ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[AD-FRL-2722-2]

Retention of the National Ambient Air Quality Standards for Nitrogen Dioxide

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: In 1971 identical primary and secondary standards for NO_2 were set at 0.053 ppm (100 $\mu g/m^3$) as an annual arithmetic average (36 FR 8186). In accordance with section 108 and 109 of the Clean Air Act, EPA has reviewed and revised the criteria upon which the existing primary and secondary nitrogen dioxide (NO_2) national ambient air quality standards (NAAQS) are based. On February 23, 1984, EPA proposed to retain the existing annual average standards and specifically requested comment on whether a separate short-term standard is requisite to protect public health.

This final rule retains the existing annual primary and secondary standards. The decision on the need, if any, for a separate short-term standard is being deferred pending the results from additional research focused on reducing the uncertainties associated with short-term health effects.

EFFECTIVE DATE: This action is effective July 19, 1985.

ADDRESSES: A docket (Number OAQPS 78-9) containing information relating to EPA's review of the NO_2 standards is available for public inspection and copying between 8:00 a.m. and 4:00 p.m. on weekdays at EPA's Central Docket Section, West Tower Lobby, Gallery I, 401 M Street, SW., Washington, D.C. A reasonable fee may be charged for copying.

Availability of Related Information. The final revised Criteria Document, "Air Quality Criteria for Oxides of Nitrogen" (EPA-600/8-82-026F, December 1982; PB-83-163337, $53.50 paper and $11.50 microfiche copy), and the final revised OAQPS Staff Paper, "Review of the National Ambient Air Quality Standards for Nitrogen Oxides: Assessment of Scientific and Technical Information" (EPA-450/5-82-002, August 1982; PB 83-132829, $13.00 paper copy and $4.50 microfiche), are available from: U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161.

A limited number of copies of other documents generated in connection with this standard review, such as the Control Techniques Document, Regulatory Impact Analysis, and Environmental Impact Statement can be obtained from: U.S. Environmental Protection Agency Library (MD-35), Research Triangle Park, N.C. 27711, telephone (919) 541-2777 (FTS 629-2777).

FOR FURTHER INFORMATION CONTACT: Mr. Michael Jones, Strategies and Air Standards Division (MD-12), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711, telephone (919) 541-5531 (FTS 629-5531).

SUPPLEMENTARY INFORMATION:

Background

Legislative Requirements Affecting This Action

Two sections of the Clean Air Act govern the establishment, review, 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 information useful in indicating the kind and extent of all identifiable effects on public health or welfare that may be expected from the presence of the pollutant in the ambient air.

Section 109(a) (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" 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 for an adequate margin of safety, is requisite to protect the public health. The secondary standard, as defined in section 109(b)(2), must specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on the criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. Welfare effects are defined in section 302(h) (42 U.S.C. 7602(h)) to include effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, climate, damage to and deterioration of property, hazards to transportation, and effects on economic values and on personal comfort and well-being.

The courts have held that the requirement for an adequate margin of safety for primary standards is intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It is also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association* v. *EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980), *cert. denied*, 101 S. Ct. 621 (1980); *American Petroleum Institute* v. *Costle*, 665 F.2d 1176, 1177 (D.C. Cir. 1981) *cert. denied*, 102 S. Ct. 1737 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, by selecting primary standards which provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful, but also to prevent lower pollutant levels that he finds pose an unacceptable risk of harm, even if that risk is not precisely identified as to nature or degree.

In weighing such risks for the purpose of providing an adequate margin of safety, EPA has considered such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. Given that the "margin of safety" requirement by definition only comes into play where no conclusive showing of harm exists, such factors, which involve unknown or only partially quantified risks, have their inherent limits as guides to action. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association* v. *EPA, supra*, 647 F.2d at 1161-62.

The courts, however, have set strict limits on the factors EPA may consider in providing an adequate margin of safety. The leading judicial decisions state that the economic and technological feasibility of attaining ambient standards are not to be considered in setting them, even in the context of a margin of safety. *Lead Industries Association* v. *EPA, supra*, 647 F.2d at 1148-1151; *American Petroleum Institute* v. *Costle, supra*, 665 F.2d at 1185, 1190. Such factors may, however, be considered to a degree in the development of State plans to implement the standards.

Section 109(d) of the Act (42 U.S.C. 7409(d)) requires periodic review and, if appropriate, revision of existing criteria and standards. If, in the Administrator's judgment, the Agency's review and revision of criteria make appropriate the

proposal of new or revised standards, such standards are to be revised and promulgated in accordance with section 109(b). Alternatively, the Administrator may find that revision of the standards is inappropriate and conclude the review by reaffirming them. The process by which EPA has reviewed the original criteria and standards for nitrogen oxides under section 109(d) is described in a later section of this notice. In addition, section 109(c) specifically requires the Administrator to promulgate a primary standard for NO_2 with an averaging time of not more than 3 hours unless he or she finds no significant evidence that such a short-term standard is required to protect public health.

States are primarily responsible for assuring attainment and maintenance of ambient air quality standards. Under section 110 of the Act (42 U.S.C. 7410), States are to submit to EPA for approval State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants included. Other federal programs provide for nationwide reductions in emissions of these and other air pollutants through the federal motor vehicle control program, which involves controls for automobile, truck, bus, motorcycle, and aircraft emissions under Title II of the Act (42 U.S.C. 7501 to 7534), and through the development of new source performance standards for various categories of stationary sources under section 111 (42 U.S.C. 7411).

Nitrogen Oxides and Existing Standards for NO_2

A variety of nitrogen oxide (NO_x) compounds and their transformation products occur naturally and as a result of human activities, Nitric oxide (NO), nitrogen dioxide (NO_2), gaseous nitric acid (HNO_3), in addition to nitrite aerosols, have all been found in the ambient air. The formation of nitrosamines in the atmosphere by reaction of NO_x with amines has been suggested, but not yet convincingly demonstrated.

Despite considerable scientific research on the potential health and welfare effects of NO_x compounds, there exists little evidence linking specific health or welfare effects to near-ambient concentrations of most of these substances. The one significant exception is NO_2. Therefore, EPA has focused its review primarily on the health and welfare effects that have been reported to be associated with exposure to NO_2.

NO_2 is an air pollutant generated by the oxidation of NO which is emitted from a variety of mobile and stationary sources. At elevated concentrations, NO_2 can adversely affect human health, vegetation, materials, and visibility. NO_x compounds may also contribute to increased rates of acidic deposition. Typical long-term ambient concentrations of NO_2 range from 0.001 ppm in isolated rural areas to a maximum annual concentration of approximately 0.08 ppm in one of the nation's most populated urban areas. The origins, concentrations, and potential effects of NO_2 are discussed in more detail in the OAQPS Staff Paper (SP, EPA, 1982a) and in the revised Criteria Document (CD, EPA, 1982b).

On April 30, 1971, EPA promulgated NAAQS for NO_2 under section 109 of the Clean Air Act (36 FR 8186). Identical primary and secondary standards for NO_2 were set at 0.053 ppm (100 $\mu g/m^3$), averaged over one year. The scientific and medical bases for these standards are contained in the original criteria document, "Air Quality Criteria for Nitrogen Oxides" (EPA, 1971). The primary standard set in 1971 was based largely on a group of epidemiology studies (Shy et al., 1970a; Shy et al., 1970b; and Pearlman et al., 1971) conducted in Chattanooga which reported respiratory effects in children exposed to low-level NO_2 concentrations over a long-term period. Reevaluation of the Chattanooga studies based on later information (especially regarding the accuracy of the air quality monitoring method for NO_2 used in the studies) indicates that these studies provide only limited qualitative evidence for an association between health effects and ambient exposures to NO_2.

Development of Revised Air Quality Criteria for NO_x

As required by the Clean Air Act Amendments of 1977, EPA has been reviewing the need for new or revised NO_2 standards since September 1977. In addition to reviewing the existing annual NO_2 standard, the Administrator is required to promulgate a short-term (less than 3 hours) NO_2 primary standard unless he or she finds that there is no significant evidence that such a standard is required to protect public health. On December 12, 1978 (43 FR 58117), EPA announced that it was in the process of reviewing and updating the original criteria document for nitrogen oxides in accordance with section 109(d)(1) of the Clean Air Act. In developing the revised criteria document, EPA has provided a number of opportunities for review and comment by organizations and individuals outside the Agency. Three drafts of the revised NO_x criteria document, prepared by EPA's Environmental Criteria and Assessment Office (ECAO), have been made available for external review. EPA has received and considered numerous and often extensive comments on each of these drafts. The Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board has held two public meetings (January 30, 1979 and November 13–14, 1980) to review successive drafts of the document, "Air Quality Criteria for Oxides of Nitrogen" (Criteria Document). These meetings were open to the public and were attended by many individuals and representatives of organizations who provided critical reviews and new information for consideration. Transcripts of the two CASAC meetings are in the docket.

In accordance with its established procedures, CASAC prepared a "closure" letter that the Administrator dated June 19, 1981 (Friedlander, 1981). The closure letter stated that the revised Criteria Document presented a balanced and comprehensive critical review of the pertinent literature on human health effects and that the document accurately reflected the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare from NO_x in the ambient air.

A number of scientific and technical issues were raised during the public review of the scientific criteria. The major issues included: (1) The extent to which controlled human exposure studies suggest that asthmatics may experience respiratory effects due to short-term NO_2 exposures, (2) the implications of studies of indoor air pollution suggesting that, in some instances, an increased prevalence of acute respiratory illness in young children and small pulmonary function changes in school age children may be associated with elevated NO_2 levels produced in homes which use gas stoves for cooking, and (3) the implications of various animal studies reporting serious respiratory system effects associated with both long-term and short-term exposures to NO_2 levels higher than those generally observed in the ambient air. A summary of these and other major scientific issues is presented in the proposal notice (49 FR 6866). EPA's responses to public comments on the drafts of the Criteria Document are in the docket.

Review of the Standards: Development of OAQPS Staff Paper

In the fall of 1980, EPA's Office of Air Quality Planning and Standards

(OAQPS) prepared the first draft of a staff paper, "Review of the National Ambient Air Quality Standards for Nitrogen Dioxide: Assessment of Scientific and Technical Information (OAQPS Staff Paper)." This draft staff paper evaluated the available scientific and technical information most revelant to the review of the air quality standards for NO_2 and presented staff recommendations on alternative approaches to revising the standards, based on the revised Criteria Document. The first draft of the paper was reviewed at two CASAC meetings (November 13–14, 1980 and February 6, 1981) and a revised draft was reviewed at a third CASAC meeting (November 18, 1981). Transcripts of all three CASAC meetings are in the docket.

Following the third CASAC meeting, the staff made some additional revisions in response to comments. EPA released the final OAQPS Staff Paper (EPA, 1982a), after receipt of the formal closure memorandum in July 1982. CASAC's closure memorandum (Friedlander, 1982) states that the OAQPS Staff Paper provides the Administrator with "the kind and amount of technical guidance needed to make any appropriate revisions to the primary and secondary standards" and that the paper provides "a balanced and thorough interpretation of the scientific evidence pertaining to NO_2."

Summary of Public Comments and Agency Responses

Overview of Comments

The following discussion summarizes in general terms the comments received from the public and from Federal and State agencies regarding the current primary and secondary annual standards and the issue of whether a short-term primary standard is needed to protect public health. Many of these comments had previously been made by the public and were reviewed and addressed by EPA and CASAC during public deliberations on drafts of the criteria document and staff paper. Significant comments on all aspects of the NO_2 proposal and Agency responses to these comments are summarized by category later in this section. A more detailed description of individual comments and Agency responses has been placed in the public docket (OAQPS 78–9).

Of the 20 written comments received during the comment period (which closed May 23, 1984) that express some opinion on the annual standard, 15 support EPA's proposal to retain the current 0.053 ppm annual standard, 4 comments favor relaxing the standard and 1 comment favors reaffirming the standard and beginning a new review to consider relaxing the standard. Those supporting retaining the current annual standard include industry groups, several state and local environmental agencies, and an environmental group.

Several comments were received on the need for a separate short-term standard. Of the 20 written comments which express an opinion on the need for a short-term standard, 12 comments oppose setting a short-term standard at this time, 5 comments favor setting a short-term standard, and 3 comments urge EPA to accelerate its research efforts on health effects associated with short-term NO_2 exposures. In addition, one of the commenters, whose first choice was to set a short-term standard, indicated they could support deferring a decision on the need for a short-term standard if EPA undertook a high priority research program over the next 3 years to examine possible short-term NO_2 health effects.

Most of the industry groups and 1 State agency which commented oppose setting a separate short-term standard while three State environmental agencies, 1 environmental group, and 1 health scientist favor setting a separate short-term standard. Two commenters, an environmental group and a public health association, indicate that an acceptable alternative to setting a short-term standard at this time would be for EPA to defer a decision on the need for a separate short-term standard while proceeding with a high priority and focused research program designed to address the uncertainties about effects due to short-term NO_2 exposures. These two commenters also urge the Agency to make a decision on the short-term standard within 3 years.

In regard to the secondary standard, one Federal agency suggested that EPA reevaluate the need for a separate secondary standard to protect vegetation from short-term exposures to NO_2 in light of three studies it provided. One environmental organization urged the Agency to set a separate secondary standard for NO_2 to protect visibility. Four comments endorsed the proposal to retain the current 0.053 ppm secondary annual standard.

Summary of Significant Comments and Agency Responses

Significant comments are summarized and responded to by category below.

I. HEALTH EFFECTS CRITERIA AND SELECTION OF THE PRIMARY STANDARDS

A. Definition of An Adverse Health Effect

Comments: Some comments urged EPA to consider the symptomatic effects observed in some asthmatics in the Kerr et al. (1979) study as adverse health effects; other comments argued that the symptoms reported are mild and reversible and, therefore, should not be considered as adverse health effects and should not be used as a basis for the primary standards.

Agency Response: As indicated in the proposal notice, EPA believes that the subtle effects observed in the Kerr et al. (1979) study are of uncertain health significance. For the primary standard, the Agency is including these effects as part of the uncertain information on health effects it considers in providing an adequate margin of safety. Also, in EPA's judgment, these mild symptomatic effects clearly affect personal comfort and well being which is defined as a "welfare" effect in the Clean Air Act. These effects, therefore, are also being considered in reviewing the current secondary standard.

Comment: Increased sensitivity to a bronchoconstrictor in asthmatics and healthy adults reported in Orehek et al. (1976) and Von Nieding et al. (1977) should be considered an adverse health effect.

Agency Response: EPA concurs with CASAC's conclusion that these studies do not clearly show adverse health effects and that they should only be considered as a factor in providing an adequate margin of safety. This is due to concern about both the validity of the statistical analyses and uncertainty regarding the significance of responses observed in studies that use a bronchoconstrictor. As noted in the Criteria Document (p. 15–20), the statistical approach used in the Orehek et al. (1976) study has been criticized because the comparisons of airway resistance were made in subjects selected not at the time of NO_2 exposure, but after the fact, following exposure to a bronchoconstrictor.

B. Use Of Animal Studies

Comment: EPA should not use the results from animal studies to support the 0.053 ppm anual standard because the data cannot be quantitatively related to health effects in humans.

Agency Response: EPA agrees that the results from the animal studies in question cannot be quantitatively extrapolated to humans at this time.

However, EPA believes it is likely that the types of respiratory effects observed in several animal species also occur in humans, albeit at unknown exposure levels. As in the case with other qualitative evidence, EPA must consider the findings from the animal studies in selecting a primary NO_2 standard that provides an adequate margin of safety.

Comment: EPA should quantitatively extrapolate the findings from animal studies to human effect levels based on the assumption that humans are equally or more sensitive than animals to NO_2.

Agency Response: EPA does not agree that the animal study findings should be quantitatively extrapolated to human effect levels at this time due to the lack of information on (1) the variation of sensitivity to different exposures across species and (2) how the dose to the target organ (uptake of NO_2) varies across species.

C. Controlled Human Exposure Studies

Comments: Some comments cited recent research reports (Linn and Hackney, 1983 and Linn and Hackney, 1984), as showing no effects in exercising healthy adults and asthmatics exposed to 4 ppm No_2. Other comments cited recent studies, most of which are in abstract form only (e.g., Bauer et al., 1984; Kleinman et al., 1983; Ahmed et al., 1982), as showing pulmonary function impairment and increased response to bronchoconstricting agents following short-term exposure to concentrations in the range 0.1 to 0.3 ppm No_2. Also, commenters claimed EPA had not reviewed the most recent studies.

Agency Response: EPA has placed in the docket (OAQPS 78-9, IV-B-1) its review of the controlled human exposure studies and other studies that have become available since completion of the Criteria Document and OAQPS Staff Paper. Based on its review, EPA concludes that the more recent controlled human exposure studies present mixed and conflicting results concerning respiratory effects in asthmatics and normals in the range of 0.1 to 4.0 ppm NO_2. Unfortunately, a more complete scientific assessment of these studies is not possible at this time because many of the studies have yet to be published in the peer-reviewed scientific literature.

D. Community Epidemiology Studies

Comments: The community studies conducted in Chattanooga should be dismissed from consideration due to unreliable ambient monitoring methods and failure to account for potentially confounding variables.

Agency Responses: As indicated in the Criteria Document and OAQPS Staff Paper, EPA agrees that the monitoring methods used in the Chattanooga studies were unreliable and that there is little basis for distinguishing the relative contribution of NO_2 exposures from those of other pollutants present in the study areas. However, EPA believes that these studies still provide limited qualitative evidence of an association between elevated long-term NO_2 exposures and the occurrence of increased acute respiratory illness and lung function impairment. The CASAC concurred with EPA's judgment that the findings of these studies are not inconsistent with the hypothesis that NO_2 in a complex mix with other pollutants in the ambient air adversely affects lung function and contributes to excess respiratory illness in children.

Comments: (a) Other combustion products of gas stoves rather than NO_2 may be responsible for the respiratory effects observed in the indoor community studies.

(b) EPA should rely more heavily on the studies by Mitchell et al. (1974) and Keller et al. (1979), which showed no correlation between living in gas stove homes and rates of various health effects.

(c) More recent analyses by the Harvard Six Cities authors (Ware et al., 1984 and Ferris et al., 1983), as well as other recent studies involving gas stove homes (Melia et al., 1983 and Schenker et al., 1983) have failed to corroborate the effects on respiratory illness and symptoms reported in the indoor community studies cited by EPA in the proposal.

(d) EPA should not use or rely on short-term NO_2 monitoring data from a group of separate studies to estimate NO_2 levels that might have occurred in the residences of the subjects included in the various indoor epidemiological studies.

Agency Responses: (a) The findings from several animal studies support the hypothesis that NO_2 may be the principal agent responsible for effects observed in residents of gas stove homes. As discussed in the OAQPS staff paper and proposal preamble, a variety of animal toxicology studies in different species have demonstrated that NO_2 exposure impairs respiratory defense mechanisms and increases susceptibility to infection. While not ruling out the possible contribution of other gas stove combustion products, the findings from these animal studies do provide a plausible basis for inferring that NO_2 is associated with the respiratory effects reported in some of the studies involving gas stove homes.

(b) As indicated in the Criteria Document, the number of children used in these "negative" studies was approximately a factor of 10 smaller than in both the British and Six-City indoor epidemiology studies which reported an association between prevalence of respiratory illness and gas cooking. The relatively small sample size would tend to lessen the likelihood of these "negative" studies finding statistically significant associations, since the main health effects being investigated appear to be relatively small differences in disease and symptom prevalence rates.

(c) EPA's assessment of the more recent indoor epidemiological studies by the British and Harvard Six City groups indicates somewhat weaker findings of an association between NO_2 and acute respiratory disease in the subjects studied than the original studies conducted by these groups which were cited in the Criteria Document and proposal notice. For example, an estimated odds ratio for respiratory illness before age 2 of 1.23 ($p < 0.01$) previously reported by the Harvard Six-City Study group (Speizer et al., 1980), has been reduced to 1.12 ($p = 0.07$) by the inclusion of additional children enrolled in the study (Ware et al., 1984). This association between residence in a gas stove home and respiratory illness before age 2 is no longer statistically significant. However, the most recent Harvard study (Ware et al., 1984) does confirm the small but statistically significant decreases in lung function in school age children, although there is some evidence that parental education levels may confound this relationship. EPA agrees with the authors of the study who state that a better understanding of the health significance of indoor pollutants such as NO_2 may require more refined measurements of personal exposures. Some other indoor epidemiological studies (most with much smaller statistical power) involving residents of electric and gas stove homes have reported statistically significant increased rates of symptoms and illness in residents of gas stove homes (Comstock et al., 1981; Helsing et al., 1982; Lebowitz et al., 1982), while other studies have failed to find any statistically significant associations (Jones et al., 1982; Melia et al., 1982; Melia et al., 1983). However, none of the recent studies has provided an assessment of short-term NO_2 levels in the residences of the subjects studied.

(d) Since there was little or no short-term NO_2 monitoring data for the residences of the subjects included in the indoor epidemiological studies, EPA

staff felt that an analysis of short-term NO_2 levels in other gas stove homes would provide a rough estimate of the range of exposures that occurred in the residences of the subjects in these epidemiological studies involving gas stove homes. EPA has acknowledged in the OAQPS Staff Paper and proposal preamble the limitations and uncertainties associated with such an approach. EPA agrees that the lack of short-term NO_2 monitoring in the actual residences of the subjects studied decreases the degree of confidence in concluding that an association exists between specific NO_2 levels and effects reported in the various indoor epidemiological studies.

E. Population Groups Most Sensitive to NO_2 Exposures

Comment: EPA's suggestion that young children, asthmatics, chronic bronchitics, and individuals with emphysema or other chronic respiratory diseases are especially sensitive to NO_2 exposures is unjustified.

Agency Response: In EPA's judgment, the scientific evidence from controlled human exposure studies and indoor epidemiological studies indicates that children and asthmatics appear to respond more readily to low-level NO_2 exposures. Although there is no experimental evidence demonstrating that some of the other groups mentioned are more sensitive to NO_2 than healthy adults, EPA believes it is reasonable to include such groups in the potentially high risk category because NO_2 is known to adversely affect the capacity and performance of the respiratory system and many individuals in these groups already have an impaired breathing capacity.

F. Ambient Air Quality Analysis

Comment: EPA has overestimated the number of days when NO_2 hourly levels will exceed 0.15 and 0.30 ppm in areas attaining the current annual NO_2 standard in its ambient air quality analysis (McCurdy and Atherton, 1983) of data collected from 1979 to 1981. EPA's analysis fails to (1) account for positive instrument calibration bias in the colorimetric measurements from 1979 California data, (2) consider positive interferent bias from nitric acid, peroxyacetyl nitrate, and other compounds in the chemiluminescent measurements, and (3) correct for anomalous data.

Agency Response: (1) EPA agrees that the California colorimetric data reported in 1979, only one of the three years of data which was used in the McCurdy and Atherton (1983) analysis, probably reflects a positive calibration bias of approximately 12 percent. (2) EPA also agrees that a positive interferent bias is possible in some of the chemiluminescent measurement data, but that the impact on peak NO_2 measurements is probably very small since the highest levels of the interferent substances (e.g., nitric acid and peroxyacetylnitrate) do not occur at the same time as the highest observed NO_2 levels. (3) EPA also agrees that its data set contained a few anomalous data points that were found during the course of the commenter's indepth analysis of the data set. All of the California and anomalous data were corrected in a recent reanalysis and update of the 1979–1981 study (McCurdy, 1985). Besides correcting for bad data the new analysis also used 1982–1983 air quality information. Results of the two studies are quite similar and EPA thinks that its original conclusion is still valid: in areas where the annual NO_2 average is at or below the current 0.053 ppm standard, days with one-hour concentrations in excess of any specified level (including levels in the range of 0.15 to 0.30 ppm) will be fewer in number than at locations where the 0.053 ppm level is exceeded.

Comment: The frequency of one-hour average NO_2 concentrations exceeding 0.25 ppm in the California South Coast Air Basin is unacceptably high even when the 0.053 ppm annual standard is met.

Agency Response: EPA agrees that a few sites in Southern California appear to have considerably more days with hourly NO_2 levels exceeding 0.25 ppm than indicated by the average or expected number of days exceeding 0.30 ppm reported in EPA's ambient air quality analysis. As stated in the proposal preamble (49 FR 6866), meeting a specified annual average does not assure that a given specified short-term level will not be exceeded (or depending on the level, will not be exceeded many times). However, EPA's air quality analyses (McCurdy and Atherton, 1983; McCurdy, 1985) indicate that in standard metropolitan statistical area (SMSAs) currently attaining the current 0.053 ppm annual standard, 90 percent of the area would be expected to have fewer than 2.0 days with a daily maximum hourly value greater than or equal to 0.20 ppm NO_2.

G. Margin of Safety

Comment: EPA has proposed an annual standard with an inappropriate margin of safety. The margin of safety was criticized as being either inadequate or too great.

Agency Response: The Clean Air Act requires that EPA set air quality standards that are requisite to protect the public health, allowing an adequate margin of safety. The legislative history of the Act makes it clear that the standards must protect against both certain and uncertain harms. The decision regarding an adequate margin of safety is a judgment which must be made by the Administrator after weighing all the medical evidence bearing on the effects of NO_2. The factors to be taken into account in setting a standard which provides an adequate margin of safety include inconclusive evidence as well as findings from studies that are considered definitive and not subject to challenge. For reasons discussed later in this notice, EPA has concluded that the margin of safety provided by the current annual standard is appropriate.

H. Short-term Primary Standard

Comment: Some commenters argued that the available scientific evidence suggests that short-term exposures at ambient levels pose little or no health risk and that EPA should conclude that no short-term standard is required. Other commenters stated that the scientific evidence strongly supported the occurrence of health effects due to short-term ambient NO_2 exposure and that EPA either should set a short-term standard now or should make a decision based on results from an accelerated research program to reduce the uncertainties about short-term effects. It was also suggested that EPA hold a public meeting to receive feedback on its research plans with respect to NO_2 health effects.

Agency Response: As discussed later in this notice, both EPA and CASAC have concluded that there is insufficient scientific evidence to support decisions on a short-term standard level, averaging time, and number of allowable exceedances which would be required to propose a separate short-term standard. At the same time, the possibility of adverse health effects at ambient short-term NO_2 levels cannot be ruled out. Given the large scientific uncertainties, the Administrator has concluded that it would be prudent to defer a decision on the need for a short-term primary standard until EPA has the results of a focused research program designed to resolve or reduce some of the major uncertainties over whether short-term NO_2 exposures at ambient levels adversely affect public health. In response to the comments received on the NO_2 proposal, EPA's Office of Health and Research held a public meeting on November 2, 1984 to review a proposed research plan for studying

the health effects of NO_2 (49 FR 40097). A copy of the research plan and a transcript of the meeting have been placed in the public docket (Number OAQPS 78-9).

II. WELFARE EFFECTS CRITERIA AND SELECTION OF THE SECONDARY STANDARD

A. Vegetation Effects

Comment: EPA should evaluate the findings of four studies (Ashenden and Mansfield, 1978; Ashenden, 1979; Taylor and Eaton, 1966; Elkiey and Ormrod, 1980) reporting effects of NO_2 on vegetation and determine whether the annual secondary standard of 0.053 ppm is sufficient to protect vegetation from short-term exposure to NO_2.

Agency Response: EPA has evaluated the four studies. Three of them are in the Criteria Document and support the conclusion in the OAQPS Staff Paper that the bulk of the data do not suggest significant effects of NO_2 on vegetation at or below current ambient levels and that an annual standard of 0.053 ppm provides sufficient protection against significant effects on vegetation. The fourth study, (Elkiey and Ormrod, 1980) published after the Criteria Document, concludes that NO_2 alone has no significant effects on leaf injury or area of turfgrass.

B. Visibility

Comment: The Clean Air Act instructs EPA to establish secondary standards to protect public welfare from any known or anticipated adverse effects, applying the same precautionary approach as in setting the primary standard. Since NO_2 affects visibility, the Agency must set a secondary standard to protect visibility.

Agency Response: Although NO_2 may play a role in atmospheric discoloration under precise laboratory conditions (in the absence of atmospheric aerosols), the brown color often ascribed to NO_2 can also result from light scattering by particles. Until the responsible agent can be identified and a quantitative relationship established between NO_2 concentration at a given point and visibility impairment due to a plume or regional haze, EPA and the CASAC question the appropriateness of a separate secondary standard for NO_2 to protect visibility and for reasons discussed later in this notice, EPA has concluded that it is not warranted at this time.

III. MISCELLANEOUS

A. Form of the Annual Standard

Comment: Some comments support the current use of the highest annual arithmetic average, while others recommend that the annual standard should be changed to a statistical form which would base attainment decisions on the average of the annual average over a three year period. Those supporting retention of the current form of the standard argue that the rationale for changing to a statistical form is less compelling because there is much less variation in meteorological conditions for annual averages than for short-term averages. They also state that a change to an average of the annual averages over a three year period would be a relaxation of the current standard unless the standard level is suitably adjusted downward. Those recommending a change to the statistical form for the annual standard argue that it would improve stability and statistical confidence in the assessment of attainment.

Agency Response: Based on his decision to maintain the level of protection provided by the current annual standards, the Administrator concludes that it would be unwise at this time to change the form of the standards to a statistical one. Although such an approach could represent a modest technical improvement, its adoption would necessitate consideration of a lower standard level or the acceptance of a reduced degree of protection. This could ultimately require revisions to ongoing State programs for attaining and maintaining the standards. In the judgment of the Administrator, the disadvantages of changing the form of the standard outweigh any potential technical improvements at this time.

Review of Primary Standard

The current primary NAAQS for NO_2 is 0.053 ppm (100 $\mu g/m^3$), averaged over one year. As indicated above, the Act requires review of the existing criteria and ambient air quality standards for NO_2 and other pollutants every five years. In addition section 109(c) specifically requires the Administrator to promulgate a primary standard for NO_2 with an averaging time of not more than 3 hours unless he or she finds no significant evidence that such a short-term standard is required to protect public health. During the current standard review for NO_2, EPA has considered whether it should retain or revise the current annual NO_2 standards and has considered the issue of whether a separate short-term standard is needed. With regard to the short-term standard, EPA has considered the following options: (1) Proposing to set a new short-term primary standard, (2) concluding that no short-term primary standard is needed at this time, and (3) deferring a decision on whether a short-term standard is needed pending results from additional scientific research.

For the reasons detailed in the proposal preamble (49 FR 6866) and below, EPA has concluded that the current 0.053 ppm annual average standards adequately protect against adverse health and welfare effects associated with long-term exposures and provide some measure of protection against possible short-term health and welfare effects. EPA is continuing to evaluate the evidence bearing on whether a separate short-term standard is requisite to protect public health and is increasing its research efforts on short-term effects. Consequently, EPA is not proposing to set a separate short-term standard at this time.

As indicated above, section 109(b)(1) of the Clean Air Act requires EPA to set primary standards, based on the air quality criteria and allowing an adequate margin of safety which, in the Administrator's judgment, are requisite to protect the public health. The legislative history of the Act makes clear the Congressional intent to protect sensitive persons who in the normal course of daily activity are exposed to the ambient environment. Air quality standards are to be established with reference to protecting the health of a representative, statistically related, sample of persons comprising the sensitive group rather than a single person in such group.

EPA's objective, therefore, is to determine whether new or revised primary standards are required, based on the existing scientific evidence, assessment of the uncertainties in this evidence, and a reasonable provision for scientific and medical knowledge yet to be acquired, as as to protect sensitive population groups with an adequate margin of safety. As for other ambient standard pollutants, none of the evidence presented in the Criteria Document shows a clear threshold of adverse health effects for NO_2. Rather, there is a continuum, ranging from NO_2 levels at which health effects are undisputed, through levels at which many, but not all scientists generally agree that health effects have been convincingly shown, down to levels at which the indications of health effects are less certain and more difficult to identify. This does not necessarily mean that there is no threshold, other than zero, for NO_2 related health effects; it simply means no precise threshold can be identified with certainty based on existing medical evidence. Thus, the standard-setting decision cannot involve appending an exact margin of safety to a known threshold effect level. Rather, it

involves a public health policy judgment that must take into account both the known continuum of effect as well as gaps and uncertainties in the existing scientific evidence.

In reviewing the need for any new or revised primary NO_2 standards, EPA must make assessments and judgments in the following areas:

1. Identification of reported effect levels and associated averaging times that medical research has linked to health effects in healthy and sensitive persons.

2. Characterization of scientific uncertainties with regard to the health effects evidence and judgments concerning which effects are important to consider in reviewing or setting primary standards.

3. Description of population groups believed to be most sensitive to NO_2 and estimates of the size of those groups.

4. Consideration of NO_2 standard levels and averaging times that provide an adequate margin of safety based on NO_2 levels and exposure periods that may affect sensitive population groups, taking into account the various uncertainties.

Based on the assessment of relevant scientific and technical information in the Criteria Document, the OAQPS Staff Paper outlines a number of key factors to be considered in each of the above areas. Both the staff and CASAC made recommendations to focus consideration on a discrete range of policy options in each area. In most respects, the Administrator has adopted the recommendations and supporting reasons contained in the OAQPS Staff Paper and the CASAC closure letters (Friedlander, 1982; Lippmann, 1984). Rather than reiterating those discussions at length, the following discussion of the final standard focuses primarily on those considerations that were most influential in the Administrator's selection of a particular option, or that differ in some respect from considerations that influenced the staff and/or CASAC recommendations.

Assessment of Health Effects Evidence

The OAQPS Staff Paper, which has been placed in the public docket (Docket No. OAQPS 78-9, II-A-7), presents a detailed and comprehensive assessment by EPA staff of the key health effect studies contained in the Criteria Document and other critical scientific issues relevant to the review of the existing annual NO_2 standard and the need, if any, for a separate short-term (less than 3 hours) NO_2 standard. This assessment is summarized in the proposed preamble (49 FR 6866).

A variety of respiratory system effects have been reported to be associated with exposure to short- and long-term NO_2 concentrations less than 2.0 ppm in humans and animals. The most frequent and significant NO_2-induced respiratory effects reported in the scientific literature at the time the Criteria Document and OAQPS Staff Paper were published include: (1) Altered lung function and symptomatic effects observed in controlled human exposure studies and in community epidemiological studies, (2) increased prevalence of acute respiratory illness and symptoms observed in outdoor community epidemiological studies and in indoor community epidemiological studies comparing residents of gas and electric stove homes, and (3) lung tissue damage, development of emphysema-like lesions in the lung, and increased susceptibility to infection observed in animal toxicology studies. As the Criteria Document concludes, results from these several kinds of studies collectively provide evidence indicating that certain human health effects may occur as a result of exposures to NO_2 concentrations at or approaching recorded ambient NO_2 levels.

At the time of proposal, based on controlled human exposure studies, EPA concluded that human pulmonary function effects of clear health concern resulting from single, short-term exposures of less than 3 hours duration have been unambiguously demonstrated only at concentrations (greater than 1.0 ppm) well in excess of ambient exposure levels typically encountered by the public. More subtle health effects that were of uncertain health significance, such as mild symptomatic effects, had been reported for some asthmatics after a single 2-hour exposure to 0.5 ppm.

The principal evidence reviewed in the OAQPS Staff Paper and proposal on the effects of repeated short-term exposures came from a series of cross-sectional epidemiological (community) studies, some ongoing, which reported increased prevalence of acute respiratory illness and impaired lung function in children living in homes with gas stoves (a source of NO_2) as compared to children living in electric stove homes. Findings from several animal studies demonstrating reduced resistance to infection due to NO_2 exposures support the belief that NO_2 exposures are probably related to the effects observed in these indoor epidemiological studies. A limitation of these studies with respect to setting an NO_2 NAAQS is that the investigators did not measure short-term NO_2 concentrations in the homes of the subjects in the indoor epidemiology studies. Based on NO_2 monitoring data from other gas stove homes, EPA staff estimated that the health effects observed in gas stove homes, if due to NO_2 exposure, were likely to be associated with frequent, repeated short-term peak exposures to NO_2 levels ranging up to 0.5 to 1.0 ppm and possibly as low as 0.15 to 0.30 ppm.

Findings from several animal studies, such as development of emphysema-like lesions and increased susceptibility to infection, indicated at the time of proposal that long-term exposures to elevated NO_2 concentrations can lead to serious adverse health effects in animals. A major limitation in making quantitative use of these studies was the lack of satisfactory methods for directly extrapolating the results to effect levels in humans.

Since proposal, EPA's ECAO has reviewed the scientific studies that have become available since CASAC closure on the Criteria Document and OAQPS Staff Paper and that were identified by EPA staff and/or in public comments on the NO_2 proposal. This review was submitted to the CASAC and was discussed at a meeting held on July 19-20, 1984; a revised document reflecting CASAC and public comments has been placed in the public docket (OAQPS 78-9, IV-B-1). It should be noted that a more complete scientific assessment of these studies is not possible at this time because many of the studies have yet to be published in the peer-reviewed scientific literature or appear only as abstracts. The principal points from ECAO's review of the new studies are summarized below.

(1) The more recent controlled human exposure studies (most of which are presently in unpublished form) present mixed and conflicting results concerning respiratory effects in asthmatics and healthy individuals at concentrations in the range of 0.1 to 4.0 ppm NO_2. Some new studies have reported an increased effect on airway resistance or lung function when challenged by a bronchoconstricting agent and NO_2 (Ahmed et al., 1982; Kleinman et al., 1983; Bauer et al., 1984) while other recent studies have reported no statistically significant effects from NO_2 alone or with a bronchoconstricting agent (Hazucha et al., 1983; Ahmed et al., 1983). It is not possible, at this time, to evaluate the reasons for these mixed results. Only Kagawa and Tsuru (1979) have reported results possibly suggestive of short-term NO_2 effects on pulmonary function without combined provocative challenge by other agents (e.g., carbachol or cold air) for a group of 6 subjects exposed to 0.15 ppm NO_2.

However, the small size of the decrements reported (all less than 5 percent) in conjunction with questions regarding the statistical analyses used suggest caution in accepting the reported findings as demonstrating NO_2 effects on pulmonary function at 0.15 ppm, especially in view of the lack of confirmatory findings by other investigators at that exposure level.

(2) The most recent indoor epidemiological studies by the British and Harvard groups indicate somewhat weaker findings of an association between NO_2 and respiratory effects than the original studies conducted by these groups cited in Criteria Document and proposal notice. For example, an estimated odds ratio for respiratory illness before age 2 of 1.23 ($p < 0.01$) previously reported by the Harvard group (Speizer et al., 1980), has been reduced to 1.12 ($p=.07$) by the inclusion in the statistical analyses of data from additional children enrolled in the study (Ware et al., 1984). The association between residence in a gas stove home and respiratory illness before age 2 is, therefore, no longer statistically significant. Nonetheless, the Ware et al. study continued to find small statistically significant decreases in pulmonary function when the data for this large sample of children were analyzed.

The associations between use of gas stoves and increased respiratory illness before age 2 and the use of gas stoves and decreases in lung function levels in school age children were both reduced when the Harvard group controlled for parental education (Ware et al., 1984). More specifically, when an adjustment for parental education was included in the analysis, the odds ratio for respiratory illness before age 2 was reduced further to 1.11 ($p=0.14$) and the decreases in lung function were 30 percent smaller and no longer statistically significant. Because level of parental education is negatively associated with the use of gas stoves and positively associated with respiratory illness and lung function level, the authors state that the adjustment for parental education "may represent confounding but may also represent overadjustment for a surrogate for gas stove use" (Ware et al., 1984).

Some other indoor epidemiological studies (with much smaller statistical power) involving electric and gas stove homes have reported statistically significant increased rates of symptoms and illness in residents of gas stove homes (Comstock et al., 1981; Helsing et al., 1982; Lebowitz et al., 1982), while other studies have failed to find any statistically significant associations with gas stove usage (Jones et al., 1982; Melia et al., 1982; Melia et al., 1983). Unfortunately, none of the recent studies has provided an assessment of short-term NO_2 levels in the residences of the subjects evaluated. Overall, then, the newly available data from indoor epidemiological studies do not appear to resolve the mixed results reported in earlier studies.

(3) The results from the more recent animal studies further substantiate the NO_2 effects on immune function and increased susceptibility to infection. However, the lack of an acceptable method at this time for quantitative extrapolation of the animal data to man greatly limits their usefulness beyond providing qualitative support for analogous effects plausibly being associated with repeated, short-term high-level and chronic exposure to NO_2.

Population Groups Most Sensitive to NO_2 Exposures

As discussed in the proposal preamble (49 FR 6866), in EPA's judgment, the available health effects data presented in the Criteria Document identify young children and asthmatics as the groups at greatest risk from ambient NO_2 exposures. EPA believes that chronic bronchitics and individuals with emphysema or other chronic respiratory diseases may also be sensitive to NO_2 exposures. In addition, based on the findings from animal studies showing increased hematological, hormonal and other systemic alterations after exposure to NO_2, there is reason to believe that persons with cirrhosis of the liver or other liver, hormonal, and blood disorders, or persons undergoing certain types of drug therapies may also be more sensitive to NO_2. Due to the lack of human experimental data for these latter groups, however, EPA is considering the potential effects on such persons only as a factor in providing an adequate margin of safety.

The U.S. Bureau of the Census (U.S. DOC, 1973) estimated that the total number of children under five years of age in 1970 was 17,163,000 and the number between five and thirteen years was 36,575,000. Data from the U.S. National Health Survey (U.S. DHEW, 1973) for 1970 indicate that there were 6,526,000 chronic bronchitics, 6,031,000 asthmatics, and 1,313,000 emphysematics at the time of the Survey. Although there is overlap on the order of about one million persons for these last three categories, it is estimated that over twelve million persons experienced these chronic respiratory conditions in the U.S. in 1970.

Margin of Safety Considerations

Selecting an ambient air quality standard with an adequate margin of safety requires that uncertainties in the health effects evidence be considered in arriving at the standard. While the lowest NO_2 concentrations reliably linked to identifiable health effects due to single or repeated peak exposures appear to be in the range of 0.5–1.6 ppm NO_2 (based on symptomatic effects (Kerr et al., 1979) and pulmonary function impairment (Suzuki and Ishikawa, 1965 and Von Nieding et al., 1971)), a clear threshold for adverse health effects has not been established. Several factors make it impossible at present to identify the minimum NO_2 level associated with adverse health effects with any confidence.

As discussed in the proposal preamble, clinical investigators have generally excluded from studies for ethical reasons individuals who may be very sensitive to NO_2 exposures, such as children, elderly individuals, and people with severe pre-existing respiratory diseases (including severe asthma). In addition, human susceptibility to health effects varies considerably among individuals. Thus, it is not certain that the available experimental evidence for NO_2 has accounted for the full range of effects and human susceptibility. Finally, there is no assurance that all adverse health effects related to low level NO_2 exposures have been identified.

Factors that have been considered in assessing whether the current NO_2 standard provides an adequate margin of safety include: (1) Concern for potentially sensitive populations that have not been adequately tested, (2) concern for the effects of repeated peak exposures and delayed effects seen in animal studies but not yet examined in controlled human exposure studies, (3) implications of the Orehek et al. (1976) study and similar studies in which bronchoconstrictors were used, (4) possible synergistic or additive effects between NO_2 and other pollutants or environmental stresses, and (5) uncertainty about the NO_2 levels and duration of exposures associated with effects reported in the "gas stove" studies.

Determinations Concerning the Averaging Time and Standard Level

As discussed previously, EPA is required both to review the adequacy of the existing 0.053 ppm annual NO_2 standard and to determine whether a

short-term (less than 3 hours) NO_2 standard is required to protect public health. Although the scientific literature supports the conclusion that NO_2 does pose a risk to human health, there is no single study or group of studies that clearly defines human exposure-response relationships at or near current ambient NO_2 levels. This situation exists because of both methodological limitations of health effects research and the lack of sufficient studies involving population groups suspected of being particularly sensitive to NO_2. Based on the review of the health effects evidence presented in the Criteria Document, however, both EPA and the CASAC have concluded that the studies reviewed in that document and the OAQPS Staff Paper have demonstrated the occurrence of health effects resulting from both short-term and long-term NO_2 exposures. As discussed below, EPA is unable to specify at this time the lowest level at which adverse health effects are believed to occur in humans due to either short- or long-term NO_2 exposures of uncertainties in the health effects data base.

Annual Standard

In reviewing the scientific basis for an annual standard, EPA finds that the evidence showing the most serious health effects associated with chronic NO_2 exposures (e.g., emphysematous-like alterations in the lung and increased susceptibility to infection) comes from animal studies conducted at concentrations well above those permitted in the ambient air by the current annual standard. The major limitation of these studies for standard-setting purposes is that currently there is no satisfactory method for quantitatively extrapolating exposure-response results from these animal studies directly to humans. However, the seriousness of these effects coupled with the biological similarities between humans and test animals suggests that there is some risk to human health from long-term exposure to elevated NO_2 levels.

Other evidence suggesting health effects related to long-term, low-level exposures, such as the community epidemiology and gas stove community studies, provides some qualitative support for concluding that there is a relationship between long-term human exposure to near-ambient levels of NO_2 and adverse health effects. However, various limitations in these studies (e.g., unreliable or insufficient monitoring data and inadequate treatment of potential confounding factors such as humidity and pollutants other than NO_2) preclude derivation of quantitative dose-response relationships.

Given the uncertainty associated with the extrapolation from animal to man, the seriousness of the observed effects, and the inability to determine from the available data an effects level for humans, EPA believes it would be prudent public health policy to maintain the current annual standard of 0.053 ppm. As discussed in the proposal notice, EPA is also concerned that any relaxation of the current annual standard would allow a rise in the frequency and severity of short-term ambient NO_2 concentrations. The results of EPA's analysis of short-term ambient concentrations in areas that meet the current 0.053 ppm annual standard and alternative annual standards in the range 0.05 to 0.08 ppm are discussed in more detail in McCurdy and Atherton (1983), McCurdy (1985), and proposal preamble (49 FR 6873). Despite the lack of a firm relationship between various averaging times, it was observed that where the annual average is at or below the current 0.053 ppm standard, days with one-hour concentrations in excess of any specified level (including levels in the range 0.15 to 0.30 ppm) tend to be fewer in number than at locations where the current annual standard is exceeded.

While it is not possible currently to quantify the margin of safety provided by the existing annual standard, two observations are relevant: (1) A 0.053 ppm standard is consistent with CASAC's recommendation (Friedlander, 1982; Lippman, 1984) to set the annual standard at the lower end of the range (0.05 to 0.08 ppm) cited in the OAQPS Staff Paper to ensure an adequate margin of safety against long-term effects and provide some measure of protection against possible short-term health effects, and (2) a 0.053 ppm standard would keep annual NO_2 concentrations considerably below the long-term levels for which serious chronic effects have been observed in animals. Maintaining the current annual primary standard is a prudent public health policy choice that will prevent any increased chronic health risk in large, populated urban areas that are now attaining the standard. Consequently, the Administrator has determined that retaining the current primary annual standard of 0.053 ppm is both necessary and sufficiently prudent to protect public health against chronic effects with an adequate margin of safety and provides some measure of protection against possible short-term health effects.

Need for a Short-Term Standard

As stated earlier in this notice, section 109(c) of the Clean Air Act specifically requires the Administrator to promulgate a primary NO_2 standard with an averaging time of not more than 3 hours unless he or she finds no significant evidence that such a short-term standard is required to protect public health. In conjunction with the review of the annual standard, EPA also has carefully examined the health effects data base to determine whether a separate short-term standard is required to protect public health. As discussed in more detail in the OAQPS Staff Paper and proposal preamble, there are considerable uncertainties about whether short-term (less than 3 hours) exposures to NO_2 at levels observed in the ambient air cause any adverse health effects in humans. Citing these uncertainties, EPA did not propose to set a separate short-term standard and solicited public comment on the need, if any, for such a standard (49 FR 6866). EPA also requested that public comments on this issue identify any scientific or technical evidence that would support any particular standard level and other relevant elements of the standard, such as averaging time, number of exceedances, and form of the standard.

EPA's assessment of the health effects evidence relevant to any decision on the need for a separate short-term standard and EPA's review of scientific studies that have become available since CASAC closure on the Criteria Document and OAQPS Staff Paper have been summarized earlier in this notice in the section, Assessment of Health Effects Evidence. More detailed information about EPA's assessment of the scientific evidence pertinent to the short-term standard issue can be found in the Criteria Document, OAQPS Staff Paper, and ECAO's review of recent studies (OAQPS 78-9, IV-B-1).

Public comments on the proposal generally argued for one of the following three positions: (1) EPA should propose a short-term primary standard, (2) EPA should conclude that no short-term standard is needed at this time, or (3) EPA should defer its decision on whether a separate short-term standard is needed until results are available from a multi-year research program focused on resolving or reducing the uncertainties surrounding the need for a short-term standard. EPA staff discussed these three options and ECAO's review of the newer scientific studies with the CASAC at the public meeting held on July 19-20, 1984. A

transcript of the meeting has been placed in the docket (OAQPS 78-9).

The CASAC, as indicated in its October 18, 1984 letter to the Administrator (Lippmann, 1984), concurred with the EPA staff that the available information was insufficient to provide an adequate scientific basis for decisions on a short-term standard level, averaging time, and number of allowable exceedances which would be required to propose a separate short-term standard. At the same time the CASAC stated that it could not rule out the possibility of adverse health effects at ambient NO_2 levels given the large uncertainties in the scientific data base. CASAC concluded that either of the remaining options, which would not propose to set a short-term standard at this time, were functionally equivalent, i.e., EPA could aggressively pursue scientific research to resolve or reduce the uncertainties about health effects related to short-term NO_2 exposures under either option selected. CASAC recommended that EPA "reaffirm the annual standard at the current level" and that EPA "defer a decision on the short-term standard while pursuing an aggressive research program on short-term effects of NO_2" (Lippmann, 1984).

Given (1) the language on the short-term standard in the Clean Air Act which requires the Administrator to establish a short-term standard unless he or she finds that there is no significant evidence that one is required to protect public health and (2) the large scientific uncertainties remaining about possible short-term effects at ambient NO_2 levels, the Administrator has concluded that it would be prudent to defer a decision on the need for a short-term standard. The Agency is committed to carrying out a focused research program designed to resolve or reduce the major uncertainties associated with the question of whether short-term NO_2 exposures at ambient levels adversely affect public health. In the meantime, the Administrator believes that continued attainment of the current 0.053 ppm annual standard will provide some measure of protection against possible short-term health effects.

Welfare Effects and the Secondary Standard

As indicated above, section 109(b) of the Clean Air Act mandates the setting of secondary NAAQS to protect the public welfare from any known or anticipated adverse effects associated with an air pollutant in the ambient atmosphere. A variety of effects on public welfare have been attributed to NO_2 and NO_x compounds. These effects include increased rates of acidic deposition, symptomatic effects in humans, vegetation effects, materials damage, and visibility impairment. The OAQPS Staff Paper (OAQPS 78-9, II-A-7) describes in detail each of the welfare effects of concern. The following discussion summarizes the welfare-related effects discussed in the OAQPS Staff Paper, and CASAC's comments relating to the secondary NO_2 NAAQS.

The issue of acidic deposition was not directly assessed in the OAQPS Staff Paper because EPA has followed the guidance which was given by CASAC on this subject at it public meeting review of the draft document, "Air Quality Criteria for Particulate Matter and Sulfur Oxides," which was held on August 20-22, 1980. The CASAC concluded that acidic deposition is a topic of extreme scientific complexity because of the difficulty in establishing firm quantitative relationships between emissions of relevant pollutants, formation of acidic wet and dry deposition products, and effects on the terrestrial and aquatic ecosystems. Secondly, acidic deposition involves, at a minimum the criteria pollutants of oxides of sulfur, oxides of nitrogen, and the fine particulate fraction of suspended particulates. Finally, the Committee felt that any document on this subject should address both wet and dry deposition, since dry deposition is believed to account for a least one-half of the total acid deposition problem. For these reasons, the Committee felt that a significantly expanded and separate document should be prepared prior to any consideration of using NAAQS as a regulatory mechanism for control of acidic deposition. CASAC suggested that a discussion of acidic precipitation be included in the criteria documents for both NO_x and particulate matter and sulfur oxides, but that plans also be made for the development of a separate, comprehensive document on acid deposition. In response to these recommendations, EPA is in the process of developing an acidic deposition document that will provide a more comprehensive treatment of this subject.

As defined in section 302(h) of the Act, welfare effects include effects on personal comfort and will being. Mild symptomatic effects were observed in 1 of 7 bronchitics and in 7 of 13 asthmatics during or after exposure to 0.5 ppm NO_2 for 2 hours in the Kerr et al. (1979) study. The authors indicate that the symptoms were mild and reversible and included slight headache, nasal discharge, dizziness, chest tightness and labored breathing during exercise. In EPA's judgment these mild symptomatic effects affect personal comfort and well being and could be considered adverse welfare effects in certain situations. CASAC generally agreed with this judgment, but felt that because short-term peaks associated with these effects are rarely observed in areas where the current annual standard of 0.053 ppm was met, the current annual standard is adequate to protect against these effects.

Evidence in the Criteria Document and information provided by plant physiologist (Heck, 1980; Tingey, 1980a; Tingey, 1980b) have indicated that visible injury to vegetation due NO_2 alone occurs at levels which are above ambient concentrations generally occurring within the U.S., except around a few point sources. Several studies (Korth et al., 1964; Haagan-Smit et al., 1952; Heck, 1964; Taylor et al., 1975; Thompson et al., 1970) on the effects of NO_2 alone on vegetation have failed to show plant injury at concentrations below 2 ppm for short-term exposures. For long-term exposures, such as a growing season, the lowest concentration reported to depress growth is approximately 0.25 ppm (Korth, 1964). The concentrations which produced injury or impaired growth in these studies are higher than those which would be expected to occur in the atmosphere for extended periods of time in areas attaining a 0.053 ppm annual standard.

In regard to vegetation from NO_2 in combination with other pollutants, plant responses to pollutant mixtures appear to vary with concentration, ratio(s) of pollutants, sequence of exposure, and other variables. Studies examining exposure to NO_2 and SO_2 as well as to O_3 and SO_2 (MacDowell and Cole, 1971; Tingey, 1973) have shown that the synergistic response is most pronounced near the threshold doses of the gas combinations tested and that, as concentrations increase beyond the threshold doses, the synergistic response diminishes, often becoming additive, or in some cases, antagonistic. In addition, studies by Ashenden (Ashenden and Mansfield, 1978; Ashenden, 1979; Ashenden and Williams, 1980) have reported growth and yield suppression from combined exposures of SO_2 and NO_2. Although the limited evidence available indicates that low levels of NO_2 and SO_2 can have a synergistic effect, this type of response is extremely variable and has not been sufficiently documented. CASAC concurred with EPA's judgment that the data do not suggest significant effects of NO_2 on vegetation at or below current ambient levels and that an annual standard of 0.053 ppm would provide

sufficient protection against significant effects on vegetation.

In regard to visibility impairment due to NO_2, the scientific evidence indicates that light scattering by particles is generally the primary cause of degraded visual air quality and that aerosol optical effects alone can impart a reddish brown color to a haze layer. Thus while it is clear that both particles and NO_2 contribute to brown haze, the CASAC concurred with EPA's judgment that the relationship between NO_2 concentrations and visibility impairment has not been sufficiently established and that a separate secondary standard to protect visibility is not warranted at this time. CASAC confirmed this judgment at its public meeting held on July 19–20, 1984.

Finally, while NO_2 has been qualitatively associated with materials damage, CASAC concurred with EPA's judgment that the available data do not suggest major effects of NO_2 on materials for concentrations at or below the current annual standard of 0.053 ppm.

Based on an evaluation of symptomatic effects, vegetation damage, visibility impairment, and materials damage, and the levels at which these effects are observed, it is EPA's judgment that the current annual standard provides adequate protection against both long- and short-term welfare effects and that there is no need for a different secondary standard. For these reasons, EPA is retaining the secondary standard at the same level as the primary standard.

Significant Harm Levels

Section 303 of the Clean Air Act authorizes the Administrator to take certain emergency actions if pollution levels in an area constitute "an imminent and substantial endangerment to the health of persons." EPA's regulations governing adoption and submittal of SIP's contain a provision (40 CFR 51.16) that requires the adoption by States of contingency plans to prevent ambient pollutant concentrations from reaching specified significant harm levels. The existing significant harm levels for NO_2 were established in 1971 (36 FR 24002) at the following levels:

2.00 ppm (3750 $\mu g/m^3$)—1-hour average
0.50 ppm (937 $\mu g/m^3$)—24-hour average

On the basis of EPA's reassessment of the earlier data and assessment of more recent scientific evidence, no modifications are being made to the existing significant harm designations. EPA has assessed the medical evidence on exposure to higher NO_2 concentrations that could lead to significant harm. This assessment can be found in Chapter 15 of the Criteria Document. Table 15–3 of the Criteria Document indicates the types and levels of effects reported for exposure to high levels of NO_2.

Regulatory and Environmental Impacts

Regulatory Impact Analysis

Under Executive Order 12291, EPA must judge whether a regulation is a "major" regulation for which a Regulatory Impact Analysis (RIA) is required. The Agency judged the NO_2 NAAQS proposal to be a major action, and, therefore, prepared a draft RIA based on information developed by several EPA contractors (Energy and Environmental Analysis, Inc., 1982 and Resources for the Future, 1982). The draft RIA was made available to the public at the time of proposal. EPA has revised and updated the RIA based on information developed by an EPA contractor (GCA, 1984). The final RIA contains estimates of the projected costs of alternative control strategies associated with attainment of alternative annual standards and the projected number of urban areas exceeding alternative annual standard levels. The final RIA is available from the address given above (see Availability of Related Information section). Neither the draft nor the final RIA or the contractor reports used to develop the RIA have been considered by the Administrator in deciding to retain the existing standards for NO_2.

The draft and final RIA's and the draft Federal Register notice were submitted to the Office of Management and Budget (OME) for review under Executive Order 12291. Any written comments from OMB and any EPA responses to those comments have been placed in the public docket (Docket No. OAQPS 78–9) and are available for public inspection and copying (see Addresses section).

Impact on 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.). EPA's analysis pursuant to this Act is summarized in a section of the report, "Cost and Economic Assessment of Regulatory Alternatives for NO_2 NAAQS" (Energy and Environmental Analysis, Inc., 1982). NAAQS for NO_2 by themselves have no direct impact on small entities; however, they force each State to design and implement control strategies for those areas not in attainment. Three possible sources of impacts on small entities include (1) the federal motor vehicle control program (FMVCP) for cars and trucks, (2) the inspection and maintenance (I&M) program, and (3) the stationary source control program.

FMVCP requirements fall primarily on automobile manufacturers, none of which are classified as small businesses. Additionally, the incremental cost of NO_x control, which is passed on to purchasers of motor vehicles—including small entities—is a small fraction of the purchase price and, thus, the impact to these purchasers should be negligible.

An I&M program for NO_x control may have a slight negative economic impact on small entities, but it may also have a positive economic impact on other small entities. The estimated per vehicle average annual cost for an NO_x I&M program is expected to be between $3.15 and $11.06 depending upon the type of inspection undertaken, whether or not an I&M program is needed for other mobile source pollutants, and the starting time for the program. These cost figures assume an I&M failure rate of 30 percent. These costs should not impose a significant negative economic impact on small entities. On the other hand, some small entities, such as gas stations and garages will be repairing failed vehicles resulting in a net increase in receipts due to an NO_x I&M program. In addition, if a decentralized I&M program is implemented using small businesses to inspect motor vehicles, then their net receipts will also increase due to receipt of the inspection fee, most of which they retain. (The remainder goes to the governmental unit sponsoring the area-wide I&M program.)

Finally, only a few stationary sources of NO_x emissions hypothetically need to implement controls to attain an annual NO_2 standard. These sources, or entities, are the largest facilities within their standard industrial class, which as a class generally contains only "large entities" within the meaning of the Regulatory Flexibility Act.

Based on the analysis summarized above, EPA concludes that no small entity group will be significantly negatively affected due to retention of the 0.053 ppm NO_2 NAAQS. Therefore, pursuant to 5 U.S.C. 605(b) the Administrator certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

Impact on Reporting Requirements

This final rule does not contain any information collection requirements subject to OMB review under the

Paperwork Reduction Act of 1980, 5 U.S.C. 3501 *et seq.*

Revisions to Part 50 Regulations

In retaining the annual NO_2 standards, EPA has made some minor revisions in the Part 50 regulations concerning the NO_2 standards. These include (1) restating the NO_2 primary and secondary standards to improve understanding by the public, (2) explicitly adding a rounding convention to aid in the interpretation of the standards by State and local air pollution control agencies, (3) explicitly stating that annual averages will be determined on a calender year basis, and (4) explicitly indicating data completeness requirements. The first two changes were discussed in the proposal notice and no comments were received from the public. The last two revisions, stating that annual averages will be determined on a calendar year basis and explicitly stating the 75 percent data completeness requirement, are simply more explicit statements of current implementation policy.

Part 51 Regulations and SIP Development

Part D of the Clean Air Act Amendments of 1977 required States to submit revisions to their State implementation plans (SIP's) by January 1, 1979, which provided for attainment of the ambient air quality standards that were not being attained as of the date of those Amendments. Currently, there are several counties in one major metropolitan area (Los Angeles) that are classified in whole or part as being "nonattainment" for NO_2. Since today's action reaffirms the NO_2 ambient standards upon which the 1979 NO_2 SIP's were based, this action will not alter any requirements of those Part D SIP's.

Federal Reference Method

The measurement principle and calibration procedure applicable to reference methods for measuring ambient NO_2 concentrations to determine compliance with the standards are not affected by this final action. The measurement principle and the calibration procedure are set forth in Appendix F of 40 CFR Part 50. Reference methods—as well as equivalent methods—for monitoring NO_2 are designated in accordance with 40 CFR Part 53. A list of all methods designated by EPA as reference or equivalent methods for measuring NO_2 is available from any EPA Regional Office, or from EPA, Department E (MD–76), Research Triangle Park, N.C. 27711.

List of Subjects in 40 CFR Part 50

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

Dated: June 6, 1985.

Lee M. Thomas,

Administrator.

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PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

For the reasons set forth in the preamble, EPA amends Title 40, Chapter I, Part 50 of the Code of Federal Regulations as follows:

1. The authority for Title 40 part 50 is revised as set forth below and the authorities following §§ 50.9 and 50.12 are removed.

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

2. Section 50.11 is revised to read as follows:

§ 50.11 National primary and secondary ambient air quality standards for nitrogen dioxide.

(a) The level of the national primary ambient air quality standard for nitrogen dioxide is 0.053 parts per million (100 micrograms per cubic meter), annual arithmetic mean concentration.

(b) The level of national secondary ambient air quality standard for nitrogen dioxide is 0.053 parts per million (100 micrograms per cubic meter), annual arithmetic mean concentration.

(c) The levels of the standards shall be measured by:

(1) A reference method based on Appendix F and designated in accordance with Part 53 of this Chapter, or

(2) An equivalent method designated in accordance with Part 53 of this Chapter.

(d) The standards are attained when the annual arithmetic mean concentration in a calendar year is less than or equal to 0.053 ppm, rounded to three decimal places (fractional parts equal to or greater than 0.0005 ppm must be rounded up). To demonstrate attainment, an annual mean must be based upon hourly data that are at least 75 percent complete or upon data derived from manual methods that are at least 75 percent complete for the scheduled sampling days in each calendar quarter.

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