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[6560-01]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL
PROTECTION AGENCY

SUBCHAPTER C—AIR PROGRAMS

[FRL 937-5]

PART 50—NATIONAL PRIMARY AND
SECONDARY AMBIENT AIR QUALITY
STANDARDSNational Primary and Secondary Ambient
Air Quality Standards for
LeadAGENCY: Environmental Protection
Agency.

ACTION: Final rulemaking.

SUMMARY: EPA is setting a national ambient air quality standard for lead at a level of 1.5 micrograms lead per cubic meter of air ($\mu\text{g Pb}/\text{m}^3$), averaged over a calendar quarter. This final rulemaking follows a 1976 court order to list lead as a criteria pollutant for the development of an ambient standard, and the Agency's issuance of a proposed standard on December 14, 1977. In response to comments received on the proposed standard, EPA has changed the averaging period for the standard from a calendar month to a calendar quarter, and has clarified the health basis used in selecting the standard level.

In establishing the level of the final standard, EPA has determined that young children (age 1-5 years) should be regarded as a group within the general population that is particularly sensitive to lead exposure. The final standard for lead in air is based on preventing most children in the United States from exceeding a blood lead level of 30 micrograms lead per deciliter of blood ($\mu\text{g Pb}/\text{dl}$). Blood lead levels above 30 $\mu\text{g Pb}/\text{dl}$ are associated with the impairment of heme synthesis in cells indicated by elevated erythrocyte protoporphyrin (EP), which EPA regards as adverse to the health of chronically exposed children. There are a number of other adverse health effects associated with blood lead levels above 30 $\mu\text{g Pb}/\text{dl}$, in children as well as in the general population, including the possibility that nervous system damage may occur in children even without overt symptoms of lead poisoning.

DATES: Effective: October 5, 1978. After promulgation, States will have nine months (until July 5, 1979), to prepare and submit to EPA plans for attainment of the standard by no later than October of 1982. EPA's final regulations for the development of State

implementation plans appear elsewhere in this FEDERAL REGISTER.

FOR FURTHER INFORMATION
CONTACT:

Mr. Joseph Padgett, Director, Strategies and Air Standards Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711, telephone 919-541-5204.

AVAILABILITY OF RELATED INFORMATION

A docket (No. OAQPS-77-1) containing the information used by EPA in the development of the proposed standard is available for public inspection and copying between 8 a.m. and 4:30 p.m., Monday through Friday, at EPA's Central Docket Section, Room 2903B, Waterside Mall, 401 M Street SW., Washington, D.C. 20460.

The Federal reference method for collecting and measuring lead and its compounds in the ambient air is published in appendix G to this promulgation. This FEDERAL REGISTER also contains proposed regulations under 40 CFR Parts 51 and 53 for equivalent lead air monitoring methods, final rules for the development of State implementation plans promulgated under 40 CFR Part 51, and an advance notice of proposed rulemaking under 40 CFR Part 51 for ambient monitoring in the vicinity of certain industrial plants with lead emissions. Additional information for the development of the State implementation plans is contained in the document Supplementary Guidelines for Lead Implementation Plans. The environmental and economic impacts of implementing this standard are described in an environmental impact statement and an economic impact assessment. These documents are available for public inspection and copying at the Central Docket Section (address above). Copies may be obtained upon request from Mr. Joseph Padgett at the above address.

The documents Air Quality Criteria for Lead and Control Techniques for Lead Air Emissions were issued at the time of proposal. The Control Techniques Document is available upon request from Mr. Joseph Padgett at the above address. The Air Quality Criteria Document can be obtained from: Mr. Michael Berry, Environmental Criteria and Assessment Office, MD-52, Office of Research and Development, U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711, telephone 919-541-2266.

SUPPLEMENTARY INFORMATION:

BACKGROUND

Lead is emitted to the atmosphere by vehicles burning leaded fuel and by certain stationary sources. Lead enters

the human body through ingestion and inhalation with consequent absorption into the bloodstream and distribution to all body tissues. Clinical, epidemiological, and toxicological studies have demonstrated that exposure to lead adversely affects human health.

EPA's initial approach to controlling lead in the air was to limit the lead emissions from automobiles, the principal source of lead air emissions. Regulations for the phasedown of lead in the total gasoline pool were promulgated in 1973, and, following litigation, modified and put into effect in 1976. The Agency has also established regulations requiring the availability of no-lead gasoline for catalyst-equipped cars. EPA also intended to control emissions from certain categories of industrial point sources under section 111 of the Clean Air Act.

In 1975, the Natural Resources Defense Council (NRDC) and others brought suit against EPA to list lead under section 108 of the Clean Air Act as a pollutant for which air quality criteria would be developed and a national ambient air quality standard established under section 109 of the Act. The Court ruled in favor of NRDC. (*NRDC, Inc. et al. v. Train*, 411 F. Supp. 864 (S.D.N.Y., 1976) aff'd 545 F.2d 320 (2d Cir. 1976).) EPA listed lead on March 31, 1976, and proceeded to develop air quality criteria and the proposed standard.

On December 14, 1977, EPA proposed a standard of 1.5 $\mu\text{g Pb}/\text{m}^3$, calendar month average, proposed the Federal reference method for monitoring air lead levels, issued the documents Air Quality Criteria for Lead and Control Techniques for Lead Air Emissions and proposed regulations for State implementation plans. EPA invited public comments during the period from December 14, 1977, to March 17, 1978, on the standard, reference method, and the SIP regulations. Additional comments on these matters were provided to EPA at a public hearing held on February 15-16, 1978.

LEGISLATIVE REQUIREMENTS FOR
NATIONAL AMBIENT AIR QUALITY STANDARDS

Sections 108 and 109 of the Clean Air Act govern the development of national ambient air quality standards. Section 108 instructs EPA to document the scientific basis for the standard:

Section 108(a)(2). The Administrator shall issue air quality criteria for an air pollutant within 12 months after he has included such pollutant in a list under paragraph (1). Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the

ambient air, in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on—

(A) Those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant;

(B) The types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and

(C) Any known or anticipated adverse effects on welfare.

Section 109 addresses the actual setting of the standard:

Section 109(b)(1). National primary ambient air quality standards, prescribed under subsection (a) shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated.

(2) Any national secondary ambient air quality standard prescribed, under subsection (a) shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. Such secondary standards may be revised in the same manner as promulgated.

In order to conform to the requirements of section 109, EPA has based the level of the lead air quality standard on information presented in the criteria document pertaining to the health and welfare implications of lead air pollution. This is in contrast to other sections of the Act under which EPA considers economic costs and technical availability of air pollution control systems in determining emissions limitations. It is clear from section 109 that the Agency should not attempt to place the standard at a level estimated to be at the threshold for adverse health effects, but should set the standard at a lower level in order to provide a margin of safety. EPA believes that the extent of the margin of safety represents a judgment in which the Agency considers the severity of reported health effects, the probability that such effects may occur, and uncertainties as to the full biological significance of exposure to lead.

Comments resulting from external review of the air quality criteria and the proposed standard highlight disagreements on a number of areas critical to EPA's rationale for the standard. However, the scientific data base provided in the document Air Quality Criteria for Lead is as extensive as that for any other regulated air pollutant. Also, at every stage of development of the air quality criteria and the standard, EPA has facilitated and received broad external participation.

EPA regards as inevitable the presence of scientific disagreement and uncertainty about key factors relevant to environmental standards. Provisions of the Act requiring timely promulgation of the standard, and requirements for periodic future review of air quality criteria and standards indicate congressional intent that the Agency proceed even where scientific knowledge is not complete or full scientific consensus is absent.

SUMMARY OF GENERAL FINDINGS FROM AIR QUALITY CRITERIA FOR LEAD

Following the listing of lead as a criteria pollutant, EPA developed the document, Air Quality Criteria for Lead. In the preparation of this document, EPA provided opportunities for external review and comment on three successive drafts. The document was reviewed at three meetings of the Subcommittee on Scientific Criteria for Environmental Lead 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. The final criteria document was issued on December 14, 1977.

From the scientific information in the criteria document, EPA draws conclusions in several key areas with particular relevance for the ambient air quality standard for lead.

1. There are multiple sources of lead exposure. In addition to air lead, these sources include: Lead in paint and ink, lead in drinking water, lead in pesticides, and lead in fresh and processed food.

2. Exposure to air lead can occur directly by inhalation, or indirectly by ingestion of lead contaminated food, water, or nonfood materials including dust and soil.

3. There is significant individual variability in response to lead exposure. Even within a particular population, individual response to lead exposure may vary widely from the average response for the same group. Certain subgroups within the general population are more susceptible to the effects of lead or have greater exposure potential. Of these, young children represent a population of foremost concern.

4. Three systems within the human body appear to be most sensitive to the effects of lead—the blood-forming or hematopoietic system, the nervous system, and the renal system. In addition, lead has been shown to affect the normal functions of the reproductive, endocrine, hepatic, cardiovascular, immunologic, and gastrointestinal systems.

5. The blood lead level thresholds for various biologic effects range from the risk of permanent, severe, neuro-

logical damage or death as blood leads approach and exceed 80 to 100 $\mu\text{g Pb/dl}$ in children down to the inhibition of an enzymes system as low as 10 $\mu\text{g Pb/dl}$.

6. Lead is a stable compound, ubiquitously distributed, which persists and accumulates both in the environment and in the human body. In developing the proposed standard, EPA used these findings to arrive at a standard level of 1.5 $\mu\text{g Pb/m}^3$, calendar month average. This level was derived from the Agency's judgment that the maximum safe blood lead level (geometric mean) for a population of young children was 15 $\mu\text{g Pb/dl}$ and, of this amount, 12 $\mu\text{g Pb/dl}$ should be attributed to nonair sources. The difference of 3.0 $\mu\text{g Pb/dl}$ was estimated to be the allowable safe contribution to mean population blood lead from lead in the air. With epidemiological data indicating a general relationship of 1:2 between air lead ($\mu\text{g Pb/m}^3$) and blood lead ($\mu\text{g Pb/dl}$), EPA determined that the level for the proposed standard should be 1.5 $\mu\text{g/m}^3$.

SUMMARY OF ANTICIPATED IMPACTS

While the level of the standard is based on health considerations, EPA has conducted economic and environmental studies to assess the potential impacts of the standard selected. EPA estimates that the existing regulations for the phase-down of lead in gasoline, combined with the increasing use of no-lead gasoline for catalyst-equipped cars, will result in attainment of the standard in urban areas where automobile exhaust is the dominant source of air lead. No additional pollution controls are anticipated for these areas.

EPA's economic analysis does indicate that there may be significant problems in attainment of the standard in the vicinity of nonferrous smelters and other large industrial sources of lead emissions. This assessment is based, however, on studies using general emission factors and plant configurations, combined with dispersion modeling. In the development of State plans to implement the standard, EPA is encouraging affected industries and State agencies to gather plant-specific technical data, ambient air quality data, and assessments of alternative engineering controls. With this information, the Agency will be able to more accurately evaluate the impact of the standard and better consider approval of alternative approaches to emission control in the State plans.

Also, EPA is encouraging affected firms and State agencies to evaluate in the early design phase, strategies which take into consideration the workplace standard for airborne lead which will be promulgated by the Occupational Health and Safety Admin-

istration (OSHA). EPA believes that this approach will facilitate application of control technologies which meet the requirements of both agencies. In working with OSHA to estimate the combined impact of the OSHA and EPA standards, in coordinating compliance strategies, and in reviewing State plans implementing the ambient standard, EPA intends to avoid an approach which would foster uncertainty in the investment decisions of affected firms.

The Agency will make every effort to insure that all opportunities to avoid plant closures are examined, while at the same time assuring protection from clear risks to the public health.

SUMMARY OF COMMENTS RECEIVED

During the comment period from December 14, 1977, to March 17, 1978, and at the public meeting on February 15-16, 1978, EPA received 95 written and oral comments addressing the proposed standard or the requirements for State implementation plans. All comments opposing the standard as excessively stringent (25) came from representatives of affected industries, and 20 of these counter-proposed 5.0 µg Pb/m³, calendar quarter average, as the appropriate level for the standard.

Comments Received Opposing the Proposed standard of 1.5 µg/m³ Calendar Month Average as Excessively Stringent

Company	Op-posed	En-dorsed
Amax Lead & Zinc, Inc.....	X	X
American Mining Congress.....	X	X
American Petroleum Institute.....	X	
ASARCO.....	X	X
Associated Ocelt Co., Ltd.....	X	X
Battery Council International.....	X	X
Bethlehem Steel Corp.....	X	X
Bunker Hill Co.....	X	X
C & D Batteries Division.....	X	X
E. I. du Pont de Nemours & Co., Inc.....	X	X
ESA Laboratories, Inc.....	X	X
Ethyl Corp.....	X	X
General Battery Corp.....	X	X
General Motors Corp.....		
Getty Refining & Marketing Co... ..	X	
HECLA Mining Co.....	X	
Houston Chemical.....	X	X
Hunt Oil Co.....	X	
Kerr-McKee Corp.....		
Lead Industries Association.....	X	X
Nalco Chemical.....	X	X
N L Industries, Inc.....	X	X
Prestolite Battery Division.....	X	X
Secondary Lead Smelters Association.....	X	X
Shell Oil Co.....	X	
St. Joe Minerals Corp.....	X	X
Texaco, Inc.....	X	X
United Machinery Group.....		
Vulcan Materials Co.....		

¹1.5 µg/m³, calendar month.
²5.0 µg/m³, calendar quarter (or other averaging period).

SUMMARY: Forty-five comments received from 29 corporations or their representatives; 25 of the 29 firms opposed the proposed standard of 1.5 µg/m³, calendar month average; 20 endorsed an alternative

standard of 5.0 µg/m³, calendar quarter average (or other averaging period).

Four comments opposed the proposed standard on the grounds that it was not sufficiently protective of health.

COMMENTS RECEIVED OPPOSING PROPOSED LEAD AIR QUALITY STANDARD OF 1.5 µg/m³, CALENDAR MONTH AVERAGE, IN FAVOR OF A MORE STRINGENT STANDARD

Natural Resources Defense Council
 Dr. Sergio Piomelli, Director; Pediatric Hematology, New York University Medical Center Public Interest Campaign
 University of Connecticut School of Medicine

Comments supporting the level of the proposed standard (17) came from the medical community, Federal agencies, State and local public health agencies, and public interest groups.

COMMENTS RECEIVED ENDORSING PROPOSED LEAD AIR QUALITY STANDARD OF 1.5 µg/m³, CALENDAR MONTH AVERAGE

STATE AND LOCAL AGENCIES

- California Department of Health
- Massachusetts Department of Public Health
- New York State Department of Environmental Conservation
- New York City Department of Environmental Protection
- Tennessee Department of Public Health
- Wisconsin Department of Natural Resources

FEDERAL AGENCIES

- Center for Disease Control, Public Health Service
- Department of Transportation
- Food and Drug Administration
- Occupational Safety and Health Administration

PUBLIC INTEREST GROUPS AND THE MEDICAL COMMUNITY

- Committee on Environmental Hazards, American Academy of Pediatrics
- D.C. Committee for Lead Elimination in the District
- League of Women Voters of the United States
- National Urban League
- Herbert Needleman, Boston Children's Hospital Medical Center
- University of North Carolina School of Public Health

In addition, EPA has received numerous comments and correspondence on the proposed standard after the official end of the comment period. Though EPA does not have a legal obligation to review these documents, it has, in the interest of fostering full public participation in the rulemaking process, reviewed these comments and correspondence as time permitted. 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 become part of the administrative record of this decision.

The comments received by EPA did not challenge three aspects of the proposed standard:

1. The basic structure of the rationale used by the Agency in deriving the level of the proposed standard.
2. The selection of young children as a population particularly at risk to lead exposure.
3. The attribution of 12 µg Pb/dl out of the target mean population blood lead level of 15 µg Pb/dl to nonair sources of lead for the purposes of setting the air standard.

Significant comments were received, however, on the following key areas relating to the standard:

1. The elevation of erythrocyte protoporphyrin (EP) as the first adverse health effect with increasing lead exposure rather than the decline of hemoglobin levels.
2. The blood lead threshold level for elevated EP.
3. The incidence of health effects in populations residing in the vicinity of industrial sources of lead particulate emissions.
4. The relationship describing the response of lead in the blood to lead in the air.
5. The statistical form and averaging period for the standard.
6. The appropriate margin of safety.
7. The limitation of the standard to the respirable fraction of total air lead particles.
8. The economic impact of the standard.
9. The State implementation plan regulations.
10. The Federal reference method for monitoring lead air quality.

11. The administrative procedures employed by EPA in the development of the standard and the provision for public participation.

A review of the comments received and their disposition has been placed in the rulemaking docket (OAQPS-77-1) for public inspection. The following paragraphs summarize the significant comments and present the Agency's findings.

THE HEALTH SIGNIFICANCE OF ERYTHROCYTE PROTOPORPHYRIN ELEVATION

Ten commenters disagreed with EPA's conclusion that the impairment of heme synthesis indicated by elevated erythrocyte protoporphyrin (EP) constituted an adverse health effect. Reasons for this disagreement included:

1. An elevated level of EP is not itself toxic to the cells in blood or other tissues.
2. EP elevation, while indicating a change in heme synthesis, does not indicate an insufficient production of heme, or hemoglobin.
3. EP elevation and the alteration of heme synthesis does not imply impair-

ment of other mitochondrial functions.

4. EP elevation is not associated with impairment of other heme proteins, particularly cytochrome P-450.

5. Elevated EP may be caused by conditions other than exposure to lead, particularly iron deficiency.

Five commenters agreed with EPA's conclusions about the health significance of elevated EP citing the following arguments:

1. The interference of lead in a fundamental cellular metabolic function to the extent that there is accumulation of a substrate is physiological impairment, even without the presence of clinical evidence of disease.

2. It is prudent medical practice to intervene where subclinical indicators of physiological impairment are present.

3. The impairment of heme synthesis resulting from genetic or dietary factors places a child at enhanced risk to lead exposure.

4. There is evidence to suggest that impaired heme synthesis may affect the function of neural or hepatic tissue even at levels where heme production is sufficient for hematopoiesis.

AGENCY RESPONSE

EPA agrees with the comments received that the initial elevation of EP as a result of exposure to lead, while indicating an impairment of heme synthesis, may not be a disease state or be seen as a clinically detectable decline in performance. However, the criteria document points out (p. 1-13) that this impairment does increase progressively with lead dose.

The hematological effects described above are the earliest physiological impairments encountered as a function of increasing lead exposures as indexed by blood lead elevations; as such, those effects may be considered to represent critical effects of lead exposure. Although it may be argued that certain of the initial hematological effects (such as ALAD inhibition) constitute relatively mild, nondebilitating symptoms at low blood lead levels, they nevertheless signal the onset of steadily intensifying, adverse effects as blood lead elevations increase. Eventually, the hematological effects reach such magnitude that they are of clear-cut medical significance as indicators of undue lead exposure.

The fact that other conditions, such as iron deficiency may also impair heme synthesis, does not obviate concern that lead is interfering with an essential biological function. There is the possibility that a nutritional deficiency is an additional stress to the heme synthetic system which may increase the sensitivity of a child to the adverse effects of lead exposure.

EPA notes that there is general agreement that heme and heme-containing proteins play important roles in the oxygen fixation pathways in all

cells. While the effects of low-level lead exposure on the heme synthetic pathway in erythroid tissue have been extensively studied in part because of the ease with which this tissue may be obtained, other cellular metabolic systems utilizing heme are less well understood. EPA does not have sufficient information to conclude that impairment of heme synthesis in other tissues is not of concern until blood lead levels are reached greater than those associated with hematological effects. The air quality criteria document does point out that this effect has been established in other tissues and that other dose-response factors may apply.

The effect of lead on the formation of heme is not limited to the hematopoietic system. Experimental animal studies have shown a lead effect on the heme-requiring protein, cytochrome P-450, an integral part of the hepatic mixed-function oxidase (chapter 11), the systemic function of which is detoxification of exogenous substances. Heme synthesis inhibition also takes place in neural tissue. (P. 13-5.)

In summary, the criteria document states:

Elevation in protoporphyrin is considered not only to be a biological indicator of impaired mitochondrial function of erythroid tissue but also an indicator of accumulation of substrate for the enzyme ferrochelatase. It therefore has the same pathophysiological meaning as increased urinary δ -ALA (vide supra). For these reasons, accumulation of protoporphyrin has been taken to indicate physiological impairment in humans, and this clinical consensus is expressed in the 1975 Statement of the Center for Disease Control (CDC), USPHS. The criterion used by CDC to indicate an effect of lead on heme function is an FEP level of 60 $\mu\text{g}/\text{dl}$ in the presence of a blood lead level above 30 $\mu\text{g}/\text{dl}$ whole blood.

More recent information relating to threshold of lead effects indicates that FEP levels begin to increase at a blood lead value of 15 to 20 $\mu\text{g}/\text{dl}$ blood in children and women and, at a somewhat higher value, 20 to 25 $\mu\text{g}/\text{dl}$ blood, in adult men. (P. 13-5.)

EPA concludes that the state of elevated EP must be regarded as potentially adverse to the health of young children. While the onset or a mild experience of this condition may be tolerated by an individual, as with other subclinical manifestations of impaired function, it is a prudent public health practice to exercise corrective action prior to the appearance of clinical symptoms. The criteria document reports that symptoms of anemia in children may occur at blood lead levels of 40 $\mu\text{g}/\text{dl}$. EPA has adopted 30 $\mu\text{g}/\text{dl}$ as a maximum safe blood lead level for individual children.

THE BLOOD LEAD THRESHOLD FOR ELEVATED ERYTHROCYTE PROTOPORPHYRIN

Comments provided by ten organizations challenged EPA's conclusion that the threshold for the elevation of EP occurs in children at a blood lead

level of 15 $\mu\text{g}/\text{dl}$. Evidence offered for a higher threshold included:

1. The threshold accepted by EPA is based on a study in which an inappropriate statistical technique, probit analysis, was employed.

2. Application of a more appropriate technique, segmented line analysis, results in a higher threshold.

3. The study in question excluded data on children with blood lead levels in excess of 30 $\mu\text{g}/\text{dl}$.

4. Other investigators have reported higher thresholds.

Comments in support of the 15 $\mu\text{g}/\text{dl}$ threshold maintained:

1. It is proper to exclude values considered abnormal if the intent of the analysis is to determine an unbiased effect threshold.

2. Other studies have reported thresholds with error bands which include 15 $\mu\text{g}/\text{dl}$.

3. Probit analysis is an appropriate technique and differs only slightly from the results obtained from segmented line analysis.

AGENCY RESPONSE

EPA agrees that the segmented line technique provides a more accurate estimate of the correlation threshold of EP elevation with increasing blood lead, about 16.7 $\mu\text{g}/\text{dl}$, and for this reason considered changing its judgments as to the maximum safe blood lead level for a population of children. However, as the target geometric mean for a population is increased, a greater percentage of children in the population will exceed the maximum safe individual level of 30 $\mu\text{g}/\text{dl}$. EPA estimates that at a population geometric mean of 15 $\mu\text{g}/\text{dl}$, 99.5 percent of children will be below 30 $\mu\text{g}/\text{dl}$. At 16.7 $\mu\text{g}/\text{dl}$ this percentage falls to 98.7. EPA regards the number of children predicted to be below 30 $\mu\text{g}/\text{dl}$ as the critical health consideration. For this reason, EPA has maintained its estimate of a geometric mean of 15 $\mu\text{g}/\text{dl}$ as the target for population blood lead.

THE INCIDENCE OF HEALTH EFFECTS IN POPULATIONS RESIDING IN THE VICINITY OF INDUSTRIAL SOURCES OF LEAD PARTICULATE EMISSIONS

Several comments cited situations in which proximity to significant point sources of airborne lead emissions appear to have little or no health impact on resident populations. This was taken to imply that the air standard was not necessary to protect public health.

AGENCY RESPONSE

EPA acknowledges the variability of the impact of exposure to air lead on the potential for adverse health consequences. It is clear that direct exposure to air lead is only one of the

routes through which human exposure occurs. It is for this reason that the Agency has accepted the concept that only a portion of the safe population mean blood lead level should be attributable to air lead exposure. The presence or absence of health effects in an exposed population is influenced by a variety of factors including: Meteorology, terrain characteristics, geological and anthropological history, personal and domestic hygiene, the occupations of the population members, and the food and nonfood materials with which they come into contact. Taking into account such variability, it remains the Agency's belief that airborne lead directly and indirectly contributes to the risk of adverse health consequences and that sufficient clinical and epidemiological evidence is available to form a judgment as to the extent of this contribution. This evidence includes epidemiological studies showing higher blood lead levels in urban areas where air lead levels were elevated in comparison to rural areas. There have also been a number of studies linking elevated blood lead levels to industrial sources of lead emissions. With regard to the 1972 study at El Paso, Tex., by the Center for Disease Control, the criteria document reports:

It was concluded that the primary factor associated with elevated blood lead levels in the children was ingestion or inhalation of dust containing lead. Data on dietary intake of lead were not obtained because the climate and proximity to the smelter prevented any farming in the area. It was unlikely that the dietary lead intakes of the children from near the smelter, and farther away were significantly different. (P. 12-15.)

With regard to the report of Yankel et al. at Kellogg, Idaho, the criteria document states:

Five factors influenced, in a statistically significant manner, the probability of a child developing an excessive blood lead level:

1. Concentrations of lead in ambient air ($\mu\text{g}/\text{m}^3$).
2. Concentration of lead in soil (ppm).
3. Age (years).
4. Cleanliness of the home (subjective evaluation coded 0, 1, and 2, with 2 signifying dirtiest).
5. General classification of the parents' occupation (dimensionless).

Although the strongest correlation found was between blood lead levels and air lead level, the authors concluded that it was unlikely that inhalation of contaminated air alone could explain the elevated blood lead levels observed. (P. 12-16.)

THE APPROPRIATE RELATIONSHIP BETWEEN LEAD IN AIR AND LEAD IN BLOOD

Several commenters questioned the Agency's estimate that, for children, one microgram of lead per cubic meter air ($\mu\text{g Pb}/\text{m}^3$) results in an increase of

two micrograms lead per deciliter blood ($\mu\text{g Pb}/\text{dl}$).

AGENCY RESPONSE

EPA has reviewed the studies discussed in the criteria document which report changes in blood lead levels with different air lead levels. The Agency believes that one of the strongest epidemiological studies is that by Azar et al. in which personal dosimeters were used to measure lead intake. This eliminated some of the uncertainty about the extent to which air quality observations accurately reflect actual exposure. From the Azar data, the relationship of lead in the air to lead in the blood, evaluated at $1.5 \mu\text{g Pb}/\text{m}^3$ was 1:1.8. The Azar study was, however, limited to an adult population.

A clinical study of adults, Griffin et al., gives roughly the same conclusion for a group of adults confined to a chamber with controlled exposure to lead aerosol. This study was conducted over a three month period with control over lead ingestion. As air lead levels in the chamber were increased from $0.15 \mu\text{g Pb}/\text{m}^3$ to $3.2 \mu\text{g Pb}/\text{m}^3$, the air lead to blood lead relationship was 1:1.7.

Because children are known to have greater net absorption and retention of lead than adults, it is reasonable to assume that the air lead to blood lead relationship for this sensitive population, exposed to air lead levels in the range of the proposed standard, is equal to if not greater than for adults. EPA also notes that the air lead to blood lead relationship is nonlinear and may result in a higher ratio at lower air levels.

In an epidemiological study of children near a smelter, Yankel et al., the response of blood lead to air lead, averaged over the exposure range, was 1.9. EPA believes that these studies as well as others reported in the criteria document, support the criteria document's conclusion that:

Ratios between blood lead levels and air lead exposures were shown to range generally from 1:1 to 2:1. These were not, however, constant over the range or air lead concentrations encountered. There are suggestive data indicating that the ratios for children are in the upper end of the range and may even be slightly above it. There is also some slight suggestion that the ratios for males are higher than those for females. (P. 12-38.)

THE STATISTICAL FORM AND PERIOD OF THE STANDARD

One commenter expressed the view that, due to the lognormal distribution of measured air lead, a not-to-be-exceeded standard of $1.5 \mu\text{g}/\text{m}^3$, calendar month average, would require sources of air lead to achieve control of their emissions to a geometric monthly mean of $0.41 \mu\text{g}/\text{m}^3$ in order to prevent

the occurrence of a violation. Another comment expressed the opinion that, with the normal operation of a 6-day sampling schedule, the number of samples which could be collected in the course of a calendar month would not provide a statistically valid estimate of the actual lead air quality for the period.

Several comments questioned the health basis for the selection of the calendar month averaging period.

EPA RESPONSE

EPA accepts the consensus of comments received on the scientific and technical difficulties presented by the selection of a calendar month averaging period. The Agency believes that the key criterion for the averaging period is the protection of health of the sensitive population. In proposing the $1.5 \mu\text{g}/\text{m}^3$ standard, EPA concluded that this air level as a ceiling would be safe for indefinite exposure of young children. The critical question in the determination of the averaging period is the health significance of possible elevations of air lead above $1.5 \mu\text{g}/\text{m}^3$ which could be sustained without violation of the average of $1.5 \mu\text{g}/\text{m}^3$. In the proposed standard, EPA chose a monthly averaging period on the basis of a study showing an adjustment period of blood lead level with a change of exposure (Griffin et al.). Because of the scientific and technical difficulties of the monthly standard, EPA has reexamined this question and concludes that there is little reason to expect that the slightly greater possibility of elevated air lead levels within the quarterly period is significant for health. This conclusion is based on the following points:

(1) From actual ambient measurements, the distribution of air lead levels is such that where the quarterly standard is achieved, there is little possibility that there could be sustained periods greatly above the average value.

(2) While it is difficult to relate the extent to which a monitoring network actually represents the exposure situation for young children, it seems likely that where elevated air lead levels do occur, they will be close to point of mobile sources of lead air pollution. Typically, young children will not encounter such levels for the full 24-hour period reported by the monitor.

(3) There is medical evidence indicating that blood lead levels reequilibrate slowly to changes in air exposure. This serves to dampen the impact of a short-term period of exposure to elevated air lead.

(4) Direct exposure to air is only one of several routes of total exposure. This lessens the impact of a change in air lead on blood lead levels.

On balance, the Agency concludes that a requirement for the averaging of air quality data over calendar quarter will improve the validity of air quality data gathered without a significant reduction in the protectiveness of the standard.

THE APPROPRIATE MARGIN OF SAFETY

Several comments received by the Agency criticized the proposed standard for incorporating an excessive margin of safety. This criticism was based either on the view that the critical health effect, impaired heme synthesis, was not of health significance or on the view that EPA had employed conservative estimates of the several factors used in calculating the standard which, when combined, resulted in an excessively stringent standard.

Other comments were received which expressed concern that the standard had little or no margin of safety, particularly for certain subgroups within the general population of young children.

AGENCY RESPONSE

EPA does not agree that the impairment of heme synthesis is a physiological response to lead exposure that is without health significance. While EPA does not find that this impairment is necessarily serious to health at the point at which it first can be detected by the elevation of erythrocyte protoporphyrin, at a threshold in a range of 15-20 µg Pb/dl, the Agency does believe that above blood levels of 30 µg Pb/dl this effect has progressed to the extent that it should be regarded as an adverse health effect.

In determining the final ambient air standard for lead, EPA has used margin of safety considerations principally in establishing a maximum safe blood lead level for individual children at 30 µg Pb/dl and in determining the percentage of children to be placed below this maximum level, about 99.5 percent. Using these factors, results in a target geometric mean population blood lead of 15 µg Pb/dl.

In establishing other factors used in calculating the standard, EPA has used margin of safety in the sense of making careful judgments based on available data, but these judgments have not been at the precautionary extreme of the range of data available to the Agency. In the case of the geometric standard deviation (GSD), studies reviewed in the criteria document showed a range of 1.3 to 1.5. A standard based on a 1.5 GSD would be far more stringent than using 1.3. EPA took the 1.3, however, because of its concern that the total geometric standard deviation contains variation attributable to monitoring and analytical methodology. In estimating the relationship between air lead and blood

lead to be 1:2, the Agency used an epidemiological study of children near a smelter, Yankel et al., where response of blood lead to air lead averaged over the exposure range was 1 to 1.9. In adopting 12 µg Pb/dl as the part of blood lead attributable to nonair sources, EPA is concerned that typical levels for this component may be much greater, and that regulatory actions by other public health programs may be necessary to achieve a 12 µg level.

Because of the variability between individuals in a population experiencing a given level of lead exposure, EPA finds it is impossible to provide the same amount of margin of safety for all members in the sensitive population, or to define the margin of safety in the standard as a simple percentage. EPA does believe that the factors it has used in designing the standard provide an adequate margin of safety for a large proportion of the sensitive population. The Agency does not believe that this margin is excessively large or on the other hand that the air standard can protect everyone from elevated blood lead levels.

THE IMPORTANCE OF THE RESPIRABLE FRACTION OF TOTAL AIR LEAD LEVEL

The Agency received a number of comments expressing concern that, because only a fraction of airborne particulate matter is respirable, an air standard based on total air lead is unnecessarily stringent.

AGENCY RESPONSE

EPA agrees that some lead particles are too small or too large to be deposited in the respiratory system. EPA cannot conclude, however, that particles outside of the respirable range do not represent an exposure hazard. A significant component of exposure can be ingestion of materials contaminated by deposition of lead from the air. In addition to the indirect route of ingestion and absorption from the gastrointestinal tract, nonrespirable lead in the environment may, at some point, become respirable through weathering or mechanical action. EPA concludes, therefore, that total airborne lead, both respirable and nonrespirable fractions, should be addressed by the air standard.

THE ECONOMIC IMPACT OF THE PROPOSED STANDARD

A number of commenters were critical of the Agency's economic impact assessment, and argued that the forecast underestimated the severity of the economic impact to certain lead industries.

AGENCY RESPONSE

The comments critical of the draft impact statement did not include data which would allow EPA to confirm the possibility of more severe economic impacts on certain source categories including primary and secondary lead smelters which could have difficulty in limiting emissions sufficiently to assure attaining the standard in their immediate vicinity. Under the Clean Air Act, the primary responsibility for implementing the standard is assigned to the States and each State is required to submit a plan to EPA demonstrating how attainment is to be achieved. The actual economic impacts of implementation are difficult to estimate at this time since, following promulgation, States will have 9 months to develop and submit these plans to EPA. The plans must demonstrate attainment as soon as practicable, but no later than 3 years following the date of plan approval. However, under certain circumstances, States may request up to a 2-year extension of this deadline. Other sections of the Clean Air Act may be used with the Administrator's discretion to grant further extensions of compliance deadlines for impacted industrial facilities.

EPA cannot at this time accurately predict the impact of this standard, but with the timetable in the Act, sees no reason to expect imminent closure of any facility. The Agency is committed to developing accurate data for specific plants in cooperation with the industry and State agencies in order to avoid the imposition of unnecessary controls. EPA's principal concern, however, must be to follow the mandate of the Clean Air Act relating to the protection of the public health.

EPA believes that the economic impact assessment is a reasonable forecast of the economic consequences of implementation of the standard.

THE PROPOSED STATE IMPLEMENTATION PLAN (SIP) REGULATIONS

A summary of comments and the Agency response is included in the preamble to the final regulations published elsewhere in this FEDERAL REGISTER.

THE FEDERAL REFERENCE METHOD FOR MONITORING LEAD AIR QUALITY

A summary of comments and the Agency's disposition is included in the preamble to the final method published elsewhere in this FEDERAL REGISTER.

THE ADMINISTRATIVE PROCEDURES EMPLOYED BY EPA IN THE DEVELOPMENT OF THE PROPOSED STANDARD AND THE PROVISION FOR PUBLIC PARTICIPATION

Two commenters requested that cross examination of witnesses be al-

lowed in the post-proposal public hearing on the proposed standard and implementation regulations. EPA also received a request to postpone the public hearing and to extend the comment period, citing the need to complete ongoing studies.

AGENCY RESPONSE

Both the request for cross-examination and the extension of the comment period were denied by the Agency. With regard to the request for cross-examination, the Agency determined that, in light of the extensive review already conducted, cross-examination was not likely to produce new information or results that would justify such a significant departure from the normal rulemaking process. Also the existence of the normal comment period was sufficient to allow interested members of the public to raise questions concerning the Agency's determinations. Further, due to the extensive review opportunities available at all stages of the regulatory development, an extension of the comment period was not believed to be sufficiently necessary to further delay the schedule for preparation of the final rule.

CLARIFICATION OF ELEMENTS OF THE STANDARD

From reviewing the comments received, EPA wishes to clarify the following points in the presentation of the rationale for the final standard:

(1) EPA is making a distinction between the blood lead level that is the threshold for detection of the biological effect, impaired heme synthesis, and the blood lead level at which this effect has progressed to an extent that it is regarded as adverse to health.

(2) EPA is making a distinction between estimating a maximum safe blood lead level for an individual child, and establishing a population target geometric mean blood lead level for the sensitive population.

(3) EPA is making a distinction between what the contribution to blood lead levels from nonair sources actually may be, and attributing a contribution from nonair sources for the purpose of standard setting.

DERIVATION OF THE NUMERICAL LEVEL OF THE FINAL STANDARD

EPA's objective in setting the level of the standard is to estimate the concentration of lead in the air to which all groups within the general population can be exposed for protracted periods without an unacceptable risk to health.

This estimate is based on EPA's judgment in four key areas:

(1) Determining the "sensitive population" as that group within the general population which has the lowest

threshold for adverse effects or greatest potential for exposure. EPA concludes that young children, aged 1 to 5, are the sensitive population.

(2) Determining the safe level of total lead exposure for the sensitive population, indicated by the concentration of lead in the blood. EPA concludes that the maximum safe level of blood lead for an individual child is 30 $\mu\text{g Pb/dl}$ and that population blood lead, measured as the geometric mean, must be 15 $\mu\text{g Pb/dl}$ in order to place 99.5 percent of children in the United States below 30 $\mu\text{g Pb/dl}$.

(3) Attributing the contribution to blood lead from nonair pollution sources. EPA concludes that 12 $\mu\text{g Pb/dl}$ of population blood lead for children should be attributed to nonair exposure.

(4) Determining the air lead level which is consistent with maintaining the mean population blood lead level at 15 $\mu\text{g Pb/dl}$. Taking into account exposure from other sources (12 $\mu\text{g Pb/dl}$) EPA has designed the standard to limit air contribution after achieving the standard to 3 $\mu\text{g Pb/dl}$. On the basis of an estimated relationship of air lead to blood lead of 1 to 2, EPA concludes that the ambient air standard should be 1.5 $\mu\text{g Pb/m}^3$.

Each of these four areas is discussed further in the following sections.

SENSITIVE POPULATION

EPA believes that the health of young children is at particular risk from lead exposure. This is because children have a greater physiological sensitivity to the effects of lead than do adults and may have greater exposure to environmental lead from playing in contaminated areas. Other sensitive populations identified by EPA include those occupationally exposed, and pregnant women and their fetuses. Comments received on the proposed standard did not challenge EPA's position that young children are the most sensitive population for determining the standard. A number of comments did point out that within the general population of children there were subgroups with enhanced risk due to genetic factors, dietary deficiencies, or residence in urban areas. EPA acknowledges the higher risk status of such groups but does not have information either in the air quality criteria or in the comments received for estimating a threshold for adverse effects separate from that of all young children. Concern about these high risk subgroups has, however, influenced EPA's determination of the percentage of the population of children (99.5 percent) to be maintained below 30 $\mu\text{g Pb/dl}$.

EPA continues to be concerned about the possible health risk of lead exposure for pregnant women and

their fetuses. The stress of pregnancy may place pregnant women in a state more susceptible to the effects of lead, and transplacental transfer of lead may affect the prenatal development of the child. There is, however, insufficient scientific information for EPA to either confirm or dismiss this suggestion, or to establish that pregnant women and fetuses are more at risk than young children.

THE MAXIMUM SAFE EXPOSURE FOR CHILDREN

In determining the maximum safe exposure to lead for children, EPA has taken the measurement of blood lead as the indicator of total lead dose. There are other possible indicators of exposure, for example the level of zinc protoporphyrin (ZPP), but most health studies reported in the criteria document utilize blood lead levels as indications of the mobile body burden of lead. The criteria document reports the following table of effect thresholds for children with increasing blood lead levels.

SUMMARY OF LOWEST OBSERVED EFFECT LEVELS IN YOUNG CHILDREN

	$\mu\text{g Pb/dl}$
δ -ALAD inhibition.....	10
Erythrocyte protoporphyrin elevation	15-20
Increased urinary δ -ALA excretion.....	40
Anemia.....	40
Coproporphyrin elevation.....	40
Cognitive (CNS) deficits.....	50-60
Peripheral neuropathies.....	50-60
Encephalopathic symptoms.....	80-100

(P. 13-8.)

The first physiological effect associated with increasing blood lead levels is the inhibition of the enzyme δ -aminolevulinic acid dehydratase (δ -ALAD), both in red blood cells (erythrocytes), and in cells in other tissues. This enzyme catalyzes the condensation of two molecules of δ -aminolevulinic acid (δ -ALA) to form protoporphobilinogen, one of the components involved in the cellular synthesis of heme. The criteria document reports that the threshold for δ -ALAD inhibition in children is 10 $\mu\text{g Pb/dl}$.

At blood lead levels above 10 $\mu\text{g Pb/dl}$, the function of δ -ALAD is increasingly inhibited by lead. The criteria document states that 40 $\mu\text{g Pb/dl}$ is the threshold for elevation of δ -ALA recognized as δ -ALA in the urine or δ -ALA-U, an indication that δ -ALA has begun to accumulate in cells.

EPA does not regard the inhibition of δ -ALAD above 10 $\mu\text{g Pb/dl}$ as adverse to health because of the absence of evidence that there is an impairment of heme synthesis until a threshold of 40 $\mu\text{g Pb/dl}$ is reached. The accumulation of δ -ALA above normal levels, indicated by δ -ALA-U, is regarded as adverse to health, both because of impaired heme synthesis, and

the possibility that δ -ALA accumulation is itself toxic to cells.

The criteria document reports that above a threshold of 15-20 $\mu\text{g Pb/dl}$ there is an elevation of protoporphyrin in erythrocytes. Protoporphyrin is an organic chemical compound used by all cells in the production of heme. In the final stage of heme synthesis, erythrocyte protoporphyrin (EP) and iron are brought together in the cell mitochondria. In the presence of lead, this step is blocked, possibly by inhibition of the enzyme ferrochelatase or by interference in the transport of iron across the mitochondrial membrane. Without incorporation into heme, the levels of protoporphyrin in the cell become elevated.

From review of the information provided by the air quality criteria document as well as the evidence and arguments offered by medical professionals commenting on the proposed standard, EPA has concluded that the effects of lead on the cellular synthesis of heme, as indicated by elevated erythrocyte protoporphyrin, are potentially adverse to the health of young children. This appears, however, to be a question of the degree to which the effect has progressed. EPA does not believe that there is significant risk to health at the point where the elevation of EP can first be correlated with an increase in blood lead (15 to 20 $\mu\text{g Pb/dl}$). On the other hand, EPA regards as clearly adverse to health the impairment of heme synthesis, and other effects of lead which result in clinical symptoms of anemia above 40 $\mu\text{g Pb/dl}$. These effects are followed quickly by the risk of nervous system deficits for some children with blood lead levels of 50 $\mu\text{g Pb/dl}$.

EPA has concluded that the maximum safe blood lead level for an individual child is 30 $\mu\text{g Pb/dl}$. This is based on the following factors:

(1) The maximum safe blood lead level should be somewhat lower than the threshold for a decline in hemoglobin levels (40 $\mu\text{g Pb/dl}$).

(2) The maximum safe blood lead level should be at an even greater distance below the threshold for risks of nervous system deficits (50 $\mu\text{g Pb/dl}$).

(3) The maximum safe blood lead level should be no higher than the blood lead range characterized as undue exposure by the Center for Disease Control of the Public Health Service, as endorsed by the American Academy of Pediatrics, because of elevation of erythrocyte protoporphyrin (above 30 $\mu\text{g Pb/dl}$).

(4) The maximum safe blood lead level for an individual need not be as

low as the detection point for the initial elevation of EP (15-20 $\mu\text{g Pb/dl}$).

The criteria document points out that data from epidemiological studies show that the log values of measured individual blood lead values in a uniformly exposed population are normally distributed with a geometric standard deviation (GSD) of 1.3 to 1.5. Using standard statistical techniques, it is possible to use the geometric standard deviation to calculate the mean population blood lead level which would place a given percentage of the population below the level of an effects threshold. A GSD of 1.5 would result in a lower geometric mean, and a more stringent standard. However, because some of the variability in the GSD is from measurement systems, EPA has used a GSD of 1.3.

Recently, analysis of the data collected by New York City's Bureau of Lead Poisoning has shown that populations of children in the New York area consistently have distributions of blood lead values with a GSD of 1.4 to 1.5. With a geometric mean of 15.0 $\mu\text{g Pb/dl}$, a GSD of 1.4 results in about two percent of the population over levels of 30 $\mu\text{g Pb/dl}$. A GSD of 1.5 would place more than four percent over 30 $\mu\text{g Pb/dl}$. EPA is concerned that such results may imply that the standard is not as precautionary as it would be if the actual GSD was 1.3. However, the Agency's best estimate is that some of the GSD is from analytical and monitoring variance, and for this reason, EPA is using the 1.3 value in calculating the final standard.

In EPA's view, use of the 99.5 percent range is not excessive. From 1970 statistics, there are approximately 20 million children in the United States below the age of 5 years, 12 million in urban areas, and 5 million in center cities where lead exposure may be high. Again, knowledge that there are special high risk groups of children within the general population deters EPA from considering lower percentages.

CONTRIBUTION TO TOTAL LEAD EXPOSURE FROM NONAIR SOURCES

In the proposed standard, EPA argued that the air standard should take into account the contribution to blood lead levels from lead sources unrelated to air pollution. No comments were received challenging this argument. EPA continues to base its calculation of the ambient air standard on the assumptions that, to an extent, the lead contribution to blood lead from nonair sources should be subtracted from the estimate of safe mean population blood lead. Without this subtraction, the combined exposure to lead from air and nonair

sources would result in a blood lead concentration exceeding the safe level.

EPA notes that the level of the standard is strongly influenced by judgments about nonair contribution to total exposure, and that there are difficulties in attempting to estimate exposure from various lead sources. Studies reviewed in the criteria document do not provide detailed or widespread information about the relative contribution of various sources to children's blood lead levels. Estimates can only be made by inference from other empirical or theoretical studies, usually involving adults. Also, it can be expected that the contribution to blood lead levels from nonair sources can vary widely, is probably not in constant proportion to air lead contribution, and in some cases may alone exceed the target mean population blood lead level.

In spite of these difficulties, EPA has attempted to assess available information in order to estimate the general contribution to population blood lead levels from air and nonair sources. This has been done with evaluation of evidence from general epidemiological studies, studies showing decline of blood lead levels with decrease in air lead, studies of blood lead levels in areas with low air lead levels, and isotopic tracing studies.

Studies reviewed by the criteria document show that the geometric mean blood lead levels for populations of children are frequently above 15 $\mu\text{g Pb/dl}$. In studies reported, the range of mean population blood lead levels for children was from 16.5 $\mu\text{g Pb/dl}$ to 46.4 $\mu\text{g Pb/dl}$ with most studies showing mean levels greater than 25 $\mu\text{g Pb/dl}$ (Fine, 1972; Landrigan, 1975; von Lindern, 1975). EPA believes that, for many of these populations, the contribution to blood lead levels from nonair sources may exceed the desired target mean blood lead level.

In a number of studies, reduction in air lead levels resulted in a decline in children's blood lead levels. A study of blood lead levels in children in New York City showed that children's mean blood lead levels declined from 30.5 $\mu\text{g Pb/dl}$ from 1970 to 1976, while during the same period air lead levels at a single monitoring site fell from 2.0 $\mu\text{g Pb/dl}$ to 0.9 $\mu\text{g Pb/dl}$ (Billick, 1977). Studies at Omaha, Nebr. (Angle, 1977) and Kellogg, Idaho (Yankel, von Lindern, 1977) also show a drop in mean blood lead levels with declines in air lead levels. As air lead levels decline there appears to be a rough limit to the drop in blood lead levels.

EPA has also examined epidemiological studies in the criteria document where air lead exposure is low, and can be assumed to be a minor contributor to blood lead. These studies provide an indication of blood lead levels resulting from a situation where nonair sources of lead are predominant.

STUDIES REPORTING BLOOD LEAD LEVELS IN CHILDREN EXPOSED TO MODERATE TO LOW AIR LEAD LEVELS

Investigator	Blood lead ¹	Air lead ²	Comment
Hammer, 1972	11.6	0.1	Children in Helena, Mont.
Angle, 1974	14.4	0.14	Suburban Children ages 1 to 4 in Omaha, Nebr.
Goldsmith, 1974	13.7	0.2 to 0.7 0.3 to 0.6	Children in Benecia, Calif.
Johnson, Tillery, 1975	10.2	0.6	Female children—mean age 9 in Lancaster, Calif.

¹In micrograms of lead per deciliter.

²In micrograms of lead per cubic meter.

The range of mean blood lead levels in those studies is from 10.2 $\mu\text{g Pb/dl}$ to 14.4 $\mu\text{g Pb/dl}$, with an average at 12.7 $\mu\text{g Pb/dl}$.

In addition to epidemiological investigations, EPA has reviewed studies that examine the source of blood lead by detecting characteristic lead isotopes. A study using isotopic tracing (Manton, 1977) suggests that for several adults in Houston, Tex., 7 to 41 percent of blood lead could be attributed to air lead sources. An earlier isotopic study (Rabinowitz, 1974) concluded that for two adult male subjects studied, approximately one-third of total daily intake of lead could be attributed to exposure to air lead levels of 1-2 $\mu\text{g Pb/m}^3$. While these results cannot be directly related to children, it is reasonable to assume that children may exhibit the same or higher percentages of air lead contribution to blood lead level because of a greater potential for exposure to indirect air sources, soil and dust.

From reviewing these areas of evidence, EPA concludes that:

1. In studies showing mean blood lead levels above 15 $\mu\text{g Pb/dl}$, it is probable that both air and nonair sources of lead contribute significantly to blood lead with the possibility that contributions from nonair sources exceed 15 $\mu\text{g Pb/dl}$.

2. Studies showing a sustained drop in air lead levels show a corresponding drop in blood lead levels, down to an apparent limit in the range of 10.2 to 14.4 $\mu\text{g Pb/dl}$.

3. Isotopic tracing studies show air contribution to blood lead to be 7-41 percent in one study and about 33 percent in another study.

In considering this evidence, EPA notes that if, from the isotopic studies, approximately two-thirds of blood lead is typically derived from nonair sources, a mean blood lead target of 15 $\mu\text{g Pb/dl}$ would attribute 10 $\mu\text{g Pb/dl}$ to non-air sources. On the other hand, the average blood lead level from the limited studies available where air exposure was low is 12.7 $\mu\text{g Pb/dl}$. In the absence of more precise information,

EPA is calculating the lead standard based on the attribution of 12 $\mu\text{g Pb/dl}$ of the blood lead level in children to lead sources unaffected by the lead air quality standard. EPA is aware that actual population blood lead levels, either individually or as a population mean, may exceed this benchmark. However, if EPA were to use a larger estimate of non-air contribution to blood lead, the result would be an exceptionally stringent standard, which would not address the principal source of lead exposure.

THE RELATIONSHIP BETWEEN AIR LEAD EXPOSURE AND RESULTING BLOOD LEAD LEVEL

EPA has reviewed the studies discussed in the criteria document which report changes in blood lead levels with different air lead levels. The Agency believes that one of the strongest epidemiological studies is that by Azar et al., which used personal dosimeters to measure lead intake. This eliminated some of the uncertainty about the extent to which air quality observations accurately reflect actual exposure. From the Azar data, the relationship of lead in the air to lead in the blood, evaluated at 1.5 $\mu\text{g Pb/m}^3$, was 1:1.8. The Azar study was, however, limited to an adult population.

A clinical study of adults, Griffin et al., gives roughly the same conclusion for a group of adults confined to a chamber with controlled exposure to lead aerosol. This study was conducted over a three month period with control over lead ingestion. As air lead levels in the chamber were increased from 0.15 $\mu\text{g Pb/m}^3$ to 3.2 $\mu\text{g Pb/m}^3$, the air lead to blood lead relationship was 1:1.7.

Because children are known to have greater net absorption and retention of lead than adults, it is reasonable to assume that the air lead to blood lead relationship for this sensitive population, exposed to air lead levels in the range of the proposed standard, is equal to if not greater than for adults. EPA also notes that the air lead to blood lead relationship is nonlinear

which will result in a higher ratio at lower air levels.

In an epidemiological study of children near a smelter, Yankel et al., the response of blood lead to air lead, averaged over the exposure range, was 1.95. This study provided information on the relationship of blood lead to air lead over a very large range of air lead values. The air lead values in the study are the result of a model calibrated by monitoring data. The relative error of the individual values, especially in the low range is larger than in the Azar study.

The authors of the study, Yankel and von Lindern, chose a log-linear model which provided a good fit to the data and gave an estimated slope of about 1.2 at an air lead of 1.5. However, EPA sees a problem with a log-linear model in that it forces a lower slope at low air lead values and a higher slope at higher lead values. This is in direct contradiction to the Azar and the Griffin studies, both of which indicate higher slopes at lower air lead values.

Because of the uncertainties in the low air lead values in the Idaho study, EPA felt that the calculation of an average slope or ratio over the entire range of data would be a moderate compromise. The calculation of an average slope gives a value of 1.95. EPA believes that these studies as well as others reported in the criteria document support the document's conclusion that:

ratios between blood lead levels and air lead exposures were shown to range, generally from 1:1 to 2:1. These were not, however, constant over the range of air lead concentrations encountered. There are suggestive data indicating that the ratios for children are in the upper end of the range and may even be slightly above it. There is also some slight suggestion that the ratios for males are higher than those for females. (pp. 12-38.)

CALCULATION OF THE AIR STANDARD

EPA has calculated the standard based on the conclusions reached in the previous sections;

1. Sensitive population: Children, ages 1-6.
2. Health basis: Maximum safe blood lead level for individual children is 30 $\mu\text{g Pb/dl}$ based on concern for impaired heme synthesis above 30 $\mu\text{g Pb/dl}$ and margin of safety for anemia above 40 $\mu\text{g Pb/dl}$ and nervous system deficits above 50 $\mu\text{g Pb/dl}$.
3. Maximum safe geometric mean blood lead for children based on placing 99.5 percent of the sensitive population below the 30 $\mu\text{g Pb/dl}$ level of concern: 15 $\mu\text{g Pb/dl}$.
4. Estimate of blood lead level attributed to non-air sources: 12 $\mu\text{g Pb/dl}$.
5. Allowable contribution to blood lead from air sources after achieving the standard: 15 $\mu\text{g Pb/dl}$ - 12 $\mu\text{g Pb/dl}$ = 3 $\mu\text{g Pb/dl}$.
6. Air lead concentration consistent with blood lead contribution from air sources: 3 $\mu\text{g Pb/dl}$ \times 1 $\mu\text{g Pb/m}^3$ air/2 $\mu\text{g Pb/dl}$ blood = 1.5 $\mu\text{g Pb/m}^3$.

SELECTION OF THE AVERAGING PERIOD FOR THE STANDARD

Based on comments received and consideration by the Agency, the proposed averaging period of a calendar month is extended to a calendar quarter. EPA believes that this change will significantly improve the validity of lead air quality data which will be gathered to monitor progress toward attainment without placing an undue burden of State and local environmental agencies, or significantly reducing the protectiveness of the standard.

The Agency believes that the key criteria for the averaging period is the protection of the health of the sensitive population. In proposing the 1.5 $\mu\text{g Pb/m}^3$ standard, EPA concluded that this air level was safe for young children with an indefinite exposure period. The critical factor in the determination of the averaging period is the health significance of possible elevations of air lead above 1.5 $\mu\text{g Pb/m}^3$ which could be encountered for short periods without causing average levels to exceed the standard. In the proposed standard, EPA chose a calendar month averaging period on the basis of a study (Griffin et al.) showing an adjustment period of blood lead level with a change in exposure. Because of the scientific and technical difficulties of the monthly standard, EPA has reexamined this question and concluded that there is little reason to expect that the slightly greater possibility of elevated air lead levels sustainable by the calendar quarter standard is significant for health. This conclusion is based on the following factors:

(1) From actual ambient measurements, there is evidence that the distribution of air lead levels is such that if the quarterly average was achieved there is little possibility that there could be sustained periods greatly above the average value.

(2) While it is difficult to relate the extent to which a monitoring network actually represents the exposure situation for young children, it seems likely that where elevated air lead levels do occur, they will be close to point or mobile sources. Typically, young children will not encounter such levels for the full 24-hour period reported by the monitor.

(3) There is medical evidence indicating that blood lead levels reequilibrate slowly to changes in air exposure. This serves to dampen the impact of a short-term period of exposure to elevated air lead.

(4) Direct exposure to air is only one of several routes of total exposure. This lessens the impact of a change in air lead on blood lead levels.

On balance, the Agency concludes that a requirement for the averaging of air quality data over a calendar quarter will improve the validity of air

quality data gathered without a significant reduction in the protectiveness of the standard.

MARGIN OF SAFETY

The Clean Air Act instructs EPA to set the level of an ambient air quality standard at a level which protects the public health with a margin of safety. One approach to using margin of safety is to estimate the air concentration of a pollutant that is the threshold for the first adverse effect detected with increasing air levels, and then set the air standard at a somewhat lower level. The extent of the safety margin between the standard and the estimated threshold for adverse effects is influenced by such factors as the severity or irreversibility of effects, the degree of uncertainty about known or suspected health effects, the size of the population at risk, and possible interactions of several pollutants in potentiating health effects. While the margin of safety is based on available scientific information, this factor is judgmental in that the Administrator must weigh the acceptability of estimated risk.

Estimating an appropriate margin of safety for the air lead standard is complicated by the multiple sources and media for lead exposure. Because of this, EPA has elected to use margin of safety considerations in estimating the maximum safe level for blood lead, and the percentage of the sensitive population to be placed below this level, rather than making a final adjustment to concentration of lead in the air. EPA has adopted 30 $\mu\text{g Pb/dl}$ as the maximum safe blood lead level for individual children, and the air standard is calculated to maintain most children below this target. On the basis of information developed in the criteria document and from public comment, blood lead levels between 30 and 40 $\mu\text{g Pb/dl}$ are associated with impairments of the heme synthetic pathway which EPA regards as adverse to health. Blood lead levels above 40 $\mu\text{g Pb/dl}$ are associated with a decline in hemoglobin levels, and levels above 50 $\mu\text{g Pb/dl}$ are associated with the risk of nervous system deficits for some children. With a geometric mean population blood of 15 $\mu\text{g Pb/dl}$ lead, most children will be well below these thresholds, but a small percentage can be expected to have blood lead levels of concern.

Because of the variability between individuals in a population experiencing a given level of lead exposure, EPA finds that it is not possible to provide the same amount of margin of safety for all members in the sensitive population, or to define a margin of safety in this standard as a simple percentage. In developing the numerical level of the standard, EPA used evidence in

the criteria document that the blood lead levels for individuals in a given population of children are log-normally distributed. The statistical properties of this distribution make it possible to calculate the percentage of the population which will fall below any given blood lead level. Individuals at each of these levels would have a different margin of safety below the maximum safe blood lead level. As a rough example, with a population of children with a geometric mean blood lead of 15 $\mu\text{g Pb/dl}$, 86 percent of the children would be below 20 $\mu\text{g Pb/dl}$, 97.5 percent would be below 25 $\mu\text{g Pb/dl}$ and 99.5 percent would be below 30 $\mu\text{g Pb/dl}$. Assuming a population of children in central urban areas where air lead was at the standard level, 693,000 children would be over 20 $\mu\text{g Pb/dl}$, 126,500 over 25 $\mu\text{g Pb/dl}$, and 20,605 above 30 $\mu\text{g Pb/dl}$.

In determining the appropriate margin of safety, the Agency has also included consideration of the following factors:

(1) In addition to the health effects discussed, the "Air Quality Criteria for Lead" report multiple biological involvements of lead in practically all cell types, tissues, and organ systems. The significance for health of these has not been fully studied.

(2) There are no beneficial effects of lead at current environmental levels.

(3) EPA has incomplete data about the extent to which children are indirectly exposed to lead from air lead which moves to other environmental media, such as water, soil and dirt, and food.

(4) Lead is chemically persistent and with continued uncontrolled emissions will continue to accumulate both in human tissue and in the environment.

(5) There is a possibility that lead exposure resulting in blood lead levels previously considered safe may in fact influence the neurological development and learning abilities of the young child. EPA does not have evidence, however, that provides more than a suggestion that this could occur at blood lead levels below 30 $\mu\text{g Pb/dl}$ for individual children.

IMPACT OF LEAD DUSTFALL ON BLOOD LEAD

In the preamble for the proposed air standard for lead, EPA pointed out that the significance of dust and soil lead as indirect routes of exposure has been of particular concern in the case of young children. Play habits and mouthing behavior between the ages of 1 and 5 have led to the conclusion that greater potential may exist in these children for ingestion and inhalation of the lead available in contaminated dust and soil. EPA is also concerned that the deposition of lead particles can lead to general contamination of the environment and increased

lead exposure from surface waters and foodstuffs.

Studies reviewed in the criteria document indicate a correlation between soil and dust levels and children's blood lead levels in highly contaminated environments (Yankel and von Lindern, 1977; Barltrop, 1974; Galke, in press). The lead threshold for concern has been reported as 1,000 parts per million (ppm) in soil (Yankel and von Lindern, 1977). At levels of between 500 and 1,000 ppm in soil, the criteria document concludes that blood lead levels begin to increase. A twofold increase in soil concentration in this range is predicted to result in a 3-6 percent rise in blood lead levels. Below 500 ppm lead in soil, no correlation has been observed with blood lead levels.

The normal background for lead in soil is cited in the criteria document as 15 ppm. Due to human activities, the average levels in most areas of the United States are considerably higher. Soil studies conducted by EPA's Office of Pesticides Programs from 1974 to 1976 in 17 urban areas reported only 3 cities with arithmetic mean concentrations in excess of 200 ppm, with the highest value 537 ppm. Concentrations in the soils surrounding large point sources of lead emissions, or heavily travelled roads may reach many thousand ppm.

Because of the many factors involved, EPA is unable to predict the relationship between air lead levels, dustfall rates, and resulting soil accumulation. Complicating factors include: Particle size distribution, rain-out, other meteorological factors, topographical features affecting deposition, and removal mechanisms.

EPA believes, however, that significant impacts on blood lead of soil and dust lead are mainly limited to areas of high soil concentration (in excess of 1,000 ppm) around large point sources and heavily travelled roads. Evidence suggests that soil lead levels in areas with air lead levels in the range of the standard are below the threshold for lead health impact (Johnson, Tillery, 1975; Johanson, 1972; EPA, 1975 Air Quality Data and Soil Levels).

Comments received on the proposed standard argued that the lead air standard should be limited to respirable size lead particulate matter, as larger particles would fall to the ground without being deposited or absorbed in the lung. EPA has decided not to accept this recommendation because, as discussed above, larger particles can contribute to lead dose by human ingestion of airborne particles, by contamination of other environmental media, or by eventual reduction to respirable size by mechanical action or weathering.

WELFARE EFFECTS

Comments received on the proposed lead air quality standard did not address the issue of welfare effects or the need for a secondary air quality standard more restrictive than the primary standard. EPA maintains its position that the primary air quality standard will adequately protect against known and anticipated adverse effects on public welfare. EPA does not have evidence that a more restrictive secondary standard would be justified.

Available evidence cited in the criteria document indicates that animals do not appear to be more susceptible to adverse effects from lead than man, nor do adverse effects in animals occur at lower levels of exposure than comparable effects in humans.

Lead is absorbed but not accumulated to any great extent by plants from soil. Lead is either unavailable to plants or is fixed in the roots and only small amounts are transported to the above ground portions. Lead may be deposited on the leaves of plants and present a hazard to grazing animals. Although some plants may be susceptible to lead in the natural environment, it is generally in a form that is largely nonavailable to them.

There is no evidence to indicate that ambient levels of lead result in significant damage to manmade materials. Effects of lead on visibility and climate are minimal.

Based on such data, EPA promulgates the secondary air quality standard for lead at 1.5 $\mu\text{g Pb}/\text{m}^3$, calendar quarter average.

ECONOMIC IMPACT ASSESSMENT

As required by Executive Orders 11821 and 12044, EPA has conducted a general analysis of the economic impact which might result from the implementation of the lead regulations. This analysis was not intended for nor was it used in the development or promulgation of the standard, and was issued for informational purposes only.

The economic impact assessment points out that the categories of sources likely to be affected by control of lead emissions are primary lead and copper smelters, secondary lead smelters, gray iron foundries, gasoline lead additive manufacturers, and lead storage battery manufacturers. This analysis further indicates that some primary and secondary lead smelters and copper smelters may be severely strained economically in achieving emission reductions that may be required in implementing the proposed air quality standard.

There are, however, uncertainties associated with evaluating the impact of attaining the standard. For smelters and foundries, attaining the standard

may require control of fugitive lead emissions, i.e., those emissions escaping from individual process operations, other than emissions from smoke stacks. Fugitive emissions are difficult to estimate, measure, and control; and it is also difficult to predict their impact on air quality near the facility. From the information available to EPA, nonferrous smelters may have great difficulty in achieving lead air quality levels consistent with the proposed standard in areas immediately adjacent to the smelter complex.

The change in averaging time from a monthly average to a calendar quarter average will affect the economic impacts associated with the lead standard because for a given level of the standard, a longer averaging period is theoretically less stringent than a shorter averaging period.

OTHER LEAD REGULATORY AND CONTROL PROGRAMS

EPA's ambient air quality standard is only one of a number of Federal, State, and local programs designed to limit exposure to lead.

In 1975, EPA promulgated the national interim primary drinking water regulation, setting a maximum contaminant level for lead. The standard, aimed at protecting children from undue lead exposure, was set at 50 $\mu\text{g Pb}/\text{liter}$. In 1977, the National Academy of Sciences concluded that a lead level at which adverse health effects are observed cannot be set with assurance at any value greater than 25 $\mu\text{g Pb}/\text{liter}$. The Office of Drinking Water is currently considering the need to revise the interim drinking water standard for lead.

Based on its toxicity, EPA has included lead on its list of priority water pollutants for which effluent guidelines are being developed under the Clean Water Act. Effluent guidelines are being developed for lead for nonferrous smelters, based on achievement of best available technology.

EPA's Office of Pesticide Programs has promulgated regulations based on the toxicity of lead which require the addition of coloring agents to the pesticide lead arsenate and specify disposal procedures for lead pesticides. Use of lead in pesticides is a small and decreasing proportion of total lead consumption in the United States.

The Resource Conservation and Recovery Act (RCRA) of 1976, through which EPA is to establish standards on how to treat, dispose, or store hazardous wastes, provides a means for specifying how used crankcase oil and other waste streams containing lead should be recycled or safely disposed of. Regulatory actions related to wastes containing lead are currently being developed under subtitle C of RCRA.

EPA has regulations for reducing the average lead content in the total gasoline pool to 0.5 grams/gallon by October 1, 1979, and regulations providing for lead-free gasoline required for cars equipped with catalytic converters and other vehicles certified for use of unleaded fuel. The former regulations are based on reducing exposure to airborne lead to protect public health. Other EPA actions which result in the reduction of airborne lead levels include ambient standards and State implementation plans for other pollutants such as particulate matter and sulfur dioxide and new source performance standards limiting emissions of such pollutants. Existing and new sources of particulate matter emissions generally use control techniques which reduce lead emissions as one component of particulate matter.

The Occupational Safety and Health Administration proposed regulations in 1975 to limit occupational exposure to lead to 100 $\mu\text{g Pb}/\text{m}^3$, 8-hour time-weighted average. The exposure limit was based on protecting against effects, clinical or subclinical, and the mild symptoms which may occur below 80 $\mu\text{g Pb}/\text{dl}$, providing an adequate margin of safety. The level of 100 $\mu\text{g Pb}/\text{m}^3$ is anticipated to limit blood lead levels in workers to a mean 40 $\mu\text{g Pb}/\text{dl}$ and a maximum of 60 $\mu\text{g Pb}/\text{dl}$. OSHA is presently reviewing the latest information on lead exposure and health effects in preparation for promulgation of the workplace standard for lead.

The Department of Housing and Urban Development (HUD) has requirements for reducing human exposure to lead through the prevention of lead poisoning from ingestion of paint from buildings, especially residential dwelling. Their activities include (1) prohibition of the use of lead-based paints on structures constructed or rehabilitated through Federal funding and on all HUD-associated housing; (2) the elimination of the immediate hazard from lead-based paint; (3) notification of purchases of HUD-associated housing constructed prior to 1950 which may contain lead-based paint; and (4) research activities to develop improved methods of detection and elimination of lead-based paint hazards, and the nature and extent of lead poisoning.

The Consumer Product Safety Commission (CPSC) promulgated regulations in September 1977 which ban: (1) Paint and other surface coating materials containing more than 0.06 percent lead; (2) toys and other articles intended for use by children bearing paint or other similar surface coating material containing more than 0.06 percent lead; and (3) furniture coated with materials containing more than 0.06 percent lead. These regulations

are based on CPSC's conclusion that it is in the public interest to reduce the risk of lead poisoning to young children from ingestion of paint and other similar surface-coating materials.

The Food and Drug Administration (FDA) adopted in 1974 a proposed tolerance for lead of 0.3 ppm in evaporated milk and evaporated skim milk. This tolerance is based on maintaining children's blood lead levels below 40 $\mu\text{g Pb}/\text{dl}$. FDA has also proposed an action level of 7 $\mu\text{g Pb}/\text{ml}$ for leachable lead in pottery and enamelware, although the exact contribution of such exposure to total human dietary intake has not been established.

The Center for Disease Control (CDC) concluded in 1975 that undue or increased lead absorption exists when a child has confirmed blood lead levels of 30-70 $\mu\text{g Pb}/\text{dl}$ or an EP elevation of 60-189 $\mu\text{g Pb}/\text{dl}$ except where the elevated EP level is caused by iron deficiency.

In developing the lead air standard, EPA has estimated both individual and population blood lead levels which it regards as safe targets. The Agency believes that these targets do not necessarily serve as precedents for other regulatory programs. There are three reasons for this view:

(1) These targets were selected on the basis of what the Clean Air Act requires. Other programs have other legislative requirements which would lead to adoption of different but equally legitimate goals.

(2) The scientific data provided by the air quality criteria allow comparison of air levels with blood lead levels, but analogous information is not available for other media. At this time, there does not appear to be the same extent of information about the impact on blood lead of lead in food, water, and nonfood ingested items. Because of this, FDA, CPSC and other EPA standards have been based on estimates of acceptable daily dose rather than on blood lead targets.

(3) Studies currently underway may provide new information relevant to estimating safe levels of lead exposure.

COMMENTS BY OTHER FEDERAL AGENCIES

Comments on the proposed lead air quality standard were received from eight Federal Agencies. Five of the Agencies endorsed the air standard while three of the Agencies commented on specific issues and neither endorsed nor opposed the standard. The Center for Disease Control and the U.S. Public Health Service voiced support for the proposed standard of 1.5 $\mu\text{g Pb}/\text{m}^3$ and urged basing the decision on the standard solely on considerations of public health. CDC is fully satisfied that EP elevation does indeed represent a subclinical manifestation of lead toxicity and that young chil-

dren are the population most at risk from lead exposure, while some subgroups of children are at special risk to lead because of conditions such as malnutrition, genetic factors, or iron deficiency.

The Consumer Product Safety Commission endorsed the approach and some of the judgments made in arriving at the proposed air standard. CPSC concurred with the position that children are the population at enhanced risk to lead exposure, and that the goal of a mean population blood lead level for children of 15 $\mu\text{g Pb}/\text{dl}$ is sufficiently low to be protective of the population at enhanced risk of exposure. CPSC views the selection of EP elevation as the adverse health effect of concern as open to challenge and suggests basing the standard on a more generally recognized severe health effect. CPSC concurs that the contribution of nonair sources to lead body burden must be evaluated in setting the air standard and suggests that a larger nonair contribution, such as 13.5 $\mu\text{g Pb}/\text{dl}$ used in the California standard, might be considered.

The Food and Drug Administration commended EPA's proposal of an ambient air quality standard for lead. FDA agrees that children aged 1-5 years old comprise the most critically sensitive population. FDA concurs that 15 $\mu\text{g Pb}/\text{dl}$ is a reasonable maximum blood lead level to use as an average national goal for children aged 1 to 5, although FDA suggests that for young children the margin of safety is disturbingly narrow. The division of the 15 $\mu\text{g Pb}/\text{dl}$ into 12 $\mu\text{g Pb}/\text{dl}$ for nonair sources and 3 $\mu\text{g Pb}/\text{dl}$ for air sources was not unreasonable in FDA's view.

The Occupational Safety and Health Administration endorsed EPA's proposed standard for lead and agrees with EPA that 15 $\mu\text{g Pb}/\text{dl}$ as an average national blood lead level goal for young children is reasonable. OSHA views their proposed standard of 100 $\mu\text{g Pb}/\text{m}^3$, 8-hour time-weighted average, and their establishment of 40 $\mu\text{g Pb}/\text{dl}$ as the threshold effect level for workers as consistent with the EPA proposed standard.

The Department of Transportation (DOT) endorsed the proposed standard of 1.5 $\mu\text{g Pb}/\text{m}^3$. Based on an analysis of the impact of the proposed standard on the highway program, DOT concluded that it is highly probable that transportation-related violations of the proposed standard would be limited to large urban areas.

In commenting on the proposed standard, the Department of the Interior (DOI) expressed concern that the burden for meeting the proposed standard will fall primarily on lead and copper smelters and battery manufacturers, and commented on the

impact of lead dustfall on ground water quality. The Tennessee Valley Authority provided specific comments on the proposed State implementation plan regulations and the proposed Federal reference method. The Department of Commerce offered comments on the potential impacts of the standard, pointing out that more consideration should be given to the potential impact of the standard on the petroleum industry.

THE FEDERAL REFERENCE METHOD

The reference method for the determination of lead in suspended particulate matter collected from ambient air describes the appropriate techniques for determining the concentration of lead and its compounds as measured as elemental lead in the ambient air. A total of eight organizations submitted written comments on the method and two persons made comments at EPA's February public hearing on the proposed air quality standard. Since proposal of the Federal reference method for lead, EPA has completed additional testing of the method and added new information on the precision of the extraction analysis procedure.

Two of the commenters recommended the addition of a nitric plus hydrochloric acid extraction procedure. The extraction procedure of the proposed method contains only nitric acid. Use of a mixed acid procedure would permit the analyst to quantitatively extract more metals than just lead, thereby allowing him to analyze the same extract for more than one metal. The analysis for lead would not be affected. EPA agrees that a mixed acid extraction procedure should be added, and the revised method contains a mixed nitric-hydrochloric acid extraction procedure.

One commenter questioned the reliability of the air volume measured in the sampling procedure because of differences between initial and final flow rates caused by buildup of particulate matter on the collecting filter. The method of sampling specifies that initial and final flow rates must fall between 40 and 60 cubic feet per minute and variations within this range cause only a slight error. If the flow rate specification is not met, the sample should be voided. For these reasons, EPA believes the air volume measurement does not suffer unduly from inaccuracies.

A question was raised as to the effect of variation in lead content across the filter of the collected sample on lead analysis, since the method calls for analysis of only one strip or one-twelfth of the filter. Our work has shown that strips taken from different positions within the filter can, on occasion, produce different lead values, but the effect appears to

be significant only when sampling near a heavily traveled roadway. The proposed method recommends analyzing additional strips, when sampling near a roadway, to minimize this error.

One commenter pointed out that the proposed sampling procedure does not collect gaseous (organic) lead compounds and recommended that EPA consider requiring the use of a method for monitoring gaseous lead. As the criteria document states, reported ambient levels of gaseous lead are very low and EPA has determined that the effort required to carry out the difficult task of monitoring for ambient gaseous lead is not justified in view of the extremely low concentration.

It was pointed out in the preamble to the proposed method that other analytical principles would probably be handled by provision for approval of the equivalent methods (40 CFR Part 53) proposed elsewhere in this FEDERAL REGISTER. Two organizations submitted requests that alternate methods (X-ray fluorescence and anodic stripping voltametry) for lead analysis be declared equivalent to the reference method. These requests will be considered when the procedures for determining equivalency are promulgated.

The final Federal reference method is based on measuring the lead content of suspended particulate matter on glass fiber filters using high volume sampling. The lead is then extracted from the particulate matter with nitric acid facilitated by heat or by a mixture of nitric acid and hydrochloric acid facilitated by ultrasonication. Finally, the lead content is measured by atomic absorption spectrometry.

The reference method specified for lead measures the lead for a single sampling period by extraction of a portion of a high-volume glass fiber filter used to collect particulate matter over a 24-hour period. Some agencies may prefer to composite filter strips from a number of sampling periods and extract and analyze it for lead. This procedure is acceptable provided the Agency shows that the compositing procedure results in the same average lead value as would be obtained from averaging individual values.

Dated: September 29, 1978.

DOUGLAS M. COSTLE,
Administrator.

REFERENCES

- Angle, C. R. and M. S. McIntire. Environmental controls and the decline of blood lead. Arch. Environ. Hlth. (in press.) 1977.
- Azar, A., R. D. Snee, and K. Habibi. An Epidemiologic Approach to Community Air Lead Exposure Using Personal Air Samplers. Environmental Quality and Safety, Supplement Vol II—Lead 254-288 (1975).
- Barltrop, D., C. D. Strehlow, J. Thornton, and J. S. Webb. Significance of high soil

concentrations for childhood lead burdens. Environ. Hlth. Persp. Expt. Iss. 7:76-84, 1974.

Billick, I. A. Curran, and D. Shier. Presentation to the U.S. EPA Lead Subcommittee of the Science Advisory Board, Washington, D.C., October 7, 1977.

Fine, P. R., C. W. Thomas, R. H. Suho, R. E. Cohnberg, and B. A. Flashner. Pediatric Blood Lead Levels A Study in 14 Illinois Cities of Intermediate Population. JAMA 221:1475-1479, September 25, 1972.

Johanson, W. C. and J. P. Luby. A Report on a Study to Determine the Blood Lead Levels in Dallas Children. Dallas Health Department, Dallas, Tex. 1972.

Johnson, D. E., J. B. Tillery, and R. J. Prevost. Levels of platinum, palladium and lead in populations of Southern California. Environ. Health Persp. 12:27-33, 1975.

Landrigan, P. J., S. H. Gehlbach, B. F. Rosenblum, J. M. Shoultz, et al. Epidemic Lead Absorption Near an Ore Smelter. The role of particulate lead. New England J. Med. 292:123-129, 1975.

Manton, W. I. Sources of Lead in Blood. Arch. Environmental Health, 32:149-156, 1977.

Rabinowitz, M. B. Lead contamination of the biosphere by human activity. A stable isotope study, PhD Thesis, University of California, Los Angeles, 1974, 120 pp.

U.S. Environmental Protection Agency. Air Quality Criteria for Lead Office of Research and Development, Washington, D.C. 20460. EPA-450/8-77-017, December 1977.

von Lindern, I. and A. J. Yankel. Presentation to the Shoshone Heavy Metals Project Committee by Idaho Department of Health and Welfare, Boise, Idaho, September 4, 1975.

Yankel, A. J. and I. von Lindern. The Silver Valley lead study. The relationship of childhood lead poisoning and environmental exposure. J. Air Pollut. Cont. Ass., August 1977.

40 CFR Part 50 is amended by adding a new § 50.12 and a new appendix G as follows:

§ 50.12 National primary and secondary ambient air quality standards for lead.

National primary and secondary ambient air quality standards for lead and its compounds, measured as elemental lead by a reference method based on appendix G to this part, or by an equivalent method, are: 1.5 micrograms per cubic meter, maximum arithmetic mean averaged over a calendar quarter.

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

APPENDIX G—REFERENCE METHOD FOR THE DETERMINATION OF LEAD IN SUSPENDED PARTICULATE MATTER COLLECTED FROM AMBIENT AIR

1. Principle and applicability.
 - 1.1 Ambient air suspended particulate matter is collected on a glass-fiber filter for 24 hours using a high volume air sampler.
 - 1.2 Lead in the particulate matter is solubilized by extraction with nitric acid (HNO₃), facilitated by heat or by a mixture

of HNO₃ and hydrochloric acid (HCl) facilitated by ultrasonication.

1.3 The lead content of the sample is analyzed by atomic absorption spectrometry using an air-acetylene flame, the 283.3 or 217.0 nm lead absorption line, and the optimum instrumental conditions recommended by the manufacturer.

1.4 The ultrasonication extraction with HNO₃/HCl will extract metals other than lead from ambient particulate matter.

2. Range, sensitivity, and lower detectable limit. The values given below are typical of the methods capabilities. Absolute values will vary for individual situations depending on the type of instrument used, the lead line, and operating conditions.

2.1 Range. The typical range of the method is 0.07 to 7.5 µg Pb/m³ assuming an upper linear range of analysis of 15 µg/ml and an air volume of 2,400 m³.

2.2 Sensitivity. Typical sensitivities for a 1 percent change in absorption (0.0044 absorbance units) are 0.2 and 0.5 µg Pb/ml for the 217.0 and 283.3 nm lines, respectively.

2.3 Lower detectable limit (LDL). A typical LDL is 0.07 µg Pb/m³. The above value was calculated by doubling the between-laboratory standard deviation obtained for the lowest measurable lead concentration in a collaborative test of the method.(15) An air volume of 2,400 m³ was assumed.

3. Interferences. Two types of interferences are possible: chemical and light scattering.

3.1 Chemical. Reports on the absence (1, 2, 3, 4, 5) of chemical interferences far outweigh those reporting their presence, (6) therefore, no correction for chemical interferences is given here. If the analyst suspects that the sample matrix is causing a chemical interference, the interference can be verified and corrected for by carrying out the analysis with and without the method of standard additions.(7)

3.2 Light scattering. Nonatomic absorption or light scattering, produced by high concentrations of dissolved solids in the sample, can produce a significant interference, especially at low lead concentrations. (2) The interference is greater at the 217.0 nm line than at the 283.3 nm line. No interference was observed using the 283.3 nm line with a similar method.(7)

Light scattering interferences can, however, be corrected for instrumentally. Since the dissolved solids can vary depending on the origin of the sample, the correction may be necessary, especially when using the 217.0 nm line. Dual beam instruments with a continuum source give the most accurate correction. A less accurate correction can be obtained by using a nonabsorbing lead line that is near the lead analytical line. Information on use of these correction techniques can be obtained from instrument manufacturers' manuals.

If instrumental correction is not feasible, the interference can be eliminated by use of the ammonium pyrrolidinedithioate-methylisobutyl ketone, chelation-solvent extraction technique of sample preparation.(8)

4. Precision and bias.

4.1 The high-volume sampling procedure used to collect ambient air particulate matter has a between-laboratory relative standard deviation of 3.7 percent over the range 80 to 125 µg/m³.(9) The combined extraction-analysis procedure has an average within-laboratory relative standard deviation of 5 to 6 percent over the range 1.5 to 15 µg Pb/ml, and an average between labo-

ratory relative standard deviation of 7 to 9 percent over the same range. These values include use of either extraction procedure.

4.2 Single laboratory experiments and collaborative testing indicate that there is no significant difference in lead recovery between the hot and ultrasonic extraction procedures.(15)

5. Apparatus.

5.1 Sampling.

5.1.1 High-volume sampler. Use and calibrate the sampler as described in reference 10.

5.2 Analysis.

5.2.1 Atomic absorption spectrophotometer. Equipped with lead hollow cathode or electrodeless discharge lamp.

5.2.1.1 Acetylene. The grade recommended by the instrument manufacturer should be used. Change cylinder when pressure drops below 50-100 psig.

5.2.1.2 Air. Filtered to remove particulate, oil, and water.

5.2.2 Glassware. Class A borosilicate glassware should be used throughout the analysis.

5.2.2.1 Beakers. 30 and 150 ml. graduated, Pyrex.

5.2.2.2 Volumetric flasks. 100-ml.

5.2.2.3 Pipettes. To deliver 50, 30, 15, 8, 4, 2, 1 ml.

5.2.2.4 Cleaning. All glassware should be scrupulously cleaned. The following procedure is suggested. Wash with laboratory detergent, rinse, soak for 4 hours in 20 percent (w/w) HNO₃, rinse 3 times with distilled-deionized water, and dry in a dust free manner.

5.2.3 Hot plate.

5.2.4 Ultrasonication water bath, unheated. Commercially available laboratory ultrasonic cleaning baths of 450 watts or higher "cleaning power," i.e., actual ultrasonic power output to the bath have been found satisfactory.

5.2.5 Template. To aid in sectioning the glass-fiber filter. See figure 1 for dimensions.

5.2.6 Pizza cutter. Thin wheel. Thickness <1mm.

5.2.7 Watch glass.

5.2.8 Polyethylene bottles. For storage of samples. Linear polyethylene gives better storage stability than other polyethylenes and is preferred.

5.2.9 Parafilm "M". American Can Co., Marathon Products, Nennah, Wis., or equivalent.

6. Reagents.

6.1 Sampling.

6.1.1 Glass fiber filters. The specifications given below are intended to aid the user in obtaining high quality filters with reproducible properties. These specifications have been met by EPA contractors.

6.1.1.1 Lead content. The absolute lead content of filters is not critical, but low values are, of course, desirable. EPA typically obtains filters with a lead content of <75 µg/filter.

It is important that the variation in lead content from filter to filter, within a given batch, be small.

6.1.1.2 Testing.

6.1.1.2.1 For large batches of filters (>500 filters) select at random 20 to 30 filters from a given batch. For small batches (<500 filters) a lesser number of filters may be taken. Cut one ¾"x8" strip from each

filter anywhere in the filter. Analyze all strips, separately, according to the directions in sections 7 and 8.

6.1.1.2.2 Calculate the total lead in each filter as

$$F_b = \mu\text{g Pb/ml} \times \frac{100 \text{ ml}}{\text{strip}} \times \frac{12 \text{ strips}}{\text{filter}}$$

where:

F_b = Amount of lead per 72 square inches of filter, µg.

6.1.1.2.3 Calculate the mean, F_b, of the values and the relative standard deviation (standard deviation/mean x 100). If the relative standard deviation is high enough so that, in the analysts opinion, subtraction of F_b (section 10.3) may result in a significant error in the µg Pb/m³ the batch should be rejected.

6.1.1.2.4 For acceptable batches, use the value of F_b to correct all lead analyses (section 10.3) of particulate matter collected using that batch of filters. If the analyses are below the LDL (section 2.3) no correction is necessary.

6.2 Analysis.

6.2.1 Concentrated (15.6 M) HNO₃. ACS reagent grade HNO₃ and commercially available redistilled HNO₃ has found to have sufficiently low lead concentrations.

6.2.2 Concentrated (11.7 M) HCl. ACS reagent grade.

6.2.3 Distilled-deionized water. (D.I. water).

6.2.4 3 M HNO₃. This solution is used in the hot extraction procedure. To prepare, add 192 ml of concentrated HNO₃ to D.I. water in a 1 l volumetric flask. Shake well, cool, and dilute to volume with D.I. water. Caution: Nitric acid fumes are toxic. Prepare in a well ventilated fume hood.

6.2.5 0.45 M HNO₃. This solution is used as the matrix for calibration standards when using the hot extraction procedure. To prepare, add 29 ml of concentrated HNO₃ to D.I. water in a 1 l volumetric flask. Shake well, cool, and dilute to volume with D.I. water.

6.2.6 2.6 M HNO₃+0 to 0.9 M HCl. This solution is used in the ultrasonic extraction procedure. The concentration of HCl can be varied from 0 to 0.9 M. Directions are given for preparation of a 2.6 M HNO₃+0.9 M HCl solution. Place 167 ml of concentrated HNO₃ into a 1 l volumetric flask and add 77 ml of concentrated HCl. Stir 4 to 6 hours, dilute to nearly 1 l with D.I. water, cool to room temperature, and dilute to 1 l.

6.2.7 0.40 M HNO₃ + X M HCl. This solution is used as the matrix for calibration standards when using the ultrasonic extraction procedure. To prepare, add 26 ml of concentrated HNO₃ plus the ml of HCl required, to a 1 l volumetric flask. Dilute to nearly 1 l with D.I. water, cool to room temperature, and dilute to 1 l. The amount of HCl required can be determined from the following equation:

$$y = \frac{77 \text{ ml} \times 0.15 \times}{0.9 \text{ M}}$$

*Mention of commercial products does not imply endorsement by the U.S. Environmental Protection Agency.

where:

y = ml of concentrated HCl required.

x = molarity of HCl in 6.2.6.

0.15 = dilution factor in 7.2.2.

6.2.8 Lead nitrate, $Pb(NO_3)_2$, ACS reagent grade, purity 99.0 percent. Heat for 4 hours at 120° C and cool in a desiccator.

6.3 Calibration standards.

6.3.1 Master standard, 1000 μg Pb/ml in HNO_3 . Dissolve 1.598 g of $Pb(NO_3)_2$ in 0.45 M HNO_3 , contained in a 1 l volumetric flask and dilute to volume with 0.45 M HNO_3 .

6.3.2 Master standard, 1000 μg Pb/ml in HNO_3/HCl . Prepare as in 6.3.1 except use the HNO_3/HCl solution in 6.2.7.

Store standards in a polyethylene bottle. Commercially available certified lead standard solutions may also be used.

7. Procedure.

7.1 Sampling. Collect samples for 24 hours using the procedure described in reference 10 with glass-fiber filters meeting the specifications in 6.1.1. Transport collected samples to the laboratory taking care to minimize contamination and loss of sample. (17).

7.2 Sample preparation.

7.2.1 Hot extraction procedure.

7.2.1.1 Cut a $\frac{3}{4}$ " x 8" strip from the exposed filter using a template and a pizza cutter as described in figures 1 and 2. Other cutting procedures may be used.

Lead in ambient particulate matter collected on glass fiber filters has been shown to be uniformly distributed across the filter (1, 3, 11) suggesting that the position of the strip is unimportant. However, another study (12) has shown that when sampling near a road-way lead is not uniformly distributed across the filter. The nonuniformity has been attributed to large variations in particle size. (16) Therefore, when sampling near a road-way, additional strips at different positions within the filter should be analyzed.

7.2.1.2 Fold the strip in half twice and place in a 150-ml beaker. Add 15 ml of 3 M HNO_3 to cover the sample. The acid should completely cover the sample. Cover the beaker with a watch glass.

7.2.1.3 Place beaker on the hot-plate, contained in a fume hood, and boil gently for 30 min. Do not let the sample evaporate to dryness. *Caution:* Nitric acid fumes are toxic.

7.2.1.4 Remove beaker from hot plate and cool to near room temperature.

7.2.1.5 Quantitatively transfer the sample as follows:

7.2.1.5.1 Rinse watch glass and sides of beaker with D.I. water.

7.2.1.5.2 Decant extract and rinsings into a 100-ml volumetric flask.

7.2.1.5.3 Add D.I. water to 40 ml mark on beaker, cover with watch glass, and set aside for a minimum of 30 minutes. This is a critical step and cannot be omitted since it allows the HNO_3 , trapped in the filter to diffuse into the rinse water.

7.2.1.5.4 Decant the water from the filter into the volumetric flask.

7.2.1.5.5 Rinse filter and beaker twice with D.I. water and add rinsings to volumetric flask until total volume is 80 to 85 ml.

7.2.1.5.6 Stopper flask and shake vigorously. Set aside for approximately 5 minutes or until foam has dissipated.

7.2.1.5.7 Bring solution to volume with D.I. water. Mix thoroughly.

7.2.1.5.8 Allow solution to settle for one hour before proceeding with analysis.

7.2.1.5.9 If sample is to be stored for subsequent analysis, transfer to a linear polyethylene bottle.

7.2.2 Ultrasonic extraction procedure.

7.2.2.1 Cut a $\frac{3}{4}$ " x 8" strip from the exposed filter as described in section 7.2.1.1.

7.2.2.2 Fold the strip in half twice and place in a 30 ml beaker. Add 15 ml of the HNO_3/HCl solution in 6.2.6. The acid should completely cover the sample. Cover the beaker with parafilm.

The parafilm should be placed over the beaker such that none of the parafilm is in contact with water in the ultrasonic bath. Otherwise, rinsing of the parafilm (section 7.2.2.4.1) may contaminate the sample.

7.2.2.3 Place the beaker in the ultrasonic bath and operate for 30 minutes.

7.2.2.4 Quantitatively transfer the sample as follows:

7.2.2.4.1 Rinse parafilm and sides of beaker with D.I. water.

7.2.2.4.2 Decant extract and rinsings into a 100 ml volumetric flask.

7.2.2.4.3 Add 20 ml D.I. water to cover the filter strip, cover with parafilm, and set aside for a minimum of 30 minutes. This is a critical step and cannot be omitted. The sample is then processed as in sections 7.2.1.5.4 through 7.2.1.5.9.

NOTE.—Samples prepared by the hot extraction procedure are now in 0.45 M HNO_3 . Samples prepared by the ultrasonic procedure are in 0.40 M HNO_3 + X M HCl.

8. Analysis.

8.1 Set the wavelength of the monochromator at 283.3 or 217.0 nm. Set or align other instrumental operating conditions as recommended by the manufacturer.

8.2 The sample can be analyzed directly from the volumetric flask, or an appropriate amount of sample decanted into a sample analysis tube. In either case, care should be taken not to disturb the settled solids.

8.3 Aspirate samples, calibration standards and blanks (section 9.2) into the flame and record the equilibrium absorbance.

8.4 Determine the lead concentration in μg Pb/ml, from the calibration curve, section 9.3.

8.5 Samples that exceed the linear calibration range should be diluted with acid of the same concentration as the calibration standards and reanalyzed.

9. Calibration.

9.1 Working standard, 20 μg Pb/ml. Prepared by diluting 2.0 ml of the master standard (6.3.1 if the hot acid extraction was used or 6.3.2 if the ultrasonic extraction procedure was used) to 100 ml with acid of the same concentration as used in preparing the master standard.

9.2 Calibration standards. Prepare daily by diluting the working standard, with the same acid matrix, as indicated below. Other lead concentrations may be used.

Volume of 20 $\mu g/ml$ working standard, ml	Final volume, ml	Concentration μg Pb/ml
0	100	0
1.0	200	0.1
2.0	200	0.2
2.0	100	0.4
4.0	100	0.8
8.0	100	1.6
15.0	100	3.0
30.0	100	6.0
50.0	100	10.0
100.0	100	20.0

9.3 Preparation of calibration curve. Since the working range of analysis will vary depending on which lead line is used and the type of instrument, no one set of instructions for preparation of a calibration curve can be given. Select standards (plus the reagent blank), in the same acid concentration as the samples, to cover the linear absorption range indicated by the instrument manufacturer. Measure the absorbance of the blank and standards as in section 8.0. Repeat until good agreement is obtained between replicates. Plot absorbance (y-axis) versus concentration in μg Pb/ml (x-axis). Draw (or compute) a straight line through the linear portion of the curve. Do not force the calibration curve through zero. Other calibration procedures may be used.

To determine stability of the calibration curve, remeasure—alternately—one of the following calibration standards for every 10th sample analyzed: concentration $\leq 1 \mu g$ Pb/ml; concentration $\leq 10 \mu g$ Pb/ml. If either standard deviates by more than 5 percent from the value predicted by the calibration curve, recalibrate and repeat the previous 10 analyses.

10. Calculation.

10.1 Measured air volume. Calculate the measured air volume as

$$V_m = \frac{Q_i + Q_f}{2} \times T$$

where:

V_m = Air volume sampled (uncorrected), m^3 .

Q_i = Initial air flow rate, m^3/min .

Q_f = Final air flow rate, m^3/min .

T = Sampling time, min.

The flow rates Q_i and Q_f should be corrected to the temperature and pressure conditions existing at the time of orifice calibration as directed in addendum B of reference 10, before calculation V_m .

10.2 Air volume at STP. The measured air volume is corrected to reference conditions of 760 mm Hg and 25° C as follows. The units are standard cubic meters, sm^3 .

$$V_{STP} = V_m \times \frac{P_2 \times T_1}{P_1 \times T_2}$$

V_{STP} = Sample volume, sm^3 , at 760 mm Hg and 298° K.

V_m = Measured volume from 10.1.

P_2 = Atmospheric pressure at time of orifice calibration, mm Hg.

P_1 = 760 mm Hg.

T_2 = Atmospheric temperature at time of orifice calibration, °K.

T_1 = 298° K.

10.3 Lead concentration. Calculate lead concentration in the air sample.

$$C = \frac{(\mu g \text{ Pb/ml} \times 100 \text{ ml/strip} \times 12 \text{ strips/filter}) - F_b}{V_{STP}}$$

where:

C=Concentration, $\mu\text{g Pb}/\text{sm}^3$.

$\mu\text{g Pb}/\text{ml}$ =Lead concentration determined from section 8.

100 ml/strip=Total sample volume.

12 strips/filter=Useable filter area, $7'' \times 9''$ /
Exposed area of one strip, $\frac{3}{4}'' \times 7''$.

F_b =Lead concentration of blank filter, μg ,
from section 6.1.1.2.3.

V_{STP} =Air volume from 10.2.

11. Quality control

$\frac{3}{4}'' \times 8''$ glass fiber filter strips containing 80 to 2000 $\mu\text{g Pb}/\text{strip}$ (as lead salts) and blank strips with zero Pb content should be used to determine if the method—as being used—has any bias. Quality control charts should be established to monitor differences between measured and true values. The frequency of such checks will depend on the local quality control program.

To minimize the possibility of generating unreliable data, the user should follow practices established for assuring the quality of air pollution data, (13) and take part in EPA's semiannual audit program for lead analyses.

12. Trouble shooting.

1. During extraction of lead by the hot extraction procedure, it is important to keep the sample covered so that corrosion products—formed on fume hood surfaces which may contain lead—are not deposited in the extract.

2. The sample acid concentration should minimize corrosion of the nebulizer. However, different nebulizers may require lower acid concentrations. Lower concentrations can be used provided samples and standards have the same acid concentration.

3. Ashing of particulate samples has been found, by EPA and contractor laboratories, to be unnecessary in lead analyses by atomic

absorption. Therefore, this step was omitted from the method.

4. Filtration of extracted samples, to remove particulate matter, was specifically excluded from sample preparation, because some analysts have observed losses of lead due to filtration.

5. If suspended solids should clog the nebulizer during analysis of samples, centrifuge the sample to remove the solids.

13. Authority.

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

14. References.

1. Scott, D. R. et al. "Atomic Absorption and Optical Emission Analysis of NASN Atmospheric Particulate Samples for Lead." *Envir. Sci. and Tech.*, 10, 877-880 (1976).

2. Skogerboe, R. K. et al. "Monitoring for Lead in the Environment." pp. 57-66, Department of Chemistry, Colorado State University, Fort Collins, Colo. 80523. Submitted to National Science Foundation for publications, 1976.

3. Zdrojewski, A. et al. "The Accurate Measurement of Lead in Airborne Particulates." *Inter. J. Environ. Anal. Chem.*, 2, 63-77 (1972).

4. Slavin, W., "Atomic Absorption Spectroscopy." Published by Interscience Company, New York, N.Y. (1968).

5. Kirkbright, G. F., and Sargent, M., "Atomic Absorption and Fluorescence Spectroscopy." Published by Academic Press, New York, N.Y. 1974.

6. Burnham, C. D. et al., "Determination of Lead in Airborne Particulates in Chicago and Cook County, Ill. by Atomic Absorption Spectroscopy." *Envir. Sci. and Tech.*, 3, 472-475 (1969).

7. "Proposed Recommended Practices for Atomic Absorption Spectrometry." *ASTM*

Book of Standards, part 30, pp. 1596-1608 (July 1973).

8. Kolrtyohann, S. R. and Wen, J. W., "Critical Study of the APCD-MIBK Extraction System for Atomic Absorption." *Anal. Chem.*, 45, 1986-1989 (1973).

9. *Collaborative Study of Reference Method for the Determination of Suspended Particulates in the Atmosphere (High Volume Method)*. Obtainable from National Technical Information Service, Department of Commerce, Port Royal Road, Springfield, Va. 22151, as PB-205-891.

10. "Reference Method for the Determination of Suspended Particulates in the Atmosphere (High Volume Method)." Code of Federal Regulations, Title 40, Part 50, Appendix B, pp. 12-16 (July 1, 1975).

11. Dubois, L., et al., "The Metal Content of Urban Air." *JAFCA*, 16, 77-78 (1966).

12. EPA Report No. 600/4-77-034. June 1977, "Los Angeles Catalyst Study Symposium." Page 223.

13. *Quality Assurance Handbook for Air Pollution Measurement System. Volume 1—Principles*. EPA-600/9-76-005, March 1976.

14. Thompson, R. J. et al., "Analysis of Selected Elements in Atmospheric Particulate Matter by Atomic Absorption." *Atomic Absorption Newsletter*, 9, No. 3, May-June 1970.

15. To be published. EPA, QAB, EMSL, RTP, N.C. 27711

16. Hirschler, D. A. et al., "Particulate Lead Compounds in Automobile Exhaust Gas." *Industrial and Engineering Chemistry*, 49, 1131-1142 (1957).

17. *Quality Assurance Handbook for Air Pollution Measurement Systems. Volume II—Ambient Air Specific Methods*. EPA-600/4-77/027a, May 1977.

[FR Doc. 78-28050 Filed 10-4-78; 8:45 am]

RULES AND REGULATIONS

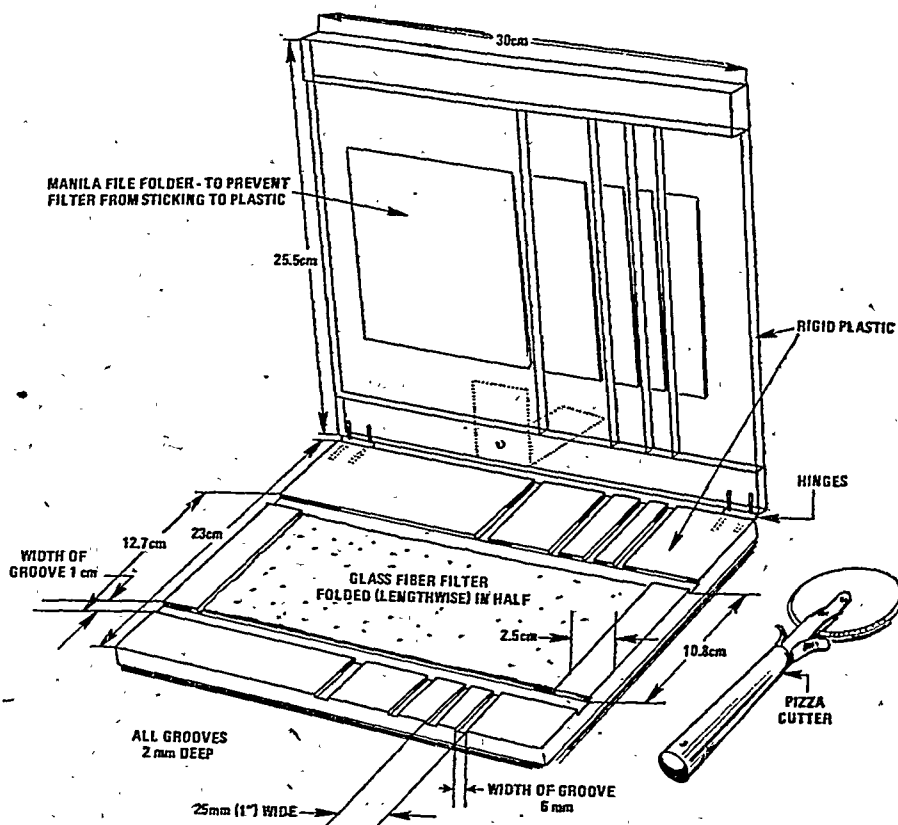


Figure 1

RULES AND REGULATIONS

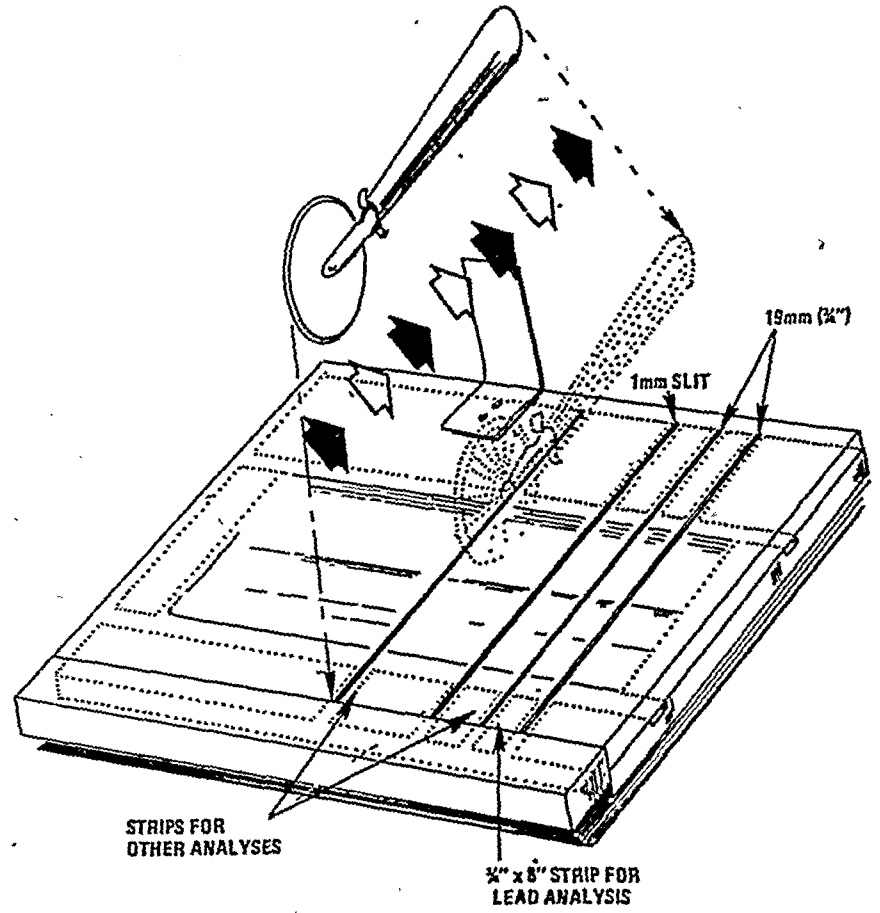


Figure 2

[6560-01]

[FRL 937-61]

PART 51—PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

Implementation Plans for Lead National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency.

ACTION: Final rulemaking.

SUMMARY: The regulations promulgated below, together with the current requirements of 40 CFR Part 51, set forth the requirements for States to follow in developing, adopting, and submitting acceptable implementation plans for the lead national ambient air quality standards (NAAQS), promulgated elsewhere in the FEDERAL REGISTER. The implementation plans are required under section 110 of the Clean Air Act. Amendments to the existing regulations for implementation plans are necessary because lead differs from other pollutants for which the existing regulations were designed. The amendments address the following topics: definitions of point source and control strategy; control strategy requirements; and air quality surveillance.

EFFECTIVE DATE: This rulemaking is effective October 5, 1978; State implementation plans for lead are due by July 5, 1979.

ADDRESSES: U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Control Programs Development Division (MD 15), Research Triangle Park, N.C. 27711.

FOR FURTHER INFORMATION CONTACT:

Joseph Sableski, Chief, Plans Guidelines Section, at the above address or at 919-541-5437 (commercial) or 629-5437 (FTS).

SUPPLEMENTARY INFORMATION:

1. BACKGROUND

On December 14, 1977, EPA proposed regulations for the preparation, adoption, and submission of implementation plans to achieve the national ambient air quality standards for lead, which were also proposed on that same date (42 FR 63087). EPA invited comments from interested persons and held a hearing on the proposed NAAQS and State implementation plan (SIP) regulations on February 15 and 16, 1978. EPA received comments on the proposed lead implementation plan requirements from 25 com-

menters. Of these, there were 10 representatives from industry, 9 from State and local governmental agencies, 4 from citizens' organizations and private citizens, and 2 from other federal agencies.

2. SUMMARY OF COMMENTS AND RESPONSES

The following discussion summarizes most of the comments received on the proposal. There were a few other comments that EPA felt were not significant to warrant discussion in the FEDERAL REGISTER and that did not affect the final regulation. A summary of all the comments received and EPA's response is available for public inspection during normal business hours in EPA's Public Information Reference Unit (PM 215), 401 M Street SW., Washington, D.C. 20460, telephone 202-755-0707.

2.1 POINT SOURCE DEFINITION

There were several comments concerning the definition of a point source. One commenter indicated that the definition of a point source is confusing and differs from that used in the provisions in the Clean Air Act concerning prevention of significant deterioration (PSD). Parts of that comment were directed toward the existing definition of point source in § 51.1(k), which, as the commenter acknowledged, is not the subject of the proposal and will not be discussed here.

Currently, § 51.1(k) defines point sources in terms of emissions per year and location of the source, as well as a listing of individual source categories. Currently, point sources of other pollutants for which NAAQS exist that are located in urban areas are defined as those that emit pollutants in excess of 100 tons per year; point sources in less urbanized areas are defined as those that emit pollutants in excess of 25 tons per year. In light of the low level of the lead standard in relation to the other standards (e.g., for particulate matter), good reason exists to define point sources for lead at a lower level of emissions than that for the current set of pollutants for which EPA has established NAAQS. Based on air analysis contained in EPA's "Supplementary Guidelines for Lead Implementation Plans," (1) EPA is defining a point source of lead as "any stationary source causing emissions in excess of 4.54 metric tons (5 tons) per year of lead or lead compounds measured as elemental lead." This represents a slight change from the proposal, which failed to account for lead compounds.

The significance of the definition of § 51.1(k) is that the emission inventory, which is used to determine the extent of possible violations of the air

quality standard and determine the effectiveness of control strategies, must include a determination of emissions from each point source. All emissions from sources other than point sources may be grouped together as area (or line) sources.

The definition of point source, which was intended to be based on actual emissions, differs from the definition in section 169 of the Clean Air Act (which pertains to prevention of significant deterioration), which is based on potential emissions. The reason for the difference is that for planning purposes, the inventory of existing sources must be based on an actual situation to be used as a baseline upon which one develops a plan. For new source review (including review for prevention of significant deterioration), one must be aware of the emissions that could be emitted from the proposed source as well as actual emissions; hence, the source size criteria for selection of new sources to be reviewed under the recently promulgated PSD regulations incorporate potential, as well as actual, emissions. The definitions of point source in § 51.1(k) for all pollutants have been revised from the proposal to clarify that the size criteria are based upon actual emissions. This implies the emissions that are emitted after any control is applied.

2.2 CONTROL STRATEGY

A number of persons provided comments concerning the control strategy aspects of the proposed regulations.

One commenter correctly noted a discrepancy between the list of source categories in §§ 51.80 ("Demonstration of attainment"), and 51.84 ("Areas around significant point sources"), for which the State must perform an analysis. The lists should have been identical—§ 51.84(a) should have also included lead-acid storage battery manufacturing plants that produce 1,200 or more batteries per day. The rulemaking promulgated below incorporates this change. The criterion for production of batteries, which was based on a monthly standard, has been raised to 2,000 batteries per day, however, to account for the slightly less stringent quarterly lead ambient standard.

Several commenters indicated that the requirements in §§ 51.83 ("Certain urbanized areas") and 51.85 ("Other areas") appeared identical and therefore one of the sections was redundant. The difference between the two sections lies in the required geographical scope of the analysis. Section 51.83 requires that the plan contain an analysis of each urbanized area that has a measured lead air concentration that is in excess of 4.0 µg/m³ quarterly mean (monthly mean in the proposal). The distinguishing provision is that

the analysis must cover at least the entire urbanized area. Section 51.85, on the other hand, requires that for any area (urbanized or not) with a recorded lead concentration that does not meet the national standard of 1.5 $\mu\text{g}/\text{m}^3$ quarterly mean (monthly mean in the proposal), the plan must contain an analysis of at least the area in the vicinity of the monitor that has recorded the concentration. Therefore, the analysis may be restricted to an evaluation of only those sources within a relatively small radius from the monitor.

Several commenters suggested that the control strategy requirements insure that the burden for solving the lead air problem be equitably distributed between mobile and stationary sources. The commenters realized that either kind of control is expensive and difficult to implement. In response, EPA maintains that the allocation of the burden of control in the SIP is the primary responsibility of the States, and therefore EPA will avoid setting criteria in 40 CFR 51 that favor control of one source category over another. EPA acknowledges that measures that are expensive and difficult to implement may have to be adopted in order to demonstrate attainment of the lead standard.

Two commenters indicated that the regulations did not provide a satisfactory treatment to problems related to background concentration. They claimed that a facility in an area of high background concentrations may be unduly penalized in efforts to attain the standard. EPA acknowledges that this problem may exist. In most cases, however, the high background air concentrations are generally due to other sources in the vicinity. It is the primary responsibility of the State to allocate the burden of emission control to the various sources causing the problem. Sources will have an opportunity to comment on the plan at the public hearing that is required before the plan is submitted to EPA.

One commenter suggested that EPA recommend analysis of fugitive dust and on-premise soil before a State initiates a program of prolonged monitoring in the vicinity of gray iron foundries. As mentioned in the preamble to the proposed regulations, EPA identified gray iron foundries as having the potential for causing violations of the national standard for lead, but this identification was based on limited data concerning the amount of fugitive emissions from the facilities. Although EPA does not feel that the degree of confidence in this identification justifies a requirement for States to analyze all gray iron foundries (of which approximately 1,500 exist), EPA encourages States to consider analysis

of these sources to the extent that time and resources permit. The commenter's suggestion concerning the analysis of fugitive dust and on-premise soil before undertaking extensive monitoring and analysis appears to offer the potential for conserving scarce resources in that States may want to restrict their monitoring and analysis efforts to those plants with relatively high lead levels in dust and soil.

The same commenter also indicated that secondary lead smelters and similar sources probably cannot be modeled because of fugitive dust and low stacks. EPA recognizes the difficulty in quantifying fugitive dust and fugitive emissions and recognizes that low stacks will generally cause higher concentrations closer to the stack than will higher stacks. The Clean Air Act requires that an approved plan must demonstrate attainment of the standard, however. EPA has, based upon preliminary analyses, determined that secondary lead smelters and other sources listed in §51.84 have the potential for causing violations of the lead standard. EPA also believes that attainment of the lead standard around such sources can best be demonstrated by the use of an atmospheric dispersion model. In many cases, States will not have the time or resources to perform detailed studies to quantify the fugitive dust and fugitive emissions from individual facilities and may have to rely on factors that were based on limited studies of other facilities or best estimates. In complying with §51.84, for cases where no ambient lead data were collected in the vicinity of the source and where a State must thus estimate the air quality impact of the sources, the State will have to decide for itself what level of control is warranted by the confidence in the data upon which the analysis is based.

In another comment concerning modeling, one commenter from a State agency claimed that the models used for assessing the monthly impact of point sources are not accessible to most air pollution control agencies. In the initial analysis of the impact of the proposed standard on point sources, it is true that EPA used the Oak Ridge National Laboratory model, "Atmospheric Transport and Dispersion Model" (ATM), (2) which is probably not available to most agencies. That analysis was revised subsequently, and another model was used, however. Also, EPA is recommending the use of other models, specifically those models for particulate matter described in EPA's "Guideline on Air Quality Models," (3) for modeling point sources for SIP development. These models are generally available.

The same commenter indicated that only ambient monitoring or upwind-downwind sampling can give a reliable assessment of the impact of sources with a large fugitive emission component. EPA acknowledges that monitoring studies generally give a more reliable estimate of the air quality impact of sources that emit fugitive emissions because no estimate need be made of the fugitive emissions, which are difficult to measure directly. Such studies cannot be done for many areas within the time and resource constraints facing the States, however, and therefore EPA regulations require the use of modeling around such point sources. States will have to make estimates of the fugitive emissions based on whatever information may exist. EPA is, however, in another part of this FEDERAL REGISTER giving advance notice of proposed rulemaking to require the installation of ambient monitors in the vicinity of three categories of point sources that have major fugitive emissions—Primary and secondary lead smelters and primary copper smelters. Presumably, after these monitors have been in place for a few years, the data yielded will provide more accurate information concerning the nature and magnitude of the lead problem from these sources. After those data become available, EPA may require States to revise their implementation plans. Furthermore, EPA intends to develop fugitive lead emission factors that are more accurate than those that currently exist.

One commenter recommended that the regulations place the proof of compliance with emission regulations on the stationary source. The commenter claimed that local enforcement agencies do not have the funds for continuous monitoring. In response, EPA has found that there are no techniques for continuous monitoring of lead emissions. The State will be required under existing regulations (40 CFR 51.19) to carry out a source surveillance program which generally consists of visual inspection of the installation of control equipment and testing of stack emissions.

Several comments addressed issues concerning control of lead in gasoline. One commenter indicated that any reduction of the lead content of gasoline or any other similar kinds of programs (presumably meaning control of fuels or the control of lead emissions from individual vehicles) that may be needed in the SIP over and above the current Federal program should be done through Federal rather than local regulation. EPA has already taken steps to control the amount of lead in gasoline through the phase-down of lead in leaded gasoline and the requirement that cars equipped with catalyst mufflers must burn un-

leaded gasoline. The level of control of lead in leaded gasoline was based on average conditions concerning lead air quality concentrations. Areas that have unique problems and that will find it impossible to demonstrate attainment of the lead standard through stationary source control or through transportation control measures may have to adopt measures such as requirements for further reduction of lead in gasoline or control of lead emissions from the tailpipe of vehicles. Currently, EPA does not foresee the need for additional mobile source control strategies and does not intend to require further nationally applicable lead-in-gasoline reductions.

Other comments concerning further reductions of the lead content of gasoline suggested that such reductions be undertaken only after sufficient data is available to indicate that the lead air quality problem is geographically broad enough and only after a finding that such a limitation is necessary to achieve a national ambient air quality standard. The commenters enumerated the problems with instituting further control of the lead content of gasoline. The commenters contended that application of more stringent local limitations of lead in gasoline could seriously disrupt the nation's gasoline distribution system, resulting in severe spot shortages, especially during the summer months when gasoline demand is at its highest.

EPA recognizes this problem and advises the States to consider the comment. Also, under section 211(c)(4)(C) of the Clean Air Act, EPA will not approve State or regional programs for further reductions of lead content of gasoline unless the State demonstrates that no other reasonable measures are available.

Also, two of the commenters recommended that 40 CFR Part 51 regulations be modified to reflect the restrictions in section 211(c)(4)(C) of the Act regarding State limitation of the lead content of gasoline. In response, EPA has incorporated the intent of the Act into the definition of "control strategy" as it pertains to restrictions on fuel additives.

Two commenters representing primary lead smelting companies recommended an alternative approach to protecting the health of persons from the ambient lead levels in the vicinity of primary lead smelters. They recommended that sources that cannot control emissions so that the lead standard will be met be allowed to conduct a public health screening and hygiene program aimed at reducing the amount of lead that children in the vicinity of the source take in and insuring that safe blood lead levels are satisfactorily maintained.

EPA believes that there are legal, technical, and equity problems with the programs that render it unacceptable as the sole means of implementation of the national standard for lead.

Concerning the legal problem, such a program assumes that the air quality standard will be violated, and presumably, the plan will not contain a demonstration that the air quality standard will be attained. Under the Clean Air Act, EPA must disapprove a plan that does not contain a demonstration that the air quality standard will be attained by the mandatory attainment date. The Act provides for the protection of health through the standard setting, planning, and implementation processes; it does not allow for a surrogate procedure whereby public health may be protected even though the ambient standards are not met.

Concerning technical problems, the relationship between emissions from a source and blood lead levels is not quantitatively certain. Even assuming a biological monitoring system were to be established, it is unclear what the source would have to do concerning its operation or emissions if the monitoring program revealed unacceptable blood lead levels. Even if a course of action were clear, the damage would have already been done, while the basic purpose of the standard setting and implementation process envisioned by section 110 of the Act is prevention of public health problems.

Concerning equity, the biological monitoring program would inconvenience the very people that are supposed to benefit from the Act. The Act envisioned that all people have an equal right to healthy air. The commenters who recommended that biological monitoring approach apparently believe that people who happen to live in areas with elevated lead levels should not be accorded equal protection, but should be made to pay extra for their health through presumably continuous participation in a blood sampling program. If a person did not want to participate, it is doubtful whether he could be forced to, so therefore his health could be placed in jeopardy.

One commenter representing a primary lead smelter warned that enclosure of smelter operations to control fugitive lead emissions may present a severe occupational health hazard to employees who must work within the enclosed space. EPA realizes these potential problems. If a source installs such enclosures, it must of course also meet any applicable regulations set forth by the Occupational Safety and Health Administration as well as control emissions to the extent specified in the applicable implementation plan.

One other commenter expressed concern that there appears to be nothing that can be done in areas where a source is employing best available control technology, yet the standard is still not being met. The Act requires that for approval, an implementation plan must demonstrate that the control strategy contained in the plan is adequate to attain and maintain the NAAQS. EPA realizes, however, that a plan which meets this criterion may, even after full implementation, not actually result in attainment by the attainment date. This would generally indicate that assumptions concerning the amount of emissions and the relationship between emissions reductions and air concentrations that were made when the plan was developed eventually were proven erroneous. If an approved plan is later found to be inadequate to attain the standard, EPA will require the State to revise the plan. If that plan has already required all measures short of those that would force significant source closures, EPA will at that time decide whether the closure must be effected or whether there are alternatives to this in the discretion given to EPA under the Act in sections 110 or 113. States should make every effort to develop and submit plans that demonstrate attainment of the standard using the best data available.

Several commenters from State air pollution control agencies indicated that the development of lead SIP's will be difficult within the timeframe provided. EPA realizes that the development of the lead plans will be competing in priorities and resources with the development of plan revisions by title I, part D, of the Clean Air Act for nonattainment areas. Where a State needs additional assistance in the development of its lead plan, or where it is unsure as to the priority of development of its lead plan, the State should consult with the appropriate EPA regional office.

2.3 AIR QUALITY MONITORING

Several commenters recommended that a minimum number of samples be taken to determine whether the standard is being attained. Also, several persons commented that the sampling should be performed more frequently, such as daily. One person indicated that determination of the attainment status should be done by annual rather than monthly averaging. At least a 3-month average would be more desirable. Another person indicated that the shorter the averaging period, the more the number of samples should be.

Concerning the minimum number of valid samples needed to determine an average, it is general practice to require at least 75 percent of the sched-

uled samples to be valid. EPA will prepare a guideline on this and other issues concerning the determination of attainment of the standard. Concerning the frequency of sampling, EPA is promulgating a national ambient air quality standard for lead in this FEDERAL REGISTER that is based on a calendar quarter, rather than calendar month as had been proposed. EPA has determined that a sampling schedule of once every 6 days is adequate to give a representative sample for a quarter.

One commenter indicated that monitoring the inner city area should be given top priority because the vehicle mix in these areas favors older cars that burn leaded gasoline. EPA's response is that if maximum exposures occur in these areas, then monitoring these areas should in fact receive first priority. The determination of acceptability of the sites will be the joint responsibility of the States and the cognizant EPA regional office.

One commenter recommended that EPA change the recommendation in the draft "Supplementary Guidelines for Lead Implementation Plans" (1) for locating lead monitors near roadways that are at or below grade level rather than near elevated roadways. The commenter suggested that the guideline require measurements to be representative of emissions and environmental exposure. The commenter indicated that the proposed guidance would exclude monitoring play areas that are located beneath elevated roadways. EPA agrees with this comment. The purpose behind excluding below grade level monitoring and monitoring near elevated roadways was to insure adequate exposure at the monitoring site. If significant population exposures consistent with the averaging time of the NAAQS were encountered in these situations, then monitoring in these locations would meet the intent of the guidance. EPA has revised the siting guidance to account for these considerations.

Several comments were directed toward the recommended location of a monitor at a given location. Two persons indicated that the allowance of 5 meters in elevation of lead air monitors is too high and that it should be changed or should allow for numerical adjustment of the data. One person suggested that the monitors be required to be placed closer to roadways because he felt that would be more representative of exposure; another suggested that the monitors are required to be placed too close to the street already in some cases and that the data from the monitors would be unrepresentative. EPA proposed a range of heights for lead monitors from 0 to 5 meters above ground level. The proposed required distance from

major roadways for the peak concentration site was 5 to 15 meters. The intent was to sample ambient air to which significant portions of the population are being exposed over the averaging time of the standard. During a typical day, even the most susceptible population group does not spend more than one-half of their time in the ambient air below the 2-meter level or within 15 meters of a major roadway. They are indoors or at considerable distances from roadways for the remainder of their time. Consequently, requiring samplers to be placed below 2 meters above the ground or closer than 5 meters to a roadway would lead to concentration measurements that would be unrepresentative of lead exposures. Further, some range of heights and distances is necessary due to practicalities involved in finding suitable sites, power availability, protection against vandalism, allowing free pedestrian movement along sidewalks, etc.

One commenter recommended that the criteria for monitoring in the vicinity of roadways not include specific distance restrictions, such as the requirement for placement of monitors between 5 and 15 meters from the traffic lane. The commenter indicated that many areas do not have housing that close to major roadways and therefore the numerical restrictions would be counterproductive to insuring accurate monitoring of maximum population exposure. EPA's response is that even though housing may not exist that close to roadways in all cases, the public has access to many such areas.

One commenter recommended that the monitoring guidelines require monitoring lead below ground level in public places such as subway stations and underground shopping areas. In response, EPA's monitoring guidance was written for purposes of determining attainment of a standard. Locating monitors in subways to determine exposures would be considered special purpose monitoring and thus could be performed if desired by the State or local agency. EPA however, does not feel that monitors placed in these situations would yield data suitable for developing implementation plans or determining national trends and strategies and thus will not require it. Furthermore, since no member of the public spends more than perhaps 8 hours out of 24 hours in such locations, monitoring there would not be representative of population exposure for a standard based upon 24-hour sampling for an entire quarter.

One commenter recommended that the regulations require ambient monitoring in the vicinity of major point sources. Not doing so may allow potentially significant public health impacts

that result from fugitive emissions at major point sources to be ignored. As mentioned above, in another part of this FEDERAL REGISTER, EPA is giving advance notice of proposed rulemaking to modify the regulations to require source owners or operators to monitor in the vicinity of primary and secondary lead smelters and primary copper smelters. EPA chose these source categories because they are considered to have the potential for causing the greatest concentrations of air lead in their vicinity and because the nature and magnitude of their fugitive emissions are relatively unknown compared to other source categories. The regulations will continue to vest authority in the regional administrators to require monitors in the vicinity of other sources. EPA will prepare guidance concerning the recommended number and siting of monitors in the vicinity of lead point sources.

Another commenter claimed that the regulations do not adequately address the locations where air quality samples will be taken and at what distance from a facility they will be taken. As mentioned above, EPA will develop guidance on the placement of lead monitors in the vicinity of point sources. The guidance for locating monitors elsewhere is highly specific in that the distances from obstructions and interferences are quantitatively described. It is not possible from a national perspective, however, to develop general regulations that would cover every conceivable situation that could occur without making the regulations unduly complex.

One commenter suggested that the lead monitors should not be required to be permanent until the State has more experience in sampling and monitoring lead. Also, several commenters recommended that EPA require initial monitoring by mobile vans or other procedures to locate the most critical sites. EPA does not intend that the required monitoring stations would remain at one place in perpetuity. EPA does, however, need some stability in monitoring site locations to allow for trends analysis. If a station once established is later found to be unrepresentative, it should be moved to a new location. EPA agrees with the intent of the comments and has always encouraged special purpose monitoring prior to establishing a permanent monitoring station. EPA will not require resource-intensive procedures to locate critical sites, however.

Several commenters recommended that the regulations require more than a minimum of two monitors per area. EPA's response is that the regulations do not preclude placing out more than two monitors. EPA is interested nationally in obtaining only enough data to establish a data trend,

determine if the Federal programs that result in the reduction of automobile lead emission are causing decreases in lead air concentrations, and determine the approximate attainment status of areas. Furthermore, the regulations would allow EPA to require additional monitors on a case-by-case basis where EPA believes that two monitors are insufficient to determine whether the national standard is being attained and maintained.

One of the commenters who recommended that the regulations require more than two monitors per area objected to placing responsibility on the EPA regional offices to require additional monitors and determine their location. The commenter claimed that this precludes both accountability of the State's actions and public participation. EPA's response is that requiring a limited number of samplers specifically to meet data needs at the national level and leaving the determination of the number and location of the remaining stations in the State network to the State and the regional office is consistent with the recommendations of EPA's Standing Air Monitoring Work Group (SAMWG). (4) In a recent action (43 FR 34892, published Aug. 7, 1978), EPA proposed that the locations of stations for all pollutants need not actually be included in the implementation plan, but the plan must contain a monitoring program which includes a monitoring network that is based upon negotiations between the State and the EPA regional office. The plan would also have to contain a commitment to annually review the adequacy of the network and to establish new stations and relocate or terminate existing stations as needed in order to keep the network responsive to data needs. EPA feels that if the entire system were part of the SIP, the only way the State could make modifications would be to propose the change, hold a public hearing, and submit the change to EPA as a plan revision. EPA would then have to propose to approve the revision, entertain public comment, and then finally promulgate its approval. EPA feels that this process is too time-consuming and would defeat the purpose of the annual review, which is to make timely adjustments to the network. Also, EPA feels that the potential benefits from this process would be too few to warrant its implementation. The proposed requirements concerning air quality monitoring, however, would require that the locations of the monitors be available at all times for public inspection. Therefore, when the State revises its SIP in order to implement the forthcoming air quality monitoring requirements, the public can at that time comment on the State system.

The public can also comment on changes to the networks at any time by submitting written comment on changes to the State or EPA regional office.

One commenter indicated that the low-volume sampler compares favorably in measurement with the high-volume sampler, which is the reference method for collection of the sample, and excludes larger particles that are not respirable and which the commenter feels are not significant from a health standpoint. The commenter implies that EPA should allow the use of the low-volume sampler. Low-volume sampling will be allowed if the agency that wishes to use it demonstrates that the method is equivalent to the reference method, using the procedures that EPA is proposing in another portion of this FEDERAL REGISTER.

3.0 OTHER CHANGES FROM PROPOSAL

3.1 AIR QUALITY SURVEILLANCE REQUIREMENTS

EPA has revised the air quality surveillance requirements for lead slightly from the proposal to render them clearer and more consistent with the general air quality surveillance requirements currently under revision that will apply to all pollutants. These revised general requirements will closely follow and implement the recommendations of EPA's Standing Air Monitoring Work Group. (4) The significant revisions of the lead requirements from the proposal include the following: A change of the date by which the entire monitoring system must be established; deletion of the references to the terms, "National Air Quality Trends Stations" (or "NAQTS") (which are now called "National Air Monitoring Stations") (or "NAMS") and "State and Local Air Monitoring Stations" (or "SLAMS"). These terms have not yet been defined by regulation, so reference to them is meaningless. Modification to the requirement that the plan contain a description of the monitoring system; and revision of the "Supplementary Guidelines on Lead Implementation Plans" to account for location of monitoring stations in urban street canyons.

As mentioned in the preamble to the proposal, EPA will eventually incorporate the lead monitoring requirements into the air quality monitoring requirements that apply to all pollutants for which NAAQS exist.

3.2 REPORTING OF DATA BASE

Under the proposal in § 51.86(c), the State would have been required to submit the air quality data collected since 1974 in the format of EPA's storage and retrieval of aerometric data

(SAROAD) system. The final regulation below retains this requirement, but provides the regional administrator with the authority to waive the requirement concerning the format of the data.

3.3 LISTS OF URBANIZED AREAS

There were several errors in the two tables of areas in the preamble to the proposal. In table 2, "Urbanized areas with lead air concentrations exceeding or equal to 1.5 $\mu\text{g}/\text{m}^3$, maximum monthly mean (1975)", the Norfolk, Va. AQCR number should have read 223 instead of 233. Table 3, "Urbanized areas with lead air concentrations equal to or exceeding 4.0 $\mu\text{g}/\text{m}^3$, maximum monthly mean (1975)" should have read as follows:

"AQCR	Urbanized area
15.....	Phoenix, Ariz.
24.....	Los Angeles—Long Beach, Calif.
29.....	San Diego, Calif.
30.....	San Francisco—Oakland, Calif.
30.....	San Jose, Calif.
67.....	Chicago, Ill.—northwestern Indlana.
215.....	Dallas, Tex.

Source: Data from EPA's Environmental Monitoring Support Laboratory, Statistical and Technical Analysis Branch."

These corrections, however, are now academic, since the averaging time of the lead standard is now quarterly. Therefore, tables 2 and 3 are revised to reflect the quarterly average. Table 2 (renumbered table 1) appears at the end of the preamble. Table 3, revised to reflect the quarterly average, now contains only one area, the Los Angeles—Long Beach, Calif., urbanized area. The list reflects only the data currently available to EPA, and generally the quarterly averages available are not truly representative due to insufficient data. There are other data available to State and local air pollution control agencies, however, that may indicate that other areas have concentrations in excess of the concentrations specified in the criteria for performing the analysis.

3.4 EXAMPLE LEAD CONTROL STRATEGY

The preamble to the proposal indicated that EPA was developing an example lead control strategy to assist the States in developing their lead implementation plans. The preamble indicated that the example was scheduled for completion by March 1978. Because EPA has received an extension for promulgating the national ambient air quality standard for lead, because the example control strategy would be based on the final implementation plan regulations promulgated below, and because of other delays, the example controls strategy will

probably not be available until November or December of 1978.

4.0 REFERENCES

1. "Supplementary Guidelines for Lead Implementation Plans." U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, N.C. 27711. (OAQPS No. 1.2-104).
2. Culkowski, W. M. and M. R. Patterson, "A Comprehensive Atmospheric Transport and Diffusion Model." (ORNL/NSR/EATS-17. Oak Ridge National Laboratory, Oak Ridge, Tenn., 1976.
3. "Guideline on Air Quality Models." Monitoring and data Analysis Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, N.C. EPA-450/2-78-027 (OAQPS No. 1.2-080), April, 1978.
4. "Air Monitoring Strategy for State Implementation Plans." Prepared by the Standing Air Monitoring Work Group. U.S. Environmental Protection Agency, Office of Air and Waste Management, Office of Air Quality Planning and Standards, Research Triangle Park, N.C. 27711. EPA-450/2-77-010. June, 1977.

TABLE 1—Urbanized Areas With Lead Air Concentrations Exceeding or Equal to 1.5 µg/m³, Maximum Quarterly Mean (1975)

AQCR No.	Area
004.....	Birmingham, Ala.
015.....	Phoenix, Ariz.
031.....	Fresno, Calif.
024.....	Los Angeles—Long Beach, Calif.
028.....	Sacramento, Calif.
024.....	San Bernardino—Riverside, Calif.
029.....	San Diego, Calif.
030.....	San Francisco—Oakland, Calif.
030.....	San Jose, Calif.
036.....	Denver, Colo.
043.....	New York, N.Y.—northeastern New Jersey.
042.....	Waterbury, Conn.
042.....	Springfield, Mass.—Chicopee-Holyoke, Connecticut.
045.....	Wilmington, Del.—New Jersey.
045.....	Philadelphia, Pa.—New Jersey.
047.....	Washington, D.C.—Maryland—Virginia.
067.....	Chicago, Ill.—northwestern Indiana.
131.....	Minneapolis—St. Paul, Minn.
070.....	St. Louis, Mo.—Illinois.
013.....	Las Vegas, Nev.
148.....	Reno, Nev.
184.....	Oklahoma City, Okla.
151.....	Scranton, Pa.
244.....	San Juan, P.R.
200.....	Columbia, S.C.
202.....	Greenville, S.C.
207.....	Knoxville, Tenn.
018.....	Memphis, Tenn.—Mississippi.
215.....	Dallas, Tex.
153.....	El Paso, Tex.
216.....	Houston, Tex.

SOURCE: Data from EPA's Environmental Monitoring Support Laboratory, Statistical and Technical Analysis Branch.

Dated: September 29, 1978.

DOUGLAS M. COSTLE,
Administrator.

The Code of Federal Regulations, Title 40, Chapter I, Part 51, is amended as follows:

1. In § 51.1, paragraph (k) is revised and paragraph (n) is amended by adding paragraph (11) as follows:

§ 51.1 Definitions.

(k) "Point source" means the following:

(1) For particulate matter, sulfur oxides, carbon monoxide, hydrocarbons, and nitrogen dioxide—

(i) Any stationary source the actual emissions of which are in excess of 90.7 metric tons (100 tons) per year of the pollutant in a region containing an area whose 1970 "urban place" population, as defined by the U.S. Bureau of the Census, was equal to or greater than 1 million;

(ii) Any stationary source the actual emissions of which are in excess of 22.7 metric tons (25 tons) per year of the pollutant in a region containing an area whose 1970 "urban place" population, as defined by the U.S. Bureau of the Census was less than 1 million; or

(iii) Without regard to amount of emissions, stationary sources such as those listed in appendix C to this part.

(2) For lead, any stationary source the actual emissions of which are in excess of 4.54 metric tons (5 tons) per year of lead or lead compounds measured as elemental lead.

(n) ***

(11) Control or prohibition of a fuel or fuel additive used in motor vehicles, if such control or prohibition is necessary to achieve a national primary or secondary air quality standard and is approved by the Administrator under § 211(c)(4)(C) of the Act.

2. Section 51.12, paragraph (e) is amended by adding subdivision (3) as follows:

§ 51.12 Control strategy: General.

(e) ***

(3) This paragraph covers only plans to attain and maintain the national standards for particulate matter, sulfur oxides, carbon monoxide, photochemical oxidants, hydrocarbons, and nitrogen dioxide.

3. Section 51.17 is amended by (1) revising the heading to read "Air quality surveillance: Particulate matter, sulfur oxides, carbon monoxide, photochemical oxidants, hydrocarbons, and nitrogen dioxide," and (2) adding paragraph (d) as follows:

§ 51.17 Air quality surveillance: Particulate matter, sulfur oxides, carbon monoxide, photochemical oxidants, hydrocarbons, and nitrogen dioxide.

(d) This section covers only plans to attain and maintain the national standards for particulate matter, sulfur oxides, carbon monoxide, photochemical oxidants, hydrocarbons, and nitrogen dioxide.

4. A new § 51.17b is added as follows:

§ 51.17b Air quality surveillance: Lead.

(a) This section covers only plans to attain and maintain the national standards for lead.

MONITORING IN CERTAIN AREAS

(b) The plan must provide for the establishment of a monitoring system that contains at least two permanent lead ambient air quality monitoring stations in each urbanized area (as defined by the U.S. Bureau of the Census)—

(1) That has a 1970 population greater than 500,000; or

(2) Where lead air quality concentrations currently exceed or have exceeded 1.5µg/m³ quarterly arithmetic mean measured since January 1, 1974.

(c) The EPA Regional Administrator may specify more than two monitoring stations if he finds that two stations are insufficient to adequately determine if the lead standard is being attained and maintained. He may also specify stations in areas outside the areas covered in paragraph (b) of this section.

(d) The monitoring system must contain at least one roadway type monitoring site and at least one neighborhood site and be sited in accordance with the procedures specified in EPA's "Supplementary Guidelines for Lead Implementation Plans."

(e) The monitors must be operated on a minimum sampling frequency of one 24-hour sample every 6 days.

(f) Existing sampling sites being used for sampling particulate matter may be designated as sites for sampling lead if they meet the siting criteria of "Supplementary Guidelines for Lead Implementation Plans."

(g) The plan must provide that all lead air quality monitoring stations will be established and operational as expeditiously as practicable, but no later than 2 years after the date of the Administrator's approval of the plan for the stations specified under paragraph (b) of this section.

(h) The analysis of the 24-hour samples may be performed for either individual samples or composites of the samples collected over a calendar month or quarter.

(i) [Reserved]

REQUIREMENTS APPLICABLE TO ALL MONITORS

(j) The plan must provide for having a description of the system available for public inspection and submission to the Administrator at his request. The description must be available at all times after the date the plan is made available for public inspection. The description must include the following information:

(1) The SAROAD site identification form.

(2) The sampling and analysis method.

(3) The sampling schedule.

(k) The monitoring method used in any station in the monitoring systems required in this section must be a reference or equivalent method for lead as defined in § 50.1 of this chapter.

5. A new subpart E is added as follows:

Subpart E—Control Strategy: Lead

- Sec.
 51.80 Demonstration of attainment.
 51.81 Emissions data.
 51.82 Air quality data.
 51.83 Certain urbanized areas.
 51.84 Areas around significant point sources.
 51.85 Other areas.
 51.86 Data bases.
 51.87 Measures
 51.88 Data availability.

AUTHORITY: Secs. 110, 301(a), Clean Air Act as amended (42 U.S.C. 7410, 7601).

Subpart E—Control Strategy: Lead

§ 51.80 Demonstration of attainment.

(a) Each plan must contain a demonstration that the standard will be attained and maintained in the following areas:

(1) Areas in the vicinity of the following point sources of lead:

Primary lead smelters.
 Secondary lead smelters.
 Primary copper smelters.
 Lead gasoline additive plants.
 Lead-acid storage battery manufacturing plants that produce 2,000 or more batteries per day.

Any other stationary source that actually emits 25 or more tons per year of lead or lead compounds measured as elemental lead.

(2) Any other area that has lead air concentrations in excess of the national standard concentration for lead, measured since January 1, 1974.

(b) The plan must demonstrate that the measures, rules, and regulations contained in the plan are adequate to provide for the attainment of the national standard for lead within the time prescribed by the Act and for the maintenance of that standard for a reasonable period thereafter.

(c) The plan must include the following:

(1) A summary of the computations, assumptions, and judgments used to determine the reduction of emissions or reduction of the growth in emissions that will result from the application of the control strategy.

(2) A presentation of emission levels, expected to result from application of each measure of the control strategy.

(3) A presentation of the air quality levels expected to result from application of the overall control strategy presented either in tabular form or as an isopleth map showing expected maximum concentrations.

§ 51.81 Emissions data.

(a) The plan must contain a summary of the baseline lead emission inventory based upon measured emissions or, where measured emissions are not available, documented emission factors. The point source inventory on which the summary is based must contain all sources that emit 5 or more tons of lead per year. The inventory must be summarized in a form similar to that shown in appendix D.

(b) The plan must contain a summary of projected lead emissions for—

(1) At least 3 years from the date by which EPA must approve or disapprove the plan if no extension under section 110(e) of the Clean Air Act is granted;

(2) At least 5 years from the date by which EPA must approve or disapprove the plan if an extension is requested under section 110(e) of the Clean Air Act; or

(3) Any other longer period if required by the appropriate EPA Regional Administrator.

(c) The plan must contain a description of the method used to project emissions.

(d) The plan must contain an identification of the sources of the data used in the projection of emissions.

§ 51.82 Air quality data.

(a) The plan must contain a summary of all lead air quality data measured since January 1974. The plan must include an evaluation of the data for reliability, suitability for calibrating dispersion models (when such models will be used), and representativeness. When possible, the air quality data used must be for the same baseline year as for the emission inventory.

(b) If additional lead air quality data are desired to determine lead air concentrations in areas suspected of exceeding the lead national ambient air quality standard, the plan may include data from any previously collected filters from particulate matter high volume samplers. In determining the lead content of the filters for control strategy demonstration purposes, a State may use, in addition to the refer-

ence method, X-ray fluorescence or any other method approved by the Regional Administrator.

(c) The plan must also contain a tabulation of, or isopleth map showing, maximum air quality concentrations based upon projected emissions.

§ 51.83 Certain urbanized areas.

For urbanized areas with measured lead concentrations in excess of 4.0 $\mu\text{g}/\text{m}^3$, quarterly mean measured since January 1, 1974, the plan must employ the modified rollback model for the demonstration of attainment as a minimum, but may use an atmospheric dispersion model if desired.

§ 51.84 Areas around significant point sources.

(a) The plan must contain a calculation of the maximum lead air quality concentrations and the location of those concentrations resulting from the following point sources for the demonstration of attainment:

Primary lead smelters.
 Secondary lead smelters.
 Primary copper smelters.
 Lead gasoline additive plants.
 Lead-acid storage battery manufacturing plants that produce 2,000 or more batteries per day.

Any other stationary source that actually emits 25 or more tons per year of lead or lead compounds measured as elemental lead.

(b) In performing this analysis, the State shall use an atmospheric dispersion model.

§ 51.85 Other areas.

For each area in the vicinity of an air quality monitor that has recorded lead concentrations in excess of the lead national standard concentration, the plan must employ the modified rollback model as a minimum, but may use an atmospheric dispersion model if desired for the demonstration of attainment.

§ 51.86 Data bases.

(a) For interstate regions, the analysis from each constituent State must, where practicable, be based upon the same regional emission inventory and air quality baseline.

(b) Each State shall submit to the appropriate EPA Regional Office with the plan, but not as part of the plan, emissions data and information related to point and area source emissions as identified in the "Supplementary Guidelines for Lead Implementation Plans."

(c) Air quality data.

(1) Each State shall submit to the appropriate EPA Regional Office with the plan, but not as part of the plan, all lead air quality data measured since January 1, 1974. This require-

ment does not apply if the data has already been submitted.

(2) The data must be submitted in accordance with the procedures and data forms specified in chapter 3.4.0 of the "AEROS User's Manual" concerning storage and retrieval of aerometric data (SAROAD) except where the Regional Administrator waives this requirement.

§ 51.87 Measures.

(a) The lead control strategy must include the following:

(1) A description of each control measure that is incorporated into the lead plan.

(2) Copies of or citations to the enforceable laws and regulations to implement the measures adopted in the lead plan.

(3) A description of the administrative procedures to be used in implementing each selected control measure.

(4) A description of enforcement methods including, but not limited to, procedures for monitoring compliance with each of the selected control measures, procedures for handling violations, and a designation of agency responsibility for enforcement or implementation.

§ 51.88 Data availability.

(a) The State shall retain all detailed data and calculations used in the preparation of the lead analyses and plan, make them available for public inspection, and submit them to the Administrator at his request.

(b) The detailed data and calculations used in the preparation of the lead analyses and control strategies are not considered a part of the lead plan.

(Secs. 110, 301(a), Clean Air Act as amended (42 U.S.C. 7410, 7601).)

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