a suppression or an augmentation of SO_2 effects through some, as yet unrecognized, chemical interaction.

e. Significance of Health Effects. Taking into account the available health effects studies and the body of comments on the health effects, the Administrator agrees with the staff assessment that a substantial percentage (20 percent or more) of mild-to-moderate asthmatic individuals exposed to 0.6 to 1.0 ppm SO_2 for 5 to 10 minutes at elevated ventilation rates, such as would be expected during moderate exercise, would be expected to have lung 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 health concern; that is, likely to cause some disruption of ongoing activities, use of bronchodilator medication, and/or possibly seeking of medical attention. The EPA agrees with other commenters that the frequency with which such effects are experienced may affect the public health concern that is appropriate. Taking into account the broad range of opinions expressed by CASAC members, medical experts, and the public, the Administrator concludes that repeated occurrences of such effects should be regarded as significant from a public health standpoint. Accordingly, the Administrator also concurs with the staff judgment that the likely frequency of occurrence of such effects should be a consideration in assessing the overall public health risk in a given situation.

2. Air Quality and Exposure Considerations

Another major basis for considering whether additional regulatory measures are appropriate to reduce the occurrence of short-term peaks of SO_2 has been the estimation of the geographic extent and the frequency of 5-minute peaks greater than 0.60 ppm SO_2 in the ambient air, and the likelihood that these peaks would result in exposure conditions that could cause significant health effects. As discussed in the staff paper supplement (EPA, 1994b) and the 1994 reproposal, the occurrence of short-term peaks of SO_2 is relatively infrequent and highly localized around point sources of

SO_2. None of the air quality or exposure information subsequently received by EPA has changed this assessment.

In 1993 and again in 1994, EPA requested that States collect and submit 5-minute SO_2 ambient monitoring data from source-based monitors. Data were submitted from both industry and State-run monitors and while much of this information was considered in the 1994 staff paper supplement (EPA 1994b) and in the 1994 reproposal, a few sites subsequently provided more data. Available data have been compiled and statistical parameters calculated in a report for EPA by Systems Applications International or SAI (1996).[6] In general, the data confirm that a substantial number of short-term peaks greater than 0.60 ppm can occur in the vicinity of certain sources.

As indicated previously, an important consideration is whether such short-term peaks of SO_2 are likely to cause episodes of bronchoconstriction in asthmatic individuals. Thus, one method of assessing the public health significance of SO_2-induced effects is to estimate the likelihood that asthmatic individuals will be exposed to such peaks while simultaneously at elevated ventilation rates (EPA, 1994a, p.51). It should be noted, however, that not all asthmatic individuals who experience such exposures will necessarily experience SO_2-induced health effects, either because of individual variability or other factors.

[6] The 5-minute concentrations ranged from 0 to > 2.5 ppm SO_2. The number of observations recorded at any monitor ranged from 308 to 48,795 hours, with the mean number of observations equalling 7,646 hours (a complete year of hourly maximum 5-minute averages would contain 8,760 observations). There were 63 monitors, located in 16 States, with continuous data sets of either the maximum 5-minute block average per hour or all of the 5-minute block averages per hour. For data sets containing all of the 5-minute block averages per hour, the maximum 5-minute block average for each hour was extracted and that parameter was used throughout the analysis. Of the 63 monitors, 26 (41 percent) registered 1 or more concentrations greater than the proposed short-term standard of 0.60 ppm SO_2 during the time periods represented for the monitors involved. For any given monitor, the number of such exceedances ranged from 0 to 139, which corresponds to 0 to 3 percent of the hours represented in the data. Of the 26 monitors measuring at least 1 exceedance, 11 monitors recorded from 1 to 5 exceedances, while 8 monitors in 4 communities recorded from 25 to 139 exceedances. While these data came from sourcebased monitors, the existing SO_2 monitoring network is designed to characterize ambient air quality associated with 3-hour, 24-hour, and annual SO_2 concentrations rather than to detect short-term peak SO_2 levels. This could have resulted in underestimates of the maximum 5-minute block averages recorded. Therefore, changes in monitor siting and density near SO_2 sources most likely to produce high 5-minute peaks could increase both the number of exceedances and the concentrations of the maximum 5-minute block averages recorded.

At the time of the 1994 reproposal, three exposure analyses were available that estimated the frequency of SO_2 exposures that could result in measurable health effects. Two of the analyses estimated the potential frequency of exposure events resulting from operation of utility boilers nationwide. For these two studies, detailed information on actual emissions was available on a plant-by-plant basis (Burton et al., 1987; Rosenbaum et al., 1992) to use in estimating ambient SO_2 concentrations and then exposures. The utility analyses estimated there would be 68,000 exposure events per year at ≥ 0.5 ppm SO_2, which would affect approximately 44,000 asthmatic individuals at elevated ventilation rates. Taking into account full implementation of the title IV program of the Act, in the year 2015, the number of exposure events at ≥ 0.5 ppm SO_2 attributable to the utility sector was estimated to drop to 40,000 per year, contingent on trading decisions.

The third exposure analysis available at the time of the 1994 reproposal estimated nationwide SO_2 exposures resulting from the operation of nonutility sources. Because actual data were not available, some conservative assumptions had to be made about operating parameters, which increased the uncertainties in the analysis (Stoeckenius et al., 1990). Probably the largest single source of uncertainty in this analysis was the emissions estimates used for the nonutility sources. The analysis estimated 114,000 to 326,000 exposures to 0.5 ppm SO_2 per year around nonutility sources. These exposures were estimated to affect 24,000 to 122,000 asthmatic individuals at elevated ventilation rates, implying that exposed individuals may be exposed more than four times a year, on average.

Combining the utility and nonutility exposure estimates results in a prediction of 180,000 to 395,000 total exposure events to 0.5 ppm SO_2 nationwide, per year. 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 $SO_2 \geq 0.5$ ppm. The number of asthmatic individuals likely to be exposed to ≥ 0.60 ppm SO_2 under the same conditions, of course, would be smaller. 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).

In response to the 1994 reproposal, several industry associations sponsored and submitted as a public comment a revised analysis of exposures around four types of nonutility sources (industrial/commercial/institutional boilers, kraft and sulfite process pulp and paper mills, and copper smelters) by Sciences International, Inc. (1995). This study incorporated new data and additional analyses designed to eliminate the need for some of the more conservative assumptions employed in the Stoeckenius et al. (1990) study. A principal feature of the new study is the use of improved source and emissions data for all four source categories examined and especially for sulfite process pulp mills and copper smelters. The new analysis estimated significantly fewer expected exposure events for the four source categories examined. In the original study, the four categories were estimated to contribute a total of 73,000 to 259,000 exposure events (Stoeckenius et al., 1990). In the revised analysis, this range decreased by an order of magnitude, to between 7,892 and 23,099 events. The same basic procedures were used to calculate expected exposures in both the 1990 and 1995 studies. However, a direct comparison of the results of the two exposure analyses may not be possible due to differences in some key details between the two studies, which are highlighted in a technical review by Stoeckenius (1995) of the Sciences International, Inc. (1995) exposure analysis. In general, that review indicates that while the Stoeckenius et al. (1990) study utilized several very conservative assumptions, which most likely led to an overestimate of exposures for these three source categories. The Sciences International, Inc. (1995) reanalysis did not provide reliable estimates of the degree of conservatism resulting from the original assumptions which could then be used for the purpose of comparison. In contrast, the updated information and data for copper smelters used in the Sciences International, Inc. (1995) reanalysis most likely resulted in a more accurate estimate of exposures for that source category than did previously available estimates (Stoeckenius, 1995).

Another industry commenter submitted an exposure analysis (see Docket No. A–84–25, VIII–G–08) that utilized actual SO_2 ambient air monitoring and demographic data from a community located near a copper-smelting facility. The results of this analysis indicate that the probability of SO_2-related episodes of bronchoconstriction in the sensitive

population of asthmatic individuals in the community is very low. There was no evidence of an association between 5-minute concentrations of $SO_2 > 0.60$ ppm and episodes of bronchoconstriction in the sensitive population.

These exposure analyses and the body of 5-minute SO_2 monitoring data underscore the views of the Administrator, the staff and the CASAC, reflected in the 1994 reproposal, that the likelihood that asthmatic individuals will be exposed to 5-minute peak SO_2 concentrations of concern, while outdoors and at elevated ventilation rates, is very low when viewed from a national perspective. Even in communities where frequent 5-minute peaks have been recorded, the likelihood of exposure is highly variable. One county public health agency submitted 5-minute SO_2 monitoring data (see Docket No. A–84–25, VIII–D–15), for the years 1993–1994, from the 10 continuous SO_2 monitors in the local surveillance network. Only monitors located near large industrial sources of SO_2 measured exceedances of 0.60 ppm SO_2. Of 29 exceedances measured over a 2-year period, approximately half of the exceedances were associated with breakdowns of the desulfurization equipment used to control SO_2 emissions from coke plants in the county. The agency noted that more than 70 percent of the hours in which exceedances were measured occurred very late at night or early in the morning, which would reduce the likelihood of the exceedances affecting the sensitive population.

Nonetheless, the 5-minute monitoring data indicate that some communities in proximity to SO_2 sources are repeatedly subjected to high short-term concentrations of SO_2 in the ambient air. Asthmatic individuals who reside in proximity to certain individual sources may be at greater risk of being exposed to such peak SO_2 levels while at elevated ventilation rates, and, therefore, at greater risk of suffering health effects than the asthmatic population as a whole. This conclusion is supported by the comments of citizens and physicians living in areas where high 5-minute peaks of SO_2 have been recorded. Citizens have reported, for example, that they developed asthma upon moving to an SO_2-impacted area; that their asthma is better, both in terms of symptoms and indicators such as peak flow measurements when they leave the SO_2-impacted area on vacation or for medical treatment; and that their peak flow measurements decrease when the wind is blowing from the direction of the local SO_2 source(s). These citizens express the belief that ambient SO_2 concentrations are responsible for their symptoms. Physicians have commented that they believe that ambient air SO_2 concentrations in their communities are negatively affecting the health of their patients. Most of these comments came from two of the six communities for which SO_2 monitoring data show repeated high 5-minute peaks greater than 0.60 ppm SO_2.

The data also indicate that asthmatic individuals living in communities in which 5-minute peaks greater than 0.60 ppm SO_2 rarely occur may be subject to much less risk of experiencing health effects that cause cessation of activities or increased medication use. Even when monitors record a substantial number of such peaks, the likelihood that a significant number of asthmatic individuals will be exposed to such peaks with some frequency while at elevated ventilation rates may range from nonexistent to fairly high depending upon such localized factors as the magnitude and frequency of the peaks, the times of occurrence, meteorological conditions in the area, the density of the population near the source(s) involved, and daily activity patterns. Thus, estimation of risk must be done on a case-by-case basis and be based on site-specific factors. In short, the data clearly show that 5-minute peaks greater than 0.60 ppm SO_2 can occur around particular industrial point sources of SO_2, that such peaks are not ubiquitous from a national perspective but instead appear to occur only in the vicinity of such sources, and that the risk of exposures that could cause significant health effects in asthmatic individuals cannot be estimated based solely on the number of recorded high 5-minute peaks of SO_2, but instead must be estimated using site-specific factors.

3. Conclusions

For reasons discussed above, based on her assessment of the relevant scientific and technical information and taking into account public comment, it is the Administrator's judgment that 5-minute peak SO_2 levels do not pose a broad public health problem when viewed from a national perspective. As discussed in some detail in the 1994 reproposal, the existing suite of SO_2 standards and associated control strategies clearly limit both the occurrence of high 5-minute peak SO_2 levels, and the likelihood that asthmatic individuals will be exposed to them while outdoors and at elevated ventilation rates.

In considering the residual risk posed by such peak concentrations, the Administrator has taken a number of factors into account. As discussed in the criteria document and staff paper supplements (EPA 1994a, p. 51, EPA 1994b, p. 59), an important consideration in determining the public health risk posed by 5-minute concentrations in the range of 0.60 to 1.0 ppm SO_2 is the frequency with which an asthmatic individual may be exposed while at an elevated ventilation rate. As discussed earlier, there is some agreement that infrequent exposures in this range may not be a cause for significant concern. As the frequency of exposure increases, so does concern about the associated public health risk. Asthmatic individuals living in communities in which 5-minute peaks in the range of 0.60 to 1.0 ppm SO_2 rarely occur may be unlikely to experience exposure events that would cause them to cease their activities or increase medication use. In particular locations, of course, the concentrations involved in exposure events can exceed 1.0 ppm SO_2, and could induce a greater response in an exposed asthmatic individual than lower concentrations. Thus, frequency of exposure events alone is not an adequate indicator of the risk to public health. As discussed above, factors such as the magnitude of 5-minute SO_2 peaks, time of day, activity patterns, and the size of the population exposed are also relevant. As a result, whether 5-minute peak SO_2 concentrations will pose a significant public health risk depends largely on highly localized factors.

Given the localized, infrequent and site-specific nature of the risk involved, the Administrator has concluded that short-term peak concentrations of SO_2 do not constitute the type of ubiquitous public health problem for which establishing a NAAQS would be appropriate. For similar reasons, the Administrator concludes that adoption of a section 303 program employing a uniform, nationwide trigger level would not be an appropriate response. With respect to the third alternative identified in the 1994 reproposal (augmenting implementation of existing SO_2 NAAQS), it has become increasingly clear that even full attainment of the existing SO_2 standards would not preclude the occurrence of high 5-minute SO_2 peaks in particular locations. Moreover, given the site-specific nature of the problem, States can more effectively identify for monitoring purposes, sources that may be causing or contributing to high 5-minute SO_2 concentrations.

For the reasons discussed previously, the Administrator has concluded that repeated exposures to 5-minute peak SO_2 levels of 0.60 ppm and above could

pose a risk of significant health effects for asthmatic individuals at elevated ventilation rates in some localized situations. The Administrator has also concluded that the residual health risks posed by short-term concentrations are most appropriately addressed at the State level. In the Administrator's judgment, the States are in a far better position than EPA to assess the highly localized and site-specific factors that determine whether the occurrence of such concentrations in a given area poses a significant public health risk to the local population, and if so, to fashion an appropriate remedial response. This view was also advanced by some States in their comments on the 1994 reproposal.

To assist the States in addressing short-term peak SO_2 levels, EPA will publish a reproposal notice superseding the March 1995 notice (59 FR 12492) that proposed revisions to 40 CFR part 51 establishing a new program under section 303 of the Act that would differ from that contemplated in the 1994 reproposal. The new program would also differ from existing programs under section 303 that are designed to protect against episodic events.

In particular, EPA plans to propose two new levels as guides to State action: A ''concern level'' at 0.60 ppm SO_2, 5-minute block average; and an ''intervention level'' at 2.0 ppm SO_2, 5-minute block average. Under the program to be proposed, the States would determine whether 5-minute peak SO_2 levels recorded in the range of 0.60 to 2.0 ppm SO_2 posed a significant public health risk and, if so, the appropriate remedial response. To assist the States in reaching such determinations, the proposal will identify, in the form of guidance, factors that EPA believes should be considered in assessing whether recorded peaks pose a significant health risk to the local population. Among other things, the factors would include the frequency and magnitude of observed 5-minute peaks, and the likelihood and frequency of exposures for asthmatic individuals at elevated ventilation rates. In assessing whether observed 5-minute peaks in this range posed a significant public health risk, thus warranting intervention, the States would be advised to take into account the above factors, as well as others they might deem appropriate. It is the Administrator's judgment that establishing such a program, in which the States would determine at the local level whether peak SO_2 levels in the range of 0.60 to 2.0 ppm SO_2 posed a significant public health risk and, if so, the appropriate remedial response, is the most effective approach for addressing this potential public health problem.

C. Final Decision on Primary Standards

For the reasons discussed above, and in the November 15, 1994 reproposal notice (58 FR 58958), it is the Administrator's judgment under section 109(d)(1) that revisions to the existing primary SO_2 NAAQS are not appropriate at this time. As provided for under the Act, the EPA will continue to assess the scientific information on health effects associated with 5-minute, 24-hour and annual SO_2 exposures as it emerges from research and ongoing SO_2 monitoring programs, and will update the air quality criteria for sulfur oxides accordingly. The revised criteria will provide the basis for the next review of the primary NAAQS for SO_2.

D. Technical Changes

There were relatively few comments on the proposed technical changes. Several environmental and public interest groups and one State preferred the running averaging convention, while industry comments supported the block averaging convention. A small number of comments were also received both for and against the change from $\mu mg/m^3$ to ppm. Taking these comments into account, EPA has decided to promulgate the technical changes set forth in the 1994 reproposal. First, the block averaging convention will be retained, and language clarifying this point will be adopted in the regulation (40 CFR 50.4 and 50.5). 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.

Although the wording of the original 24-hour, 3-hour, and annual SO_2 standards may have been ambiguous on the matter, the earliest actions of the EPA signify that the block averaging convention was intended for these standards (OAQPS, l986), and block averages have generally been used in implementing the standards. Given a fixed standard level, the use of the alternative, running averages, would represent a tightening of the standards (Faoro, 1983; Possiel, 1985). For reasons explained in this notice and in the April 21, 1993, notice on the secondary NAAQS (58 FR 21351), the Administrator has already determined that protection of the public health and welfare does not require tightening the existing standards. Therefore, EPA will retain the block averaging convention for the 24-hour, 3-hour, and annual standards.

The second technical change to be adopted is that the levels for the primary and secondary NAAQS will be stated in ppm rather than $\mu g/m^3$ (40 CFR 50.4 and 50.5). This will be done to make the SO_2 NAAQS consistent with those for other pollutants and to facilitate public understanding of the standards. Although the ppm levels are slightly less than their current $\mu g/m^3$ counterparts, the differences are considered negligible (Frank, 1988).

Finally, the explicit rounding conventions and the data completeness and handling conventions put forth in the reproposal will be adopted.

IV. Regulatory Impacts

A. Executive Order 12866

Under Executive Order 12866, the Agency must determine whether a regulatory action is ''significant'' and, therefore, subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The order defines ''significant regulatory action'' as one that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material 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 entitlements, grants, user fees, or loan programs or the rights and obligations or 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, OMB has notified EPA that it considers this a ''significant regulatory action'' within the meaning of the Executive Order. The EPA has submitted this action to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public docket and made available for public inspection at EPA's Air and Radiation Docket Information Center (Docket No. A–84–25).

The EPA has judged that today's decision on the SO_2 primary NAAQS is not an economically-significant regulatory action as defined by Executive Order 12866 because there are no additional costs or other impacts as a result of not revising the standards. The EPA, therefore, has deemed unnecessary the preparation of a final regulatory impact statement.

B. Regulatory Flexibility Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator certifies that this rule will not have a significant impact on a substantial number of small entities. The Regulatory Flexibility Act requires that all Federal agencies consider the impacts of final regulations on small entities, which are defined to be small businesses, small organizations, and small governmental jurisdictions (5 U.S.C. 601 *et seq.*). A decision not to revise the existing primary NAAQS for SO_2 would, of course, impose no new requirements on small entities. In addition, the SIPs necessary to implement the existing primary standards have been substantially adopted and implemented. Additional SIP requirements will be needed only for those areas or sources which are designated as nonattainment for the existing primary standards now or in the future. Given the current air quality and attainment status, however, it is very unlikely that new SIP requirements would be required that would significantly affect a substantial number of small entities.

C. Impact on Reporting Requirements

There are no reporting requirements directly associated with an ambient air quality standard promulgated under section 109 of the Act (42 U.S.C. 7400). There are, however, reporting requirements associated with related sections of the Act, particularly sections 107, 110, 160, and 317 (42 U.S.C. 7407, 7410, 7460, and 7617). This final action will not result in any changes in these reporting requirements since it would retain the existing levels and averaging times for the primary standards. The current standards are covered under EPA Information Collection Request Number 940.13.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under sections 202, 203, and 205, respectively, of the UMRA, EPA generally must: (1) Prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year; (2) develop a small government agency plan; and (3) identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule.

Because the Administrator has decided not to revise the existing primary NAAQS for SO_2, this action will not impose any new expenditures on governments or on the private sector, or establish any new regulatory requirements affecting small governments. Accordingly, EPA has determined that the provisions of sections 202, 203, and 205 of the UMRA do not apply to this final decision.

E. Environmental Justice

Executive Order 12848 requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionally high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. These requirements were addressed in the draft Regulatory Impact Analysis (59 FR 58958; November 15, 1994) and taken into account by EPA in reaching its determination that revisions to the existing primary SO_2 NAAQS are not appropriate at this time.

List of Subjects in 40 CFR Part 50

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

Dated: May 14, 1996.

Carol M. Browner,

Administrator.

References

Burton, C.S.; Stockenius, T.E.; Stocking, T.S.; Carr, E.L.; Austin, B.S.; Roberson, R.L. (1987) Assessment of exposures of exercising asthmatics to short-term SO_2 levels as a result of emissions from U.S. fossil-fueled power plants. Systems Applications, Inc., San Rafael, CA. Pub. No. 87/176, September 23, 1987.

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.

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 (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 (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 Air 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 (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. A–79–28, II–B–11.

Frank, N. U.S. EPA, Technical Support Division (1988), Memorandum to John Haines, Air Quality Management Division, January 5, 1988, Docket No. A–84–25, II–B–3.

National Institutes of Health (1991), Guidelines for the diagnosis and management of asthma, Bethesda, MD: U.S. Department 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. A–79–28, II–A–15.

Possiel, N.C., U.S. EPA, Model Applications Section (1985), Analysis of Running Versus Block SO_2 Model Estimates, Memorandum to Henry C. Thomas, Standards Development Section, August 27, 1985, Docket No. A–79–28, II–B–12.

Public Hearing (1995), Transcript of meeting held in Research Triangle Park, NC on February 8, 1995, Docket No. A–84–25, VIII–F–17.

Rosenbaum, A.S.; Hudischewskyj, A.B.; Roberson, R.L.; Burton, C.S. (1992) Estimates of Future Exposures of Exercising Asthmatics to Short-term Elevated SO_2 Concentrations Resulting from Emissions of U.S. Fossil-fueled Power Plants: Effects of the 1990 Amendments to the Clean Air Act and a 5-minute Average Ambient SO_2 Standard. Pub. No. SYSAPP–92/016, April 23, 1992.

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. Respir. Dis. 142: 555–562.

Sciences International, Inc. (1995), Estimate of the Nationwide Exercising Asthmatic Exposure Frequency to Short-Term Peak Sulfur Dioxide Concentrations in the Vicinity of Non-Utility Sources. Alexandria, VA, Docket No. A–84–25, VIII–D–71.

Stoeckenius, T.E. (1995), Technical Review of NMA's Report on: 'Estimate of the Nationwide Exercising Asthmatic Exposure Frequency to Short-Term Peak Sulfur Dioxide Concentrations in the Vicinity of Non-Utility Sources.' ENVIRON International Corporation, Novato, CA, Docket No. A–84–25, VIII–A–01.

Stoeckenius, T.E.; Garelick, B.; Austin, B.S.; O'Connor, K.; Pehling, J.R. (1990). Estimates of Nationwide Asthmatic Exposures to Short-term Sulfur Dioxide Concentrations in the Vicinity of Non-Utility Sources. Systems Applications Inc., San Rafael, CA, Pub. No. SYSAPP–90/129, December 6, 1990.

Systems Applications International (1996) Summary of 1988–1995 Ambient 5–Minute SO_2 Concentration Data. Systems Applications International, Research Triangle Park, NC, Docket No. A–84–25, VIII–A–02.

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_2 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_2 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 concern.
- 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_2 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 short-term, 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_2 clinical studies are surrogates for more sensitive asthmatics. Estimates of the size of the asthmatic population that experience exposures to short-term peaks of SO_2 (0.2–0.5 parts per million (ppm) SO_2 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_2 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 standard.

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 Street, SW., Washington, D.C. 20460

Subject: Clean Air Scientific Advisory Committee Closure on the Supplements to Criteria Document and Staff Position Papers for SO_2

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 ground-level 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 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 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 Committee.

For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is 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 follows:

§ 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 shall 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 shall be rounded up).

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

(d) To demonstrate attainment, the annual arithmetic mean and the second-highest 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 fewer 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 24.

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 shall 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 3-hour block average shall be computed as the sum of the hourly averages divided by 3.

[FR Doc. 96–12863 Filed 5–21–96; 8:45 am]
BILLING CODE 6560–50–P

40 CFR Part 75

[FRL–5506–6]

Acid Rain Program: Continuous Emission Monitoring

AGENCY: Environmental Protection Agency (EPA).

ACTION: Amendment to final rule; correction.

SUMMARY: On May 17, 1995, EPA published direct final amendments to the Continuous Emission Monitoring (CEM) rule in the Acid Rain Program for the purpose of making implementation of the program simpler, streamlined, and more efficient. The amendments to the original January 11, 1993 rule became final and effective on July 17, 1995. During the public comment period on the direct final rule and its companion proposed rule, EPA received significant, adverse comments on those amended provisions that related to notifications for periodic relative accuracy test audits. EPA is removing the provisions added in the direct final rule related to notifications. EPA will address the removed provisions in a future final rule. EPA is also extending the public comment period on the removed provisions for 15 days to allow the public to respond to the significant, adverse comments. All other provisions of the direct final rule remain final.

In addition, EPA is publishing technical corrections of typographical and similar inadvertent errors in the final rule, as promulgated May 17, 1995.

DATES: *Effective date:* The effective date of the amended rule provisions and corrections is May 22, 1996.

Comment date: Comments in response to the significant, adverse comments on the direct final rule must be received on or before June 6, 1996.

ADDRESSES: Any written comments in response to the significant, adverse comments on the direct final rule must be identified as being in response to such comments in Docket No. A–94–16 and must be submitted in duplicate to: EPA Air Docket (6102), U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460. The docket is available for public inspection and copying between 8:30 a.m. and 3:30 p.m., Monday through Friday, at the above address. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Margaret Sheppard, Acid Rain Division (6204J), U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, (202) 233–9180.

SUPPLEMENTARY INFORMATION: EPA received significant, adverse comments on certain provisions of the direct final rule amending part 75 from a group of utilities called the Texas Subgroup. These comments were apparently submitted on time, but EPA became aware of this only after the provision became final. After the close of the comment period, the Texas Subgroup submitted a letter, dated November 2, 1995, clarifying its comments. The comments and the November 28, 1995 letter are found in Docket No. A–94–16, items V–D–23 and V–D–24. The Texas Subgroup made significant, adverse comments on the provisions of §§ 75.21(d)and 75.61(a)(5). Therefore, those provisions in the direct final rule are being removed and are considered proposed provisions until EPA takes further comment and addresses the comments in a future final rule.

The Texas Subgroup commented adversely upon the requirements in §§ 75.21(d) and 75.51(a)(5) for notifications of the date on which periodic Relative Accuracy Test Audits (RATAs) will be performed. The direct final provisions require submission of written notification to the Administrator, the appropriate EPA Regional Office, and the applicable State or local air pollution control agency at least 21 days before the scheduled date of a RATA. The date may be rescheduled if written or oral notice is provided to EPA and to the appropriate State or local air quality agency at least seven days before the earlier of the original scheduled date or the new test date. The Texas Subgroup felt that this provision created additional paperwork. In addition, they felt the provisions could force utilities to delay rescheduled RATAs unnecessarily for seven days simply to meet the notification requirement.

In discussions with EPA, the Texas Subgroup suggested that perhaps the provisions are not needed or the provisions could be revised to provide more flexibility in the case where a RATA is rescheduled. Some possibilities that the Texas Subgroup discussed with EPA included: allowing utilities to receive permission from EPA, State and local agency Acid Rain Program contacts to proceed with testing in less than seven days from the date of notification; creating an ''emergency'' notification two days after the new testing date is known, similar