

[6560-01-M]

## Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL  
PROTECTION AGENCY

## SUBCHAPTER C—AIR PROGRAMS

[FRL 1018-2]

PART 50—NATIONAL PRIMARY AND  
SECONDARY AMBIENT AIR QUALITY  
STANDARDSRevisions to the National Ambient  
Air Quality Standards for Photo-  
chemical OxidantsAGENCY: Environmental Protection  
Agency.

ACTION: Final rulemaking.

**SUMMARY:** In accordance with the provisions of Sections 108 and 109 of the Clean Air Act as amended, EPA has reviewed and revised the criteria upon which the existing primary and secondary photochemical oxidant standards are based. These standards were promulgated in 1971 (36 FR 8186) and were both set at an hourly average level of 0.08 part per million (ppm) not to be exceeded more than 1 hour per year. On June 22, 1978, EPA proposed changes in the standard (43 FR 26962) based on the findings of the revised criteria. The proposed changes included (1) raising the primary standard to 0.10 ppm, (2) retaining the 0.08 ppm secondary standard, (3) changing the chemical designation of the standard from photochemical oxidants to ozone, and (4) changing to a standard with a statistical rather than deterministic form. The final rulemaking will make three further changes in the standard: (1) Raising the primary standard to 0.12 ppm, (2) raising the secondary standard to 0.12 ppm, and (3) changing the definition of the point at which the standard is attained to "when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than one."

**EFFECTIVE DATE:** This revision is effective immediately upon publication. The normal 30-day delay in effectiveness is not required, when, as in this case, a restriction is eased.

FOR FURTHER INFORMATION  
CONTACT:

Mr. Joseph Padgett, Director (MD-12), Strategies and Air Standards Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, Telephone: 919-541-5204 (FTS 629-5204).

**AVAILABILITY OF RELATED INFORMATION:** A docket (Number OAQPS 78-8) containing information used by EPA in revising the standards is available for public inspection and copying between 8:00 a.m. and 4:30 p.m. Monday through Friday, at EPA's Central Docket Section, Room 2903 Waterside Mall, 401 M Street SW, Washington DC 20460. These materials include the "Air Quality Criteria for Ozone and Other Photochemical Oxidants" and "Control Techniques for Volatile Organic Emissions from Stationary Sources," both of which were issued simultaneously when this standard was proposed. The control techniques document and staff papers pertaining to the form of the ozone standard, risk assessment method, secondary standard, and health panel assessment are available upon request from Mr. Joseph Padgett. Statements of the environmental, economic, and energy impacts of implementing this standard revision are also available upon request from Mr. Joseph Padgett, at the address shown above. The air quality criteria document can be obtained from: Mr. Michael Berry (MD-52), Environmental Criteria and Assessment Office, Office of Research and Development, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, Telephone: 919-541-2266 (FTS 629-2266).

This preamble describes revisions to 40 CFR Part 50, Appendix H, "Interpretation of the National Ambient Air Quality Standards for Ozone," and Appendix D, "Measurement Principle and Calibration Procedure for the Measurement of Photochemical Oxidants Corrected for Interferences Due to Nitrogen Oxides and Sulfur Dioxide," that are related to the revision of the air quality standard for ozone. In addition, elsewhere in this issue of the FEDERAL REGISTER EPA is promulgating revisions to 40 CFR Part 50, Appendix D, replacing (superseding) the current calibration procedure with a new, superior calibration procedure based on ultraviolet photometry.

Revisions to 40 CFR Part 51, substituting the word "ozone" for "photochemical oxidants" throughout that part, and to Section 51.14, pertaining to control strategies, are being promulgated by EPA elsewhere in this issue of the FEDERAL REGISTER.

## SUPPLEMENTARY INFORMATION:

## BACKGROUND

On April 30, 1971, the Environmental Protection Agency promulgated in the FEDERAL REGISTER (36 FR 8186) National Ambient Air Quality Standards for photochemical oxidants. The scientific, technical, and medical bases for these standards are contained in the air quality criteria document for photochemical oxidants, published by

the U.S. Department of Health, Education, and Welfare in March 1970. Both the primary and secondary standards were set at an hourly average level of 0.08 ppm not to be exceeded more than once per year. The asthma study cited as evidence for the original standard is based on work by Schoettlin and Landau (1961). As discussed in the June 22, 1978, proposed revision to the original standard, EPA has reassessed its conclusions regarding this study. This reassessment, plus the evaluation of medical evidence accumulated since 1970, led EPA to propose, on June 22, 1978, a revised primary standard of 0.10 ppm (43 FR 26962). EPA did not propose a change in the secondary welfare standard at that time. The proposal was accompanied by publication of revised criteria and control techniques documents, as well as various staff papers relating to the standard itself and to implementation of the standard. EPA solicited written comments on the proposed standard and, to accept oral testimony, sponsored four public hearings (Washington, D C.—July 18; Atlanta, Ga.—August 17; Dallas, Tex.—August 22; Los Angeles, Calif.—August 24).

Oxidants are strongly oxidizing compounds, which are the primary constituents of photochemical smog. The oxidant found in largest amounts is ozone (O<sub>3</sub>), a very reactive form of oxygen. Oxidants also include the group of compounds referred to collectively as peroxyacylnitrates (PANs) and other compounds, all produced in much smaller quantities than ozone.

Most of these materials are not emitted directly into the atmosphere but result primarily from a series of chemical reactions between oxidant precursors (nitrogen oxides and organic compounds) in the presence of sunlight. The principal sources of organic compounds are the hydrocarbon emissions from automobile and truck exhausts, gasoline vapors, paint solvent evaporation, open burning, dry cleaning fluids, chemical plants and other industrial operations. Nitrogen oxides are emitted primarily from combustion sources such as electric power generation units, gas and oil-fired space heaters, and automobile, diesel and jet engines.

The reductions in emissions of nitrogen oxides and organic compounds are achieved through Federal and State programs that have been formalized in regulations promulgated under the Clean Air Act. The Federal programs provide for reduction in emissions nationwide through the Federal Motor Vehicle Control Program, the Federal program for control of aircraft emissions, National Emission Standards for Hazardous Air Pollutants, and the development of New Source Performance Standards. The State programs

provide for additional control measures through State Implementation Plans in those areas of the country where the Federal programs are not sufficiently stringent to permit attainment of air quality standards.

#### LEGISLATIVE REQUIREMENTS AFFECTING THIS PROMULGATION

Two sections of the Clean Air Act govern the development of a National Ambient Air Quality Standard: Section 108 instructs EPA to document the scientific basis (criteria) for the standard, and Section 109 provides guidance on establishing standards and reviewing the criteria.

Air quality criteria are required by Section 108(a)(2) to reflect accurately 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.

The Administrator is required to propose, simultaneously with the issuance of these criteria, primary and secondary ambient air quality standards based upon such criteria. The primary standard is defined in Section 109(b)(1) as the ambient air quality standard the attainment and maintenance of which in the Administrator's judgment, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. The secondary standard (Section 109(b)(2)) must specify a level the attainment and maintenance of which in the Administrator's judgment, based on such criteria, are requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. These adverse welfare effects, which are discussed in Section 302(h) of the Act, include effects on soils, water, crops, vegetation, man-made materials, animals, weather, visibility, hazards to transportation, economic values, personal comfort and well-being, and other factors.

The Clean Air Act specifies that primary National Ambient Air Quality Standards are to be based on scientific criteria relating to the level that should be attained to protect public health adequately. Considerations of cost of achieving those standards or the existence of technology to bring about needed reductions of emissions are not germane to such a determination, as the words of the Act and its legislative history clearly indicate. Section 109(d) directs the Administrator to complete a review of all existing standards and criteria before the end of 1980 and at 5-year intervals thereafter and to revise them in whatever manner that review reveals is neces-

sary. This promulgation is the result of such a review.

Assuring attainment and maintenance of ambient air quality standards is the responsibility of the States. Under section 110 of the Act, they are to submit to EPA for approval State Implementation Plans (SIPs) that provide for the necessary legal requirements for sources of the relevant pollutant so as to demonstrate attainment and maintenance of the standards by certain deadlines. In many areas of the country the ambient air quality standards are not being attained, despite the fact that the deadline for attainment has long since passed. As a remedy, Part D of the Act requires states with violations of ambient air quality standards to submit revised SIPs to ensure attainment of the standards and to meet certain new requirements of Part D by January 1, 1979. (Section 129(c), Pub. L. 95-95, note under 42 U.S.C. 7502.) The Act does not authorize the Administrator to extend that deadline, and consequently this revision of the photochemical oxidant standard does not affect the deadline for submittal of SIP revisions.

Section 110(a)(1) requires that SIP revisions be submitted within 9 months after a standard is revised. However, this provision refers to situations where a standard is tightened, with the result that existing SIPs are no longer adequate to attain and maintain the standard in question. Where a standard is relaxed, no SIP revision is required by the law, since states may have more stringent controls than necessary if they choose.

Furthermore, the change in the chemical species designation of the standard from photochemical oxidants to ozone does not make this standard subject to the provision of section 110(a)(1) cited above. The intent of the standard (total oxidant reduction), the control strategies, and the index of progress toward attainment (measured ozone levels) remain unchanged.

#### SUMMARY OF GENERAL FINDINGS FROM AIR QUALITY CRITERIA FOR OZONE AND PHOTOCHEMICAL OXIDANTS

On April 20, 1977, EPA announced (42 FR 20493) that it was reviewing and updating the 1970 criteria document for photochemical oxidants in accordance with provisions of section 109(d)(1) of the Clean Air Act as amended. The notice called for information and data that would be helpful in revising the document. In preparing the criteria document, EPA provided a number of opportunities for external review and comment. Two drafts of the document have been made available for external review, and EPA received more than 50 written comments on the first draft and approximately

20 on the second draft. The American Petroleum Institute has submitted extensive information that EPA considered in this standard review. The criteria document was the subject of two meetings of the Subcommittee on Scientific Criteria for Photochemical Oxidants of EPA's Science Advisory Board. Each of these meetings was open to the public, and a number of individuals presented both critical review and new information for EPA's consideration. A full discussion of comments received during the review process, as well as EPA's disposition of these comments, can be found in the docket (OAQPS 78-8) assembled for this rulemaking.

From EPA's review of the scientific information presented in the criteria document, several key areas with particular relevance to setting the ozone standard have emerged:

1. *Threshold concept*—Although the concept of an adverse health effect threshold has utility in setting ambient air quality standards, the adverse health effect threshold concentration cannot be identified with certainty. The lowest concentration which causes measured health effects in a scientific experiment depends on the particular subjects who have been studied because sensitivity to pollutants varies among different members of the population. Only limited studies can be performed on groups of unusually sensitive persons. Most experimental studies of human subjects are performed on small numbers of relatively healthy persons who do not fully reflect the range of human sensitivity. Also, the air to which the subjects are exposed does not include the full mix of chemicals other than the pollutant being studied which are in the ambient air. Some of these chemicals may be additive with the given pollutant in causing the adverse health effect, so that lower levels of the pollutant will result in the effect. Animal exposure studies cannot provide precise models of sensitive human populations. Thus, adverse health effect thresholds for sensitive persons are difficult or impossible to determine experimentally, while the threshold for healthy persons or animals is not likely to be predictive of the response of more sensitive groups. In this notice of rulemaking EPA uses the terminology "probable effects level" to refer to the level that in its best judgment is most likely to be the adverse health effect threshold concentration. It is the fact that the adverse health effect threshold concentration is actually unknown that necessitates the margin of safety required by the Act.

2. *Ozone health effects*—Ozone is a pulmonary irritant that affects the respiratory mucous membranes, other

lung tissues and respiratory functions. Clinical and epidemiological studies have demonstrated that ozone impairs the normal mechanical function of the human lung and causes clinical symptoms such as chest tightness, coughing and wheezing. These effects may occur in sensitive individuals, as well as in healthy exercising persons, at short-term ozone concentrations between 0.15 and 0.25 ppm. The clinical studies data base for these effects is far more extensive than that which was available in 1970, and these effects have now been demonstrated at lower levels than those cited in the 1970 criteria document.

3. *Effects on Asthmatics*—The best available evidence suggests that an elevated proportion of asthmatics experience attacks on days when the peak hourly oxidant concentrations reach about 0.25 ppm. This finding is based on a reevaluation of the study by Schoettlin and Landau (1961).

4. *Toxicologic findings*—The key finding from toxicologic studies is the increased susceptibility to bacterial infection in laboratory animals exposed to 0.10 ppm ozone and a bacterial challenge. Infection rates are lower for animals exposed only to the bacterial challenge. Other effects such as biochemical changes, morphological abnormalities, and genetic changes have been found in some studies of animals exposed to ozone concentrations as low as 0.1 to 0.3 ppm. While the data from animal studies cannot be directly extrapolated to man, they can be taken as indicators of the full range of effects that may occur in humans. The epidemiology study by Durham (1974) that reported increased rates of illness in college students following periods of elevated air pollution levels (with peak oxidant being the pollution variable most strongly associated with illness) further increases our concern regarding the implications for man of the animal study findings.

5. *Ozone effects on aging processes*—A limited amount of data suggests that ozone may accelerate the aging process in living organisms. Exposure of rabbits to unspecified concentrations of ozone for 1 hour per week for a year has been reported to induce premature aging symptoms such as premature cartilage calcification, severe depletion of body fat, and the general signs of aging (Stokinger, 1965).

6. *Pollutant interactions*—The fact that ozone exposure is frequently accompanied by exposure to other pollutants, such as sulfur dioxide (SO<sub>2</sub>), has prompted several investigators to conduct laboratory evaluations of exposure of human subjects to combinations of O<sub>3</sub> and other pollutants. Simultaneous exposures to 0.37 ppm O<sub>3</sub> and 0.37 ppm SO<sub>2</sub> were reported to

produce larger changes in pulmonary function than exposure to either pollutant alone. No obvious effects were observed in other simultaneous exposure tests using 0.25 ppm O<sub>3</sub> and 0.3 ppm nitrogen dioxide (NO<sub>2</sub>), as well as O<sub>3</sub>, NO<sub>2</sub>, and 30 ppm carbon monoxide (CO). Nevertheless, the SO<sub>2</sub>-O<sub>3</sub> synergism findings support the need for an adequate margin of safety in the ozone standard.

7. *Mortality studies*—No studies have conclusively linked exposure to ozone or photochemical oxidants with an increase in human mortality. A number of epidemiologic studies have been designed and conducted to demonstrate this effect, but in each case the results have been negative or inconclusive.

8. *Welfare effects*—Ozone accelerates the aging of many materials, resulting in rubber cracking, dye fading and paint erosion. These effects are linearly related to the total dose of ozone and can occur at very low levels, given long-duration exposures. Damage to vegetation, as expressed by decreased growth and yield, is related to the long-term (growing season) mean of the daily maximum 6- to 8-hour-average ozone concentrations.

9. *Causes and control of oxidant pollution*—All presently available evidence indicates that around urban centers with severe oxidant problems, the major concern is the formation of photochemical oxidants from man-made organic and nitrogen oxide emissions. Control of these emissions will result in significant reductions in ambient ozone, peroxyacetylnitrate (PAN), aldehydes and photochemical aerosol.

As is the case with most standard-setting activities, the data base on ozone will continue to expand after the standard is set. EPA will continue to inform itself of new research results and also will accelerate the schedule for its own research on the health effects of ozone and other photochemical oxidants at low exposure levels. The Agency plans to make the results of these studies available as they are completed and to issue an interim report on all new research results in two years.

#### RULEMAKING PETITIONS

The Agency was petitioned by the American Petroleum Institute (API) and 29 member companies on December 9, 1976, and by the City of Houston on July 11, 1977, to revise the criteria, standards and control strategy guidelines for photochemical oxidants. EPA had already begun such a revision when both petitions were filed, and the Agency responded that it was deferring decision on these petitions until the rulemaking was completed. EPA considers this final rulemaking and the accompanying one on control

strategy guidelines to be the Agency's final action on these petitions. A summary of the two petitions and EPA's response is given below.

The API petition requested that EPA revise the air quality criteria document for photochemical oxidants in light of new information regarding the causes, effects, and extent of air pollution attributed to ozone and other oxidants. EPA has published a revised air quality criteria document for photochemical oxidants; in the Agency's judgment, this document accurately reflects the latest scientific information regarding the causes, effects, and extent of air pollution attributed to ozone and other oxidants.

The second request in the API petition was that EPA establish a national primary ambient air quality standard based on new studies that allegedly demonstrate no significant adverse human health effects at or below ozone levels of 0.25 ppm for 2-hour exposures. As requested by API and as required under the Clean Air Act, the Agency has considered all new studies published since 1971 that are relevant to setting a revised primary standard the attainment and maintenance of which would, in the Administrator's judgment, protect the public health with an adequate margin of safety. EPA disagrees with API's conclusion that new studies conducted since 1971 demonstrate no significant adverse human-health effects at or below 0.25 ppm.

A more detailed discussion of EPA's judgments regarding reported or probable health consequences at concentrations below 0.25 ppm is presented in the rationale for revising the primary standard and in the response to comments, which appear elsewhere in this notice.

The third request by API was that the national secondary ambient air quality standard be based on adverse effects on public welfare as indicated by studies using ozone-specific measurement methods. In addition, API concluded that Congress intended that EPA weigh the overall economic and social impact of a lower secondary standard against adverse effects of a pollutant. EPA has reviewed the data presented in the criteria document and concluded that there is currently no evidence of a significant decrease in yield or growth to commercially important crops for short-term exposures to ozone concentrations below 0.12 ppm. EPA believes a secondary standard more stringent than the primary standard is unnecessary and that a cost-benefit analysis is not required.

In their petitions, both API and Houston requested EPA to state the primary and secondary standards so as to permit reliable assessments of compliance. EPA agrees that the present

deterministic form of the oxidant standard has several limitations and has made reliable assessment of compliance difficult. The revised ozone air quality standards are stated in a statistical form that will more accurately reflect the air quality problems in various regions of the country and allow more reliable assessment of compliance with the standards.

The API and Houston petitions requested that EPA specify the use of an appropriate measurement method for monitoring ambient concentrations of ozone. API suggested the use of ethylene chemiluminescence calibrated by either gas phase titration (GPT) or ultraviolet (UV) photometry. As a result of EPA's continuing evaluation of several calibration techniques, the Agency has defined the reference method to be ethylene chemiluminescence calibrated by UV photometry. (See the amendment to Appendix D of 40 CFR Part 50 elsewhere in this edition of the FEDERAL REGISTER.) EPA is allowing the use of a modified version of the current calibration method (acidified KI) as an interim measure to avoid problems that would result from immediate conversion to UV photometry.

Both the API and Houston petitions requested revision of the State Implementation Plan (SIP) requirements (1) to delete the assumption of no background concentration of photochemical oxidants and (2) to specify more reliable, alternative oxidant prediction relationships to replace Appendix J of 40 CFR Part 51 for determining the degree of necessary precursor emission reductions.

With respect to the first point, EPA recognizes that background concentrations and transport of ozone from upwind locations can contribute to high levels of ozone in or near an urban area during the afternoon hours. Therefore, several revisions are being made in control strategy and implementation guidelines for ozone. The revised guidelines set forth procedures for consideration of both upwind transport and irreducible natural background by the States in calculating the necessary reductions in hydrocarbon emissions. In response to the second request, EPA has determined that Appendix J of 40 CFR Part 51 no longer represents an acceptable analytical relationship between hydrocarbons and ozone. Appendix J is, therefore, being deleted. EPA will now allow States to use any of four analytical techniques to determine the amount of hydrocarbon reduction necessary to demonstrate attainment of the national ozone air quality standards: (1) Photochemical dispersion models, (2) Empirical Kinetics Modeling Approach (EKMA), (3) Empirical and statistical models,

and (4) Proportional rollback. These four techniques are discussed further in the revision of Part 51, which appears elsewhere in this edition of the FEDERAL REGISTER.

The Houston petition requested that EPA consider information in their petition relative to atmospheric conditions and other factors that affect photochemical oxidants in the Houston area. The petition claimed that the air pollution problems in Houston warrant special attention in standard-setting and "tailor-made" control strategies, because the emission and meteorology situations and the overall pollution picture in that area are "unique."

In response to the above claim, it should be noted that the majority of the data presented in the revised criteria document are based on ozone exposure. Nearly all of the clinical and toxicological studies are based on the effects of ozone. The biomedical data also suggest that many of the effects observed during periods of elevated photochemical oxidant concentrations are reasonably attributable primarily to ozone in the ambient air. Since the primary and secondary standards are based on the effects of ozone, the differences between areas in their overall photochemical oxidant mixtures do not bear upon the setting of national ozone air quality standards.

EPA agrees with the Houston petition that components of the photochemical oxidant mixture other than ozone may have an adverse impact on health and/or welfare. The data base is not, however, sufficient at this time to justify a separate standard for PAN or other non-ozone oxidants. While EPA does not propose to establish separate standards for the non-ozone constituents of the mixture at this time, those measures taken to reduce ozone precursor emissions will also reduce PAN and other non-ozone oxidant concentration levels.

In response to Houston's request for a unique standard based on their local situation, it must be realized that the Clean Air Act does not contemplate separate standards for different cities. Dealing in terms of national ambient air quality standards, the Act charges EPA to identify the air quality levels which must be attained and maintained to ensure, with an adequate margin of safety, that adverse health effects will not occur.

The Houston petition also requested that EPA include realistic requirements for the reduction of oxides of nitrogen as conditions in the Houston area may indicate to be necessary to achieve the revised standards. EPA's response is that it is the responsibility of the State of Texas and the City of Houston to submit State Implementation Plan provisions tailored to the sit-

uation prevailing in Houston. If the current SIP is not representative of the most efficient means of reducing ozone in Houston, then, with Houston's assistance, Texas should submit a revision that is consistent with local emission and meteorological conditions.

#### SUMMARY OF COMMENTS RECEIVED

EPA has solicited public comment and critique on proposed revisions to the photochemical oxidant air quality standard during all phases of the standard development process. Prior to proposal (April 20, 1977), EPA announced (42 FR 20493) that it was reviewing and updating the criteria document and called for information that might be helpful in revising the document. Public comments were received on two drafts of the criteria document, and the public was invited to two meetings of the Subcommittee on Scientific Criteria for Photochemical Oxidants of EPA's Science Advisory Board. In addition, the Agency held a public meeting on January 30, 1978, to receive comments from interested parties prior to development of any formal Agency position on the initial proposed revision of the standard. In particular, EPA actively solicited the participation of the State and Territorial Air Pollution Program Administrators (STAPPA) and the Association of Local Air Pollution Control Officials (ALAPCO) in this meeting; several representatives of these groups offered comments at the meeting. The results of this meeting are discussed in the proposed regulation (43 FR 26970) and a transcript of the meeting is available in docket OAQPS 78-8.

Following proposal, EPA held four public meetings to receive comments on the proposed standard revisions. Meetings were held in Washington, D.C.—July 18; Atlanta, Ga.—August 17; Dallas, Tex.—August 22; and Los Angeles, Calif.—August 24; transcripts are available in docket OAQPS 78-8. In addition, 168 written comments were received during the formal comment period, which extended through October 16, 1978.

The principal comments and Agency responses are summarized in the following paragraphs (individual responses to comments are contained in docket OAQPS 78-8). EPA also received comments on the proposed standard after October 16. Although EPA does not have a legal obligation to review these comments, all significant issues raised in the post-October 16 comments have been addressed and responded to as part of the discussion of comments in this preamble. As with all other documents considered or examined by EPA as part of its decision process, these documents have been placed in the public docket and have

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become part of the administrative record of this decision.

The majority of comments received (132 out of 168) opposed EPA's proposed standard revision, favoring either a more relaxed or a more stringent standard. State air pollution control agencies (and STAPPA) generally supported a standard level of 0.12 ppm on the basis of their assessment of an adequate margin of safety. Municipal groups generally supported a standard level of 0.12 ppm or higher, whereas most industrial groups supported a standard level of 0.15 ppm or higher. Environmental groups generally encouraged EPA to retain the 0.08 ppm standard.

Comments on the proposed revisions were received from five Federal agencies. Three of the agencies endorsed the proposed primary standard, but one of these agencies requested that EPA consider formulating the standard on a daily maximum hourly average basis. Another agency expressed concern that EPA had inadequately substantiated the rationale for raising the primary standard level and requested that the final revisions provide further analysis in this regard. Finally, the Executive Office of the President/Council on Wage and Price Stability suggested, through the Regulatory Analysis Review Group, that the proposed standard was unnecessarily stringent, recommending that EPA set the primary standard using an alternative methodology that focuses on the marginal costs per person-hour of ozone effects avoided.

Groups and individuals submitting comments are identified below:

**COMMENTS RECEIVED ENDORSING CURRENT PRIMARY STANDARD LEVEL OF 0.08 PPM**

**ORGANIZATION AND AGENCIES**

- American Lung Association of Colorado
- American Lung Association of Colorado, West Region
- American Lung Association of Louisiana
- American Lung Association of New Jersey
- American Lung Association of New York State, Inc.
- Bangor-Brewer TB and Health Association, Maine
- California Lung Association
- Connecticut State Department of Health
- Environmental Confederation of Southwest Florida
- Environmental Defense Fund
- Ms. Nancy C. Fahden, Supervisor District Two, Contra Costa County (Calif.) Board of Supervisors
- Florida Lung Association
- Greenleaf Nurseries, Warsaw, Indiana
- Issac Walton League, Manasota Chapter
- League of Women Voters of the U.S.
- League of Women Voters of Dallas, Texas
- Maine Health Systems Agency
- Maine Lung Association
- Medford-Ashland Air Quality Maintenance Advisory Committee, Oregon
- Michigan Lung Association

- Michigan Lung Association, Saginaw Valley Region
- National Air Conservation Commission, American Lung Association
- Natural Resources Advisory Committee, Cedar Grove, N.J.
- Natural Resources Defense Council
- New Mexico Lung Association
- Oregon Environmental Council
- Oregon Lung Association
- Queensboro Lung Association, Jamaica, N.Y.
- Sierra Club
- Sierra Club, Houston Chapter
- South Shore (Ohio) Christmas Seal Association
- Southwestern Ohio Lung Association
- U.S. Department of the Interior
- Washington Air Quality Coalition
- Yale Environmental Law Association

*Summary:* 35 comments from organizations, agencies or their representatives and 38 comments from concerned citizens supporting the current primary standard level of 0.08 ppm.

**COMMENTS RECEIVED ENDORSING PROPOSED PRIMARY STANDARD LEVEL OF 0.10 PPM**

**ORGANIZATIONS AND AGENCIES**

- Air Pollution Control League of Greater Cincinnati
- Air Quality Advisory Committee, California Department of Health
- California Air Resources Board
- Coalition of Labor and Business (COLAB), Concord, California
- Colorado Department of Health
- Connecticut Department of Environmental Protection
- Massachusetts Department of Environmental Quality Engineering
- Public Health Service, U.S. Department of HEW
- Regional Planning Commission for Jefferson, Orleans, St. Bernard and St. Tammany Parishes, Louisiana
- Rhode Island Lung Association
- Southern Alameda County Board of Realtors, California
- U.S. Department of Energy
- U.S. Department of Transportation
- Wasatch Front Regional Council, Utah
- Wayne County Department of Health, Michigan

**COMMENTS RECEIVED ENDORSING A PRIMARY STANDARD LEVEL HIGHER THAN 0.12 PPM AND/OR CONTENDING PROPOSED STANDARD TOO STRINGENT**

Wisconsin State Department of Natural Resources

*Summary:* 16 comments from organizations, agencies or their representatives and 1 comment from a concerned citizen endorsing the proposed primary standard level of 0.10 ppm.

**COMMENTS RECEIVED ENDORSING A PRIMARY STANDARD LEVEL OF 0.12 PPM**

**STATE AND LOCAL AGENCIES**

- Alabama Air Pollution Control Commission
- Berkeley, Charleston, and Dorchester (S.C.) Council of Governments
- City of Philadelphia, Pennsylvania
- Georgia Department of Natural Resources
- Indiana State Board of Health
- Kansas Department of Health and Environment
- Kentucky Department for Natural Resources and Environmental Protection
- Maryland Environmental Health Administration
- Michigan Department of Natural Resources
- Nebraska Department of Environmental Control
- Nevada Department of Conservation and Natural Resources
- New York Department of Environmental Conservation
- North Carolina Department of Natural Resources and Community Development
- Pennsylvania Department of Environmental Resources
- Tennessee Department of Public Health
- Utah Bureau of Air Quality
- Virginia Air Pollution Control Board

**ORGANIZATIONS AND COMPANIES**

- Area Cooperation Committee of Tidewater and Virginia Peninsula Chambers of Commerce
  - Evansville, Indiana, Chamber of Commerce
  - Sierra Pacific Power Company
  - State and Territorial Air Pollution Program Administrators
  - Texas Oil Marketers Association
  - Vulcan Materials Company, Wichita, Kansas
- Summary:* 17 comments from State and local agencies and 6 comments from organizations and corporations supporting a primary standard level of 0.12 ppm.

Organization or agency:	Endorse standard higher than 0.12 ppm	Proposed standard too stringent
American Petroleum Institute (API).....	X	X
Association of Local Air Pollution Control Officials.....		X
Associated Building Industry of Northern California.....		X
Cook County Dept. of Environmental Control, Illinois.....		X
Dow Chemical Company.....	X	
Eastman Kodak Company.....	X	
General Motors Corporation.....	X	X
Great Plains Legal Foundation.....		X
Greater San Antonio Chamber of Commerce, Texas.....		X
Houston Chamber of Commerce, Texas.....		X
Iowa-Illinois Gas and Electric Company.....		X
Louisiana Air Control Commission.....	X	
Manufacturing Chemists Association.....		X
Monsanto Chemical Intermediates Co.....	X	X
Motor Vehicle Manufacturers Association.....	X	X
National Flexible Packaging Association.....	X	X
New Orleans Public Service, Inc.....	X	
Oklahoma State Dept. of Health.....		X

COMMENTS RECEIVED ENDORSING A PRIMARY STANDARD LEVEL HIGHER THAN 0.12 PPM AND/OR  
CONTENDING PROPOSED STANDARD TOO STRINGENT—Continued

	Endorse standard higher than 0.12 ppm	Proposed standard too stringent
Owens-Illinois .....	X	X
Rio Blanco Oil Shale Company .....	X	
St. Louis County, Missouri .....	X	
San Antonio Metropolitan Health District, Texas .....	X	
Shell Oil Company .....		X
Stearns-Roger, Inc., Denver, Colorado .....		X
Tennessee Eastmen Corp. ....		X
Texas Air Control Board .....		
Texas Chemical Council .....	X	
U.S. Council on Wage and Price Stability .....		X
Utah Manufacturers Association .....		X
Virginia Air Pollution Control Board .....		X
Western Oil and Gas Association .....		X
White River Shale Project .....		X

Summary: 15 comments from organizations, agencies, and companies and 4 comments from concerned citizens supporting a primary standard level higher than 0.12 ppm. 23 comments stating the proposed standard is too stringent.

The principal issues raised during the comment period relate to the following topics:

- I. Health effect criteria and selection of the primary standard.
  - A. Definition of an Adverse Health Effect.
  - B. EPA's interpretation of cited studies.
  - C. Margin of safety.
  - D. Use of animal studies.
  - E. Exposure of sensitive groups.
  - F. Synergistic effects and chemical species designation of the standard.
- II. Risk assessment method.
- III. Welfare effects and the secondary standard.
- IV. Implementation and attainability.
  - A. Value of hydrocarbon control and timing of SIP submissions.
  - B. Consideration of control costs.
  - C. Natural background concentrations.
  - V. Procedural issues.

The comments received have been reviewed and a document detailing their disposition has been placed in the rulemaking docket (OAQPS 78-8) for public inspection. The following sections summarize the significant comments and present the Agency's responses.

**I. HEALTH EFFECT CRITERIA AND SELECTION OF THE PRIMARY STANDARD**  
**A. DEFINITION OF AN ADVERSE HEALTH EFFECT**

*Comment.* The proposed standard is unsuitable because EPA has never defined what constitutes "protection of public health." As a specific example, EPA has not shown that pulmonary function and ventilatory pattern changes are adverse health effects.

*Agency Response.* As stated in the criteria document, the available evidence regarding pulmonary function changes observed in clinical exposures of healthy subjects to ozone does not

suggest that small changes in lung function (unaccompanied by discomfort symptoms or impairment of oxygen uptake) would interfere with normal activity in healthy individuals. However, even small changes in people with underlying respiratory disease such as asthma, chronic bronchitis, and emphysema can interfere with normal activity and, thus, may signal impairment of public health.

*Comment.* EPA should identify where adverse effects begin in the continuum of responses to pollutants.

*Agency Response.* In conducting a preliminary risk assessment, EPA interviewed several biomedical experts to obtain their judgments as to the risk of exceeding the threshold of adverse health effects in sensitive persons for alternative standard levels. An essential feature of this risk assessment procedure is the utilization of the experts' judgments as to the point in the continuum of physiological responses to ozone that must be exceeded for an adverse health effect to occur. As an example, discussions with several experts indicated that a 1 percent decrease in pulmonary function (e.g., forced expiratory volume 1-second test) would be inconsequential, whereas a 50 percent decrease would be a severe effect in sensitive persons; the experts' judgments varied as to the point at which adverse effects would begin, but fell within the range of a 5 to 15 percent decrease.

*Comment.* Quickly reversible irritation experienced for a short period of time is a welfare effect related to personal comfort and well-being and should therefore be considered in connection with the secondary standard.

*Agency Response.* The criteria document states that physical discomfort, as manifested by symptoms such as difficulty in breathing, chest tightness, and pain on deep inspiration, has usually been observed in clinical studies in conjunction with pulmonary

function changes. Even when reversible, respiratory symptoms may restrict normal activity or limit the performance of tasks. In clinical studies, exposure of *healthy subjects* to realistic levels of ozone (0.3 ppm) has produced discomfort sufficient to prevent completion of experimental protocols, particularly when vigorous exercise was involved. Accordingly the criteria document concluded that increased rates of respiratory symptoms constitute impairment of public health. On this topic, a physician affiliated with the California Department of Health stated (docket OAQPS 78-8, IV-F-31) that it was his medical opinion that symptoms such as those described above constitute adverse health effects, inasmuch as they signal pulmonary function decrements and an increased pulmonary work load for affected individuals. He expressed his concern for the long-term effect of repeated exposure to levels of ozone sufficient to induce such symptoms. EPA concurs in this view and considers such symptoms, even though transitory, to be of concern in selecting the level of the primary standard.

**B. EPA'S INTERPRETATION OF CITED STUDIES**

**1. DeLucia and Adams (1977)**

*Comments.* (a) EPA misread the DeLucia and Adams study in claiming significant effects have been reported at 0.15 ppm for one hour.

(b) Mouthpiece breathing may have invalidated the DeLucia and Adams study.

(c) Since DeLucia and Adams demonstrated effects at 0.15 ppm in healthy individuals, more susceptible populations would be expected to sustain effects at lower levels.

*Agency Responses.* (a) EPA acknowledges that DeLucia and Adams failed to demonstrate any statistically significant decrements in pulmonary function resulting from exposure to 0.15 ppm for one hour. (The investigators did observe statistically significant decrements in pulmonary function resulting from exposure to 0.30 ppm for one hour.) In groups as small as those tested by DeLucia and Adams (six subjects), however, tests of statistical significance are difficult to interpret. The criteria document concluded that the study by DeLucia and Adams, although unreplicated, has raised the question of whether O<sub>3</sub> concentrations as low as 0.15 ppm exert effects in a portion of healthy subjects exercising vigorously. Indeed, DeLucia and Adams specifically state that the two most sensitive subjects sustained markedly impaired respiratory function and exercise ventilatory patterns during the two most stressful exercise protocols in the four ozone-exposure

experiments (i.e., both 0.15 ppm and 0.30 ppm).

Furthermore, DeLucia and Adams state that most of the subjects experienced subjective symptoms of discomfort (e.g., congestion, chest pain, and cough) when exposed to 0.15 ppm for one hour under the most stressful exercise protocol (equivalent to running about 6 miles in an hour). These symptoms occurred at a lower exercise rate when the subjects were exposed to 0.30 ppm. DeLucia and Adams did not report the incidence of these symptoms in a quantitative manner, but this fact does not remove EPA's concern about the implications for healthy persons such as those studied by DeLucia and Adams, or for more susceptible persons who may sustain more severe reactions or who may be affected at lower concentrations than those observed.

(b) As noted in the criteria document, persons tend to breathe through their mouths when exercising. Thus, DeLucia and Adams' utilization of mouthpieces to dispense O<sub>3</sub>, probably represents actual exposures in persons who, in the course of their normal daily activities, are undergoing exercise.

(c) EPA agrees with this comment, as noted above. EPA considered the implications of this study for more susceptible members of the population in its determination of the margin of safety for the ozone standard.

#### 2. Schoettlin and Landau (1961)

*Comments.* (a) There are still problems with reliance on this study because (1) ambiguities remain in its interpretation and (2) more recent studies of effects of ozone on asthmatics have failed to corroborate this study's conclusions.

(b) EPA's interpretation of the concentration at which Schoettlin and Landau correlated increased incidence of asthmatic attacks is unnecessarily conservative. There is good reason to believe that the 0.25-ppm oxidant concentration cited by Schoettlin and Landau was a daily peak (2-minute average) concentration rather than a daily maximum hourly average concentration, as EPA claims. Furthermore, the level of ozone occurring on these high oxidant days would have been less than the level of oxidant reported.

*Agency Responses.* (a) The criteria document recognizes limitations that make it difficult to interpret the Schoettlin and Landau study unequivocally. Nevertheless, Schoettlin and Landau did conclude that the proportion of asthmatics having attacks was significantly greater on days when the oxidant concentration exceeded 0.25 ppm than on days when the concentration was below that level. EPA

does not believe that this conclusion has been refuted by more recent studies. The reported results of the recent epidemiological study by Kurata et al (1976) are qualitatively similar to those of Schoettlin and Landau. EPA's analysis (docket OAQPS 78-8, IV-A-1) of the data presented in the Kurata study indicates that a statistically significant elevation of the asthma index occurred on days when the maximum instantaneous (2-minute average) oxidant concentrations exceeded 0.28 ppm. While the exact hourly average equivalent of this value is not known, it must be less than or equal to 0.28 ppm, and is probably in the range of 0.20 to 0.27 ppm.

(b) EPA acknowledges that it is uncertain from Schoettlin and Landau's paper what averaging time was used in correlating oxidant concentration and incidence of asthma attacks. As stated in the criteria document, however, consultations with the authors have established that daily asthma attack rates were correlated with daily *maximum hourly average* oxidant levels. EPA considers that these consultations (docket OAQPS 78-8, IIA-C-2) have satisfactorily resolved the controversy regarding the averaging times used by Schoettlin and Landau.

EPA agrees with the comment that ozone levels may have been lower than the oxidant readings with which Schoettlin and Landau correlated asthma attack incidence. Ozone levels have been shown to range from approximately 65 percent to nearly 100 percent of the total oxidant levels. This fact provides reason for concern that ozone in the ambient air at daily maximum hourly average concentrations less than 0.25 ppm may adversely affect asthmatic persons.

#### 3. Hammer et al. (1974)

*Comments.* (a) This study has methodological problems (such as the failure to adjust the data for smoking habits and allergy histories) that undermine confidence in its conclusions.

(b) It is uncertain that oxidants caused the increase in symptoms observed in this study.

*Agency Responses.* (a) Hammer et al. conducted a longitudinal survey of an essentially constant group of subjects over a period of time. Consequently, in order for the authors' failure to adjust the data for smoking habits and allergy histories to have biased the results, the survey response pattern on high pollution days would have differed with respect to the distribution of smokers and allergic persons as compared with the pattern on low pollution days. Such an occurrence seems unlikely; furthermore, the criteria document noted that the results of this epidemiological study are generally consistent with the results of clinical

exposure studies. This fact, along with the extensive data base evaluated (about 53,000 person-days of observation), enhances the reliability of Hammer's study.

(b) Hammer et al. found that symptom frequencies were more closely correlated to photochemical oxidants than to several other environmental parameters (e.g., carbon monoxide and nitrogen dioxide). In addition, the criteria document noted that the oxidant levels at which cough and chest discomfort were observed to increase in the student nurse population were quite similar to ozone concentrations that have been observed to produce impairment of pulmonary function and respiratory irritation in experimental exposures of healthy subjects performing intermittent light exercise (0.37 ppm for 2 hours). Consequently, it is reasonable to propose that photochemical oxidants—and specifically ozone in the ambient air—contributed substantially to observed increases in rates of cough, chest discomfort, and headache.

#### 4. Hazucha (1973)

*Comment.* Results reported by Hazucha on impairment of pulmonary function at ozone levels of 0.25 ppm for 2 hours are not statistically significant.

*Agency Response.* The small number of subjects (three) examined at that exposure precludes the application of statistical methods to the results. The absolute value of the pulmonary function decrements (about 5 percent) is the more relevant factor in evaluating the results of this study.

As described in the criteria document, the small pulmonary function changes observed by Hazucha in a 2-hour exposure of healthy subjects undergoing intermittent light exercise lie along a continuum of responses when compared with results at higher concentrations and similar exposure regimes. There is no indication that 0.25 ppm is the threshold for that exercise level, and indeed the study by DeLucia and Adams (1977) has shown symptomatic effects in *healthy* individuals that are indicative of pulmonary function impairment at levels as low as 0.15 ppm under a more strenuous exercise protocol.

#### 5. Studies in which effects were not observed at levels above 0.15 ppm

*Comments.* (a) The 1977 National Academy of Sciences (NAS) document, Ozone and Other Photochemical Oxidants, was cited in several comments as concluding that effects in human subjects have been observed only from ozone exposures above 0.25 ppm.

(b) Linn et al. (1978) failed to find any significant pulmonary effects in asthmatics exposed to 0.20-0.25 ppm for 2 hours under conditions of heat and exercise.

(c) Hackney et al. (1975) observed human health effects only at exposures above 0.25 ppm for 2 hours.

*Agency Responses.* (a) The NAS document states that "some limited studies show evidence of human health effects of exposure to pure ozone at concentrations as low as 0.25 ppm \* \* \*". This document was prepared before publication of the DeLucia and Adams study, which suggests effects at lower levels. Furthermore, this NAS document in no way concludes that effects resulting from ozone, as it occurs in the ambient photochemical mix, do not occur at concentrations below 0.25 ppm.

(b) Although Linn et al. found statistically significant changes in one of several measures of pulmonary function in their laboratory study, the manner in which the investigators conducted the study (e.g., persons with marked respiratory disability were excluded from the study) and analyzed the data are such that the observed results probably underestimate the effects that would occur at similar ambient exposure levels. There was a slight increase in symptom scores during ozone exposure, and statistically significant changes in blood biochemical factors were observed. While the clinical significance of these latter changes is uncertain, they do represent alterations in normal body functions and cannot be discarded in selecting a standard that protects public health with an adequate margin of safety.

(c) Although the criteria document states that Hackney et al. observed no lung function changes of note at 0.25 ppm for 2 hours even among "reactive" subjects (persons giving a history of cough, chest discomfort, or wheezing in response to allergy or air pollution exposure), closer inspection of the Hackney et al. (1975) studies reveals that dose-response relationships hold for sensitive subjects for lung function and blood biochemical effects across the range of exposure from 0.20 to 0.50 ppm ozone.

#### 6. Other Human Studies

*Comments.* (a) Von Nieding et al. (1976) have demonstrated effects on pulmonary function of healthy individuals at 0.10 ppm ozone.

(b) EPA cannot justify a conclusion that Japanese epidemiological studies indicate a risk of symptomatic effects in human beings from ozone exposures below 0.15 ppm for one hour.

*Agency Responses.* (a) EPA is concerned about the findings of von Nieding et al. showing decreased oxygen pressure in arterialized blood and increased airway resistance after 2 hours of exposure to 0.10 ppm ozone and intermittent light exercise. The criteria document points out, however, that the investigators used non-standard

physiologic measurement methods. Thus, although von Nieding's findings cannot be ignored in the standard-setting process, they are unconfirmed, and must be interpreted cautiously.

(b) Makino and Mizoguchi (1975) reported an epidemiological study of Tokyo students that showed increased rates of discomfort symptoms on days when the oxidant level (believed to be a daily maximum hourly average concentration) exceeded 0.15 ppm as compared with days when it fell below 0.10 ppm. The criteria document reviewed this and several other Japanese epidemiological studies, and concluded that the studies were appropriately designed but that it is very difficult to interpret their results. In setting a standard with an adequate margin of safety, however, EPA must consider evidence such as these Japanese studies and must evaluate the uncertainties which medical research has not yet resolved.

#### 7. Validity of Clinical Studies in General

*Comment.* At the August 22, 1978 public hearing in Dallas, testimony was presented alleging that the ozone generators used in clinical health studies produce other toxic materials in addition to ozone. Experimental data obtained using a new total oxidant monitoring method indicated that these additional oxidants were present in large quantities (as high as 300 percent greater than ozone). It was hypothesized that the adverse effects noted in clinical studies may be preponderantly caused by the additional oxidants and not ozone.

*Agency Response.* EPA has concluded that the experimental evidence offered to support these findings is unconvincing and cannot be substantiated. The results of an experimental program initiated by EPA after the Dallas hearing indicate that the new monitoring technique which supposedly measured ozone and any additional oxidants has a variable chemical reaction relationship (stoichiometry) with ozone depending on whether or not oxygen is present. The higher oxidant readings obtained by this technique appear to result from this variable stoichiometry rather than representing the presence of any additional non-ozone oxidants. Furthermore, an exhaustive search for such oxidants in the output of ozone generators operating under various conditions (using as the input stream either dry or humidified tank air or oxygen, with very low or background concentrations of hydrocarbons, mostly methane) failed to produce any evidence of non-ozone oxidants. Consequently, EPA judges the hypothesis offered by this comment to be experimentally unsupportable. A report documenting the results of

EPA's experimental program has been placed in the docket (OAQPS 78-8, IV-A-2).

#### C. MARGIN OF SAFETY

*Comment.* EPA has proposed a 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. As stated in the legislative history of the Clean Air Act, the standard must protect against hazards that research has not yet identified. EPA feels that 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 ozone. The factors to be taken into account include inconclusive evidence as well as findings from studies that are considered definitive and not subject to challenge. For example, in selecting an adequate margin of safety, the Administrator must consider: (1) findings from animal studies that show increased susceptibility to infectious respiratory disease and other serious effects at relatively low ozone levels, (2) the concern that health studies may not always reflect the health impact in more sensitive segments of the population, and (3) studies suggesting that ozone may produce an enhanced effect when combined with other air pollutants commonly present in the urban atmosphere but not present in clinical study chambers.

#### D. USE OF ANIMAL STUDIES

*Comment.* EPA has failed to give appropriate consideration to the results of animal studies, especially those involving young animals and those examining reduced resistance to infection.

*Agency Response.* EPA is concerned about the studies which have demonstrated effects in young animals and decreased resistance to infection in animals exposed to ozone. The infection effect has been demonstrated at exposures as low as 0.08 ppm for 3 hours. The criteria document concluded that these findings have definite human health implications, although different exposure levels may be associated with such effects in humans. For this reason, these results cannot be the sole factor used in selecting the level of the primary standard. However, as is the case with other inconclusive evidence, EPA must consider these studies in selecting an adequate margin of safety.

*Comment.* There is no evidence of reduced resistance to infection in epi-



demographic studies in places such as Los Angeles.

**Agency Response.** Epidemiological studies have been inconclusive in demonstrating this effect in man. However, EPA does not agree with this comment. The study by Durham (1974) of air pollution effects on college students, indicates that rates of new illness increase following short-term exposures to elevated pollutant concentrations. The pollutant variable most strongly associated with illness was peak oxidant. Also, several studies documenting increased levels of mucous membrane irritation during periods of ozone exposure suggest indirectly that susceptibility to infection may rise during these periods. Furthermore, although animal study findings cannot be directly extrapolated to man, the criteria document concludes that the reactions observed in mice represent effects on basic biological responses to infectious agents, and there is no reason to believe that the pollutant-induced alterations of basic defense mechanisms that occur in mice could not occur in human beings. Thus, these studies cannot be ignored in the standard-setting process.

#### E. EXPOSURE OF SENSITIVE GROUPS

**Comment.** EPA is being unnecessarily stringent in selecting the sensitive population. The standard could be much less stringent without endangering the health of such persons if EPA accounted for the portion of time that persons are indoors and, thus, not exposed to higher ambient concentrations.

**Agency Response.** The legislative history of the Clean Air Act makes quite clear Congress' intention to protect sensitive persons (asthmatics and emphysematous patients are cited as examples) 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 sample of persons comprising the sensitive group rather than a single person in such a group. Standards must be based on a judgment of a safe air quality level and not on an estimate of how many persons will intersect given concentration levels. EPA interprets the Clean Air Act as providing citizens the opportunity to pursue their normal activities in a healthy environment.

#### F. SYNERGISTIC EFFECTS AND CHEMICAL SPECIES DESIGNATION OF STANDARD

**Comment.** There were objections to the proposed change of the chemical designation of the standard from photochemical oxidants to ozone because the health impacts of photochemical air pollution arise not only from ozone, but also from the spectrum of

other gaseous and particulate pollutants that co-exist with ozone. There was also concern that the change in the chemical designation signalled a change in emphasis in oxidant control efforts that would impede progress in the reduction of non-ozone components of the photochemical oxidant mixture such as peroxyacetylnitrate (PAN). Specific concern was expressed regarding the eye-irritating components of the mixture, since at ambient levels ozone alone is not an eye irritant.

**Agency Response.** Certain clinical studies (such as Hazucha and Bates, 1975) have demonstrated the potential for greater health impacts resulting from exposure to ozone in combination with other pollutants which occur in the ambient air than from exposure to ozone alone. The ozone standard is not intended merely to protect against the levels of ozone that have been demonstrated to produce effects in clinical studies where subjects have been exposed to highly purified air to which ozone alone has been added. Rather, setting an ozone standard with an adequate margin of safety involves, among other considerations, evaluating the effects of ozone as it occurs in the ambient air, in combination with other pollutants.

One reason for changing the chemical designation of the standard from photochemical oxidants to ozone is to correct an inconsistency between the title of the standard (photochemical oxidants) and the chemical species (ozone) that has always been measured by the reference method used to estimate ambient oxidant levels and determine compliance with the standard. Consequently, no redirection of control efforts is contemplated; i.e., reductions in hydrocarbon and nitrogen oxide emissions will continue to be required in order to reduce the levels of the secondarily generated pollutant (ozone) measured to determine compliance with the standard.

The criteria document examined the issue of whether or not measures taken to reduce ozone will also reduce other manifestations of photochemical pollution such as eye irritation. The evidence from laboratory and theoretical studies indicates that, for urban atmospheres, reductions in hydrocarbon and nitrogen oxide emissions should have even greater impacts on ambient PAN than on ambient ozone. Similarly, laboratory data suggest a linear relation between hydrocarbon emissions and ambient levels of photochemically produced aldehydes. Since PAN and such aldehydes as formaldehyde and acrolein are known to be eye irritants, the criteria document concludes that emission control measures for ozone reduction will probably have a positive effect on reducing eye irritation in

those situations where eye irritation is associated with photochemical processes (e.g., Los Angeles).

#### II. RISK ASSESSMENT METHOD

**Comment.** The risk assessment method should not be used at this time because it has not been reviewed adequately by the Science Advisory Board or the scientific community.

**Agency Response.** The risk assessment method is not being used to set the ozone standard. In determining what ozone standard has an adequate margin of safety, however, the findings of the initial application of the risk assessment method to ozone have been considered. EPA agrees that the method has not received sufficient review. The method will be published in the open literature and the Science Advisory Board is forming an ad hoc subcommittee to review the method.

**Comment.** EPA's risk assessment method is incomplete.

**Agency Response.** EPA agrees with the comment. As applied to ozone, the risk assessment method assesses the risk (probability) that ozone would contribute to health effects in some sensitive people if alternative standards were just met. A complete risk picture would also include information on:

- (a) a best point estimate of the number of people affected;
- (a') the "expected number" (in a statistical sense) of people affected;
- (a'') various risks (probabilities) that the actual number of people affected would be various amounts greater than the expected number;
- (b) a best point estimate of the amount of health damage;
- (b') the "expected" health damage; and
- (b'') various risks (probabilities) that the actual health damage would be various amounts greater than the expected health damage.

As noted in the draft EPA document explaining the risk assessment method, there are complex technical problems that must be dealt with in responsibly developing information of this type suitable for use in setting National Ambient Air Quality Standards. EPA is presently developing the capability to generate this type of information and will only consider its risk assessment method complete when the method includes this capability.

**Comment.** The main problem with the risk assessment method stems from its purpose. Instead of estimating health damage, EPA provides a table of risk numbers without providing an estimate of their health significance; these numbers serve no function.

**Agency Response.** EPA agrees that the risk estimates provided do not serve the function of estimating

health damage, but the Agency does not agree that the estimates are without value. The function of these estimates is to indicate the varying risk (or probability) that some sensitive people would suffer health effects in a given period of time if alternative ozone standards were just met. For each health effect category, the response that is of sufficient concern to be deemed a health effect has been decided upon and its seriousness described. As EPA interprets the Clean Air Act, this determination, which is an important step in the process of setting National Ambient Air Quality Standards, is a function that is to be served by a risk assessment.

There were many comments on both the procedural and the technical aspects of the risk assessment method. EPA will consider these comments in the detailed responses to be placed in the docket. Some of the comments identify improvements that can be made in the risk assessment method, while others reflect misunderstandings that will be dealt with in the detailed docket responses. Some of the comments provide discussion and opinions on various complex issues that arise in the conduct of a program involving the difficult subject areas of risk assessment and standard-setting methodology. EPA will take these comments into advisement as it develops its risk assessment and standard-setting methodologies.

### III. WELFARE EFFECTS AND THE SECONDARY STANDARD

*Comment.* EPA's proposal to retain the existing secondary standard is based entirely on evidence of possible damage to extremely sensitive vegetation. An adequate economic analysis that considers the incremental costs and benefits of alternative secondary standard levels should be conducted. EPA should then weigh the economic costs of pollution control measures against the benefits of reduced damages from lower ozone concentration levels before setting a secondary standard.

*Agency Response.* The Clean Air Act requires EPA to set a national secondary ambient air quality standard at a level that, in the judgment of the Administrator, is requisite to protect the public welfare from any known or anticipated adverse effects. The term "public welfare," which is defined in Section 302(h) of the Clean Air Act, includes among other things effects on crops, vegetation, wildlife, visibility, and climate, "as well as effects on economic values and on personal comfort and well-being."

EPA has carefully examined the data presented in the criteria document concerning ozone-related damage to vegetation, crops, materials,

and visibility. A staff paper, "Evaluation of Alternative Secondary Ozone Air Quality Standards," has been placed in the docket (OAQPS 78-8, IV-A-3).

With regard to damage to materials, the paper concludes that no effect-based rationale can be offered to decide the level of the secondary standard. Damage to materials is linearly related to the total dose sustained by the material. As a result, the annual average concentration will determine the rate at which material damage occurs. Current evidence indicates that annual average concentrations for remote rural areas are comparable to urban areas, due to strong night-time scavenging of ozone in urban areas by man-made pollutants. Reducing the peak 1-hour concentration in urban areas will have virtually no impact on the annual average concentration. Therefore, there would be no measurable reduction in materials damage if a more stringent secondary standard level was selected.

The criteria document states that there is a limited amount of data suggesting an association between ambient ozone and visibility degradation, particularly in the Los Angeles area. On the basis of EPA's evaluation to date of the information presented in the criteria document, however, EPA is unable to conclude at this time that a secondary ozone standard more stringent than the primary standard is necessary to prevent visibility deterioration. The relationship between visibility and ambient ozone will be considered further in the development of subsequent PSD programs designed to protect against significant deterioration of air quality.

Finally, EPA has concluded that there is currently no evidence indicating that a significant decrease in yield or growth or commercially important crops or indigenous vegetation will result from the long-term (growing season) mean of the daily maximum 7-hour-average ozone concentrations which is expected to occur when the primary standard is attained. Consequently, EPA does not believe that a secondary standard more stringent than the primary standard is necessary to protect vegetation from ozone-related yield reduction effects.

On the basis of these conclusions, EPA does not believe that a detailed cost-benefit analysis of alternative standard levels is required, since a secondary standard more stringent than the primary standard is not necessary to protect the public welfare adequately.

*Comment.* The current secondary standard of 0.08 ppm should be retained to protect vegetation and crops. There is significant reduction in

growth and yield to crops exposed to 0.10 ppm of ozone.

*Agency Response.* The claims that significant reduction in growth and yield occurs in crops as a result of short-term exposures to ozone at levels around 0.10 ppm are undocumented. While sensitive plants may incur foliar injury at low ozone levels, there is currently no evidence that significant yield or growth effects in commercially important crops or indigenous flora are associated with the long-term (growing season) mean of the daily maximum 7-hour-averaging ozone concentrations expected to occur when the primary standard is attained. Consequently, EPA does not believe that a secondary standard more stringent than the primary standard is necessary to prevent ozone-related yield reduction effects in vegetation.

### IV. IMPLEMENTATION AND ATTAINABILITY

#### A. VALUE OF HYDROCARBON CONTROL AND TIMING OF SIP SUBMISSIONS

EPA received comments on the effectiveness of hydrocarbon controls in reducing levels of ozone in the ambient air as well as on the issue of whether or not the statutory deadline for submission of revised State Implementation Plans (SIPs) for nonattainment areas should be postponed because of the changes in the photochemical oxidants standard. The Agency responses to these comments are contained in the accompanying FEDERAL REGISTER notice dealing with the revision of the 40 CFR Part 51 regulations pertaining to the implementation of the standard.

#### B. CONSIDERATION OF CONTROL COSTS

*Comment.*

Cost of control should be considered in selecting the level of the primary standard.

*Agency Response.* The Agency's position with respect to control cost consideration was stated in the preamble to the proposed regulation (43 FR 26963); this position remains unchanged. The Clean Air Act specifies that primary National Ambient Air Quality Standards are to be based on scientific criteria relating to the level that should be attained to protect public health adequately. Considerations of cost of achieving these standards or of the existence of technology to bring about needed reductions of emissions are not germane to such a determination, as the words of the Act and its legislative history clearly indicate. EPA has, however, analyzed the cost and economic impacts of the control programs required to attain alternative ozone standard levels in order that the public may be better informed

of the consequences of the Agency's decision. This analysis and the comments received in response to it are available to the States for their use in developing strategies to implement the standard.

*Comment.* The cost estimates presented in EPA's cost and economic impact assessment document are understated.

*Agency Response.* EPA has carefully reviewed and considered these comments and is publishing a revised economic impact assessment, which is available from Mr. Padgett at the previously mentioned address.

#### C. NATURAL BACKGROUND CONCENTRATIONS

Several comments were made regarding the contribution of natural sources to ambient ozone concentrations. These comments focus on (1) the extent to which natural background was considered in developing the proposed standards and related control programs and (2) the attainability of these standards, considering the possibility that natural background may at times contravene the proposed levels. Some of the comments suggested that EPA ignored, or did not adequately consider, natural background in developing the proposed standards and related control programs. While this topic was not emphasized in the preamble to the proposed rulemaking, EPA was, and is, cognizant of the background levels that can be attributed to natural sources. This matter was treated extensively in the revised criteria document. Furthermore, EPA procedures for preparation of control plans recommend allowance for natural background in developing control strategies for ozone.

For several years, EPA has been conducting an active field and laboratory research program seeking to determine the nature and extent of background concentrations of ozone. The results of these studies have been widely publicized in EPA reports, scientific literature, and public conferences. One comment suggested that EPA had ignored evidence of natural source impacts reported in contract work conducted for the Agency and that this information had not been released for public review. Actually, all pertinent information available to EPA was considered. However, there may have been some contractually developed information that had not been released or could not be specifically cited because the contract studies were still in progress and the resulting data had not been fully validated or analyzed. Subsequent to the comment, all information in question were released publically or arrangements have been

made to release them as soon as possible.

EPA's review of data related to the background contribution leads the Agency to conclude that such levels are usually well below the proposed levels of the standard, especially during the season of the most active production of photochemical ozone. It is possible, however, that natural events could occasionally cause contravention of the promulgated standard levels. EPA policy (see 40 CFR 51.12(d)) permits data for such occurrences to be disregarded for regulatory purposes. Such events are usually distinguishable because they tend not to coincide with conditions conducive to buildup of man-caused, photochemically produced ozone. Field measurements at some remote sites, where man-caused ozone is likely to be negligible, have shown low—but not insignificant—rates of exceedances of the 0.08-ppm level originally proposed for the secondary standard. The frequencies decrease markedly for concentrations above 0.12 ppm, so that natural exceedances of the standards being promulgated can be considered quite rare at any particular location.

One comment indicated that stratospheric tracer levels measured at surface sites increase by about 40 percent between the front and back side of high pressure systems in the Eastern United States, thus suggesting that stratospheric ozone, through subsidence and horizontal circulation in highs, plays a significant role in the widespread buildup of ozone that tends to occur in the back side of highs in the Eastern U.S. during the photochemically active season. EPA's estimate is that, even if commonly occurring natural ozone background were increased by 40 percent, the resulting concentration would be insufficient to exceed the standard levels being promulgated. Also, a corresponding increase between the tracer and ozone of stratospheric origin would not be expected, since the tracer is chemically stable near the surface, while ozone is rapidly depleted by reactions with surfaces and with air contaminants.

Some comments referred to a possibly significant contribution to ozone concentrations from reactions involving organic compounds emitted by vegetation. Such emissions are abundant, relative to man-made emissions, but are relatively diffuse spatially. Some of the comments cited a recent statistical study that reported a high correlation between vegetative growth in the Bay Area of California, as indicated by winter rainfall, and the frequency of days with concentrations above 0.08 ppm. EPA has not, however, seen sufficient physical evidence of a relative abundance of natural organ-

ics or associated ozone increases in ambient air to consider vegetative sources as significant contributors to high ambient ozone levels. The principal source of natural ozone is still considered to be the stratosphere, with gradual transfer accounting for the more commonly observed background levels, and sporadic intrusions being the principal cause of anomalous high values.

Although research will continue to assess more definitively the contribution of natural sources of ozone, EPA believes that adequate consideration has been given to this issue in developing control programs and implementation guideline documents.

#### V. PROCEDURAL ISSUES

*Comment.* EPA's use of an "Advisory Panel on Health Effects of Photochemical Oxidants" was procedurally incorrect in that certain legal requirements on establishment and use of Advisory Committees were not met.

*Agency Response.* The ad hoc Advisory Panel consisted of a group of medical experts retained by EPA as consultants for the purpose of obtaining their interpretation of the evidence presented in a preliminary version of the criteria document. As such, EPA did not regard the Panel as an advisory body within the meaning of the Advisory Committee Act of 1972. In any case, the Panel's report has been in the docket and subject to comment since proposal, and bases for its recommendations have been fully aired.

*Comment.* In revising its criteria document, EPA failed to comply with the recommendations of the statutory scientific review body, the Science Advisory Board (SAB), as evidenced by the SAB's refusal to approve the criteria document.

*Agency Response.* The function of the Science Advisory Board subcommittee is to advise EPA regarding the scientific and technical accuracy, the manner of presentation, and the adequacy of the criteria document. Inevitably, no two scientists ever agree completely on the importance, accuracy and manner of presentation of data. In the final analysis the responsibility for the criteria document rests with EPA and, therefore, the decision regarding the content of the document must also rest with EPA.

EPA solicits the advice of its scientific advisors and has attempted to respond to the specific comments made by members of the SAB subcommittee established to review the criteria document by incorporating suggested changes in the document. Following the last SAB subcommittee meeting in February 1978, members of the subcommittee who had specific comments were consulted by EPA personnel, and

their comments and criticisms were discussed with them prior to making the changes in the document. It has always been Agency policy that once the EPA staff had considered the changes suggested by the SAB and, where appropriate, incorporated them into the criteria document, the Agency would proceed with publication. Consequently, EPA feels that the criteria document adequately reflects the latest scientific knowledge pertaining to the effects of ozone and other photochemical oxidants.

*Comment.* EPA has failed to submit the proposed standard to the SAB for review as required by the Environmental Research, Development, and Demonstration Authorization Act of 1978 (Pub. L. 95-155). EPA should do so before promulgating the standard.

*Agency Response.* The development of the ozone standard revision, which began in 1976, followed the procedural process in place before the enactment of Public Law 95-155. Accordingly, the SAB was asked to review only the criteria document. The independent committee established in accordance with the 1978 Act held its first session in October 1978, when there was not adequate time for it to review the standard. The thorough review of the technical and scientific basis for the criteria document, which is in turn the basis for the standard, substantially complies with the objectives of the Act.

#### SELECTING THE LEVEL OF THE PRIMARY STANDARD

EPA's objective in setting the standard level is to select an ozone concentration that will reflect an accurate consideration of the existing medical evidence and an adequate assessment of the uncertainties in this evidence, and, thus, will protect all population groups with an adequate margin of safety.

The criteria document supports the contention that a clear threshold of adverse health effects cannot be iden-

tified with certainty for ozone. Rather, there is a continuum consisting of ozone levels at which health effects are certain, through levels at which scientists can generally agree that health effects have been clearly demonstrated, and down to levels at which the indications of health effects are less certain and harder to identify. Given such a body of evidence, in selecting a standard with an adequate margin of safety the decisionmaker is taking into account the uncertainty about whether a possible standard will prevent adverse health effects.

This uncertainty results from several factors. First, human susceptibility to health effects varies, and we cannot be certain that experimental evidence has accounted for the full range of susceptibility. Second, we cannot be certain that all effects occurring at low ozone levels have been identified and demonstrated. Third, variations in weather create uncertainty as to the expected annual maximum ozone concentrations.

The Clean Air Act, as the Administrator interprets it, does not permit him to take factors such as cost or attainability into account in setting the standard; it is to be a standard that will adequately protect public health. He recognizes that controlling ozone to very low levels is a task that will have significant impact on economic and social activities. This recognition causes him to reject as an option the setting of a zero-level standard as an expedient way of protecting public health without having to decide among uncertainties. However, it is public health, and not economic impact, that must be the compelling factor in the decision. Thus, the decision as to what standard protects public health with an adequate margin of safety is based on the uncertainty that any given level is low enough to prevent health effects, and on the relative acceptability of various degrees of uncertainty, given the seriousness of the effects.

In selecting the proper level for the standard, EPA must make assessments and judgments in five critical areas:

1. Reported effect levels from human studies.
2. Characterizing the sensitive population.
3. Nature and severity of effects.
4. Probable adverse health effect level in sensitive persons.
5. Judgment of a standard level below the probable effect level that provides an adequate margin of safety.

#### REPORTED EFFECT LEVELS

In the preamble to the proposed standard (43 FR 26965), EPA presented a table of demonstrated effect levels in man ranging from 0.15 to 0.30 ppm. On the basis of suggestions received during the comment period, that table has been expanded to include a greater number of studies where effects have been reported. EPA believes that this is a more complete representation of the medical evidence since it includes some less conclusive studies at low levels that cannot be discarded in weighing the full body of health data. Nonetheless, the table must be used with caution and in conjunction with qualifying statements made in the criteria document regarding the technical merit of each study, particularly the less conclusive studies at lower concentrations.

While this table does not provide an undisputed value for adverse health effect levels in sensitive individuals, it does indicate that normal body functions are most likely disrupted at relatively low ozone concentrations. The studies also indicate that the intensity and significance of effects increases as the pollutant level increases. The reported findings leave open the question of increased intensity of effects in more sensitive persons, and the concern that effects reported in some studies may occur at lower concentrations when ozone is present in combination with other urban pollutants.

## RULES AND REGULATIONS

[6560-01-C]

REPORTED EFFECT LEVELS  
 Compilation of Results Reported in Human Studies Examining Ozone or Oxidant Exposure

Concentration, ppm	Exposure Duration, hours (for clinical studies); Averaging time (for epidemiological studies)	Pollutant Measured (O <sub>3</sub> = ozone, O <sub>x</sub> = oxidant)	Reported Effect(s)	Reference(s)
0.01 - 0.30	hourly average	O <sub>3</sub>	Lung function parameters in about 25% of Japanese school children tested were significantly correlated with O <sub>3</sub> concentrations (over the range of 0.01 - 0.30 ppm) in the 2 hours prior to testing.	Kagawa and Toyama (1975); Kagawa et al. (1976)
0.03 - 0.30	hourly average	O <sub>x</sub>	Although significant correlation was observed between decreased athletic performance and O <sub>x</sub> concentrations in the range of 0.03 - 0.30 ppm, the criteria document states that inspection of the data reveals no obvious relationship between performance and O <sub>x</sub> values below 0.10-0.15 ppm.	Wayne et al. (1967)
0.10	2	O <sub>3</sub>	Decreased O <sub>2</sub> pressure in arterialized blood, increased airway resistance observed using non-standard measurement techniques.	von Nieding et al. (1976)
0.10 - 0.15	probably daily maximum hourly average	O <sub>x</sub>	Increased rates of respiratory symptoms and headache were reported by Japanese students on days when O <sub>x</sub> concentrations exceeded 0.15 ppm as compared to days when O <sub>x</sub> concentrations were less than 0.10 ppm.	Makino and Mizoguchi (1975)
0.15	1	O <sub>3</sub>	Subjective symptoms of discomfort were observed by most subjects, and discernible but not statistically significant changes in respiratory patterns occurred while performing vigorous exercise.	DeLucia & Adams (1977)
0.20	3	O <sub>3</sub>	Reduction in visual acuity (night vision) observed.	Lagerwerff (1963)
0.20 - 0.25	2	O <sub>3</sub>	Asthmatic patients exposed under intermittent light exercise conditions showed no statistically significant changes in respiratory function. Symptom scores increased slightly during O <sub>3</sub> exposures. Small but statistically significant blood biochemical changes occurred.	Linn et al. (1978)
0.25	2	O <sub>3</sub>	Small changes in lung function were observed in 3 subjects performing intermittent light exercise.	Hazucha (1973)
0.25	2 and 4	O <sub>3</sub>	No lung function changes of note were observed in "reactive" subjects (who had histories of cough, chest discomfort or wheezing associated with air pollution or allergy) while performing intermittent, light exercise.	Hackney et al. (1975)
0.25	daily maximum hourly average	O <sub>x</sub>	The average number of asthma patients having attacks was statistically significantly elevated on days when O <sub>x</sub> levels exceeded 0.25 ppm.	Schoettlin and Landau (1961)
0.25	0.5 - 1	O <sub>3</sub>	Blood samples of exposed subjects had increased rates of spherizing of red blood cells	Brinkman et al. (1964)
0.28	daily maximum instantaneous (2-minute) average	O <sub>x</sub>	Although the reported results are inconclusive, EPA's examination of the evidence presented suggests exacerbation of asthma when O <sub>x</sub> levels are above 0.28 ppm.	Kurata et al. (1976)
0.30	1	O <sub>3</sub>	Subjective symptoms of discomfort and statistically significant changes in pulmonary function were observed in subjects undergoing vigorous exercise.	DeLucia and Adams (1977)
0.30	daily maximum hourly average	O <sub>x</sub>	Increased rates of cough, chest discomfort, and headache were observed in student nurses on days when the O <sub>x</sub> concentrations exceeded 0.30 ppm.	Hammer et al. (1974)
0.37	2	O <sub>3</sub>	Discomfort symptoms and significant changes in lung function were observed in subjects undergoing intermittent light exercise.	Hazucha et al. (1973); Folinsbee et al. (1975); Silverman et al. (1976)
0.37	2	O <sub>3</sub>	Exposure to O <sub>3</sub> and SO <sub>2</sub> together produced changes in lung function substantially greater than the sum of the separate effects of the individual pollutants.	Hazucha and Bates (1975)
0.37	2	SO <sub>2</sub>		
0.37	2	O <sub>3</sub>	The observed O <sub>3</sub> - SO <sub>2</sub> interactive effect on lung function was considerably smaller than that seen by Hazucha and Bates. The authors concluded that the earlier study probably more nearly simulated a smog episode in regions having high oxidant and sulfur pollution.	Bell et al. (1977)
0.37	2	SO <sub>2</sub>		

## SENSITIVE POPULATION

The legislative history of the Clean Air Act indicates that, in setting primary ambient air quality standards, EPA is to direct its efforts at groups of "particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment." (U.S. Senate Serial No. 93-18, 93d Cong. 2d Sess. p. 410).

Clinical and epidemiological studies have shown that persons with chronic obstructive airway disease, particularly asthmatics, appear most sensitive to changes in ozone concentrations. This sensitivity results from the fact that their airways are hyper-reactive to irritants such as ozone. These people are, thus, judged to be the principal sensitive group of concern in setting the standard.

Studies have also established that exercise effectively increases the ozone dose delivered to the target tissues in the respiratory tract. Thus, persons engaging in exercise are particularly vulnerable to the acutely irritating effects of ozone. The response of these groups to such changes in concentrations has not, however, been systematically studied.

## NATURE AND SEVERITY OF EFFECTS

*Impaired Pulmonary Function and Clinical Symptoms*—Ozone is a pulmonary irritant that affects the mucous lining, other lung tissue, and respiratory function. Changes in lung function appear as increased airway resistance and as reductions in vital capacity, expiratory flow rates, and diffusion capacity. These effects are greater in exercising individuals and individuals with hyper-reactive airways (i.e., individuals with a history of developing symptoms during light activity in smog or history of asthma). Changes in lung function are accompanied by clinical symptoms such as coughing, chest tightness, and lower chest soreness.

Because the human respiratory system is endowed with a large reserve, even airway-resistance increases of 50 to 100 percent will not ordinarily be perceived in normal individuals. As stated in the criteria document, however, two considerations suggest that oxidant-associated changes in lung function may signal impairment of public health. First, in people with underlying respiratory illness such as asthma, chronic bronchitis, and emphysema, even small decrements in lung function often interfere with normal activity. Second, at experimental ozone concentrations as low as 0.30 ppm, decrements in lung function have usually been accompanied by physical discomfort, as manifested in symptoms such as sore throat, chest pain, cough, and headache. At times

this discomfort has been great enough to prevent the completion of experimental protocols, particularly when subjects have been exercising vigorously. It appears quite likely that the pulmonary irritant properties of ozone (and perhaps other oxidants) underlie both the discomfort and the decrements in function. Thus, at least when associated with ozone exposure, changes in lung function often represent a level of discomfort which, even among healthy people, may restrict normal activity or impair the performance of tasks.

*Decreased Resistance to Infection*—This effect is represented by an increased rate of mortality in laboratory animals subjected to both a bacterial challenge and exposures to ozone. According to some studies, the effect may be enhanced by the addition of such stresses as exercise or the addition of other pollutants in combination with the ozone dose. Despite the uncertainties involved in predicting human effects from animal studies, medical experts agree that decreased resistance to infection probably does occur in man. The Durham study (1974) reporting increased illness in college students following periods of elevated pollution levels (with peak oxidant being the pollution variable most strongly associated with illness) reinforces this hypothesis and adds to EPA's concern about the relationship of ozone to the occurrence of such an effect in man.

*Aggravation of Chronic Respiratory Disease*—Although the relationship between ambient oxidant or ozone levels and chronic pulmonary disease has not been fully assessed, available evidence suggests that the incidence and severity of asthma attacks increase when short-term total oxidant concentrations exceed 0.25 to 0.28 ppm. Also, several investigators have reported a relationship between short-term oxidant exposure and aggravation of other chronic obstructive lung diseases. However, their reports are inconclusive since short-term fluctuations in cigarette smoking habits were not considered in their data analyses.

Air pollution is one of the many stresses that can precipitate an asthma attack or worsen the disease state in persons with chronic cardio-pulmonary disease. Other factors that can precipitate attacks include respiratory infections, passage of cold fronts, seasonal pollens, extreme heat or cold, and emotional disturbances.

*Eye Irritation*—Eye irritation is associated with selected chemical species (such as PAN) in the photochemical oxidant mix and with other organic vapors. While there is no evidence that eye irritation is produced by ozone, an ozone standard will serve to

limit this effect because control measures that reduce ozone will also reduce the eye-irritating components in the total oxidant mix.

*Biochemical Effects*—Experimental exposures of human subjects to ozone have produced changes in blood biochemistry, such as increased fragility of red blood cells and altered enzyme activities in the serum. The significance of these ozone-mediated changes is not yet known, but the criteria document states that changes of the magnitude observed in human experimental exposures have not yet been linked to any clinical diseases.

*Carcinogenic, Mutagenic and Related Effects*—Studies have been conducted in an attempt to relate ozone to carcinogenic, mutagenic, and related effects. Available evidence in these areas is not particularly helpful in setting ambient ozone standards because most of the studies have not yet been replicated (in spite of some attempts to do so), and because some effects observed in lower life forms are of questionable significance for man. The criteria document states that the significance of effects such as chromosomal aberrations has not been established and that some studies have produced conflicting results. In addition, EPA's Science Advisory Board recommended that certain studies on the mutagenic effects of ozone, which have not been replicated, not be emphasized in the criteria document.

## PRIMARY STANDARD

As illustrated in the table of reported effect levels, there is no clear threshold air concentration of ozone indicated by the data as the onset of adverse health effects. It is EPA's best judgment that physiological responses probably occur in extremely sensitive persons at very low levels. At what point these responses become an adverse health effect and at what level they most likely occur in sensitive persons must necessarily be an informed judgment. As stated in the proposal, this judgment is based on (1) the Agency's understanding of the medical evidence presented in the criteria document and in the table of reported effect levels, (2) the findings of the advisory panel on health effects, and (3) the judgment of medical experts as to the adverse effect level in sensitive persons. The health experts who were consulted were asked to focus not only on the most sensitive population group, but also on a very sensitive portion of that group (specifically, those persons who are more sensitive than 99 percent of the sensitive group, but less sensitive than 1 percent of that group). The lowest adverse health effect level estimate cited by the health panel and the median value developed through the expert inter-

view process are reasonably consistent, ranging from 0.15 to 0.18 ppm. (See table below.) On the basis of the effect levels cited in the criteria document, it is EPA's judgment that the most probable level for adverse health effects in sensitive persons, as well as in health-

ier (less sensitive) persons who are exercising vigorously, falls in the range of 0.15-0.25 ppm. While the evidence is more convincing and the effects more pronounced at the higher end of this range, the data shows effects of concern at the lower concentration.

though evidence of reduced resistance to bacterial infection has not reached the point where it can be meaningfully used to extrapolate concentrations that would similarly affect man, these studies cannot be dismissed in selecting a standard level that provides an adequate margin of safety. Despite the present inability to extrapolate to an effect level in humans, most experts agree that ozone exposures may well result in decreased resistance to infection in humans. Further, it is the kind of effect that is serious enough in its implications to raise a need for caution. Thus, it is prudent public health practice to set a standard more stringent than the probable effect level estimated from human studies, in order to account in some measure for these unquantified, but possibly serious, effects.

PROBABLE EFFECT LEVEL ESTIMATES  
[Estimates for Sensitive Population Segments]

	Aggravation of asthma, emphysema, and chronic bronchitis	Reduced resistance to bacterial infection (animal studies)	Reduction in pulmonary function	Chest discomfort and irritation of the respiratory tract
Health panel judgment of effect level.	0.15-0.25 ppm	Not available	0.15-0.25 ppm	0.15-0.25 ppm
Probable or median effect level as estimated from interviews with health experts (Range of estimates given in parentheses).	0.17 ppm (0.14-0.25 ppm)	0.18 ppm (0.07-0.38 ppm)	0.15 ppm (0.07-0.18 ppm)	0.15 ppm (0.11-0.18 ppm)

In order to set an ambient air quality standard that protects the public health with an adequate margin of safety, EPA must deal with the uncertainty inherent in the judgment that the probable level for adverse effects in sensitive persons is in the range of 0.15-0.25 ppm.

Because the nature and intensity of effects vary from pollutant to pollutant and because medical research produces new and different findings as science progresses, EPA does not believe that a fixed acceptable margin of safety can be established for all pollutants or for a single pollutant over time. Each decision on a standard level must be made on the best evidence available at the time and should include consideration of such factors as:

1. *Concern for more sensitive individuals*—Sensitive persons may respond to ozone differently from the less sensitive persons who generally are tested in clinical studies. Individuals with underlying respiratory illness such as asthma, chronic bronchitis, and emphysema are particularly sensitive to even modest impairments of pulmonary function resulting from ozone exposure. For ethical reasons, clinical investigators normally do not expose persons with these illnesses and thus caution that such studies may not represent the full range of sensitivity to ozone. Also of concern are individuals engaged in vigorous outdoor activity (construction work, tennis, jogging, etc.) where the effects of ozone are enhanced or may occur at lower ambient concentrations.

2. *Pollutant interactions*—There is real concern that effects reported in some ozone studies may occur at lower concentrations and may be enhanced when ozone is present in combination

with other urban pollutants. Laboratory studies of a single pollutant (e.g., ozone in clean, filtered air); while important in elucidating physiological effects peculiar to that pollutant, cannot be viewed as providing definitive evidence of the minimum level at which these effects occur when that pollutant is present as only a part of the total insult delivered to an individual in the urban environment. Also of concern are other toxic oxidant species, such as PAN, that are often present with ozone in the ambient photochemical pollution mixture and cause other adverse effects such as eye irritation. Thus, the effects of ozone must be considered in the context of the total environment of the exposed individual; this environment includes concentrations of other pollutants consistent with their maximum allowable levels, high relative humidity, high ambient temperature, and high levels of physical stress.

3. *Long-term deleterious effects of ozone*—Unfortunately, there are few studies that have attempted to document the long-term adverse effect of human exposure to repeated peaks of ozone. Some animal studies do indicate that long-term ozone exposures act as an inducer of biochemical or morphological changes. Some of these changes are transient and, on a short-term basis, may have a physiological significance in that they confer a resistance against further lung injury in an oxidant environment (a similar response has been observed in human clinical studies). Some animal studies have indicated, however, that effects from continued exposure can result in an emphysema-like condition (e.g., P'an et al., 1972).

4. *Animal infectivity studies*—Al-

5. *Inconclusive studies reporting effects at low levels*—A similar caution is suggested by both the Makino and Mizoguchi epidemiological study and the von Nieding clinical study reporting effects at levels around 0.10 ppm.

6. *Uncertainties arising from air quality variations due to meteorology*—Since EPA's revised standard is statistically based and permits an expected number of allowable violations per year, there is concern about the magnitude of these excursions and how they might impact an exposed sensitive individual.

7. *Effects of calibration procedure change*—Another factor that has been considered in establishing a margin of safety is the variability that exists in the measurement and calibration techniques used in health studies and how these measurements may differ from those made with the ultraviolet (UV) reference calibration procedure being promulgated elsewhere in this issue of the FEDERAL REGISTER. Most of the relevant clinical studies utilized monitoring instruments calibrated with the current (NBKI colorimetric) reference calibration procedure or modifications thereof. EPA's best judgment is that the reference NBKI procedure shows a positive bias of about 10 percent with respect to the UV procedure when these techniques are compared under carefully controlled experimental conditions. However, due to the variability that can reasonably be expected in any clinical exposure monitoring measurements, as well as the uncertainty introduced by the modified calibrations procedures, EPA cannot determine a precise quantitative factor to adjust the findings of these health studies. In the case of the study done by DeLuca and Adams (1977), the authors have indicated to EPA that the reported ozone values

might be high with respect to the UV calibration procedure. While the exact magnitude of any required adjustment in the reported ozone values is uncertain, adjusted values could range from 0.12 to 0.15 ppm for the 0.15 ppm value reported by the authors, and from 0.23 to 0.30 ppm for the 0.30 ppm concentration. EPA will continue its evaluation of this issue through its program of clinical exposure studies.

8. *Findings from the preliminary risk assessment*—The preamble to the proposed standard described a preliminary risk assessment method performed to aid EPA in accurately treating the uncertainties associated with a standard decision. While this method cannot be used at this time as the sole tool for making that decision, the Agency does believe that the findings resulted from this initial application of the method do not permit any relaxation of the standard above 0.12 ppm.

After reviewing the comments received from all segments of the public, including those from the public health community, EPA remains convinced that at levels in the range of 0.15-0.25 ppm, adverse health effects will almost certainly be experienced by significant numbers of sensitive persons. Unless the standard is set somewhat below that level, the Agency would not be exercising that degree of prudence called for by the "adequate margin of safety" requirement of the Clean Air Act. The Administrator must exercise the informed scientific judgment that Congress has authorized him to bring to bear on these difficult problems.

There is no collection of facts or medical evidence that permits selecting an undisputed value for the standard level. EPA proposed a standard of 0.10 ppm, taking several factors into account in providing a margin of safety, as discussed above. Among those were epidemiological studies indicating effects below 0.15 ppm which the criteria document did not fully endorse, but which EPA thought it unwise to disregard. (See 43 FR 26966.) Also considered were animal studies indicating reduced resistance to bacterial infection, although extrapolation to human effects levels is not possible. (*Id.*) During the comment periods, EPA received informed scientific opinion disputing the interpretation and application of such studies. Based on its current understanding of these studies, EPA has concluded that they do not dictate as wide a margin of safety as was established in the proposal. EPA does believe, however, that these studies do suggest the real possibility of significant human adverse health effects below 0.15 ppm. Consequently, the Administrator has determined that a standard of 0.12 ppm is necessary and is sufficiently prudent

unless and until further studies demonstrate reason to doubt that it adequately protects public health.

#### WELFARE EFFECTS AND THE SECONDARY STANDARD

The Clean Air Act mandates the setting of a national secondary ambient air quality standard to protect the public welfare from any known or anticipated adverse effects associated with an air pollutant in the ambient air. Ozone and other photochemical oxidants constitute a form of air pollution that has been shown to affect vegetation and materials and that may have an impact on visibility. The economic loss resulting from current oxidant levels has been estimated to be in the range of several hundred million dollars per year nationwide. Non-quantifiable losses to the natural environment occur as well. A staff paper, "Assessment of Welfare Effects and the Secondary Air Quality Standard for Ozone," was placed in the docket at the time of proposal. The following paragraphs summarize this report and information received after its release.

Exposure of vegetation to harmful levels of ozone may result in leaf injury, decreased growth and yield, or reproductive effects. Visible leaf injury is the most readily detectable and frequently reported symptom of ozone damage; however, it is not an accurate indicator of yield or growth reduction.

In the June 22, 1978, FEDERAL REGISTER proposal (43 FR 26968-26969), it was stated that several investigators suggested that foliar injury rates in the range of 5 to 10 percent could produce detectable reductions in growth or yield, depending on the timing of the injury and other environmental factors. Since proposal of the standard in June, EPA has discussed the matter further with several experts in the field of air pollution damage to vegetation, particularly regarding what level of leaf injury should be of concern in protecting against significant reductions in yield or growth in commercially important crops and indigenous flora. These experts emphasized the uncertainty associated with correlating yield reduction with foliar injury. Some stated that detectable yield reductions would not occur until leaf injury reached values as high as 10 to 20 percent, and others felt that foliar injury was an inappropriate indicator of yield reduction.

The foliar responses of plants to ozone exposures are not linearly dependent on the dose (product of concentration and exposure duration) sustained by the plant. A given dose applied over a short period of time is more damaging than if it were applied over a longer period. EPA used a mathematical model to summarize, for

several crops, the experimental results which depict the variation in foliar response with short-term (0.5-hour to 8-hour) ozone exposures. The notice of proposed rulemaking predicted (on the basis of the mathematical model) that a secondary ozone air quality standard set at an hourly average concentration of 0.08 ppm, expected to be exceeded only once per year, would prevent any important commercial crop from receiving more than 3 percent leaf injury. On the basis of this prediction and the aforementioned assumptions regarding the relationship of foliar injury and yield reduction, EPA proposed to set the secondary standard level at 0.08 ppm.

As a result of its further consultations with researchers, EPA decided to reassess the uncertainties associated with the judgments that led to the proposed 0.08 ppm 1-hour average secondary standard. These experts pointed out that there are large uncertainties in the assumptions relating yield reduction to foliar injury. The mathematical model used to predict foliar injury was based on chamber studies, not on studies conducted under field conditions. The experts cautioned that these chamber studies generally represent experimental conditions in which the most sensitive varieties of a given species are used and in which moisture and temperature are optimal for producing injury. In addition, a given short-term dose of ozone, which can produce 5, 10, or even 20 percent foliar injury in a given plant, is unlikely to have an impact on yield unless the plant is exposed during a critical stage in the plant's life cycle.

Consequently, EPA has decided to base its decision on the secondary ozone air quality standard on the information currently available on growth and yield reduction in commercially important crops and indigenous vegetation exposed to ozone under field conditions. As discussed in a staff paper that has been placed in the docket (OAQPS 78-8, IV-A-3), "Evaluation of Alternative Secondary Ozone Air Quality Standards," these data indicate that growth and yield responses are related to the long-term (growing season) mean of the daily maximum 6- to 8-hour-average ozone concentrations. Based on an examination of this information, and the available air quality data, EPA concludes that there is currently no evidence indicating that a significant decrease in growth or yield of commercially important crops or indigenous flora will result from the long-term mean of the daily maximum 7-hour-average ozone concentrations expected to occur when the primary standard is attained. Consequently, EPA believes that a secondary standard more stringent than the primary standard is not necessary on



the basis of ozone-related yield reduction effects in vegetation.

Materials damage resulting from ozone can be described as an acceleration of aging processes; for example, rubber cracking, dye fading, and paint weathering. In contrast to the effects of ozone on vegetation, these effects are linearly dependent on the total ozone dose sustained by the material. As a result, the annual average concentration will determine the rate at which material is damaged. Any non-zero ozone concentration (including natural background levels) will contribute to the deterioration of sensitive materials over a sufficient exposure duration. While peak 1-hour ozone concentrations in urban areas tend to be considerably higher than in rural areas remote from man-made emission sources, the annual average concentrations observed in these areas are essentially the same. This finding is believed to be due to the impact of very low urban-area nighttime ozone concentrations on the annual average values; nighttime ozone levels in remote areas are not reduced as much from the daytime levels due to the absence of scavenging by man-made urban pollutants. As peak ozone levels in urban areas are reduced through control of man-made pollutants, scavenging will also be reduced resulting in little if any change in the annual average. Consequently, no effect-based rationale can be offered to decide the level of the secondary standard needed to protect materials. Accordingly, EPA believes that a secondary standard more stringent than the primary standard is not necessary on the basis of ozone damage to materials.

The criteria document states that there is a limited amount of data suggesting an association between ambient ozone and visibility degradation, particularly in the Los Angeles area. On the basis of EPA's evaluation to date of the information presented in the criteria document, however, EPA is unable to conclude at this time that a secondary ozone standard more stringent than the primary standard is necessary to prevent visibility deterioration. The relationship between visibility and ambient ozone will be considered further in the development of subsequent PSD programs designed to protect against significant deterioration of air quality.

On the basis of these conclusions with respect to ozone damage to vegetation and materials and the association of ozone with visibility reduction in some areas, EPA is revising the secondary ozone air quality standard level to 0.12 ppm.

#### OTHER ASPECTS OF THE STANDARD

On the basis of EPA's evaluation of evidence submitted and comments re-

ceived during the public review process, no major changes will be made in the following aspects of the proposed standard: (1) Averaging time: 1 hour; (2) chemical species: ozone; (3) form: statistical; and (4) a separate standard for PAN is not being promulgated. As discussed below, changes will be made in (1) the set of hourly averages from which the number of exceedances of the standard level is counted, and (2) the exclusion criteria for missing data.

#### DAILY MAXIMUM HOURLY AVERAGE INTERPRETATION OF THE STANDARD

The maximum ozone concentrations which will occur in any given time period will vary from one period to the next, even if precursor emissions remain constant. These variations are mainly due to the random nature of meteorological factors which affect the formation and dispersion of ozone in the atmosphere. The present deterministic form of the standard, which permits only a single hourly exceedance of the standard level in any year, inadequately deals with this situation. The risk to public health contributed to by ozone can be managed better if the ozone standard reflects the fact that maximum ozone concentrations are probabilistic in nature. Consequently, EPA is changing the standard to a statistical form that allows one expected exceedance per year.

The proposed standard would have allowed one expected hourly exceedance per year. EPA is further modifying the standard so that the one expected exceedance will be given a daily interpretation; that is, a calendar day will exceed the standard level if the maximum hourly average concentration for the day exceeds the level of the standard. This modification means that a day with two hourly values over the standard level counts as one exceedance of the standard level rather than two; similarly for days with more than two hourly values over the standard level. As was indicated in the proposal notice, the daily interpretation has some advantages and it is evident from the comments received that there is considerable support for the use of this interpretation.

It should be understood that the change to a daily interpretation is not predicated on a reinterpretation of health data. In making this change, EPA is not concluding that 3 hours of exposure above a given level, for example, are no worse than 1 hour of exposure above the same level as long as the 3 hours of exposure occur during the same day. The impact of ozone is related to the total dose delivered to the respiratory tract, and obviously for a given concentration a 3-hour exposure gives a greater dose than a 1-hour exposure. In the case of ozone, the pattern of hourly levels is mainly

determined by meteorological fluctuations, and EPA's decision to promulgate a daily standard does not affect meteorological fluctuations. Ozone precursor emissions are not easily manipulated on a short-term basis, so there is little likelihood that emission sources could readily alter emission patterns to take advantage of the daily interpretation.

The change to a daily interpretation does make the standard slightly less stringent, and hence there is a small increase in the risk to health. In general, the reduction in emissions of organic compounds needed to meet the standard under the daily interpretation will be smaller. As discussed in a report placed in the docket (OAQPS 78-8, IV-A-4), the long-term increase in health risk at an average geographical location is estimated to be equivalent to the increase that would result from raising the level of the standard to 0.123 ppm and keeping the hourly interpretation of the number of exceedances.

#### EXCLUSION CRITERIA FOR MISSING DATA

EPA is additionally modifying the standard with respect to the treatment of missing data. The proposed standard permitted certain missing values to be excluded from the estimated exceedances calculation if either of two exclusion criteria were satisfied. The first criterion recognized the impact of short-term meteorological influences by allowing a missing value to be excluded if the adjacent values were below an arbitrary limit (75 percent of the standard level). This criterion should be relatively easy to incorporate into data-handling schemes and has been retained, although it now applies to daily maximum hourly average values. The second criterion dealt with comparisons with data from the previous 3 years. The purpose of this second criterion was to accommodate situations for which ozone data for a particular season are not available but for which known seasonal patterns of ozone and related meteorological factors make it unlikely that the level of the standard would have been exceeded.

This second criterion would be more difficult to implement because it necessitates the cross-referencing of earlier historical data. For newly established monitors, the historical data needed to invoke this exclusion would not be available. Thus, this second criterion in the proposal is difficult to implement and could be potentially burdensome in geographic areas where the climate makes high ozone values during certain seasons very unlikely. It is also possible to accomplish the intended purpose of this exclusion through provisions of the recently proposed 40 CFR Part 58 (see 43 FR

34892) that would grant waivers of the ozone monitoring requirements for certain times of the year at the discretion of the appropriate Regional Administrator. Therefore, the second exclusion criterion has been eliminated, and the computation formulas for estimating the expected number of exceedances have been modified to reflect the number of required monitoring days for the year.

*Definition of When the Standard is Attained*—EPA is adding Appendix H to 40 CFR Part 50 to explain when the standard is or is not being attained. Certain modifications to the proposal were necessary to accommodate the daily interpretation and the previously mentioned changes in the treatment of missing data. In order to implement the change from an hourly to a daily interpretation, it is necessary to define what is meant by a valid day of ozone data. Such a definition must ensure that a sufficient number of hours of the day have been monitored and that the hourly values in question reflect the time of day when high ozone values are likely to occur. At the same time, this criterion should be relatively easy to implement, it should allow time for routine maintenance, and yet it should protect against high values being ignored merely because not enough hours of the day were measured. Accordingly, a daily maximum hourly average concentration will be considered valid if 75 percent of the hourly values from 9:01 a.m. to 9:00 p.m. (LST) were recorded or if an hourly value above the level of the standard was measured. This validity criterion is intended as a minimum requirement and not as a recommended schedule.

The computation formula for calculating the estimated number of exceedances per year has been modified to correspond to the daily interpretation of the standard. Allowance has also been made for any situation in which the Regional Administrator has granted a waiver of the ozone monitoring requirements under the provisions of the recently proposed 40 CFR Part 58 and, therefore, the total number of required monitoring days is less than a full year. The use of the exclusion criterion may result in an underestimate of the probability of an exceedance in some situations but is relatively easy to implement and should suffice to account for the effect of missing data. It should be noted that the formula given in Appendix H is necessary to show attainment. Accounting for missing data can never, however, decrease the number of exceedances, and thus it is possible to establish non-attainment without the use of this equation.

These modifications to Appendix H are intended to simplify somewhat the

calculations and to allow for more flexible monitoring schedules. The comments received on Appendix H were varied. A few commenters thought it was too complicated while others suggested even more complex techniques. Most comments were, however, supportive of (or, at least, neutral toward) the proposed approach. One suggestion was to employ a minimum percent completeness requirement, rather than estimating the number of exceedances. The problem with that approach, however, is that it remains unclear as to what should be done with data sets that fail to meet such a completeness requirement.

Some comments discussed the use of 3 years of data. As indicated in the proposal, the choice of a 3-year period represents a compromise between added stability and reasonably current status assessments. Even under the present deterministic form of the standard, attainment designations (e.g., 40 CFR Part 81, Section 107) have been based on more than 1 year. Furthermore, although 3 years are used in estimating the expected number of exceedances under the statistical form of the standard being promulgated, it is still possible to establish non-attainment after one year if, for example, four or more exceedances were reported. Therefore, an upper bound to exceedances during a single year still applies under the new form.

#### ECONOMIC, ENERGY, AND ENVIRONMENTAL IMPACTS

As has been noted, the Clean Air Act specifically requires that National Ambient Air Quality Standards be based on scientific criteria relating to the level that should be attained to protect public health and welfare adequately. EPA interprets the Act as excluding any consideration of the cost of achieving such a standard in determining the level of the primary standard. However, in compliance with the requirements of Executive Orders 11821 and 11949 and OMB Circular A-107 and with the provisions of the recently issued Executive Order 12044 for rulemaking proceedings that are currently pending, EPA has prepared an analysis of economic impacts associated with efforts to attain this standard.

Ozone air pollution is a pervasive problem throughout the country. Most urban and many rural areas exceed the existing standard. Even with the less stringent standard, most of the major urban areas are not expected to attain the standard in the near term. Control of the organic precursor materials that generate photochemical oxidants is a major effort in this country and a multibillion-dollar program. The existing control pro-

gram includes measures to reduce organic emissions from automobile and truck exhausts, production of chemical and petroleum products, the dry-cleaning industry, most painting operations (including the automotive industry), and other industrial operations.

Because the attainment problem in most urban areas is so severe, the relaxation of the standard is not expected to change the level of control requirements in the near term. The move to a 0.12 ppm standard will, however, eliminate the theoretical need for major control programs in many rural and wilderness areas that currently exceed the present standard.

With the relaxation of the standard, EPA's economic impact analysis indicates that most urban areas are expected to achieve the standard by 1987. Even with aggressive control programs, however, it will be very difficult for some urban areas to achieve the standard within the next 10 years.

In addition, a document has been prepared assessing the impacts that efforts to attain the standard may have on the nation's energy requirements. This document examines the extent to which ozone precursors will be controlled by recovery of organic materials that would otherwise be emitted to the atmosphere, with resultant energy savings. Furthermore, an additional energy conservation should result in those areas that utilize transportation control measures to reduce precursor emissions by reducing the total number of vehicle-miles travelled. Because of such energy savings, EPA believes that ozone precursor control measures may well lessen the nation's energy requirements.

Finally, environmental impacts associated with control of oxidant precursors have been examined in a document available in docket number OAQPS 78-8. This study indicates that modifying the current standard should have minimal environmental impacts.

Copies of these analyses of the economic, energy, and environmental impacts involved in the revised ozone standard are available from Joseph Padgett at the address given earlier.

#### REVISIONS TO PART 50 REGULATIONS

In addition to the revised standard, this action necessitates two other revisions to 40 CFR Part 50 as follows:

1. In Appendix D, as well as in the table of sections for Part 50, the title is revised to read as follows: "Appendix D—Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere." The substitution of "ozone" for "photochemical oxidants corrected for interferences due to nitrogen oxides and sulfur dioxide" is a result

of the change in the chemical species designation of the standard.

2. Appendix H, "Interpretation of the National Ambient Air Quality Standards for Ozone," is added because additional guidance is necessary to understand the statistical nature of the revised standard.

#### REVISIONS TO PART 51 REGULATIONS

Elsewhere in this issue of the FEDERAL REGISTER, three revisions to 40 CFR Part 51 are promulgated concurrently with the revision to the photochemical oxidant standard. They are as follows:

1. The term "photochemical oxidants" is changed to "ozone" throughout Part 51.

2. Section 51.14, "Control strategy: Carbon monoxide, hydrocarbons, photochemical oxidants, and nitrogen dioxide," is revised to (a) allow the states to use any of four analytical techniques in the place of Appendix J to calculate the percent hydrocarbon reduction needed to attain the ozone standard, and (b) require that the states consider background ozone concentrations and ozone transport.

3. Appendix J is deleted from Part 51.

#### FEDERAL REFERENCE METHOD

The measurement principle and calibration procedure applicable to reference methods for measuring ambient ozone concentrations to determine compliance with the standard are not affected by this rulemaking. Elsewhere in this issue of the FEDERAL REGISTER, however, EPA is replacing (superseding) the current calibration procedure with a new, superior calibration procedure based on ultraviolet photometry. The measurement principle and the current calibration procedure are set forth in Appendix D of 40 CFR Part 50 (as amended in the February 18, 1975, issue of the FEDERAL REGISTER, 40 FR 7042). Reference methods—as well as equivalent methods—for monitoring ozone are designated in accordance with 40 CFR Part 53 (40 FR 7044). A list of all methods designated by EPA as reference or equivalent methods for measuring ozone is available from any EPA regional office, or from EPA, Department E (MD-76), Research Triangle Park, NC 27711.

Dated: January 26, 1979.

DOUGLAS M. COSTLE,  
Administrator.

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EPA amends Part 50 of Chapter I, Title 40, of the Code of Federal Regulations as follows:

1. Section 50.9 is revised to read as follows:

§ 50.9 National primary and secondary ambient air quality standards for ozone.

(a) The level of the national primary and secondary ambient air quality standards for ozone measured by a reference method based on Appendix D to this part and designated in accordance with Part 53 of this chapter, is 0.12 part per million (235  $\mu\text{g}/\text{m}^3$ ). The standard is attained when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 part per million (235  $\mu\text{g}/\text{m}^3$ ) is equal to or less than 1, as determined by Appendix H.

2. In Appendix D, as well as in the table of sections for Part 50, the title is revised to read as follows:

APPENDIX D—MEASUREMENT PRINCIPLE AND CALIBRATION PROCEDURE FOR THE MEASUREMENT OF OZONE IN THE ATMOSPHERE

3. Appendix H is added as follows:

APPENDIX H—INTERPRETATION OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE

#### 1. General

This appendix explains how to determine when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm (235  $\mu\text{g}/\text{m}^3$ ) is equal to or less than 1. An expanded discussion of these procedures and associated examples are contained in the "Guideline for Interpretation of Ozone Air Quality Standards." For purposes of clarity in the following discussion, it is convenient to use the term "exceedance" to describe a daily maximum hourly average ozone measurement that is greater than the level of the standard. Therefore, the phrase "expected

number of days with maximum hourly average ozone concentrations above the level of the standard" may be simply stated as the "expected number of exceedances."

The basic principle in making this determination is relatively straightforward. Most of the complications that arise in determining the expected number of annual exceedances relate to accounting for incomplete sampling. In general, the average number of exceedances per calendar year must be less than or equal to 1. In its simplest form, the number of exceedances at a monitoring site would be recorded for each calendar year and then averaged over the past 3 calendar years to determine if this average is less than or equal to 1.

**2. Interpretation of Expected Exceedances**

The ozone standard states that the expected number of exceedances per year must be less than or equal to 1. The statistical term "expected number" is basically an arithmetic average. The following example explains what it would mean for an area to be in compliance with this type of standard. Suppose a monitoring station records a valid daily maximum hourly average ozone value for every day of the year during the past 3 years. At the end of each year, the number of days with maximum hourly concentrations above 0.12 ppm is determined and this number is averaged with the results of previous years. As long as this average remains "less than or equal to 1," the area is in compliance.

**3. Estimating the Number of Exceedances for a Year**

In general, a valid daily maximum hourly average value may not be available for each day of the year, and it will be necessary to account for these missing values when estimating the number of exceedances for a particular calendar year. The purpose of these computations is to determine if the expected number of exceedances per year is less than or equal to 1. Thus, if a site has two or more observed exceedances each year, the standard is not met and it is not necessary to use the procedures of this section to account for incomplete sampling.

The term "missing value" is used here in the general sense to describe all days that do not have an associated ozone measurement. In some cases, a measurement might actually have been missed but in other cases no measurement may have been scheduled for that day. A daily maximum ozone value is defined to be the highest hourly ozone value recorded for the day. This daily maximum value is considered to be valid if 75 percent of the hours from 9:01 a.m. to 9:00 p.m. (LST) were measured or if the highest hour is greater than the level of the standard.

In some areas, the seasonal pattern of ozone is so pronounced that entire months need not be sampled because it is extremely unlikely that the standard would be exceeded. Any such waiver of the ozone monitoring requirement would be handled under provisions of 40 CFR Part 58. Some allowance should also be made for days for which valid daily maximum hourly values were not obtained but which would quite likely have been below the standard. Such an allowance introduces a complication in that it becomes necessary to define under what conditions a missing value may be assumed to have been less than the level of the standard. The following criterion may be used for ozone:

A missing daily maximum ozone value may be assumed to be less than the level of the standard if the valid daily maxima on both the preceding day and the following day do not exceed 75 percent of the level of the standard.

Let z denote the number of missing daily maximum values that may be assumed to be less than the standard. Then the following formula shall be used to estimate the expected number of exceedances for the year:

$$e = v + [(v/n) * (N - n - z)] \quad (1)$$

(\*Indicates multiplication.)

Where:

- e = the estimated number of exceedances for the year,
- N = the number of required monitoring days in the year,
- n = the number of valid daily maxima,
- v = the number of daily values above the level of the standard, and
- z = the number of days assumed to be less than the standard level.

\*Indicates multiplication.

This estimated number of exceedances shall be rounded to one decimal place (fractional parts equal to 0.05 round up).

It should be noted that N will be the total number of days in the year unless the appropriate Regional Administrator has granted a waiver under the provisions of 40 CFR Part 58.

The above equation may be interpreted intuitively in the following manner. The estimated number of exceedances is equal to the observed number of exceedances (v) plus an increment that accounts for incomplete sampling. There were (N-n) missing values for the year but a certain number of these, namely z, were assumed to be less than the standard. Therefore, (N-n-z) missing values are considered to include possible exceedances. The fraction of measured values that are above the level of the standard is v/n. It is assumed that this same fraction applies to the (N-n-z) missing values and that (v/n)\*(N-n-z) of these values would also have exceeded the level of the standard.

**AUTHORITY:** Sections 109 and 301 of the Clean Air Act, as amended (42 U.S.C. 7409, 7601).

[FR Doc. 79-4056 Filed 2-7-79; 8:45 am]

[6560-01-M]

[FRL 1018-3]

**PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS**

**Calibration of Ozone Reference Methods**

**AGENCY:** U.S. Environmental Protection Agency.

**ACTION:** Final rule.

**SUMMARY:** Appendix D to 40 CFR Part 50 prescribes a measurement principle upon which reference methods for the measurement of ozone\* in

\*The term "ozone" is used herein to be consistent with another EPA action in this

the atmosphere must be based. This appendix also specifies a procedure to be used for calibrating those ozone reference methods. EPA has evidence that another calibration procedure for ozone reference methods is significantly more accurate and less variable than the procedure currently specified in Appendix D. Accordingly, EPA is amending 40 CFR Part 50, Appendix D, to replace (supersede) the current calibration procedure with a superior calibration procedure based on ultraviolet photometry.

**EFFECTIVE DATE:** This action is effective immediately upon publication because the revised standard to which it applies is immediately effective.

**FOR FURTHER INFORMATION CONTACT:**

Mr. Larry J. Purdue, Telephone 919-541-2665 (FTS: 629-2665).

**ADDRESS:** Department E (MD-77), Environmental Monitoring and Support Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

**SUPPLEMENTARY INFORMATION:**

**BACKGROUND**

Part 50 of Title 40, Chapter I of the Code of Federal Regulations specifies the National Ambient Air Quality Standards for several air pollutants including ozone. Appendixes to Part 50 provide information concerning the reference methods which are used to measure those pollutants. In particular, Appendix D to Part 50 describes a measurement principle upon which ozone reference methods must be based, and specifies a calibration procedure to be used for calibrating such methods. Previously, the calibration procedure specified by Appendix D was based on assay of ozone with 1% neutral buffered potassium iodide (NBKI) and was known as the "NBKI procedure."

On June 22, 1978, EPA indicated its conclusion that another calibration procedure was clearly superior to the NBKI procedure, and accordingly EPA proposed an amendment to Appendix D to replace the NBKI procedure with the new procedure, based on ultraviolet (UV) photometry (43 FR 26971-26984). The rationale for the proposed amendment was discussed in the preamble to that proposal. Interested persons and organizations were afforded an opportunity to comment on all aspects of the proposed changes. The amendment, revised slightly after consideration of the public comments, is being promulgated today in conjunc-

Issue of the FEDERAL REGISTER substituting "ozone" for "photochemical oxidants corrected for interferences due to nitrogen oxides and sulfur dioxide," which was formerly used in Part 50.