ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[AD-FRL–5659–5]

RIN 2060–AE66

National Ambient Air Quality Standards for Particulate Matter: Proposed Decision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In accordance with sections 108 and 109 of the Clean Air Act (Act), EPA has reviewed the air quality criteria and national ambient air quality standards (NAAQS) for particulate matter (PM) and for ozone (O_3). Based on these reviews, EPA proposes to change the standards for both classes of pollutants. This document describes EPA's proposed changes with respect to the NAAQS for PM. The EPA's proposed actions with respect to O_3 are being proposed elsewhere in today's Federal Register.

With respect to PM, EPA proposes to revise the current primary PM_{10} standards by adding two new primary $PM_{2.5}$ standards set at 15 μg/m^3, annual mean, and 50 μg/m^3, 24-hour average, to provide increased protection against a wide range of PM-related health effects, including premature mortality and increased hospital admissions and emergency room visits (primarily in the elderly and individuals with cardiopulmonary disease); increased respiratory symptoms and disease (in children and individuals with cardiopulmonary disease such as asthma); decreased lung function (particularly in children and individuals with asthma); and alterations in lung tissue and structure and in respiratory tract defense mechanisms. The proposed annual $PM_{2.5}$ standard would be based on the 3-year average of the annual arithmetic mean $PM_{2.5}$ concentrations, spatially averaged across an area. The proposed 24-hour $PM_{2.5}$ standard would be based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each monitor within an area. The EPA also solicits comment on two alternative approaches for selecting the levels of $PM_{2.5}$ standards. The EPA proposes to revise the current 24-hour primary PM_{10} standard of 150 μg/m^3 by replacing the 1-expected-exceedance form with a 98th percentile form, averaged over 3 years at each monitor within an area, and solicits comment on an alternative proposal to revoke the 24-hour PM_{10} standard. The EPA also proposes to retain the current annual primary PM_{10} standard of 50 μg/m^3. Further, EPA proposes new data handling conventions for calculating 98th percentile values and spatial averages (Appendix K), proposes to revise the reference method for monitoring PM as PM_{10} (Appendix J), and proposes a new reference method for monitoring PM as $PM_{2.5}$ (Appendix L).

The EPA proposes to revise the current secondary standards by making them identical to the suite of proposed primary standards. In the Administrator's judgment, these standards, in conjunction with the establishment of a regional haze program under section 169A of the Act, would provide appropriate protection against PM-related public welfare effects including soiling, material damage, and visibility impairment.

DATES: Written comments on this proposed rule must be received by February 18, 1997.

ADDRESSES: Submit comments in duplicate if possible on the proposed action to: Office of Air and Radiation Docket and Information Center (6102), Attention: Docket No. A–95–54, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Public hearings: The EPA will announce in a separate Federal Register document the date, time, and address of the public hearing on this proposed rule.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Koman, MD–15, Air Quality Strategies and Standards Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone: (919) 541–5170.

SUPPLEMENTARY INFORMATION:

Docket

Docket No. A–95–54 incorporates by reference the docket established for the air quality criteria document (Docket No. ECAO–CD–92–0671). The docket may be inspected at the above address between 8:00 a.m. and 5:30 p.m. on weekdays, and a reasonable fee may be charged for copying.

Availability of Related Information

Certain documents are available from the U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. Available documents include: Air Quality Criteria for Particulate Matter (Criteria Document) (three volumes, EPA/600/P–95–001aF thru EPA/600/P–95–001cF, April 1996, NTIS # PB–96–168224, $234.00 paper copy); and Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information (Staff Paper) (EPA–452/R–96–013, July 1996, NTIS # PB–97–115406, $47.00 paper copy and $19.50 microfiche). (Add a $3.00 handling charge per order.) A limited number of copies of other documents generated in connection with this standard review, such as technical support documents pertaining to air quality, monitoring, and health risk assessment, can be obtained from: U.S. Environmental Protection Agency Library (MD–35), Research Triangle Park, NC 27711, telephone (919) 541–2777. These and other related documents are also available for inspection and copying in the EPA docket identified above.

The Staff Paper and human health risk assessment support documents are now available on the Agency's Office of Air Quality Planning and Standards' (OAQPS) Technology Transfer Network (TTN) Bulletin Board System (BBS) in the Clean Air Act Amendments area, under Title I, Policy/Guidance Documents. To access the bulletin board, a modem and communications software are necessary. To dial up, set your communications software to 8 data bits, no parity and one stop bit. Dial (919) 541–5742 and follow the on-screen instructions to register for access. After registering, proceed to choice ''<T> Gateway to TTN Technical Areas'', then choose ''<E> CAAA BBS''. From the main menu, choose ''<1> Title I: Attain/Maint of NAAQS'', then ''<P> Policy Guidance Documents.'' To access these documents through the World Wide Web, click on ''TTN BBSWeb'', then proceed to the Gateway to TTN Technical areas, as above. If assistance is needed in accessing the system, call the help desk at (919) 541–5384 in Research Triangle Park, NC.

Implementation Activities

When revisions to the primary and secondary PM standards are implemented by the States, the utility, petroleum, mining, iron and steel, automobile, and chemical industries are likely to be affected, as well as other manufacturing concerns that emit PM or precursors to PM. The extent of such effects will depend on implementation policies and control strategies adopted by the States to assure attainment and maintenance of revised standards.

The EPA is developing appropriate policies and control strategies to assist States in the implementation of the proposed revisions to the PM NAAQS. The resulting implementation strategies

will be proposed for public comment in the future.

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I. Background

A. Legislative Requirements

Two sections of the Act govern the establishment, review, and revision of NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify pollutants which ''may reasonably be anticipated to endanger public health and welfare'' and to issue air quality criteria for them. These air quality criteria are to ''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 [a] pollutant in the ambient air * * * .''

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one ''the attainment and maintenance of which, in the judgment of the Administrator, based on the criteria and allowing an adequate margin of safety, [are] requisite to protect the public health.'' The margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting, as well as to provide a reasonable degree of protection against hazards that research has not yet identified. Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, by selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that she finds may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The Act does not require the Administrator to establish a primary NAAQS at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

A secondary standard, as defined in section 109(b)(2), must ''specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on [the] criteria, are requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.'' Welfare effects as defined in section 302(h) [42 U.S.C. 7602(h)] include, but are not limited to, ''effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

Section 109(d)(1) of the Act requires periodic review and, if appropriate, revision of existing air quality criteria and NAAQS. Section 109(d)(2) requires appointment of an independent scientific review committee to review criteria and standards and recommend new standards or revisions of existing criteria and standards, as appropriate. The committee established under section 109(d)(2) is known as the Clean Air Scientific Advisory Committee (CASAC), a standing committee of EPA's Science Advisory Board.

B. Related Control Requirements

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the Act (42 U.S.C. 7410) and related provisions, States are to submit, for EPA approval, State implementation plans (SIP's) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration program (42 U.S.C. 7470–7479) for these pollutants. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants through the Federal Motor Vehicle Control Program under Title II of the Act (42 U.S.C. 7521–7574), which involves controls for automobile, truck, bus, motorcycle, and aircraft emissions; the new source performance standards under section 111 (42 U.S.C. 7411); and the national emission standards for hazardous air pollutants under section 112 (42 U.S.C. 7412).

C. Review of Air Quality Criteria and Standards for PM

Particulate matter is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes. Particles originate from a variety of anthropogenic stationary and mobile sources as well as from natural sources. Particles may be emitted directly or formed in the atmosphere by transformations of gaseous emissions such as sulfur oxides (SO_X), nitrogen oxides (NO_X), and volatile organic compounds (VOC). The chemical and physical properties of PM vary greatly with time, region, meteorology, and source category, thus complicating the assessment of health and welfare effects.

The last review of PM air quality criteria and standards was completed in

July 1987 with notice of a final decision to revise the existing standards (52 FR 24854, July 1, 1987). In that decision, EPA changed the indicator for particles from total suspended particles (TSP) to PM_{10}.[1] Identical primary and secondary PM_{10} standards were set for two averaging times: (1) 50 μg/m^3, expected annual arithmetic mean, averaged over 3 years, and (2) 150 μg/m^3, 24-hour average, with no more than one expected exceedance per year.[2]

The EPA formally initiated the current review of the air quality criteria for PM in April 1994 by announcing its intention to develop a revised Air Quality Criteria Document for Particulate Matter (henceforth, the ''Criteria Document''). Thereafter, the EPA presented its plans for review of the criteria and standards for PM under a highly accelerated, court-ordered schedule[3] at a public meeting of the CASAC in December 1994. Several workshops were held by EPA's National Center for Environmental Assessment (NCEA) to discuss important new health effects information in November 1994 and January 1995. External review drafts of the Criteria Document were made available for public comment and were reviewed by CASAC at public meetings held in August and December 1995 and February 1996. The CASAC came to closure in its review of the Criteria Document, advising the Administrator in a March 15, 1996 closure letter (Wolff, 1996a) that ''although our understanding of the health effects of PM is far from complete, a revised Criteria Document which incorporates the Panel's latest comments will provide an adequate review of the available scientific data and relevant studies of PM.'' CASAC and public comments from these meetings and from subsequent written comments and the closure letter were incorporated as appropriate in the final Criteria Document (U.S. EPA, 1996a).

External review drafts of a staff paper prepared by the Office of Air Quality Planning and Standards (OAQPS), Review of the National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information (henceforth, the ''Staff Paper'') were made available for public comment and were reviewed by CASAC at public meetings in December 1995 and May 1996.[4] The CASAC came to closure in its review of the Staff Paper, advising the Administrator in a June 13, 1996 closure letter (Wolff, 1996b) that ''the Staff Paper, when revised, will provide an adequate summary of our present understanding of the scientific basis for making regulatory decisions concerning PM standards.'' CASAC and public comments from these meetings, subsequent written comments, and the CASAC closure letter were incorporated as appropriate in the final Staff Paper (U.S. EPA, 1996b).

The principal focus of this current review of the air quality criteria and standards for PM is on recent epidemiological evidence reporting associations between ambient concentrations of PM and a range of serious health effects. Particular attention has been given to several size-specific classes of particles, including PM_{10} and the principal fractions of PM_{10}, referred to as the fine ($PM_{2.5}$)[5] and coarse ($PM_{10-2.5}$)[6] fractions. As discussed in the Criteria Document, fine and coarse fraction particles can be differentiated by their sources and formation processes and their chemical and physical properties, including behavior in the atmosphere. Detailed discussions of atmospheric formation, ambient concentrations, and health and welfare effects of PM, as well as quantitative estimates of human health risks associated with exposure to PM, can be found in the Criteria Document and Staff Paper.

This review of the scientific criteria for PM has occurred simultaneously with the review of the criteria for ozone (O_3). These criteria reviews as well as related implementation strategy activities to date have brought out important linkages between O_3 and PM. A number of community epidemiological studies have found similar health effects to be associated with exposure to O_3 and PM, including, for example, aggravation of respiratory disease (e.g., asthma), increased respiratory symptoms, and increased hospital admissions and emergency room visits for respiratory causes. Laboratory studies have found potential interactions between O_3 and various constituents of PM. Other key similarities relating to exposure patterns and implementation strategies exist between O_3 and PM, specifically fine particles. These similarities include: (1) Atmospheric residence times of several days, leading to large urban and regional-scale transport of the pollutants; (2) similar gaseous precursors, including NO_X and VOC, which contribute to the formation of both O_3 and fine particles in the atmosphere; (3) similar combustion-related source categories, such as coal and oil-fired power generation and industrial boilers and mobile sources, which emit particles directly as well as gaseous precursors of particles (e.g., SO_X, NO_X, VOC) and O_3 (e.g., NO_X, VOC); and (4) similar atmospheric chemistry driven by the same chemical reactions and intermediate chemical species that form both high O_3 and fine particle levels. High fine particle levels are also associated with significant impairment of visibility on a regional scale.

These similarities provide opportunities for optimizing technical analysis tools (i.e., monitoring networks, emission inventories, air quality models) and integrated emission reduction strategies to yield important co-benefits across various air quality management programs. These co-benefits could result in a net reduction of the regulatory burden on some source category sectors that would otherwise be impacted by separate O_3, PM, and visibility protection control strategies.

In recognition of the multiple linkages and similarities in effects and the potential benefits of integrating the Agency's approaches to providing for appropriate protection of public health and welfare from exposure to O_3 and PM, EPA plans to complete the review of the NAAQS for both pollutants on the same schedule. Accordingly, today's Federal Register contains a separate notice announcing proposed revisions to the O_3 NAAQS. Linking the O_3 and PM review schedules provides an important opportunity to materially improve the nation's air quality management programs—both in terms of communicating a more complete description of the health and welfare effects associated with the major components of urban and regional air pollution, and by helping the States and local areas to plan jointly to address both PM and O_3 air pollution at the same time with one process, and to

[1] PM_{10} refers to particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers.

[2] A more complete history of the PM NAAQS is presented in section II.B of the OAQPS Staff Paper, Review of National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information (U.S. EPA, 1996b).

[3] A court order entered in *American Lung Association* v. *Browner*, CIV–93–643–TUC–ACM (D. Ariz., October 6, 1994), as subsequently modified, requires publication of proposed and final decisions on the review of the PM NAAQS by November 29, 1996 and June 28, 1997, respectively.

[4] The Staff Paper evaluates policy implications of the key studies and scientific information in the Criteria Document, identifies critical elements that EPA staff believes should be considered, and presents staff conclusions and recommendations of suggested options for the Administrator's consideration.

[5] $PM_{2.5}$ refers to particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers.

[6] $PM_{10-2.5}$ refers to those particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers but greater than 2.5 micrometers.

work together with industry to address common sources of air pollution. The EPA believes this integrated approach will lead to more effective and efficient protection of public health and the environment.

II. Rationale for Proposed Decisions on Primary Standards

This notice presents the Administrator's proposed decisions to establish new annual and 24-hour $PM_{2.5}$ primary standards and to revise the form of the current 24-hour PM_{10} primary NAAQS, based on a thorough review, in the Criteria Document, of the latest scientific information on known and potential human health effects associated with exposure to PM at levels typically found in the ambient air. These decisions also take into account and are consistent with: (1) Staff Paper assessments of the most policy-relevant information in the Criteria Document, upon which staff recommendations for new and revised primary standards are based; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the Criteria Document and Staff Paper at public meetings, in separate written comments, and in the CASAC's closure letters to the Administrator; and (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately.

As discussed more fully below, the rationale for the proposed revisions of the PM primary NAAQS includes consideration of: (1) Health effects information, and alternative views on the appropriate interpretation and use of the information, as the basis for judgments about the risks to public health presented by population exposures to ambient PM; (2) insights gained from a quantitative risk assessment conducted to provide a broader perspective for judgments about protecting public health from the risks associated with PM exposures; and (3) specific conclusions regarding the need for revisions to the current standards and the elements of PM standards (i.e., indicator, averaging time, form, and level) that, taken together, would be appropriate to protect public health with an adequate margin of safety.

As with virtually any policy-relevant scientific research, there is uncertainty in the characterization of health effects attributable to exposure to ambient PM. As discussed below, however, there is now a greatly expanded body of health effects information as compared with that available during the last review of the PM standards. Moreover, the recent evidence on PM-related health effects has undergone an unusually high degree of scrutiny and reanalysis over the past several years, beginning with a series of workshops held early in the review process to discuss important new information. A number of opportunities were provided for public comment on successive drafts of the Criteria Document and Staff Paper, as well as for intensive peer review of these documents by CASAC at several public meetings attended by many knowledgeable individuals and representatives of interested organizations. In addition, there have been a number of important scientific conferences, symposia, and colloquia on PM issues, sponsored by the EPA and others, in the U.S. and abroad, during this period. While significant uncertainties exist, the review of the health effects information has been thorough and deliberate. In the judgment of the Administrator, this intensive evaluation of the scientific evidence has provided an adequate basis for regulatory decision making at this time, as well as for the comprehensive research plan recently developed by EPA, and reviewed by CASAC and others, for improving our future understanding of the relationships between ambient PM exposures and health effects.

A. Health Effects Information

This section outlines key information contained in the Criteria Document (Chapters 10–13) and the Staff Paper (Chapter V) on known and potential health effects associated with airborne PM, alone and in combination with other pollutants that are routinely present in the ambient air. The information highlighted here summarizes: (1) The nature of the effects that have been reported to be associated with ambient PM; (2) sensitive subpopulations that appear to be at greater risk to such effects; (3) an integrated evaluation of the health effects evidence; and (4) the PM fractions of greatest concern to health.

Since the last review of the PM criteria and standards, the most significant new evidence on the health effects of PM is the greatly expanded body of community epidemiological studies. The Criteria Document stated that these recent studies provide ''evidence that serious health effects (mortality, exacerbation of chronic disease, increased hospital admissions, etc.) are associated with exposures to ambient levels of PM found in contemporary U.S. urban airsheds even at concentrations below current U.S. PM standards'' (U.S. EPA, 1996a, p. 13–1). Although a variety of responses to constituents of ambient PM have been hypothesized to contribute to the reported health effects, the relevant toxicological and controlled human studies published to date have not identified an accepted mechanism(s) that would explain how such relatively low concentrations of ambient PM might cause the health effects reported in the epidemiological literature. The discussion below notes the key issues raised in assessing community epidemiological studies, including alternative interpretations of the evidence, both for individual studies and for the evidence as a whole.

1. Nature of the Effects

As discussed in the Criteria Document and Staff Paper, the key health effects categories associated with PM include: (1) Premature mortality; (2) aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions and emergency room visits, school absences, work loss days, and restricted activity days); (3) changes in lung function and increased respiratory symptoms; (4) changes to lung tissues and structure; and (5) altered respiratory defense mechanisms. Most of these effects have been consistently associated with ambient PM concentrations, which have been used as a measure of population exposure, in a number of community epidemiological studies. Additional information and insights on these effects are provided by studies of animal toxicology and controlled human exposures to various constituents of PM conducted at higher-than-ambient concentrations. Although, as noted above, mechanisms by which particles cause effects have not been elucidated, there is general agreement that the cardio-respiratory system is the major target of PM effects.

a. Mortality

i. Short-Term Exposure Studies

As discussed in the Staff Paper, the most notable evidence on the health effects of community air pollution containing high concentrations of PM has come from the dramatic pollution episodes of Belgium's industrial Meuse Valley, Donora, Pennsylvania, and London, England. Based on analyses of a series of episodes in London, there was general acceptance in the last Criteria Document (U.S. EPA, 1982a) and in critical reviews of PM-associated health effects that London air pollution at high concentrations (at or above 500–

1000 μg/m^3 of PM[7] and sulfur dioxide (SO_2)) was causally related to increased mortality. Further analyses of daily mortality over 14 London winters suggested that particles were more likely to be responsible for the associations of health effects with air pollution than SO_2, and that the association continued to the lower concentrations of PM measured in London (150 μg/m^3, measured as BS).

From 1987 to present, numerous epidemiological studies using improved statistical techniques and expanded particle monitoring data have reported statistically significant[8] positive associations between increased daily or several-day average concentrations of PM [as measured by a variety of indices, including TSP, PM_{10}, $PM_{2.5}$, sulfate, and BS] and premature mortality in communities across the U.S. as well as in Europe and South America. Of 38 analyses and reanalyses of these studies (referred to as daily mortality studies) published between 1988 and 1996, most found statistically significant associations between increases in short-term ambient PM concentrations and total non-accidental mortality (U.S. EPA, 1996a, Table 12–2).

More specifically, the effects estimates for PM_{10} reported in these studies fall within a range of approximately 2 to 8 percent increase in the relative risk[9] of mortality for a 50 μg/m^3 increase in 24-hour average PM_{10} concentrations. The consistency in these results is notable, particularly since these studies examined PM-mortality relationships in 18 different locations varying significantly in climate, human activity patterns, aerosol composition, and amounts of co-occurring gaseous pollutants [e.g., SO_2 and ozone(O^3)], using a variety of statistical techniques. A rough estimate of the incremental relative risk attributed to PM concentrations seen in the worst London episode also falls within this range (U.S. EPA, 1996b, p. V–13). It is also important to note that the magnitude of the relative risks, while significant from a public health perspective because the potentially exposed population is large, are small compared to those usually found in epidemiological studies of occupational and other risk factors.

Some of these daily mortality studies examined PM-mortality associations for both total non-accidental mortality and cause-specific mortality. In general, such studies have reported higher relative risks for respiratory and cardiovascular causes of death than for total mortality, as well as higher risks for mortality in the elderly (>65 years of age) than for mortality in the general population.

ii. Long-Term Exposure Studies

By the time of the previous review of the PM criteria in 1987, numerous epidemiological studies of a cross-sectional design had reported statistically significant associations linking higher long-term (single or multi-year) concentrations of various indices of PM with higher mortality rates across numerous U.S. communities. However, the usefulness of such studies for quantitative purposes was at that time limited by the lack of supporting evidence available from daily mortality studies or the toxicological literature, and by unaddressed confounders and methodological problems inherent in these cross-sectional studies.

More recently, epidemiological studies of a prospective-cohort design have been conducted, including in particular the Six City study (Dockery et al., 1993) and the American Cancer Society (ACS) study (Pope et al., 1995), that lend support to the earlier cross-sectional studies of mortality. These two recent studies reflect significant methodological advances over the earlier studies, including the use of subject-specific information, and provide evidence for an association between long-term PM concentrations and mortality. At least some fraction of mortality was reported to reflect cumulative PM impacts in addition to those associated with short-term concentrations (U.S. EPA, 1996a, p. 13–34).

The Six City study, which followed more than 8,000 adults for 14 years, found that long-term PM concentrations ($PM_{15/10}$, $PM_{2.5}$, and sulfate) in six U.S. cities were statistically significantly associated with increased rates of total mortality and cardiopulmonary mortality, even after adjustment for smoking, education level, and occupation. Specifically, this study reported increases in relative risk of 26% and 37% for total and cardiopulmonary-related mortality, respectively, between the cities with the highest and lowest PM concentrations. The ACS study was designed to follow up on the findings from the Six City study, using a much larger number of individuals (more than half a million adults followed for seven years) and cities. The ACS investigators reported that, after adjustment for other risk factors, multi-year concentrations of $PM_{2.5}$ (for 47 U.S. cities) and sulfate (for 151 cities) were found to be statistically significantly associated with both total and cardiopulmonary mortality. The ACS study reported increases in relative risk of 17% and 31% for total and cardiopulmonary mortality, respectively.

Some reviewers have raised concerns regarding the adequacy of the adjustment for confounders in these prospective-cohort studies, maintaining that other uncontrolled factors may be responsible for the observed mortality rates (Lipfert and Wyzga, 1995; Moolgavkar and Luebeck, 1996; Moolgavkar, 1994). The Criteria Document indicates, however, that it is unlikely that these studies overlooked plausible confounders, although the addition of factors not taken into account might well alter the magnitude of the association (U.S. EPA, 1996a, p. 12–180). In particular, the Criteria Document cautions that the magnitude of relative risks associated with PM concentrations reported in these studies may be overestimated because some of the effects may be due to historical PM concentrations that were significantly higher than the ones used to estimate population exposures in these studies.

The Criteria Document concludes that the Six City and ACS studies, taken together with the earlier cross-sectional studies, suggest that: 1) there may be increases in mortality in disease categories that are consistent with long-term exposure to PM, and 2) at least some fraction of these deaths reflects cumulative PM impacts greater than those reported in the daily mortality studies (U.S. EPA, 1996a, p. 13–34).

iii. Degree of Lifespan Shortening

The degree of lifespan shortening associated with PM exposure in these studies is viewed by many as an important consideration in evaluating mortality effects in a public health context. The epidemiological findings of associations between short- and long-term ambient PM concentrations and premature mortality provide some insight into this issue. The mortality effects estimates associated with long-term PM concentrations in the prospective-cohort studies are

[7] Measured as British Smoke (BS), which gauges the darkness of PM collected on a filter and is most sensitive to combustion generated carbon particles. When calibrated to a mass measurement, as in the historical London studies, BS is an indicator of fine mode particles.

[8] Statistically significant results are reported at a 95% confidence level.

[9] Many of the recent epidemiological studies report effects estimates in terms of a percentage increase in the risk of mortality in the study population (as compared to the baseline rate in the population as a whole) associated with a specific increase in ambient PM concentrations measured by one or more outdoor monitors. These effects estimates generally are based on a statistical model of the entire study period, which typically spanned multiple years or seasons.

considerably larger (Six City study) to somewhat larger (ACS study) than those from the daily mortality studies, suggesting that a substantial portion of the deaths associated with long-term PM exposure may be independent of the deaths associated with short-term exposure (U.S. EPA, 1996a, p. 13–44). The Criteria Document suggests that the extent of lifespan shortening implied by the long-term exposure studies could be on the order of years (U.S. EPA, 1996a, p. 13–45).

As discussed in the Staff Paper, attempts to quantitatively evaluate the extent of lifespan shortening in the daily mortality studies to date provide no more than suggestive results, with the investigators recognizing that more research is needed in this area (U.S. EPA, 1996b, p. V–19–20). The limited analyses available suggest that at least some portion of the daily mortality associated with PM may occur in individuals who would have died within days in the absence of PM exposure (U.S. EPA, 1996b, p. V–19–20). Researchers in this area also note that it is possible that the reported deaths might be substantially premature if a person becomes seriously ill but would have otherwise recovered without the extra stress of PM exposure (U.S. EPA, 1996b, p. V–19–20).

Quantification of the degree of lifespan shortening inherent in the long- and short-term exposure mortality studies is difficult and requires assumptions about life expectancies given other risk factors besides PM exposure, including the ages at which PM-attributable deaths occur and the general levels of medical care available to sensitive subpopulations in an area. Because of these uncertainties, it is not possible to develop with confidence quantitative estimates of the extent of life-shortening accompanying the increased mortality rates that have been associated with exposures to PM (U.S. EPA, 1996a, p. 13–45).

b. Aggravation of Respiratory and Cardiovascular Disease

Given the statistically significant positive associations between ambient PM concentrations and mortality outlined above, it is reasonable to expect that community epidemiological studies should also find increased PM-morbidity associations. As noted in the Criteria Document, this is indeed the case. Twelve of the 13 epidemiological studies of hospital admissions in North America (U.S. EPA, 1996a, Table 13–3) report statistically significant positive associations between short-term concentrations of PM and hospital admissions for respiratory-related and cardiac diseases. More specifically, these studies report increases from 6 to 25 percent in the relative risk of hospital admissions for respiratory disease, pneumonia, and chronic obstructive pulmonary disease (COPD), for a 50 μg/m^3 increase in 24-hour average PM_{10} concentrations. A smaller, but statistically significant, increase in relative risk of 2 percent was reported in one study of hospital admissions for ischemic heart disease.[10]

Indirect measures of morbidity, including school absences, restricted activity days, and work loss days have also been used as indicators of acute respiratory conditions in community studies of PM. For example, the statistically significant association reported between short-term PM concentrations and school absences is consistent with an effect from PM exposure, because respiratory conditions are the most frequent cause of school absences (U.S. EPA, 1996a, Chapter 12). Recent studies have also reported statistically significant associations between short-term PM concentrations and both (1) respiratory-related restricted activity days and (2) work loss days (U.S. EPA, 1996b, p. V–22).

c. Altered Lung Function and Increased Respiratory Symptoms

Community epidemiological studies of ambient PM concentrations and laboratory studies of human and animal exposures to high concentrations of PM components show that PM exposure can be associated with altered lung function and increased respiratory symptoms. A number of epidemiological studies in the U.S. (U.S. EPA, 1996a, Tables 13–3 and 13–4) show associations between short-term PM concentrations and increased upper and lower respiratory symptoms and cough, as well as decreases in pulmonary function [e.g., forced expiratory capacity for one second (FEV_1) and peak expiratory flow rate (PEFR)]. Taken together, these studies suggest that sensitive individuals, such as children (especially those with asthma or pre-existing respiratory symptoms), may have increased or aggravated symptoms associated with PM exposure, with or without reduced lung function.

Results from respiratory symptom studies of long-term PM concentrations (U.S. EPA, 1996a, Table 13–5) are consistent with and supportive of the associations reported for short-term PM concentrations. Studies conducted in multiple U.S. communities in recent years have reported that increased symptoms of respiratory ailments in children, including bronchitis, are associated with increasing annual PM concentrations across the communities (U.S. EPA, 1996a, p. 12–372). Recent evidence for an association between long-term exposure to PM and decreased lung function in children and adults is suggestive, but more limited (U.S. EPA, 1996a, p. 12–202).

The increased risk for respiratory symptoms and related respiratory morbidity reported in the epidemiological studies is important not only because of the immediate and near-term symptoms produced, but also because of the longer-term potential for increases in the development of chronic lung disease. Specifically, recurrent childhood respiratory illness has been suggested to be a risk factor for later susceptibility to lung damage (U.S. EPA, 1996b, p. V–27).

d. Alteration of Lung Tissue and Structure

Community epidemiological studies have generally not been used to evaluate the extent to which exposure to PM directly alters lung tissues and cellular components, although some autopsy studies have found limited qualitative evidence of such effects from community air pollution (U.S. EPA, 1996b, p. V–27). Evidence of morphological (i.e., structural) damage from PM exposure has come primarily from animal and occupational studies of high concentrations of acid aerosols and other PM components, including coarse particle dusts. While morphological alterations have been extensively studied for exposures to acid aerosols, such studies have been conducted at concentrations well above current ambient levels. Long-term exposure of animals to somewhat lower concentrations of acid mixtures have been shown to induce morphological changes, which may be relevant to clinical small airway disease. Recent work in animals using lower concentrations, approaching ambient levels, of ammonium sulfate and nitrate suggest morphometric changes that could lead to a decrease in compliance or a ''stiffening'' of the lung (U.S. EPA, 1996b, p. V–27–29).

Occupational exposure to crystalline silica, which is a component of coarse dust, has been associated with a specific form of pulmonary inflammation and fibrosis (silicosis) (U.S. EPA, 1996a, p. 11–127). Based on analyses of the silica content of resuspended crustal material collected from several U.S. cities as part of the last review, staff concluded that

[10] Ischemic heart disease is a general term for heart diseases in which there is an insufficient blood supply to the heart muscle.

the risk of silicosis at levels permitted by the current annual PM_{10} NAAQS was low. The 1982 Staff Paper (U.S. EPA, 1982b) summarized qualitative evidence for morphometric changes associated with long-term exposure to crustal dusts, as suggested by autopsy studies of humans and animals exposed to various crustal dusts near or slightly above current ambient levels in the Southwest; however, no inferences regarding quantitative exposures of concern can be drawn from these studies.

e. Changes in Respiratory Defense Mechanisms

Responses to air pollutants often depend upon their interaction with respiratory tract defense mechanisms that can detoxify or physically remove inhaled material (e.g., antigenic stimulation of the immune system and mucocilliary clearance). Either depression or over-activation of such defense systems may be involved in the development of lung diseases (U.S. EPA, 1996a, p. 11–55). Acid aerosols (H_2SO_4) have been shown to alter mucocilliary clearance in healthy human subjects at levels as low as 100 $\mu g/m^3$; such effects are also reported in animals (U.S. EPA, 1996a, pp. 11–60–61). Persistent impairment of clearance may lead to the inception or progression of acute or chronic respiratory disease, and may be a plausible link between acid aerosol exposure and respiratory disease.

Alveolar macrophages play a role in resistance to bacterial infection, the induction and expression of immune reactions, and the production of a number of biologically active chemicals that are involved in respiratory defense mechanisms (U.S. EPA, 1996a, pp. 11–56–66). Various exposures to PM constituents (e.g., acid aerosols, sulfates, and road dust) at concentrations that range from near to well above ambient levels have been shown to affect such macrophage functions in experimental animals (U.S. EPA, 1996b, pp. V–29–31).

2. Sensitive Subpopulations

The recent epidemiological information summarized in the Criteria Document provides evidence that several subpopulations are apparently more sensitive (i.e., more susceptible than the general population) to the effects of community air pollution containing PM. As discussed above, the observed effects in these subpopulations range from the decreases in pulmonary function reported in children to increased mortality reported in the elderly and in individuals with cardiopulmonary disease. Such subpopulations may experience effects at lower levels of PM than the general population, and the severity of effects may be greater.

Based on a qualitative assessment of the epidemiological evidence of effects associated with PM for subpopulations that appear to be at greatest risk with respect to particular health endpoints (U.S. EPA, 1996a, Tables 13–6, 13–7), the Staff Paper draws the following conclusions with respect to sensitive subpopulations (U.S. EPA, 1996b, pp. V–31–36):

(1) Individuals with respiratory disease (e.g., COPD, acute bronchitis) and cardiovascular disease (e.g., ischemic heart disease) are at greater risk of premature mortality and hospitalization due to exposure to ambient PM.

(2) Individuals with infectious respiratory disease (e.g., pneumonia) are at greater risk of premature mortality and morbidity (e.g., hospitalization, aggravation of respiratory symptoms) due to exposure to ambient PM. Also, exposure to PM may increase individuals— susceptibility to respiratory infections.

(3) Elderly individuals are also at greater risk of premature mortality and hospitalization for cardiopulmonary causes due to exposure to ambient PM.

(4) Children are at greater risk of increased respiratory symptoms and decreased lung function due to exposure to ambient PM.

(5) Asthmatic children and adults are at risk of exacerbation of symptoms associated with asthma, and increased need for medical attention, due to exposure to PM.

3. Evaluation of Health Effects Evidence

As discussed above, a range of serious health effects in sensitive subpopulations has been associated with ambient PM concentrations in a large number of community epidemiological studies. Questions as to whether the reported associations represent causal relationships can be addressed by consideration of the adequacy and strength of the individual studies; the consistency of the associations, as evidenced by repeated observations by different investigators, in different places, circumstances, and time; the coherence of the associations (i.e., the logical or systematic interrelationships between different types of health effects); and the biological plausibility of the reported associations. Because of limitations in the available evidence from controlled laboratory studies of PM components, it is generally recognized that an understanding of biological mechanisms that could explain the reported associations has not yet emerged. Thus, the following discussion focuses on the epidemiological evidence as a basis for assessing the weight of evidence for inferences about the causality of the relationships between health effects and exposures to ambient PM concentrations. In particular, issues associated with interpreting individual study results are presented, followed by a discussion of the consistency and coherence of the health effects evidence as a whole.

a. Interpretation of Individual Study Results

While it is widely accepted that serious effects are causally related to the high concentrations of air pollution observed in the historical episodes, there is less consensus as to the most appropriate interpretation of the more recent studies finding associations of such effects with ambient PM concentrations below the levels of the current NAAQS (e.g., Schwartz, 1994b; Dockery et al., 1995; Moolgolvkar et al., 1995b; Moolgolvkar and Luebeck, 1996; Li and Roth, 1995; Samet et al., 1996; Wyzga and Lipfert, 1995b):

> In this regard, several viewpoints currently exist on how best to interpret the epidemiology data: one sees PM exposure indicators as surrogate measures of complex ambient air pollution mixtures and reported PM-related effects represent those of the overall mixture; another holds that reported PM-related effects are attributable to PM components (per se) of the air pollution mixture and reflect independent PM effects; or PM can be viewed both as a surrogate indicator as well as a specific cause of health effects. In any case, reduction of PM exposure would lead to reductions in the frequency and severity of the PM-associated health effects. (U.S. EPA, 1996a, p. 13–31)

Such alternative interpretations as to the causality underlying the reported PM-effects associations result from a number of specific issues that have been raised regarding the adequacy and strength of individual studies.

Of particular concern is the possibility that independent risk factors, related to both ambient PM concentrations and the reported effects, could potentially confound or modify the apparent PM-effects associations. Possible independent risk factors include weather-related variables and other pollutants present in the ambient air (e.g., SO_2, CO, O_3, NO_2), which have been addressed to varying degrees in most of the epidemiological studies. Other concerns are related to the influence of the choice of statistical models used by investigators and to the uncertainties introduced by the imprecision in measurements of ambient air pollutants, as well as the use of such measurements as surrogates for population exposures.[11] The Criteria

[11] In subsequent discussions, the term ''exposure misclassification'' is used to refer to combined uncertainties introduced by the related issues of

Document and Staff Paper evaluated the studies with respect to each of these issues, as summarized below:

(1) Many recent studies, including a reanalysis by the Health Effects Institute (HEI) (Samet et al., 1996), have considered the influence of weather on the results reported in studies of short-term exposures, because fluctuations in weather are associated with both changes in PM and other pollutant levels and the reported health effects. The Criteria Document concludes that the PM effects estimates are relatively insensitive to the different methods of weather adjustment used in these studies, that the role of weather-related variables has been addressed adequately, and that it is highly unlikely that weather can explain a substantially greater portion of the health effects attributed to PM than has already been accounted for in the models (U.S. EPA, 1996a, p. 13–54).

(2) A number of recent reanalyses of daily mortality studies have examined the influence of other pollutants that commonly occur in the ambient air together with PM. Most attention has been focused on Philadelphia, where extensive data are available on TSP, NO_2, O_3, CO, and SO_2. In fact, reanalyses of the Philadelphia data have led HEI investigators to conclude that a single pollutant cannot be readily identified as the best predictor of air pollution-related mortality in Philadelphia based on analyses of Philadelphia data alone (Samet et al., 1996). Based on such single-city analyses, some have argued that estimated PM effects may be overstated or potentially non-existent due to confounding by other pollutants that might actually be responsible for the effects. While it is reasonable to expect that other pollutants may play a role in modifying the magnitude of the estimated effects of PM on mortality, either through pollutant interactions or independent effects, the extent of any such co-pollutant modification is less clear. The Criteria Document notes that some mortality and morbidity studies have found little change in the PM relative risk estimates after inclusion of other co-pollutants in the model, and, in analyses where the PM relative risk estimates were reduced, the PM effects estimates typically remained statistically significant. Accordingly, the Criteria Document concludes that the PM-effects associations are valid and, in a number of studies, not seriously confounded by co-pollutants (U.S. EPA, 1996a, p. 13–57).

(3) Many investigators have examined how the choice of statistical models or the ways in which they were specified may have influenced reported PM-effects associations. In reviewing this issue, the Criteria Document finds that, while model specification is important and can influence PM-effects estimates, appropriate modeling strategies have been adopted by most investigators (U.S. EPA, 1996a, section 13.4.2.2). The Criteria Document concludes that, ''the largely consistent specific results, indicative of significant positive associations of ambient PM exposures and human mortality/morbidity effects, are not model specific, nor are they artifactually derived due to misspecification of any specific model. The robustness of the results of different modeling strategies and approaches increases our confidence in their validity'' (U.S. EPA, 1996a, p. 13–54).

(4) A difficulty noted by many reviewers in interpreting the epidemiological studies, particularly for quantitative purposes, is the uncertainty and possible bias introduced by the use of outdoor monitors to estimate a population-level index of exposure. Even in studies where outdoor PM levels near population centers are well represented by monitors, the extent to which fluctuations in outdoor concentrations are found to affect indoor concentrations and personal exposure to PM of outdoor origin remains an issue of importance. This issue is particularly salient since some of the sensitive subpopulations in the daily mortality and hospital admissions studies can be expected to spend more time indoors than the general population. Some commentors have expressed concerns regarding the lack of correlation shown in some studies that made cross-sectional comparisons of outdoor PM with indoor or personal exposures to PM (which includes PM from the indoor and personal environment). The Criteria Document found, however, that on a longitudinal basis (e.g., day-to-day), personal exposure to PM_{10} can be well correlated with outdoor measurements, and that the effects reported in the short-term epidemiological studies are not due to indoor-generated particles (U.S. EPA, 1996a, p. 1–10). Specifically, the Criteria Document concluded that ''the measurements of daily variations of ambient PM concentrations, as used in the time-series epidemiological studies of Chapter 12, have a plausible linkage to the daily variations of human exposures to PM from ambient sources, for the populations represented by the ambient monitoring stations'' (U.S. EPA, 1996a, p. 1–10).

The strength of the correspondence between outdoor concentrations and personal exposure levels on a day-to-day basis serves to reduce, but not eliminate, the potential error introduced by using outside monitors as a surrogate for personal exposure. Some commentors have suggested the net effect of misclassifying total exposure to PM might bias reported relationships between outdoor PM and mortality (or morbidity) effects towards a linear, non-threshold relationship, when in fact a threshold model of response may be more appropriate. While such a threshold has not been demonstrated in studies to date, the potential influence of exposure misclassification serves to increase the uncertainty in the reported concentration-response relationships, particularly for the lower range of concentrations.

(5) A closely related issue, namely errors in the measurement of the concentrations of air pollutants, can also introduce uncertainty and bias in effects estimates reported in epidemiological studies of PM and co-pollutants. While questions about the magnitude of measurement error and its effect on the PM-health effects associations have not been resolved, some aspects of this issue have been examined in two recent studies (Schwartz and Morris, 1995; Schwartz et al., 1996). These results suggest that the influence of measurement error for individual variables is to bias the PM-effects estimates downward (i.e., to underestimate effects). These analyses, however, do not assess the potential effect of exposure misclassification on effects estimates for different components of PM, or for other co-pollutants. In such multiple pollutant analyses, measurement error or, more generally, exposure misclassification can theoretically bias effects estimates of PM or co-pollutants in either direction, introducing further uncertainties in the estimated concentration-response relationships for all pollutants (U.S. EPA, 1996b, pp. V–39–43). A comprehensive, formal treatment of the potential influences of exposure misclassification is, therefore, an important research need. As noted below, however, the available evidence on the consistency of the PM effects relationships in multiple urban locations with widely varying indoor/outdoor conditions and a variety of monitoring approaches makes it less likely that the observed findings are an artifact of errors in measurement of pollution or of exposure.

errors in measurement of pollution and in the use of outdoor measurements to index population exposures.

b. Consistency and Coherence of the Health Effects Evidence

As discussed above, the individual epidemiological studies indicate that health effects are likely associated with PM, even after taking into account issues regarding the adequacy and strength of these studies. However, because individual studies are inherently limited as a basis for addressing questions of causality, the consistency and coherence of the evidence across the studies have also been considered in the Criteria Document (U.S. EPA, 1996a, section 13.4.2.5) and Staff Paper (U.S. EPA, 1996b, pp. V–54–58), as summarized below.

Of the more than 80 community epidemiological studies that evaluated associations between short-term concentrations of various PM indicators and mortality and morbidity endpoints (U.S. EPA, 1996a, Tables 12–2, 12–8 to 13), more than 60 such studies reported positive, statistically significant associations. These studies have been conducted by a number of different investigators, in a number of geographic locations throughout the world (with different climates and co-pollutants), using a variety of statistical techniques, and with varying temporal relationships. Despite these differences, the finding of statistically significant associations is relatively consistent across the studies (U.S. EPA, 1996a, Table 12–2).

More specifically, in looking across those studies that evaluated associations between short-term PM_{10} concentrations and mortality and morbidity endpoints, various aspects of consistency and coherence can be observed. These observations are discussed below in reference to Figure 1 (adapted from Figure V–2 in the Staff Paper). Figure 1 displays the estimated relative risk for a 50 $\mu g/m^3$ increase in measured 24-hour PM_{10} levels, derived from studies that the Criteria Document concluded permit quantitative comparisons across various cause-specific mortality and morbidity endpoints (i.e., respiratory hospital admissions, COPD or ischemic heart disease hospital admissions, and cough and lower and upper respiratory symptoms) (U.S. EPA, 1996b, Tables V–4, V–6; U.S. EPA, 1996a, Section 12.3.2.2).

Figure 1 illustrates that the effects estimates for each health endpoint are relatively consistent across the studies. Some variation would be expected, however, due to the differences among the study areas in the concentrations and relative composition of PM and other air pollutants, and in the demographic and socioeconomic characteristics of the study populations, including the distributions of sensitive subpopulations, as well as a result of random error. Thus, the Criteria Document concludes that the relatively small ranges of variability in the effects estimates observed in these studies are consistent with expectations based on assuming causal relationships between mortality and morbidity effects and PM exposure (U.S. EPA, 1996a, Section 13.4.1.1).

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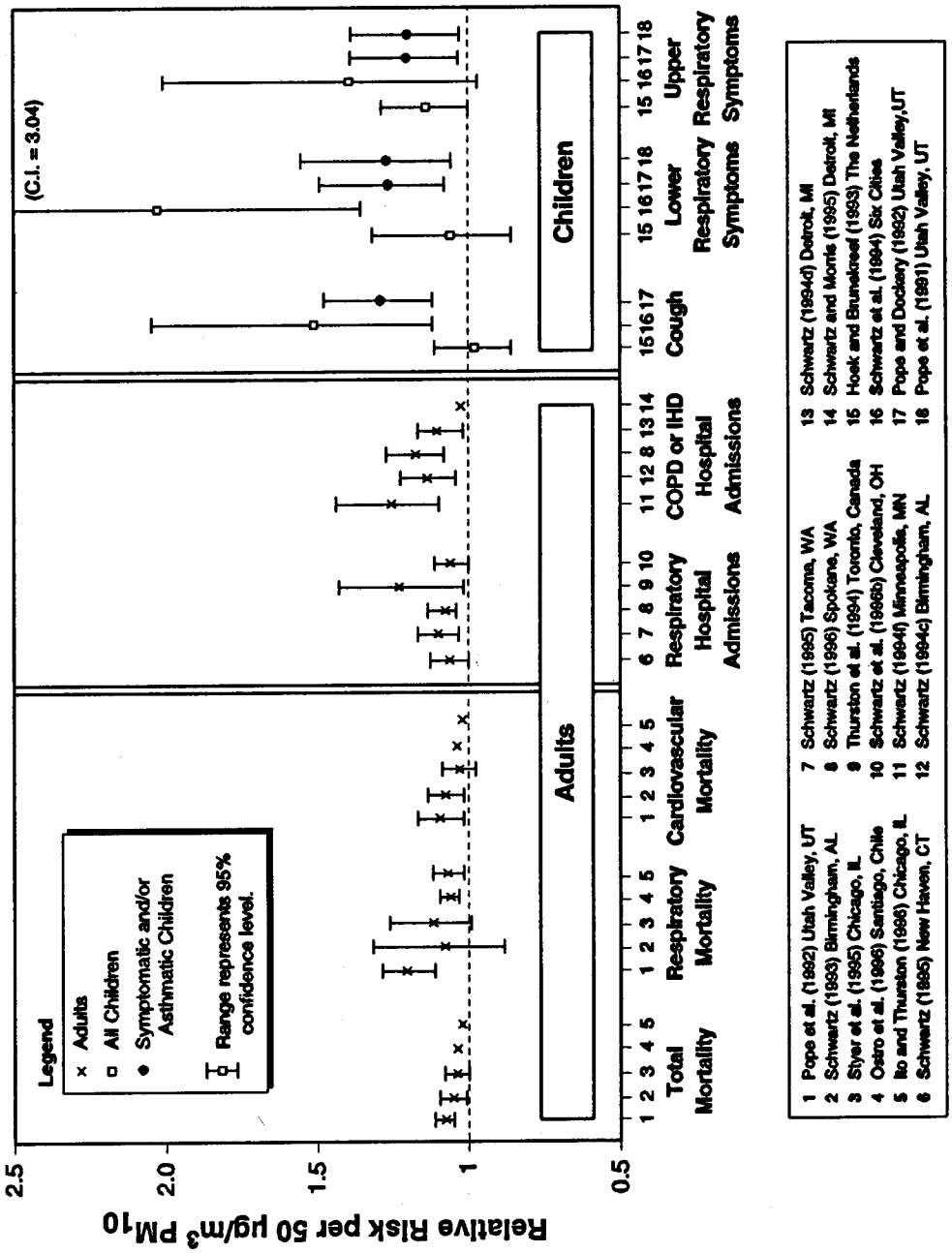
Figure 1. Relationship Between Relative Risk per 50 $\mu g/m^3$ PM_{10} and Specific Causes of Mortality and Morbidity in Adults and Children



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As noted above, it is reasonable to expect that co-pollutants present in the study areas might modify the apparent effects of PM by atmospheric interactions (e.g., through dissolution/adsorption or aerosol formation reactions) or by independent and/or interactive effects on sensitive subpopulations (e.g., respiratory function changes from exposures to O_3 or SO_2). Moreover, the possibility of exposure misclassification for primary gaseous pollutants (e.g., CO, SO_2) could diminish their apparent significance relative to PM. If such PM effects modification was occurring to an appreciable degree, the associations with PM would be expected to be consistently high in areas with high co-pollutant concentrations, and consistently low in areas with low co-pollutant concentrations. On the contrary, in an examination of reported PM_{10}-mortality associations as a function of the varying levels of co-pollutants in study areas, consistent effects estimates were observed across wide ranges of co-pollutant concentrations (U.S. EPA, 1996b, Figures V–3a, V–3b). While it is possible that different pollutants may serve to confound or otherwise influence particles in different areas, it seems unlikely that this would lead to such similar associations and consistent relative risk estimates as have been reported for PM in a large number of studies.

In addition to the consistency observed in the PM associations for each health endpoint, these studies also exhibit coherence in the kinds of health effects that have been associated with PM exposure. For example, the association of PM with mortality is mainly linked to respiratory and cardiovascular causes, which is coherent with the observed PM associations with respiratory- and cardiovascular-related hospital admissions.

Coherence is also observed across studies of both short- and long-term exposures to PM. For example, the existence of statistically significant PM-mortality associations from long-term as well as short-term exposures reinforces the likelihood that PM is a causal factor for premature mortality relative to that which might be reasonably inferred from either type of study alone. Furthermore, the fact that mortality has been associated with both short- and long-term exposures is important with respect to the credibility of ambient PM as a cause of mortality involving significant life-years lost. If there was no evidence of excess mortality from studies of long-term exposures, it might be inferred based on the short-term studies that reported daily mortality was due solely to lifespan shortening of only days or weeks in individuals already near death.

This qualitative coherence is further supported by the quantitative coherence across several health endpoints. For example, if the relationships were causal, PM-related hospitalization would be expected to occur substantially more frequently than PM-related mortality (even though many deaths attributed to air pollution probably do not occur in hospitals). The Criteria Document notes that is indeed the case (U.S. EPA, 1996a, p. 13–64 and Table 13–8). Based on the relative risk estimates from the short-term exposure studies, expected increases in respiratory- and cardiovascular-related hospital admission rates associated with PM are substantially larger than the expected increases in mortality rates for the same causes.

The coherence in the epidemiological evidence is strengthened by those studies in which different health effects are associated with ambient PM concentrations in the same study population. Specifically, studies of Detroit, Birmingham, Philadelphia, and Utah Valley all find that ambient PM concentrations in each of these cities are associated with increases in a variety of respiratory- and cardiovascular-related health effects in the elderly and adult subpopulations in these cities (U.S. EPA, 1996a, p. 13–66).

As summarized above, there is evidence that PM exposure is associated with increased risk for health effects ranging in severity from asymptomatic pulmonary function decrements, to respiratory and cardiopulmonary illness requiring hospitalization, to excess mortality from respiratory and cardiovascular causes (U.S. EPA, 1996a, p. 13–67). The consistency and coherence of the epidemiological evidence greatly adds to the strength and plausibility of the reported associations. The Criteria Document concludes that the overall coherence of the health effects evidence suggests (a likely causal role of ambient PM in contributing to the reported effects) (U.S. EPA, 1996a, p. 13–1).

4. Particulate Matter Fractions of Concern

The previous criteria and standards review included an integrated examination of available literature on the potential mechanisms, consequences, and observed responses to particle deposition in the major regions of the respiratory tract (U.S. EPA, 1982b). The review concluded with general agreement that particles that deposit in the thoracic region (tracheobronchial and alveolar regions) (i.e., particles smaller than 10 μm diameter), were of greatest concern for public health. Thus, the PM NAAQS were revised as a result of the last review from TSP to PM_{10} standards. Particle dosimetry and mechanistic considerations developed in the current review continue to support the view that, for particles that typically occur in the ambient air, those that are capable of penetrating to the thoracic regions of the respiratory tract are of greatest concern to health (U.S. EPA, 1996b, Section V).

Section V.F of the Staff Paper summarizes the evidence regarding the health effects associated with the fine ($PM_{2.5}$) and coarse ($PM_{10-2.5}$) fractions of PM_{10}. Both fine and coarse fraction particles can deposit in the thoracic regions of the respiratory tract. However, based on atmospheric chemistry, exposure, and mechanistic considerations, the Criteria Document concludes it would be most appropriate to ''consider fine and coarse mode particles as separate subclasses of pollutants'' (U.S. EPA, 1996a, p. 13–94), and to measure them separately as a basis for planning effective control strategies.

Given the significant physical and chemical differences between the two subclasses of PM_{10} (U.S. EPA, 1996b, pp. V–69–78), it is reasonable to expect that differences may exist between fine and coarse fraction particles in both the nature of potential effects and the relative concentrations required to produce such effects. The Criteria Document highlights a number of specific components of PM that could be of concern to health, including components typically within the fine fraction (e.g., acid aerosols including sulfates, certain transition metals, diesel particles, and ultrafine particles), and other components typically within the coarse fraction (e.g., silica, resuspended dust, and bioaerosols). While components of both fractions can produce health effects, in general the fine fraction appears to contain more of the reactive substances potentially linked to the kinds of effects observed in the epidemiological studies. The fine fraction also contains by far the largest number of particles and a much larger aggregate surface area than the coarse fraction. The greater surface area of the fine fraction increases the potential for surface absorption of other potentially toxic components of PM (e.g., metals, acids, organic materials), and dissolution or absorption of pollutant

gases and their subsequent deposition in the thoracic region.

The Staff Paper presents the available quantitative and qualitative information on the effects of fine particles and its constituents (U.S. EPA, 1996b, pp. V–60–63). Because of the number of pertinent studies published since the last review, far more quantitative epidemiological data exist today for relating fine particles to mortality, morbidity, and lung function changes in sensitive subpopulations, in terms of both short- and long-term ambient concentrations, than was the case for PM_{10} at the conclusion of the last review.[12] Like the more numerous PM_{10} studies, the fine particle studies (e.g., studies using $PM_{2.5}$, sulfates) generally find statistically significant positive associations between fine particle concentrations and mortality and morbidity endpoints, with more than 20 studies conducted in a number of geographic locations throughout the world, including the U.S., Canada, and Europe. More specifically, daily mortality effects estimates reported for $PM_{2.5}$ fall within the range of approximately 3 to 6 percent increases in relative risk for a 25 $\mu g/m^3$ increase in 24-hour average $PM_{2.5}$ concentrations, for those cities with statistically significant positive associations (U.S. EPA, 1996b, Table V–12). This collection of studies shows qualitative coherence in the types of health effects associated with fine particle exposure including mortality, morbidity, symptoms, and changes in lung function (U.S. EPA, 1996b, Tables V–11 to V–13).

By contrast, the current review finds much less direct epidemiological or toxicological evidence regarding the potential effects of coarse fraction particles at typical ambient concentrations. As discussed in the Staff Paper, community epidemiological studies directly comparing the effects of fine and coarse fraction particles provide evidence that reported PM associations with mortality and decreased lung function in children are more likely associated with fine fraction particles (U.S. EPA, 1996b, pp. V–63–67). On the other hand, both past and current reviews of occupational and toxicological literature have found ample qualitative reasons for concern about higher-than-ambient concentrations of coarse fraction particles. At such elevated levels, coarse fraction particles are linked to short-term effects such as aggravation of asthma and increased upper respiratory illness, which are consistent with enhanced deposition of coarse fraction particles in the tracheobronchial region (U.S. EPA, 1996a, p. 13–51). Children may be particularly sensitive to such an effect, since they typically spend more time in outdoor activities, such that they may encounter higher exposures and doses of coarse fraction particles than other potentially sensitive populations.

In addition, long-term deposition of insoluble coarse fraction particles in the alveolar region may have the potential for enhanced toxicity, in part because clearance from this region of the lung is significantly slower than from the tracheobronchial region. Limited qualitative support for this concern is found in autopsy studies of animals and humans exposed to various ambient crustal dusts at or slightly above ambient levels typical in the Southwest.

Unlike the case for fine particles, the clearest community epidemiological evidence regarding coarse fraction particles finds such effects only in areas with numerous marked exceedances of the current PM_{10} standard (U.S. EPA, 1996a, p. 13–51). In this regard, it appears that the weight of the available evidence allowing direct comparisons between the two size fractions of PM_{10} suggests that ambient coarse fraction particles are either less potent or a poorer surrogate for community effects of air pollution than are fine fraction particles.

B. Quantitative Risk Assessment

The Staff Paper presents the results of a quantitative assessment of health risks for two example cities, including risk estimates for several categories of health effects associated with: (1) existing PM air quality levels, (2) projected PM air quality levels that would occur upon attainment of the current PM_{10} standards, and (3) projected PM air quality levels that would occur upon attainment of alternative $PM_{2.5}$ standards. As an integral part of this assessment, qualitative and, where possible, quantitative characterizations of the uncertainties in the resulting risk estimates have been developed, as well as information on baseline incidence rates for the health effects considered. The risk assessment is intended as an aid to the Administrator in judging which alternative PM NAAQS would reduce risks sufficiently to protect public health with an adequate margin of safety, recognizing that such standards will not be risk-free.

As discussed in Section A above, the Criteria Document concludes that the overall consistency and coherence of the epidemiological evidence suggests a likely causal role of ambient PM in contributing to adverse health effects. An alternative interpretation is that PM may be serving as an index for the complex mixture of pollutants in urban air. The manner in which the PM epidemiological evidence is used in this risk assessment is consistent with either of these alternative interpretations of the evidence.

Despite the consistency and coherence of the epidemiological evidence reporting health effects associated with PM, EPA cautions that quantitative risk estimates derived from these studies include significant uncertainty, and thus, should not be viewed as demonstrated health impacts. EPA believes, however, that they do represent reasonable estimates as to the possible extent of risk for these effects given the available information.

1. Overview

The following discussion briefly summarizes the scope of the risk assessment and key components of the risk model. A more detailed discussion of the risk assessment methodology and results is presented in the Staff Paper and technical support documents (Abt Associates, 1996a, b).

The risk assessment focused on selected health effects endpoints discussed above for which adequate quantitative information is available (U.S. EPA, 1996a, Table VI–2), including increased daily mortality, increased hospital admissions for respiratory and cardiopulmonary causes, and increased respiratory symptoms in children. All concentration-response relationships used in the assessment were based on findings from human epidemiological studies, and consequently rely on fixed-site, population-oriented, ambient monitors as a surrogate for actual PM exposures.

Risk estimates were developed for the urban centers of two example cities, one eastern (Philadelphia County) and one western (Southeast Los Angeles County), for which sufficient PM_{10} and $PM_{2.5}$ air quality data were available. Risk estimates were calculated only for ambient PM levels in excess of estimated annual average background levels.[13] This approach of estimating

[12] The 1986 Staff Paper cited PM studies conducted in essentially 3 locations as a basis for the 24-hour standard, and 4 studies involving a total of 10 cities as a basis for the annual standard; none measured PM_{10} directly (EPA, 1986b).

[13] As discussed in Chapter IV of the Staff Paper, annual average background levels of $PM_{2.5}$ are estimated to range from approximately 1–4 $\mu g/m^3$ in western areas and 2–5 $\mu g/m^3$ in eastern areas, with the maximum 24-hour levels estimated to reach as high as about 15–20 $\mu g/m^3$ over the course of a year. Background PM is defined in the Staff Paper as the distribution of PM concentrations that

Continued

risks in excess of background was judged to be more relevant to policy decisions regarding ambient air quality standards than risk estimates that include effects potentially attributable to uncontrollable background PM concentrations. For these analyses, an estimate of the annual average background level was used, rather than a maximum 24-hour value, since estimated risks were aggregated for each day throughout the year. Risks have been estimated for a recent year of PM air quality data in each of the two example cities. Risk estimates were calculated for Los Angeles County with PM levels adjusted downward to just attain the current PM_{10} standards. Finally, risk estimates were also calculated for both example cities where PM levels were further adjusted to just attain various alternative $PM_{2.5}$ standards.

As discussed in Chapter 13 of the Criteria Document, the interpretation of specific concentration-response relationships is the most problematic issue in conducting risk assessments for PM-associated health effects at this time, due to (1) the absence of clear evidence regarding mechanisms of action for the various health effects of interest; (2) uncertainties about the shape of the concentration-response relationships; and (3) concern about whether the use of ambient $PM_{2.5}$ and ambient PM_{10} fixed-site monitoring data adequately reflects the relevant population exposures to PM that are responsible for the reported health effects. The reported study results used in this assessment are based on linear concentration-response models extending only down to the lowest PM concentrations observed within each study. [14] Thus, concentration-response relationships were not extrapolated below the range of the PM concentration air quality data reported in any given study. Alternatively, the data do not rule out the possibility of an underlying non-linear, threshold concentration-response relationship. Although these alternative interpretations of study results could significantly affect estimated risks, only very limited information is available to aid in resolving this issue (U.S. EPA, 1996a, section 13.6.5). Thus, the approach taken in the PM risk assessment is to address alternative concentration-response models through sensitivity and integrated uncertainty analyses to develop ranges of estimated risks, rather than characterizing any particular set of risk estimates as representing the ''best'' estimates.

Risk estimates for PM-associated health effects in excess of background PM levels (i.e., excess risk) were initially developed based on a set of ''base case'' assumptions. These base case assumptions reflect the use of: (1) Mid-point estimates from the ranges of estimated annual average background concentrations for the eastern and western regions of the U.S. to represent typical background levels; (2) essentially linear concentration-response relationships down to the lowest PM level observed in each study; and (3) annual distributions of 24-hour PM_{10} and $PM_{2.5}$ concentrations that were obtained by taking a recent year of PM air quality data in each example city and adjusting all PM concentrations exceeding the estimated background concentration level by the same percentage to simulate attainment of alternative standards (referred to as a ''proportional rollback'' approach). While there are many different methods of adjusting PM air quality distributions to reflect future attainment of alternative standards, analysis of historical data (Abt, 1996b) support the use of such a proportional method for adjusting air quality values.

For comparison with alternative standards, it is desirable to estimate health risks associated with PM air quality that do not include the effect of concentrations in excess of those allowed by the current PM_{10} standards. Since the air quality in one of the two cities examined, Los Angeles, exceeded the current PM_{10} standards, both PM_{10} and $PM_{2.5}$ concentrations were proportionally rolled back (preserving the $PM_{2.5}/PM_{10}$ ratio) to air quality concentrations that just attain the current PM_{10} standards. While this necessarily introduces additional uncertainty into the risk estimates, it is required in order to compare risks associated with attaining the current PM_{10} standards with risks associated with attainment of alternative $PM_{2.5}$ standards.

Sensitivity analyses have been conducted to examine the impact on the risk estimates of these and other assumptions, by varying each assumption independently. For example, the impact of using alternative estimates for background concentrations was examined by replacing the mid-point estimate with the lower and the upper end of the range of estimated annual average background levels. In addition, integrated uncertainty analyses have been conducted specifically for the excess mortality associated with PM exposures to examine the range of risk estimates when several key assumptions and uncertainties are considered simultaneously, rather than one at a time. The key issues examined in the integrated uncertainty analyses include: (1) Variability in the underlying concentration-response relationship resulting from combining the results of $PM_{2.5}$ mortality studies in six cities to estimate the relative risks in the two example cities; (2) consideration of alternative potential threshold concentrations; (3) inclusion of the range of estimates for PM background levels; and (4) use of alternative PM air quality adjustment procedures to simulate attainment of alternative standards based on analysis of historical data.

2. Key Observations

The discussion below highlights the key observations and insights from the risk assessment, together with important caveats and limitations.

(1) Fairly wide ranges of estimates of the incidence of PM-related mortality and morbidity effects were calculated for the two locations analyzed when the effects of key uncertainties and alternative assumptions were considered.

This point is illustrated below for mortality estimates using base case and alternative assumptions, as well as for morbidity estimates using base case assumptions alone.[15] For example, the incidence of mortality associated with short-term $PM_{2.5}$ exposures upon attainment of the current PM_{10} standards was estimated to range from approximately 400 to 1,000 deaths per year in Los Angeles County (with a population of 3.6 million) under base case assumptions, and from approximately 100 to 1,000 deaths using alternative assumptions considered in the integrated uncertainty analysis.[16] For Philadelphia County (with a population of 1.6 million), a city with better air quality than Los Angeles and already well below the current PM_{10}

would be observed in the U.S. in the absence of anthropogenic emissions of PM and precursor emissions of VOC, NO_x, and SO_x in North America.

[14] See Table VI–2 in the Staff Paper (U.S. EPA, 1996b) for information about the reported PM mean and range of concentration levels observed in the various epidemiological studies used in the risk assessment.

[15] In the examples presented here the ranges of estimated incidences are based on the 90 percent credible intervals from the risk analyses. The 90 percent credible interval represents the range from the 5th percentile to the 95th percentile of the estimated risk distribution, and provides a reasonable characterization of the range of estimated values that results from the various uncertainties that could be incorporated quantitatively in the risk analyses.

[16] Incidence estimates of roughly 400 to 1,000 excess deaths per year represent roughly 2 to 4 percent of the total mortality incidence in Los Angeles County.

standards, estimated mortality associated with short-term $PM_{2.5}$ exposures ranged from approximately 200 to 500 deaths per year under base case assumptions, and from approximately 20 to 500 deaths per year under alternative assumptions considered in the integrated uncertainty analyses.[17]

Morbidity effects associated with exposures to $PM_{2.5}$ are estimated using base case assumptions to range from approximately 250 to 1,600 respiratory-related hospital admissions per year and from 23,000 to 58,000 cases of respiratory symptoms in children per year for Los Angeles.[18] For Philadelphia County, morbidity effects associated with exposures to $PM_{2.5}$ are estimated using base case assumptions to range from about 70 to 450 respiratory-related hospital admissions and from 6,000 to 15,000 cases of respiratory symptoms per year.[19]

(2) Risk estimates associated with attainment of alternative $PM_{2.5}$ standards described in the Staff Paper show highly variable reductions in PM-associated risk which are a function of the particular city and the levels of the standards.

Risk estimates for PM-associated mortality and morbidity health effects have been estimated for alternative annual $PM_{2.5}$ standards[20] of 15 and 20 μg/m³, alone and in combination with alternative daily standards[21] ranging from 25 to 65 μg/m³. For two cases considering only annual $PM_{2.5}$ standards, the mean estimates (using base case assumptions) of excess mortality and morbidity associated with short-term $PM_{2.5}$ exposures in Los Angeles County were reduced by roughly 45–50% for attainment of an annual $PM_{2.5}$ standard level of 15 μg/m³, and by roughly 20–25% for attainment of an annual standard level of 20 μg/m³.[22] These estimates of risk reduction are incremental to the risk reductions associated with attainment of the current PM_{10} standards as explained above. Similarly, for an area already in attainment with the current PM_{10} standards (Philadelphia County), mean estimates of excess morbidity and mortality associated with short-term exposures to $PM_{2.5}$ were not affected by an annual standard of 20 μg/m³ but were reduced by about 15–20% upon attainment of an annual $PM_{2.5}$ standard of 15 μg/m³.[23]

As noted above, risk estimates for PM-associated mortality and morbidity health effects also have been estimated for alternative 24-hour $PM_{2.5}$ standards ranging from 25 to 65 μg/m³ (in combination with an annual standard of 20 μg/m³). These combinations of standards result in cases for which the 24-hour standard was generally controlling the degree of risk reduction. Mean estimates of excess mortality and morbidity associated with short-term $PM_{2.5}$ exposures in Los Angeles County were reduced by roughly 85% for a daily standard of 25 μg/m³, and by roughly 40–50% for a daily standard of 65 μg/m³, beyond the risks associated with attainment of the current PM_{10} standards when base case assumptions were used.[24] Similarly, for Philadelphia County, the mean estimates of excess mortality and morbidity were reduced by roughly 70–75% for a daily standard of 25 μg/m³, and about 10% for a daily standard of 65 μg/m³.[25]

(3) Based on the results from the sensitivity analyses of key uncertainties and the integrated uncertainty analyses, the single most important factor influencing the uncertainty associated with the risk estimates is whether or not a threshold concentration exists below which PM-associated health risks are not likely to occur.

Alternative assumed threshold concentrations considered in these analyses result in as much as a 3- to 4-fold difference in estimated risk associated with PM exposures in Los Angeles County (U.S. EPA, 1996b, Figure VI–8; Abt Associates, 1996b, Exhibits 7.19 and 7.20) depending on the likelihood imputed to various $PM_{2.5}$ threshold concentrations. In an area with PM concentrations well below the current PM standards (e.g., Philadelphia County), differences in risk associated with a recent year of PM air quality may be even greater for alternative threshold assumptions, since these locations would be expected to have a greater proportion of PM concentrations below assumed threshold concentrations.

(4) Based on results from the sensitivity analyses of key uncertainties and/or the integrated uncertainty analyses, quantitative consideration of the following uncertainties is estimated to have a much more modest impact on the risk estimates: (a) Inclusion of individual co-pollutant species when estimating PM effect sizes (based on reported estimates of effects modification); (b) the choice of approach to adjusting the slope of the concentration-response relationship when analyzing alternative possible threshold concentrations; (c) the value chosen to represent average background PM concentrations; and (d) the choice of air quality adjustment approaches for simulating attainment of alternative PM standards.

(5) Additional sources of uncertainty associated with risk analyses of alternative $PM_{2.5}$ standard scenarios which could not be addressed quantitatively include: (a) Uncertainty in the pattern of air quality concentration reductions that would be observed across the distribution of 24-hour $PM_{2.5}$ concentrations in areas attaining the standards, and (b) uncertainty concerning the degree to which PM concentration-response relationships may reflect contributions from other pollutants, or the particular contribution of certain constituents of $PM_{2.5}$, and whether such constituents would be reduced in similar proportion as the reduction in $PM_{2.5}$.

To the extent concentrations of other combustion source co-pollutants are reduced more or less than $PM_{2.5}$ concentrations in attaining alternative $PM_{2.5}$ standards, estimates of health effects reduced by such standards would be expected to be related to the degree to which these co-pollutants in fact play a role in producing or modifying PM-associated effects. Similarly, if specific constituents of $PM_{2.5}$ mass have differing potencies in

[17] Incidence estimates of 200 to 500 excess deaths per year associated with PM exposures represent roughly 1 to 2.5 percent of total mortality in Philadelphia County.

[18] Incidence estimates of 250 to 1,600 respiratory-related hospital admissions associated with PM exposures represent roughly 1.5 to 10 percent of total respiratory-related hospital admissions in Los Angeles County. Incidence estimates of 23,000 to 58,000 cases of respiratory symptoms represent roughly 15 to 40 percent of total respiratory symptom cases in Los Angeles County.

[19] Incidence estimates of 70 to 450 cardiopulmonary-related hospital admissions associated with PM exposures represent roughly 0.5 to 3.5 percent of total respiratory-related hospital admissions in Philadelphia County. Incidence estimates of 6,000 to 15,000 cases of respiratory symptoms associated with PM exposures represent roughly 10 to 30 percent of total respiratory symptom cases in Philadelphia County.

[20] The annual standards analyzed were simulated by adjusting the annual average concentration at the population-oriented monitor in the study area with the highest measured values to the standard level under consideration.

[21] The alternative daily standards analyzed were the 1-expected-exceedance form of the standard.

[22] In Los Angeles County, a 45–50% reduction in excess mortality and morbidity associated with short-term $PM_{2.5}$ exposures represents decreases of roughly 320 excess deaths, 540 cardiopulmonary-related hospital admissions, and 22,000 cases of respiratory symptoms; a 20–25% reduction represents decreases of roughly 150 excess deaths, 250 cardiopulmonary-related hospital admissions, and 11,000 cases of respiratory symptoms.

[23] In Philadelphia County, a 15–20% reduction in excess mortality and morbidity associated with short-term $PM_{2.5}$ exposures represents decreases of roughly 60 excess deaths, 70 cardiopulmonary-related hospital admissions, and 2,000 cases of respiratory symptoms.

[24] In Los Angeles County, an 85% reduction in excess mortality and morbidity associated with short-term $PM_{2.5}$ exposures represents decreases of roughly 590 excess deaths, 1000 cardiopulmonary-related hospital admissions, and 37,000 cases of respiratory symptoms; a 40–50% reduction represents decreases of roughly 280 excess deaths, 480 cardiopulmonary-related hospital admissions, and 20,000 cases of respiratory symptoms.

[25] In Philadelphia County, a 70–75% reduction in excess mortality and morbidity associated with short-term $PM_{2.5}$ exposures represents decreases of roughly 260 excess deaths, 320 cardiopulmonary-related hospital admissions, and 8,000 cases of respiratory symptoms; a 10% reduction represents decreases of roughly 40 excess deaths, 50 cardiopulmonary-related hospital admissions, and 1,000 cases of respiratory symptoms.

producing effects relative to other $PM_{2.5}$ constituents, estimates of risk reduced would be expected to vary if these constituent concentrations are reduced to different degrees by control strategies designed to attain alternative $PM_{2.5}$ standards.

(6) The peak 24-hour $PM_{2.5}$ concentrations appear to contribute a relatively small amount to the total health risk posed by the entire air quality distribution as compared to the risks associated with the low to mid-range concentrations.

Standards with a 24-hour averaging time are traditionally based on the highest 24-hour values observed in a year, concentrations for which the risk on an individual day is highest. However, examining a typical distribution of ambient 24-hour $PM_{2.5}$ concentrations over the course of a year in conjunction with $PM_{2.5}$ concentration-response relationships, as illustrated in Figures 2a, 2b, and 2c, the peak $PM_{2.5}$ concentrations contribute much less to the total health risk over a year than the low- to mid-range $PM_{2.5}$ concentrations.

More specifically, Figures 2a, 2b, and 2c illustrate some of the characteristics of the integration of air quality distributions and concentration-response relationships as used to predict total risk from ambient particle exposures across a year. These figures show the relative contribution of different portions of a typical urban ambient $PM_{2.5}$ concentration distribution to mortality risk from short-term exposures. As shown in Figures 2b and 2c, low- to mid-range concentrations (e.g., 10–50 $\mu g/m^3$) account for the largest amount of estimated mortality risk on an annualized basis.

The portion of the air quality distribution that contributes significantly to total health risk over the course of a year is, of course, smaller if effects thresholds are assumed or if much higher levels of estimated background $PM_{2.5}$ concentrations are used (Figure 2c). However, even with this assumption, most of the aggregate risk associated with short-term exposures likely results from the large number of days during which the 24-hour average concentrations are in the low- to mid-range, below peak 24-hour concentrations. Even though higher 24-hour concentrations, including peaks above 70 $\mu g/m^3$, clearly contribute more mortality per day than low- to mid-range concentrations, the much larger number of days within the low- to mid-ranges results in this interval being associated with the largest proportion of the total risk.

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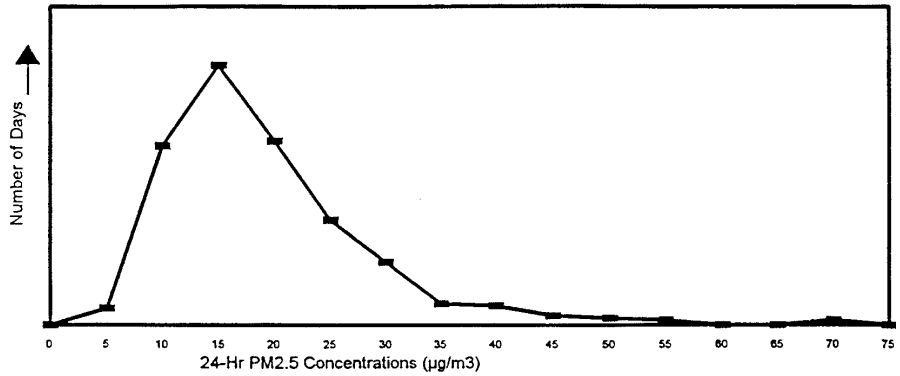

Figure 2a. Illustrative Air Quality Distribution of 24-Hour $PM_{2.5}$ Concentrations—This figure shows an example of a frequency distribution of the number of days exceeding various 24-hour average $PM_{2.5}$ concentrations over a year.

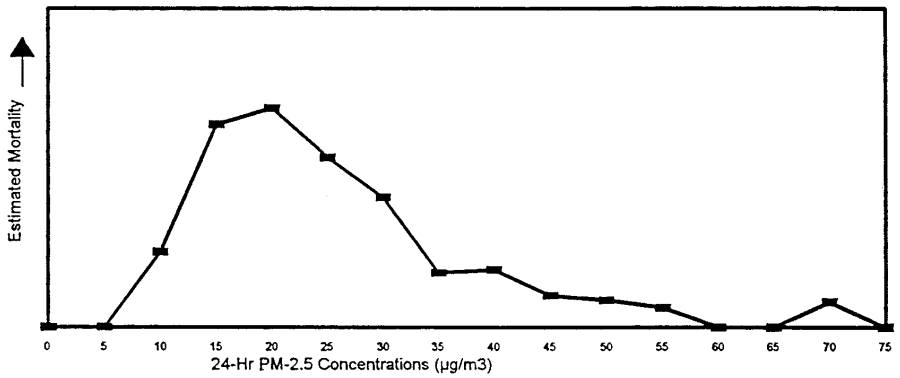

Figure 2b. Estimated Mortality Risks Using A Non-Threshold Concentration-Response Relationship—This figure illustrates the proportion of estimated mortality incidence, using a non-threshold concentration-response relationship, associated with each concentration range shown above in Figure 2a.

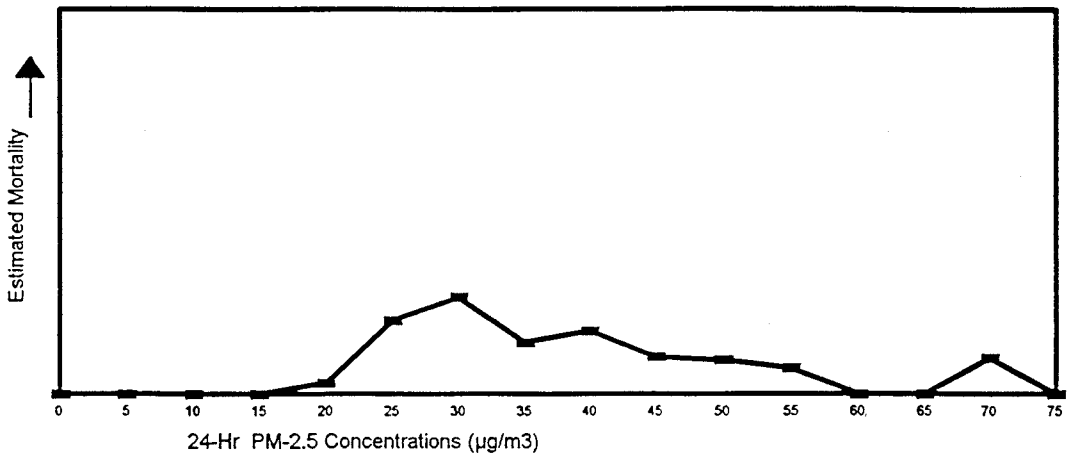

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Figure 2c. Estimated Mortality Risks Using An Illustrative Threshold Concentration-Response Relationship—This figure illustrates the proportion of estimated mortality incidence, using an example threshold concentration of 18 µg/m^3 $PM_{2.5}$, associated with each concentration range shown above in Figure 2a.

An annual $PM_{2.5}$ standard would almost certainly require areas whose air quality concentrations are above those necessary for attainment to reduce $PM_{2.5}$ concentrations across a wide range of the 24-hour air quality distribution rather than just a few high 24-hour values, thus resulting in more significant risk reduction than would a 24-hour standard set so as to control the peak concentrations. Further, an annual standard would be expected to lead to greater consistency in the risk reduced in different geographic areas having similar initial air quality than would a 24-hour standard of similar impact, in terms of the number of areas affected. Such a 24-hour standard would focus on reducing the highest 24-hour concentrations rather than on the entire air quality distribution.

(7) There is greater uncertainty about estimated excess mortality (and other effects) associated with PM exposures as one considers increasingly lower concentrations approaching background levels.

As discussed in Section A above, one of the most important uncertainties related to estimating excess mortality associated with PM exposures is the shape of the concentration-response relationship. The existing epidemiological data reporting excess mortality associated with PM exposures do not rule out the possibility that there may be a threshold concentration below which excess mortality associated with PM exposures does not occur. As one considers progressively higher PM concentrations it is increasingly unlikely that there is a threshold at these higher levels. In contrast, as one considers increasingly lower PM concentrations, there is increasing uncertainty about the shape and magnitude of the estimated concentration-response relationship over the lower range of concentrations. This increasing uncertainty is due to questions about: (1) The possible impact of multiple co-pollutants on the estimated concentration-response relationships; (2) whether exposure misclassification associated with the use of ambient monitors as a measure of population exposure might be masking a non-linear relationship; and (3) whether a biological threshold may exist below which excess mortality associated with PM exposures does not occur. In addition, there is uncertainty about background levels, and thus about the extent to which effects associated with PM exposures at concentrations approaching estimated background levels are attributable to controllable, non-background sources of ambient PM.

C. Need for Revision of the Current Primary PM Standards

The overarching issue in the present review of the primary NAAQS is whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the existing standards should be revised and, if so, what revised or new standards would be appropriate. The concluding section of the integrative summary of health effects information in the Criteria Document provides the following summary of the science with respect to this issue:

The evidence for PM-related effects from epidemiologic studies is fairly strong, with most studies showing increases in mortality, hospital admissions, respiratory symptoms, and pulmonary function decrements associated with several PM indices. These epidemiologic findings cannot be wholly attributed to inappropriate or incorrect statistical methods, misspecification of concentration-effect models, biases in study design or implementation, measurement errors in health endpoint, pollution exposure, weather, or other variables, nor confounding of PM effects with effects of other factors. While the results of the epidemiology studies should be interpreted cautiously, they nonetheless provide ample reason to be concerned that there are detectable health effects attributable to PM at levels below the current NAAQS (U.S. EPA, 1996a, p. 13–92).

Given the nature of the health effects in question, this finding clearly suggests that revision of the current NAAQS is appropriate. The extensive PM epidemiological data base provides evidence of serious health effects (e.g., mortality, exacerbation of chronic disease, increased hospital admissions) in sensitive subpopulations (e.g., the elderly, individuals with cardiopulmonary disease). Although the increase in relative risk is small for the most serious outcomes (see Figure 1), it

is likely significant from an overall public health perspective, because of the large number of individuals in sensitive subpopulations that are exposed to ambient PM and the significance of the health effects (U.S. EPA, 1996a, p. 1–21).

While the lack of demonstrated mechanisms that explain the range of epidemiological findings is an important caution, which presents difficulties in providing an integrated assessment of PM health effects research, qualitative information from laboratory studies of the effects of particle components at high concentrations and dosimetry considerations suggest that the kinds of effects observed in community studies (e.g., respiratory- and cardiovascular-related responses) are at least plausibly related to PM.[26] Indeed, the Criteria Document and Section V.E of the Staff Paper point to the consistency of the results of the epidemiological studies from a large number of different locations and the coherent nature of the observed effects as being suggestive of a likely causal role of ambient PM in contributing to the reported effects.

Given the evidence that such effects may occur at levels below the current standards, the serious nature and potential magnitude of the public health risks involved, and the need to consider the fine and coarse fractions as distinct classes of particles, the Staff Paper and the CASAC (Wolff, 1996b) concluded that revision of the current standards is clearly appropriate. Moreover, at the May 1996 public meeting (U.S. EPA, 1996e), and in separate written comments (including Lippmann et al., 1996), a majority of CASAC panel members recommended revisions that would strengthen the health protection provided by the current PM standards. Based on the rationale and recommendations contained in the Staff Paper and the CASAC closure letter, the Administrator concludes that the current PM standards should be revised.

D. Indicators of PM

In formulating alternative approaches to establishing adequately protective, effective, and efficient PM standards, it is necessary to specify the fraction of particles found in the ambient air that should be used as the indicator(s) for the standards. In this regard, the most recent assessment of scientific information in the Criteria Document, summarized in Chapters IV and V of the Staff Paper, continues to support past staff and CASAC recommendations regarding the selection of size-specific indicators for PM standards. More specifically, the Staff Paper finds that the following conclusions reached in the 1987 review remain valid:

(1) Health risks posed by inhaled particles are influenced both by the penetration and deposition of particles in the various regions of the respiratory tract and by the biological responses to these deposited materials.

(2) The risks of adverse health effects associated with deposition of ambient fine and coarse fraction particles in the thoracic (tracheobronchial and alveolar) regions of the respiratory tract are markedly greater than for deposition in the extrathoracic (head) region. Maximum particle penetration to the thoracic region occurs during oronasal or mouth breathing.

(3) The risks of adverse health effects from extrathoracic deposition of general ambient PM are sufficiently low that particles which deposit only in that region can safely be excluded from the standard indicator.

(4) The size-specific indicator(s) should represent those particles capable of penetrating to the thoracic region, including both the tracheobronchial and alveolar regions.

These conclusions, together with information on the dosimetry of particles in humans, were the basis for the promulgation in 1987 of a new size-specific indicator for the PM NAAQS, PM_{10}, that includes particles with an aerodynamic diameter smaller than or equal to a nominal 10 μm. The recent information on human particle dosimetry contained in the Criteria Document provides no basis for changing 10 μm as the appropriate cut point for particles capable of penetrating to the thoracic regions.

The Staff Paper concludes, however, that continued use of PM_{10} as the sole indicator for the PM standards would not provide the most effective and efficient protection from the health effects of particulate matter (U.S. EPA, 1996b, pp. VII–4–11). The recent health effects evidence and the fundamental physical and chemical differences between fine and coarse fraction particles have prompted consideration of separate standards for the fine and coarse fractions of PM_{10}. In this regard, the Criteria Document concludes that fine and coarse fractions of PM_{10} should be considered separately (U.S. EPA, 1996a, p. 13–93). Taking into account such information, CASAC found sufficient scientific and technical bases to support establishment of separate standards relating to these two fractions of PM_{10}. Specifically, CASAC advised the Administrator that ''there is a consensus that retaining an annual PM_{10} NAAQS * * * is reasonable at this time'' and that there is ''also a consensus that a new $PM_{2.5}$ NAAQS be established'' (Wolff, 1996b).

While it is difficult to distinguish the effects of either fine or coarse fraction particles from those of PM_{10}, comparisons between fine and coarse fraction particles presented in the Staff Paper suggest that fine particles are a better surrogate for those components of PM that are linked to mortality and morbidity effects at levels below the current standards (U.S. EPA, 1996b, P. VII–18). Moreover, a regulatory focus on fine particles would likely also result in controls on gaseous precursors of fine particles (e.g., SO_X, NO_X, VOC), which are all components of the complex mixture of air pollution that has most generally been associated with mortality and morbidity effects. The Staff Paper concludes that, in contrast to fine particles, coarse fraction particles are more clearly linked with certain morbidity effects at levels above those allowed by the current 24-hour standard.

The Administrator concurs with staff and CASAC recommendations to control particles of health concern (i.e., PM_{10}) through separate standards for fine and coarse fraction particles. The following sections outline the basis for the Administrator's decision on specific indicators for fine and coarse particle standards.

1. Indicators for the Fine Fraction of PM_{10}

The Administrator concludes that it is appropriate to control fine particles as a group, as opposed to singling out particular components or classes of fine particles. The qualitative literature, evaluated in Chapter 11 of the Criteria Document and summarized in Section V.C of the Staff Paper, has reported various health effects associated with high concentrations of a number of fine particle components (e.g., sulfates, nitrates, organics, transition metals), alone or in some cases in combination with gases. Community studies have found significant associations between fine particles or PM_{10} and health effects in various areas across the U.S. where such fine particle components correlate significantly with particle mass. As noted above, it is not possible to rule out any one of these components as contributing to fine particle effects. Thus, the Administrator finds that the present data more readily support a standard based on the total mass of fine particles.

[26] Epidemiological studies alone cannot be used to demonstrate mechanisms of action, but they can provide evidence useful in making inferences with regard to causal relationships (U.S. EPA, 1996b, p. V–9).

In specifying a precise size range for a fine particle standard, both the staff and CASAC recommend $PM_{2.5}$ as the indicator of fine particles (Wolff, 1996b). The particle diameter reflecting the mass minimum between the fine and coarse modes typically lies between 1 and 3 µm, and the scientific data support a sampling cut point to delineate fine particles in this range. Because of the potential overlap of fine and coarse particle mass in this intermodal region, EPA recognizes that any specific sampling cut point would result in only an approximation of the actual fine-mode particle mass. Thus, the choice of a specific diameter within this size range is largely a policy judgment. The staff and CASAC recommendation for a 2.5 µm sampling cut point is based on considerations of consistency with the community health studies, the limited potential for intrusion of coarse fraction particles into the fine fraction, and availability of monitoring technology.[27] $PM_{2.5}$ encompasses all of the potential agents of concern in the fine fraction, including most sulfates, acids, fine particle transition metals, organics, and ultrafine particles, and includes most of the aggregate surface area and particle number in the entire distribution of atmospheric particles.

The Administrator concurs with staff and CASAC recommendations, and concludes that $PM_{2.5}$ is the appropriate indicator for fine particle standards. Details of this definition are further specified in the Federal Reference Method discussed in section V below and proposed in a new Appendix L.

2. Indicators for the Coarse Fraction of PM_{10}

The Criteria Document and Staff Paper conclude that epidemiological information, together with dosimetry and toxicological information, support the need for a particle indicator that addresses the health effects associated with coarse fraction particles within PM_{10} (i.e., $PM_{10-2.5}$). As noted above, coarse fraction particles can deposit in those sensitive regions of the lung of most concern. Although the role of coarse fraction particles in much of the recent epidemiological results is unclear, limited evidence from studies where coarse fraction particles are the dominant fraction of PM_{10} suggest that significant short-term effects related to coarse fraction particles include aggravation of asthma and increased upper respiratory illness. In addition, qualitative evidence suggests potential chronic effects associated with long-term exposure to high concentrations of coarse fraction particles.

In selecting an indicator for coarse fraction particles, the Administrator took into account the views of several CASAC panel members who suggested using the coarse fraction directly (i.e., $PM_{10-2.5}$) as the indicator. However, the Administrator notes that the existing ambient data base for coarse fraction particles is smaller than that for fine particles, and that the only studies of clear quantitative relevance to effects most likely associated with coarse fraction particles have used undifferentiated PM_{10}. In fact, it was the consensus of CASAC that it is reasonable to consider PM_{10} itself as a surrogate for coarse fraction particles, when used in conjunction with $PM_{2.5}$ standards. The monitoring network already in place for PM_{10} is large. Therefore, in conjunction with the decision to have separate standards for $PM_{2.5}$, the Administrator concludes, consistent with CASAC recommendations, that it is appropriate to retain PM_{10} as the particle indicator for standards intended to protect against the effects most likely associated with coarse fraction particles.

E. Averaging Time of $PM_{2.5}$ Standards

As discussed above, the Administrator has concluded that $PM_{2.5}$ is an appropriate indicator for standards intended to provide protection from effects associated primarily with fine particles. The recent health effects information includes reported associations with both short-term (from less than 1 day to up to 5 days) and long-term (from generally a year to several years) measures of PM. On the basis of this information, summarized in Chapter V of the Staff Paper, the Administrator has considered both short- and long-term $PM_{2.5}$ standards.

1. Short-term $PM_{2.5}$ Standard

The current 24-hour averaging time is consistent with the majority of community epidemiological studies, which have reported associations of health effects with 24-hour concentrations of various PM indicators such as PM_{10}, fine particles, and TSP. Such health effects, including premature mortality and increased hospital admissions, have generally been reported with same-day, previous day, or longer lagged single-day concentrations, although some studies have reported stronger associations with multiple-day average concentrations. In any case, the Administrator recognizes that a 24-hour $PM_{2.5}$ standard can effectively protect against episodes lasting several days, since such a standard would provide protection on each day of a multi-day episode, while also protecting sensitive individuals who may experience effects after even a single day of exposure.

Although most reported effects have been associated with daily or longer measures of PM, evidence also suggests that some effects may be associated with PM exposures of shorter durations. For example, controlled human and animal exposures to specific components of fine particles, such as acid aerosols, suggest that bronchoconstriction can occur after exposures of minutes to hours. Some epidemiological studies of exposures to acid aerosols have also found changes in respiratory symptoms in children using averaging times less than 24 hours. However, such reported results do not provide a satisfactory quantitative basis for setting a fine particle standard with an averaging time of less than 24 hours, nor do current gravimetric mass monitoring devices make such shorter durations generally practical at present. Further, the Administrator recognizes that a 24-hour average $PM_{2.5}$ standard which leads to reductions in 24-hour average concentrations is likely to lead as well to reductions in shorter-term average concentrations in most urban atmospheres, thus providing some degree of protection from potential effects associated with shorter duration exposures.

For these reasons, the Administrator has concluded that a short-term $PM_{2.5}$ standard with a 24-hour averaging time can serve to control short-term ambient $PM_{2.5}$ concentrations, thus providing protection from health effects associated with short-term (from less than 1-day to up to 5-day) exposures to $PM_{2.5}$.

2. Long-Term $PM_{2.5}$ Standard

Community epidemiological studies have reported associations of annual and multi-year average concentrations of PM_{10}, $PM_{2.5}$, sulfates, and TSP with an array of health effects, notably premature mortality, increased respiratory symptoms and illness (e.g., bronchitis and cough in children), and reduced lung function. The relative risks associated with such measures of long-term exposures, although highly

[27] Some commentors have recommended the use of a smaller cutpoint at 1 µm (PM_1) to further reduce coarse particle intrusion. PM_1 has not been used in health studies, although in most cases collected mass should be similar to those for cutpoints of 2.1 or 2.5 µm. While this indicator could reduce intrusion of coarse particles, it might also omit portions of hygroscopic acid sulfates in high humidity environments. PM_1 sampling technologies have been developed; however, PM_1 samplers have not been widely used in the field to date, and there are some concerns about loss of certain organic materials relative to an instrument with a larger size cut.

uncertain, appear to be larger than those associated with short-term exposures. Based on the available epidemiology, and consistent with the limited relevant toxicological and dosimetric information, the Administrator concludes that significant, and potentially independent, health consequences are likely associated with long-term PM exposures.

The Administrator has considered this evidence, which suggests that some health endpoints reflect the cumulative effects of PM exposures over a number of years. In such cases, an annual standard would provide effective protection against persistent long-term (several years) exposures to PM. Requiring a much longer averaging time would also complicate and unnecessarily delay control strategies and attainment decisions.

The Administrator has also considered the seasonality of emissions of fine particles and their precursors in some areas (e.g., wintertime smoke from residential wood combustion, summertime regional acid sulfate and ozone formation), which suggests that some effects associated with annual average concentrations might be the result of repeated seasonally high exposures. However, different seasons are likely of concern in different parts of the country, and the current evidence does not provide a satisfactory quantitative basis for setting a national fine particle standard in terms of a seasonal averaging time.

In addition, the Administrator recognizes that an annual standard would have the effect of controlling air quality broadly across the yearly distribution of 24-hour $PM_{2.5}$ concentrations, although such a standard would not as effectively limit peak 24-hour concentrations as would a 24-hour standard. Thus, as discussed above in Section B above (see especially Figures 2a, 2b, 2c), an annual standard could also provide protection from health effects associated with short-term exposures to $PM_{2.5}$.

For these reasons, the Administrator has concluded that a long-term $PM_{2.5}$ standard with an annual averaging time can serve to control both long- and short-term ambient $PM_{2.5}$ concentrations, thus providing protection from health effects associated with long-term (seasonal to several years) and, to some degree, short-term exposures to $PM_{2.5}$.

3. Combined Effect of Annual and 24–Hour Standards

Having concluded that both 24-hour and annual $PM_{2.5}$ standards are appropriate, the Administrator considered the potential combined effects of such standards on PM concentration levels and distributions prior to considering the form and level of each standard. The existing health effects evidence could, of course, be used to assess the form and level of each standard independently, with short-term health effects evidence being used as the basis for a 24-hour standard and the long-term health effects evidence as the basis for an annual standard. Some CASAC panel members apparently used this approach as a basis for their views on appropriate averaging times and standard levels. In particular, a few members focused only on a 24-hour $PM_{2.5}$ standard in light of the relative strength of the short-term exposure studies. On the other hand, two members focused only on an annual standard, recognizing that strategies to meet an annual standard would provide protection against effects of both short- and long-term exposures.

The Administrator has focused on a policy approach that considers the consistency and coherence, as well as the limitations, of the body of evidence as a whole, and recognizes that there are various ways to combine two standards to achieve an appropriate degree of public health protection. Such an approach to standard setting that integrates the body of health effects evidence and air quality analyses, and considers the combined effect of the standards, has the potential to result in a more effective and efficient suite of standards than an approach that only considers short- and long-term evidence, analyses, and standards independently.

In considering the combined effect of such standards, the Administrator notes that while an annual standard focuses on annual average $PM_{2.5}$ concentrations, it would also result in fewer and lower 24-hour peak concentrations. Alternatively, a 24-hour standard which focuses on peak concentrations would also result in lower annual average concentrations. Thus, either standard could be viewed as providing both short- and long-term protection, with the other standard serving as a ''backstop'' in situations where the daily peaks and annual averages are not consistently correlated.

The Administrator believes that the suite of $PM_{2.5}$ standards can be most effectively and efficiently defined by treating the annual standard as the generally controlling standard for lowering both short- and long-term $PM_{2.5}$ concentrations. As a supplement to the annual standard, the 24-hour standard would serve as a backstop to provide additional protection against days with high peak $PM_{2.5}$ concentrations, localized ''hot spots,'' and risks arising from seasonal emissions that would not be well controlled by a national annual standard. In reaching this view, the Administrator took into account the factors discussed below.

(1) Based on one of the key observations from the quantitative risk assessment (Section B, Figures 2a, 2b, 2c), the Administrator notes that much if not most of the aggregate annual risk associated with short-term exposures results from the large number of days during which the 24-hour average concentrations are in the low- to mid-range, below the peak 24-hour concentrations. As a result, lowering a wide range of ambient 24-hour $PM_{2.5}$ concentrations, as opposed to focusing on control of peak 24-hour concentrations, is the most effective and efficient way to reduce total population risk. Further, there is no evidence suggesting that risks associated with long-term exposures are likely to be disproportionately driven by peak 24-hour concentrations. Thus, an annual standard that controls an area's attainment status is likely to reduce aggregate risks associated with both short- and long-term exposures with more certainty than a 24-hour standard.

(2) The consistency and coherence of the health effects data base is more directly related to long-term measures of air quality (e.g., the annual distributions of 24-hour PM concentrations), rather than to 24-hour concentrations on individual days. More specifically, judgments about the quantitative consistency of the large number of short-term exposure studies reporting associations with 24-hour concentrations arise from comparing the relative risk results derived from analyzing the associations across the entire duration of the studies, which typically spanned at least an annual time frame.

(3) An annual average measure of air quality is more stable over time than are 24-hour measures. Thus, a controlling annual standard is likely to result in the development of more consistent risk reduction strategies over time, since an area's attainment status will be less likely to change due solely to year-to-year variations in meteorological conditions that affect the formation of fine particles, than under a controlling 24-hour standard.

Under this policy approach, the annual $PM_{2.5}$ standard would serve in most areas as the target for control programs designed to be effective in lowering the broad distribution of $PM_{2.5}$ concentrations, thus protecting not only

against long-term effects but also short-term effects as well. In combination with such an annual standard, the 24-hour $PM_{2.5}$ standard would be set so as to protect against the occurrence of peak 24-hour concentrations and those that present localized or seasonal effects of concern in areas where the highest 24-hour-to-annual mean $PM_{2.5}$ ratios are appreciably above the national average.

The Administrator recognizes that this policy approach represents a new way of thinking about the combined effects of short- and long-term standards, and that there are alternative views about this approach. Accordingly, the Administrator solicits comment on this policy approach for defining the most effective and efficient suite of $PM_{2.5}$ standards.

F. Form of $PM_{2.5}$ Standards

1. Annual Standard

As discussed in some detail during the last review of the PM NAAQS (see 49 FR 10408, March 20, 1984; 52 FR 24634, July 1, 1987), the expected annual arithmetic mean (i.e., the annual arithmetic mean averaged over 3 years) is a relatively stable measure of air quality that reflects the total cumulative dose of PM to which an individual or population is exposed. Short-term peaks have an influence on the arithmetic mean that is proportional to their frequency, magnitude, and duration, and, thus, their contribution to cumulative exposure and risk. As a result, the annual arithmetic mean form of an annual standard provides protection across a wide range of the air quality distribution contributing to exposure and risk, in contrast to other forms, such as the geometric mean, that deemphasize the effects of short-term peak concentrations. On this basis, the Administrator concurs with the Staff Paper recommendation, supported by CASAC, to use the 3-year average annual arithmetic mean as the form for an annual $PM_{2.5}$ standard, consistent with the current form of the annual PM_{10} standard.

The Staff Paper and some CASAC panel members also recommended that consideration be given to calculating the $PM_{2.5}$ annual arithmetic mean for an area by averaging the annual arithmetic means derived from multiple, primarily population-oriented monitoring sites within a monitoring planning area. In considering a calculation method for annual arithmetic averages that involves spatial averaging of monitoring data, the Administrator specifically took into account the following factors:[28]

(1) Many of the community-based epidemiological studies examined in this review used spatial averages, when multiple monitoring sites were available, to characterize area-wide PM exposure levels and the associated population health risk. Even in those studies that used only one monitoring location, the selected site was chosen to represent community-wide exposures, not the highest value likely to be experienced within the community. Thus, spatial averages are most directly related to the epidemiological studies used as the basis for the proposed revisions to the PM NAAQS.

(2) Under the policy approach advanced earlier, the annual $PM_{2.5}$ standard would be intended to reduce aggregate population risk from both long- and short-term exposures by lowering the broad distribution of $PM_{2.5}$ concentrations across the community. An annual standard based on spatially averaged concentrations would better reflect area-wide PM exposure levels than would a standard based on concentrations from a single monitor with the highest measured values.

(3) Under this policy approach, the 24-hour $PM_{2.5}$ standard would be intended to supplement a spatially averaged annual $PM_{2.5}$ standard by providing protection against peak 24-hour concentrations, localized ''hot spots,'' and risk arising from seasonal emissions that would not be as well controlled by an annual standard. Accordingly, the 24-hour $PM_{2.5}$ standard should be based on the single population-oriented monitoring site within the monitoring planning area with the highest measured values.

Based on these considerations, the Administrator believes that the form of a $PM_{2.5}$ annual standard should be expressed as the annual arithmetic mean, temporally averaged over 3 years and spatially averaged over all designated monitoring sites. Such designations would be based on criteria contained in the proposed revision to the monitoring siting guidance in 40 CFR Part 58 that accompanies this notice. In the Administrator's judgment, an annual $PM_{2.5}$ standard expressed in this form, established in conjunction with a 24-hour $PM_{2.5}$ standard, would provide the most appropriate target for reducing area-wide population exposure to fine particle pollution.

On the other hand, the Administrator is mindful that adoption of spatial averaging for an annual $PM_{2.5}$ standard would add a degree of complexity to the monitor siting requirements for a new $PM_{2.5}$ monitoring network and the specification of those areas across which spatial averaging should be permitted. These issues are addressed more fully in the accompanying proposed revisions to 40 CFR Part 58. Of particular concern is whether appropriate and effective criteria can be developed and implemented for determining areas within which spatial averaging would be reflective of the area-wide population risk. The EPA recognizes that some monitoring planning areas may have to be subdivided into smaller subareas to reflect gradients in particle levels (e.g., upwind suburban sites, central city sites, downwind sites) as well as topographical barriers or other factors that may result in a monitoring planning area having several distinct air quality regimes.

Because of the importance of this issue, the notice of proposed revisions to 40 CFR Part 58 specifically requests broad public input on the approaches advanced in that notice with respect to the selection of sites and designation of areas for spatial averaging. Recognizing the complexities that spatial averaging may introduce into risk management programs and that unforeseen issues may arise from public comment on the 40 CFR Part 58 notice, the Administrator also requests comment on the alternative of basing the annual standard for $PM_{2.5}$ on the population-oriented monitor site within the monitoring planning area with the highest 3-year average annual mean. Based on comments received, the Administrator may choose either of these two approaches for specifying the form of the annual $PM_{2.5}$ standard at the time of promulgation of any revisions to the PM standards. Proposed methods for using monitored concentrations to make a comparison with a spatially averaged annual mean standard, as well as associated calculations and other data handling conventions, are presented below in the section on proposed revisions to Appendix K.

2. 24-Hour Standard

The current 24-hour PM_{10} standard is expressed in a ''1-expected-exceedance'' form. That is, the standard is formulated on the basis of the expected number of days per year (averaged over 3 years) on which the level of the standard will be exceeded. The test for determining attainment of the current 24-hour

[28] Spatial averaging of monitoring data is also discussed in the notice of a proposed decision on the O_3 NAAQS published today. Different considerations apply in the two cases principally because of differences between (1) the nature of the health effects evidence for $PM_{2.5}$ and O_3; (2) the proposed suite and annual and 24-hour $PM_{2.5}$ standards, in contrast to a single proposed O_3 standard; and (3) the existence of an established, extensive O_3 monitoring network, in contrast to the absence at present of such a network for $PM_{2.5}$.

standard is presented in Appendix K to 40 CFR Part 50.

Since promulgation of the current 24-hour PM_{10} standard in 1987, a number of concerns have been raised about the 1-expected-exceedance form. These include, in particular, the year-to-year stability of the number of exceedances, the stability of the attainment status of an area, and the complex data handling conventions specified in Appendix K, including the procedures for making adjustments for missing data and less-than-every-day monitoring.

In light of these concerns, the Staff Paper and several CASAC panel members (Wolff, 1996b) recommended that consideration be given to adoption of a more stable and robust form for 24-hour PM standards. In considering this recommendation, the Administrator noted that the use of a concentration-based percentile form would have several advantages over the current 1-expected-exceedance form:

(1) Such a concentration-based form is more directly related to the ambient PM concentrations that are associated with health effects. Given that there is a continuum of effects associated with exposures to varying levels of PM, the extent to which public health is affected by exposure to ambient PM is related to the actual magnitude of the PM concentration, not just whether the concentration is above a specified level. With an exceedance-based form, days on which the ambient PM concentration is well above the level of the standard are given equal weight to those days on which the PM concentration is just above the standard (i.e., each day is counted as one exceedance), even though the public health impact on the two days is significantly different. With a concentration-based form, days on which higher PM concentrations occur would weigh proportionally more than days with lower PM concentrations for the design value, since the actual concentrations are used directly in determining whether the standard is attained.

(2) More specifically, a concentration-based percentile form would also compensate for missing data and less-than-every-day monitoring, thereby reducing or eliminating the need for complex data handling procedures in the Appendix K test for attainment. As a result, an area's attainment status would be based directly on monitoring data rather than on a calculated value adjusted for missing data or less-than-every-day monitoring.

(3) Further, a concentration-based form, averaged over 3 years, also has greater stability than the expected exceedance form and, thus, would facilitate the development of more stable implementation programs by the States.

In light of these advantages, and taking into account the CASAC recommendation as well as concerns regarding adjustments for missing data and less-than-every-day monitoring, the Administrator believes that adoption of a concentration percentile form for the 24-hour $PM_{2.5}$ standard would be appropriate.

Having reached this view, the Administrator considered various specific percentile values for such a form. In doing so, she took into account two factors. First, the 24-hour $PM_{2.5}$ standard is intended to supplement the annual $PM_{2.5}$ standard by providing a ''back stop'' to provide additional protection against extremely high peak days, localized ''hot spots,'' and risks arising from seasonal emissions. Second, the form of the 24-hour $PM_{2.5}$ standard should provide an appropriate degree of increased stability relative to the current form. A more stable statistic would reduce the impact of a single high exposure event that may be due to unusual meteorological conditions alone, and thus would provide a more stable basis upon which to design effective control programs.

With these purposes in mind, the Administrator observed that while a percentile value such as the 90th or 95th would provide substantially increased stability when compared to a more extreme air quality statistic (e.g., the current 1-expected-exceedance form), it would likely not serve as an effective ''back stop,'' because it would allow a large number of days with peak $PM_{2.5}$ concentrations above the standard level. For example, in a 365 day data base, the 90th and 95th percentiles would equal the 37th and 19th highest 24-hour concentrations, respectively. On the other hand, a percentile value selected much closer to the tail of the air quality distribution (e.g., a 99th or greater percentile) would not likely provide significantly more health protection nor significantly increased stability as compared to the current form. In balancing these issues, the Administrator believes that a 98th percentile value form of a standard, set at an appropriate level, would achieve the desired outcomes of both a 24-hour standard that would serve as an effective supplement to the $PM_{2.5}$ annual standard and a more stable form. Proposed methods for using monitored concentrations to make a comparison with a concentration percentile form of a 24-hour standard, averaged over 3 years, as well as associated calculations and other data handling conventions, are presented below in the section on proposed revisions to Appendix K.

G. Levels for the Annual and 24-Hour $PM_{2.5}$ Standards

As discussed in Section E above, the Administrator believes that an annual $PM_{2.5}$ standard can provide the requisite reduction in risk associated with both annual and 24-hour averaging times in most areas of the U.S. Under this approach, the 24-hour standard would be intended to provide supplemental protection against extreme peak fine particle levels that may occur in some localized situations or in areas with distinct variations in seasonal fine particle levels. In reaching judgments as to appropriate levels to propose for both the annual and 24-hour $PM_{2.5}$ standards, the Administrator has considered the combined protection afforded by both the annual and 24-hour standards, taking into account the forms discussed above in Section F.

With this approach in mind, the Administrator has considered the available health effects evidence and related air quality information presented in the Criteria Document and summarized in Chapters IV–VII of the Staff Paper and in Section A above, which provides the basis for decisions on standard levels that would reduce risk sufficiently to protect public health with an adequate margin of safety, recognizing that such standards will not be risk free. In so doing, the Administrator has considered both the strengths and the limitations of the available evidence and information, as well as alternative interpretations of the scientific evidence advanced by various CASAC panel members (Wolff, 1996b; Lippmann et al., 1996) and public commenters, arising primarily from the inherent uncertainties and limitations in the health effects studies.

Beyond those factors, but clearly related to them, a range of views have been expressed by CASAC panel members and the public as to the appropriate policy response to the available health effects evidence and related air quality information. Toward one end of the spectrum, the view has been expressed that only a very limited policy response is appropriate in light of the many key uncertainties and unanswered questions that, taken together, call into question the fundamental issue of causality in the reported associations between ambient levels of $PM_{2.5}$ and mortality and other serious health effects. Toward the other end, the view has been expressed that the consistency and coherence of the epidemiological evidence can appropriately be interpreted as

demonstrating causality in the relationships between $PM_{2.5}$ and health endpoints that are clearly adverse, and that uncertainties in the underlying health effects information should be treated, regardless of their nature, as warranting a maximally precautionary policy response. A third view would suggest an intermediate policy response, taking into account not only the consistency and coherence of the health effects evidence, but also the recognition of key uncertainties and unanswered questions that increasingly call into question the likelihood of PM-related effects as $PM_{2.5}$ concentrations decrease below the mean values in areas where effects have been observed and/or as such concentrations approach background levels.

Reflecting these divergent views, both of the science itself and of how the science should be used in making policy decisions on proposed standards, the Administrator has considered three alternative approaches to selecting appropriate standard levels, as described below.

(1) One approach would place great weight on the uncertainties and limitations in the available health effects studies considered individually, such as the possible existence of effects thresholds and unanswered questions regarding the causal agent(s) responsible for the reported health effects, and on the limited amount of research currently available that has measured $PM_{2.5}$ directly. This approach would recognize $PM_{2.5}$ as a component of air pollution that should be addressed through a NAAQS, since serious health effects have been linked to the complex mix of urban air pollution containing PM (or some subset of particles within the fine fraction for which $PM_{2.5}$ appears to be a reasonable surrogate). Beyond that recognition, however, this approach would reflect the judgment that significant new regulatory programs directed toward fine particle concentrations well below those permitted under the current PM_{10} standards may be premature until additional research has addressed the key uncertainties and unanswered questions especially with regard to plausible physiological mechanisms for effects at such low exposure levels.

Such an approach would be based on the judgment that the current scientific evidence has not demonstrated adverse public health effects from fine particle concentrations well below those corresponding to the current standard and that it would be difficult to target regulatory programs toward the specific pollutants that may be responsible for the health effects of concern in the absence of an understanding of the mechanism(s) by which these effects are produced. Although there is currently significant uncertainty regarding nationwide ambient concentrations of $PM_{2.5}$,[29] since little actual monitoring data are available, the Administrator believes that such an approach could be reflected by setting a standard near the upper end of the range recommended in the Staff Paper; i.e., an annual standard level up to 20 $\mu g/m^3$ in combination with a 24-hour standard of up to 65 $\mu g/m^3$.[30]

A policy decision to set $PM_{2.5}$ standards at these levels would recognize that, while the scientific evidence demonstrating adverse effects from fine particles specifically is not conclusive, fine particles should nonetheless be regulated separately through $PM_{2.5}$ standards, to provide public health protection with an adequate margin of safety, as specified in the Act. Such standards would result in the establishment of new regulatory programs to reduce potential health risks in areas where current levels are high enough to warrant serious concern. Such standards would also result in the establishment of a new monitoring network to better characterize fine particle levels and composition in major population areas throughout the U.S. This would in turn facilitate further research into health effects associated with ambient $PM_{2.5}$ levels, which would likely lead to a better understanding in the future of the key uncertainties and unanswered questions that currently exist, especially with regard to mechanisms and the identification of components of urban air pollution, and specifically of fine particles, on which to focus future regulatory efforts.

(2) In sharp contrast, a second approach would place great weight on the consistency and coherence of the entire body of epidemiological evidence, the seriousness of the associated health effects (e.g., premature mortality and increased hospital admissions), and the magnitude of the incidence of such effects that can be estimated from plausible assumptions in an analysis of the quantitative effects evidence. While recognizing that uncertainties and unanswered questions remain, this approach would suggest policy decisions that would result in major new regulatory programs directed at fine particles even as additional research is ongoing.

Such an approach could be viewed as a maximally precautionary response, reflecting judgments that the likely effects are as serious and potentially adverse to large numbers of sensitive individuals as the reported evidence might suggest, and that uncertainties in the evidence should be treated, regardless of their nature, as warranting greater protection. Such an approach would be predicated on interpreting the epidemiological evidence as sufficient to have made a compelling case for causality in relationships between $PM_{2.5}$ and health effects at the lower concentrations observed in these studies. Based on uncertain estimates of $PM_{2.5}$ air quality, such an approach could be reflected by an annual standard level at the lower end of the range recommended in the Staff Paper, i.e., an annual standard level down to about 12 $\mu g/m^3$, in combination with a 24-hour standard set within the lower part of the range recommended in the Staff Paper, from 20 $\mu g/m^3$, at which the 24-hour standard might primarily control, up to about 50 $\mu g/m^3$, where the annual standard might primarily control.[31]

A policy decision to set $PM_{2.5}$ standards at these levels would not only result in a new monitoring network and facilitate additional health effects research, but would likely result in major reductions in $PM_{2.5}$ levels throughout the U.S., with associated reductions in risks to public health. Commensurate reductions in health risks would result only if, in fact, there is a continuum of health risk down to the lower end of the ranges of air quality observed in the key epidemiological studies, and if the reported associations

[29] Nationwide $PM_{2.5}$ estimates have been derived from the nationwide PM_{10} air quality data base but reflect a significant degree of uncertainty due to the highly variable relationship between $PM_{2.5}$ and PM_{10} air quality values across locations and seasons (Fitz-Simons et al., 1996).

[30] In presenting their opinions on the appropriate policy choice for $PM_{2.5}$ standards, several CASAC panel members supported levels consistent with this approach. In addition, three CASAC members expressed a preference for standards that would be equivalent in stringency to the current PM_{10} standards; with the suggestion that standard levels of 25 to 30 $\mu g/m^3$, annual average, and $\geq$75 $\mu g/m^3$, 24-hour average (presumably for the same 1-expected-exceedence form used for comparison of options in the Staff Paper), would approximate equivalence (Wolff, 1996b). As CASAC recognized, the wide variability in $PM_{2.5}/PM_{10}$ ratios in time and location precludes defining uniform $PM_{2.5}$ standards that would provide close to ''equivalent'' protection to the current standard in all or even most areas. However, based on estimated $PM_{2.5}$ data for 1993–95, the combination of 20 $\mu g/m^3$, annual spatially averaged mean, and 65 $\mu g/m^3$, 24-hour, 98th percentile, standards is likely to be less stringent than the current standards in terms of the numbers of counties predicted not to meet that alternative.

[31] This range of levels for a 24-hour $PM_{2.5}$ standard is consistent with the levels recommended by four CASAC panel members, although no members supported an annual $PM_{2.5}$ standard as low as 12 $\mu g/m^3$.

are, in fact, causally related to $PM_{2.5}$. By setting standards at levels where the possibility of effects thresholds are more likely and there is greater potential that other elements in the air pollution mix (or some subset of particles within the fine fraction) are at least in part responsible for or modifying the effects being causally attributed to $PM_{2.5}$, such standards might result in regulatory programs that go beyond those that are needed to effectively reduce risks to public health. The policy goal of such an approach would be to focus maximal regulatory efforts on controlling potential risks to public health, with a large margin of safety that takes into account the uncertainties and limitations in the available evidence or treating them as warranting increased protection in all cases.

In assessing these two sharply contrasting alternative approaches, the Administrator is mindful that the proponents of each, both within the scientific community and in the public at large, can advance reasoned and potentially persuasive arguments in support of their preferred policy approaches. In considering the bases for these two contrasting views, however, the Administrator was drawn to consider a third approach representing an intermediate policy response, as discussed below.

(3) The third approach would focus primarily on standard levels designed to limit annual $PM_{2.5}$ concentrations to somewhat below those where the body of epidemiological evidence is most consistent and coherent. Such an approach would recognize both the strengths and the limitations of the full range of scientific and technical information on the health effects of PM, as well as associated uncertainties, as interpreted by the Criteria Document, Staff Paper, and CASAC. The Administrator believes that such an approach would appropriately reflect the weight of the evidence as a whole.

In identifying $PM_{2.5}$ standard levels consistent with this overall approach, the Administrator has placed greatest weight on those epidemiological studies reporting associations between health effects and direct measures of fine particles, most notably those recent studies conducted in North America (summarized in Tables V–12 to V–14 of the Staff Paper). Key considerations and study results upon which this approach is based are presented below.

As previously discussed, the Administrator is proposing to select the level of the annual standard so as to protect against the range of effects associated with both short- and long-term exposures to PM, with the 24-hour standard level selected to provide supplemental protection against peak concentrations that might occur over limited areas and/or for limited time periods. In selecting the level of an annual standard, therefore, the Administrator has considered epidemiological studies of both short- and long-term exposures to fine particles.

The effects estimates from the daily studies (in Table V–12 of the Staff Paper) are based on analyses of daily $PM_{2.5}$ concentrations that occurred over the course of the year(s) studied. While effects may occur over the full range of concentrations observed in the studies, the strongest evidence for daily $PM_{2.5}$ effects is associated with annual concentrations at or above the mean levels reported for these studies.[32] Given the serious nature of the potential effects, the Administrator believes it is both prudent and appropriate to select a level for an annual standard at or below such concentrations. An examination of the annual means from the combined Six City analysis of daily mortality and respiratory symptoms (Schwartz et al., 1996a), together with those from studies in individual cities for which statistically significant PM-effects associations are reported (from Table V–12 in the Staff Paper), finds mean concentrations ranging from about 16 to 21 $\mu g/m^3$. In addition, the mean concentrations in cities where short-term exposure associations characterized in the Criteria Document as nearly statistically significant (U.S. EPA, 1996a, p. 13–40) range from about 11 $\mu g/m^3$ to 30 $\mu g/m^3$. Taken together, this evidence suggests that an annual standard level of about 15 $\mu g/m^3$ may be appropriate to reduce the risk of short-term effects of fine particles.

The Administrator also examined this level in light of the effects reported in epidemiological studies of long-term exposures to fine particles (Table V–13 in the Staff Paper), which may reflect the accumulation of daily effects over time as well as potential effects uniquely associated with long-term exposures. Even though subject to additional uncertainties, the long-term studies provide important insights with respect to the overall protection afforded by an annual standard. The most direct comparison with the daily fine particle mortality studies is provided by two long-term cohort studies (Dockery et al., 1993; Pope et al., 1995). The annual mean $PM_{2.5}$ concentration for the multiple cities included in both of these studies (6 and 47 cities, respectively) was 18 $\mu g/m^3$ each study (U.S. EPA, 1996b, p. E–10). The Staff Paper assessment of the concentration-response results from these studies concluded that the evidence for increased risk was more apparent at annual concentrations at or above 15 $\mu g/m^3$ (Table E–3 in the Staff Paper). As noted in the Staff Paper and the Criteria Document, however, the estimated magnitude of effects may be related to somewhat higher historical concentrations than the affected communities experienced during the time period of the studies; this consideration suggests that a level of 15 $\mu g/m^3$ would incorporate a margin of safety.

Taking the epidemiological studies of both short- and long-term exposures together, the Administrator believes the concordance of evidence for PM effects and associated levels provides clear support for an annual $PM_{2.5}$ standard level of about 15 $\mu g/m^3$. This level is below the range of annual data most strongly associated with both short- and long-term effects, and because even small changes in annual means in this concentration range can make significant differences in overall risk reduction and total population exposures, the Administrator believes it would provide an adequate margin of safety. Moreover, the means in areas where $PM_{2.5}$ concentrations were statistically significantly associated with daily mortality (about 16 to 21 $\mu g/m^3$) reflect an 8-year average; thus, the proposed use of a 3-year average mean would provide additional protection. Although the possibility of effects at lower annual concentrations cannot be excluded, the evidence for that possibility is highly uncertain and, as previously discussed, the likelihood of significant health risk, if any, becomes smaller as concentrations approach the lower end of the range of air quality observed in the key epidemiological studies and/or background levels.

For the reasons specified above, however, an annual, spatially averaged standard cannot be expected to offer fully effective and efficient protection against all potential short-term effects in areas with strong local or seasonal sources. The broad-based community studies considered in this review generally could not evaluate such peak exposure conditions directly. Given the public health purposes of the 24-hour standard, the Administrator believes it should be set at a level that generally supplements the control provided by an annual standard and reasonably reflects the peak levels observed in

[32] As discussed in Appendix E of the Staff Paper (U.S. EPA, 1996b, p. E–4), there is generally the greatest statistical confidence in the association at and above the mean concentration.

communities where health effects have been associated with daily levels of fine particles.

An examination of air quality in cities where short-term exposure associations are characterized in the Criteria Document as statistically significant or nearly so (U.S. EPA, 1996a, p. 13–40) shows that the 98th percentile 24-hour average $PM_{2.5}$ concentrations ranged from approximately 35 μg/m³ to 90 μg/m³ (Koman, 1996), with the majority of cities ranging from above 40 to above 50 μg/m³. Based on this examination of relevant air quality information, the Administrator believes that a 98th percentile 24-hour $PM_{2.5}$ standard of 50 μg/m³ (at the monitoring site within the monitoring planning area with the highest 3-year average) would provide an appropriate supplement or ''backstop'' to a spatially averaged annual mean standard of 15 μg/m³.

In the Administrator's judgment, the factors discussed above provide ample reason to believe that both annual and 24-hour $PM_{2.5}$ standards are appropriate to protect public health from adverse health effects associated with short- and long-term exposures to ambient fine particles. Further, she believes these factors provide a clear basis for judging that an annual standard set at 15 μg/m³, in combination with a 24-hour standard set at 50 μg/m³, would protect public health with an adequate margin of safety.

The Administrator is mindful, however, that in assessing these factors a series of judgments had to be made with respect to both the interpretation of the underlying scientific evidence and the treatment of inherent uncertainties and limitations in the available information in making policy choices. Accordingly, the Administrator solicits broad public comment, not only on her proposed decision to establish new $PM_{2.5}$ standards of 15 μg/m³, annual average, and 50 μg/m³, 24-hour average, but also on the two alternative approaches described above. Based on the comments received and the accompanying rationale, the Administrator may choose at the time of final promulgation to adopt other standards within the range of these alternative approaches in lieu of the standards she is proposing today.

H. Conclusions Regarding the Current PM_{10} Standards

1. Averaging Time and Form

In conjunction with the proposed $PM_{2.5}$ standards, the new function of PM_{10} standard(s) would be to protect against potential effects associated with coarse fraction particles in the size range of 2.5 to 10 μm. As noted above, coarse fraction particles are plausibly associated with certain effects from both long- and short-term exposures. Based on qualitative considerations, deposition of coarse fraction particles in the respiratory system could be expected to aggravate effects in individuals with asthma. The Criteria Document and Staff Paper found support for this expectation in limited epidemiological evidence on the effects of coarse fraction particles, suggesting that aggravation of asthma and respiratory infections and symptoms may be associated with daily or episodic increases in PM_{10} that is dominated by coarse fraction particles. The potential buildup of insoluble coarse fraction particles in the lung after long-term exposures to high levels should also be considered.

Based on assessments of the available information in the Criteria Document and Staff Paper, both the staff and CASAC recommended retention of an annual PM_{10} standard. The staff, with CASAC concurrence, recommended retention of the current expected annual mean form of the standard, which is the same form being proposed for the annual $PM_{2.5}$ standard. As noted in the staff assessment, the current annual PM_{10} standard offers substantial protection against both long- and short-term effects of coarse fraction particles.

The staff and CASAC also recommended that consideration be given to retention of a 24-hour standard to provide additional protection against potential effects of short-term exposures to coarse fraction particles. The staff, with CASAC concurrence, also recommended that if a 24-hour standard is retained, the form of the standard should be revised to provide a more robust target for practical coarse particle controls. For the reasons outlined above regarding the form of the 24-hour $PM_{2.5}$ standard, the Administrator believes the 98th percentile concentration based form would also be an appropriate form for a 24-hour PM_{10} standard.

2. Levels for Alternative Averaging Times

a. Annual PM_{10} Standard

As a result of the more limited information for coarse fraction particles, the Administrator's approach for selecting a level of the standard is directly related to the approach taken in the last review of the PM NAAQS. In that review, evidence from limited quantitative studies was used in conjunction with support from the qualitative literature in selecting the level of the current annual PM_{10} standard. The staff assessment of the major quantitative basis for the level of that standard (Ware et al., 1986), together with a more recent related study (Dockery et al., 1989), now finds the same range of levels of concern (40–50 μg/m³) as was found in the previous standard review. The staff finds that it is possible, but not certain, that coarse fraction particles, in combination with fine particles, may have influenced the observed effects at these levels. Based on particle deposition considerations, it is possible that cumulative deposition of coarse fraction particles could be of concern in children, who are more prone to be active outdoors than sensitive adult subpopulations.

Qualitative evidence of other long-term coarse particle effects, most notably from long-term buildup of silica-containing materials, supports the need for a long-term standard, but does not provide evidence of effects below the range of 40–50 μg/m³ (U.S. EPA, 1996a, p. 13–79). The staff concludes that the qualitative evidence with respect to biological aerosols also supports the need to limit coarse materials, but should not form the major basis for a national standard (U.S. EPA, 1996a, p. 13–79). In addition, the nature and distribution of such materials, which vary from endemic fungi (e.g., valley fever) to pollens larger than 10 μm, are not appropriately addressed by traditional air pollution control programs.

Based on its review of the available information, CASAC found ''a consensus that retaining an annual PM_{10} NAAQS at the current level is reasonable at this time'' (Wolff, 1996b). Taking into account the above considerations, as more fully detailed in the Staff Paper and the CASAC recommendations, the Administrator proposes to retain the current annual PM_{10} standard of 50 μg/m³ to protect against the long- and short-term effects of coarse fraction particles.

b. 24–Hour PM_{10} Standard

As discussed above, EPA staff and CASAC also recommended that consideration should be given to a 24-hour standard for coarse fraction particles as measured by PM_{10}. Unlike the case for the annual standard, however, the staff found that the original quantitative basis for the level of the current 24-hour PM_{10} standard (150 μg/m³) is no longer appropriate. Instead, the staff found the main quantitative basis for a short-term standard is provided by the two community studies of exposure to fugitive dust referenced above. Because these studies reported multiple large

exceedences of the current 24-hour standard, and because of limitations in the studies themselves, they provide no basis to lower the level of the standard below 150 μg/m³. Moreover, none of the qualitative literature regarding the potential short-term effects of coarse particles provides a basis for a lower standard level. Both EPA staff and CASAC recommended that if a 24-hour PM_{10} standard is retained, the level of the standard should be maintained at 150 μg/m³, although with a revised form.

In the judgment of the Administrator, retention of a 24-hour PM_{10} standard at the level of 150 μg/m³ with a 98th percentile form would provide adequate protection against the short-term effects of coarse particles that have been identified to date in the scientific literature. However, analyses of the available air quality relationships show that such a standard might not add greatly to the protection afforded by the current PM_{10} annual standard (Fitz-Simons et al., 1996). As noted in the Staff Paper and by some CASAC panel members, it is possible that the current annual standard might provide adequate protection against both long- and short-term effects of coarse particles, especially when viewed in conjunction with the overall proposal to add new annual and 24-hour $PM_{2.5}$ standards. Therefore, the Administrator also solicits comment on the alternative of retaining the current annual PM_{10} standard and revoking the current 24-hour PM_{10} standard.

I. Proposed Decisions on Primary Standards

For the reasons discussed above, and taking into account the information and assessments presented in the Criteria Document and the Staff Paper, the advice and recommendations of CASAC, and public comments to date, the Administrator proposes to amend the current suite of PM_{10} standards by adding new $PM_{2.5}$ standards and by revising the form of the current 24-hour PM_{10} standard. Specifically, the Administrator proposes to add two new primary $PM_{2.5}$ standards set at 15 μg/m³, annual mean, and 50 μg/m³, 24-hour average. The proposed new annual $PM_{2.5}$ standard would be met when the 3-year average of the annual arithmetic mean $PM_{2.5}$ concentrations, spatially averaged across an area, is less than or equal to 15 μg/m³, with fractional parts of 0.05 or greater rounding up. The Administrator solicits comment on the alternative of using the 3-year average of the annual arithmetic mean $PM_{2.5}$ concentrations at each monitor within an area rather than a spatially averaged value. The proposed new 24-hour $PM_{2.5}$ standard would be met when the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each monitor within an area is less than or equal to 50 μg/m³, with fractional parts of 0.5 or greater rounding up. Data handling conventions are specified in proposed revisions to Appendix K, as discussed in Section IV below, and a reference method for monitoring PM as $PM_{2.5}$ is specified in a proposed new Appendix L, as discussed in Section V below.

In recognition of alternative views as to the appropriate policy response, the Administrator also solicits comments on two alternative sets of new annual and 24-hour $PM_{2.5}$ standards: (1) An annual standard set at a level up to 20 μg/m³, in combination with a 24-hour standard set at a level up to 65 μg/m³; and (2) an annual standard set at a level as low as 12 μg/m³, in combination with a 24-hour standard set at a level within the range of 20 to 50 μg/m³.

The Administrator also proposes to retain the current annual PM_{10} standard at the level of 50 μg/m³, which would be met when the 3-year average of the annual arithmetic mean PM_{10} concentrations at each monitor within an area is less than or equal to 50 μg/m³, with fractional parts of 0.5 or greater rounding up. Further, the Administrator proposes to retain the current 24-hour PM_{10} standard at the level of 150 μg/m³, but to revise the form such that the standard would be met when the 3-year average of the 98th percentile of the monitored concentrations at the highest monitor in an area is less than or equal to 150 μg/m³, rounding to the nearest 10 μg/m³. Data handling conventions are specified in proposed revisions to Appendix K, as discussed in Section IV below, and revisions to the reference method for monitoring PM as PM_{10} (Appendix J) are proposed as discussed in Section V below. The Administrator also solicits comment on the alternative of revoking the current 24-hour PM_{10} standard.

III. Rationale for Proposed Decision on the Secondary Standards

The Criteria Document and Staff Paper examined the effects of PM on such aspects of public welfare as visibility, materials damage, and soiling. The following discussion of the rationale for the proposed secondary standards focuses on those considerations most influential in the Administrator's proposed decision.

A. Visibility Impairment

This section of the notice presents the Administrator's proposed decision to address the effects of PM on visibility by setting secondary standards identical to the suite of proposed primary standards, in conjunction with the establishment of a regional haze program under section 169A of the Act.[33] In the Administrator's judgment, this approach is the most effective way to address visibility impairment given the sharp regional variations in concentrations of non-anthropogenic PM as well as other factors (e.g., humidity) that affect visibility. By augmenting the protection provided by secondary standards set identical to the proposed suite of primary standards with a regional haze program, the Administrator believes that an appropriate degree of visibility protection can be achieved in the various regions of the country.

In coming to this proposed decision, the Administrator took into account several factors, including: (1) Staff assessments of the most policy-relevant information in the Criteria Document and Staff Paper; (2) the degree of visibility improvement expected through attainment of the recommended primary standards; (3) the regional variation of naturally occurring levels of PM and visual range; (4) difficulties inherent in attempting to address visibility impairment by setting national secondary standards; and (5) EPA's authority to develop a national regional haze program under section 169A of the Act that can allow for regionally-specific approaches to protecting visibility. The Administrator's consideration of each of these factors is discussed below.

The Administrator first concluded, based on information presented in the Criteria Document and Staff Paper, that impairment of visibility is an important effect of PM on public welfare, and that it is experienced throughout the U.S., in multi-state regions, urban areas, and remote class I Federal areas[34] alike. Visibility is an important welfare effect because it has direct significance to people's enjoyment of daily activities in all parts of the country. Individuals value good visibility for the well-being it provides them directly, both where they live and work, and in places where

[33] Congress adopted section 169A of the Act because of concern that the NAAQS and Prevention of Significant Deterioration programs may not provide adequate visibility protection nationally, particularly for ''areas of great scenic importance.'' *See* H.R. Rep. No. 294, 95th Congress, 1st Session, 203–205 (1977).

[34] There are 156 mandatory class I Federal areas protected by the visibility provisions in sections 169A and 169B of the Act. These areas are defined in section 162 of the Act as those national parks exceeding 6000 acres, wilderness areas and memorial parks exceeding 5000 acres, and all international parks which were in existence on August 7, 1977.

they enjoy recreational opportunities. Visibility is highly valued in significant natural areas, such as national parks and wilderness areas, because of the special emphasis given to protecting these lands now and for future generations.

Visibility conditions are determined by the scattering and absorption of light by particles and gases, from both natural and anthropogenic sources. Visibility is often described in terms of visual range, light extinction, or deciviews.[35] The classes of fine particles principally responsible for visibility impairment are sulfates, nitrates, organic matter, elemental carbon (soot), and soil dust. Fine particles are more efficient per unit mass at scattering light than coarse particles. The scattering efficiency of certain classes of fine particles, such as sulfates, nitrates, and some organics, increases as relative humidity rises because these particles can absorb water and grow to sizes comparable to the wavelength of visible light. In addition to limiting the distance that one can see, the scattering and absorption of light caused by air pollution can also degrade the color, clarity, and contrast of scenes.

The Administrator also considered the information in the Criteria Document and Staff Paper describing estimated background levels of PM and natural light extinction. In the United States, estimated annual average background levels of $PM_{2.5}$ are lower in the West than in the East. Because visibility in a pristine environment is very sensitive to an additional 1 or 2 $\mu g/m^3$ of $PM_{2.5}$ in the atmosphere, estimated light extinction due to natural background levels of $PM_{2.5}$ varies fairly significantly between the East and the West. Based on estimated background light extinction levels summarized in Table VIII–2 of the Staff Paper, naturally occurring visual range in the East is approximately 105 to 195 kilometers, whereas in the West it is approximately 190 to 270 kilometers. Increased light scattering of certain particles due to higher average relative humidity in the East is an important factor leading to this regional difference.

The Administrator also assessed potential visibility improvements[36] on urban and regional scales that would result from attainment of the proposed primary standards for $PM_{2.5}$ are attained. In many cities having annual average $PM_{2.5}$ concentrations exceeding 17 $\mu g/m^3$, improvements in annual average visibility resulting from attainment of the proposed primary standards are expected to be perceptible (i.e., to exceed 1 deciview). Based on annual average $PM_{2.5}$ data reported in Table 12–2 of the Criteria Document and Table V–12 in the Staff Paper, many cities in the Northeast, Midwest, and Southeast, as well as Los Angeles, would be expected to see perceptible improvement in visibility.

In Washington, D.C., for example, where the IMPROVE network[37] shows average $PM_{2.5}$ levels at about 19 $\mu g/m_3$ during 1992–1995, approximate annual average visibility would be expected to improve from 21 km visual range (29 deciview) to 27 km (27 deciview). Annual average visibility in Philadelphia, where annual $PM_{2.5}$ levels have been recently measured at 17 $\mu g/m^3$, would be expected to change from about 24 to 27 km, an improvement of about 1 deciview. In Los Angeles, where recent data shows annual average $PM_{2.5}$ levels at approximately 30 $\mu g/m^3$, visibility would be expected to improve from about 19 to 34 km (30 to 24 deciview) if the proposed annual standard is attained.

It is important to note that some urban areas would be expected to have annual average $PM_{2.5}$ concentrations reduced below the proposed primary standard level of 15 $\mu g/m^3$ when implementation of regional control strategies for PM and other air quality programs, such as those addressing acid rain and mobile sources, are taken into account together. On the other hand, some urban areas with annual $PM_{2.5}$ levels at or below the 15 $\mu g/m^3$ level would be expected to see little, if any, improvement in annual average visibility. This may be particularly true of certain western urban areas that are dominated by coarse rather than fine particles.

The Administrator also considered the potential effect on urban visibility when the proposed 24-hour $PM_{2.5}$ standard of 50 $\mu g/m^3$ is attained. In some urban areas, attainment of the 24-hour standard would be expected to reduce to some degree the number and intensity of ''bad visibility'' days (i.e., the 20% of days having the greatest impairment over the course of a year). For example, maximum 24-hour $PM_{2.5}$ concentrations have been recorded in recent years at over 140 $\mu g/m^3$ at several California locations, and at over 70 $\mu g/m^3$ in Philadelphia. If the level and frequency of peak PM concentrations are reduced, improvements would be expected in those days where visibility is worst. Some of these improvements in peak concentrations may even be experienced in urban areas having annual averages below the annual standard.

Having concluded that attainment of the proposed annual and 24-hour $PM_{2.5}$ standards would lead to visibility improvements in many eastern and some western urban areas, the Administrator also considered potential improvements to visibility on a regional scale. In the rural East, attainment of the proposed $PM_{2.5}$ standards could result in regional visibility improvement (e.g., in certain mandatory Federal Class I areas such as Shenandoah and Great Smoky Mountains National Parks) if regional control strategies are adopted and carried out in order to reduce the impact of long-range transport of fine particles such as sulfates. It is important to recognize that fine particle emission reductions achieved by other air quality programs, such as those to reduce acid rain or mobile source emissions, are also expected to improve Eastern regional visibility conditions (U.S. EPA, 1993). In the West, strategies to attain the recommended standards are less likely to significantly improve visibility on a regional basis. However, areas downwind from large urban areas, such as Southern California, would likely see some improvement in annual average visibility.

Based on the foregoing, the Administrator concludes that attainment of secondary standards set at the level of the proposed primary standards for $PM_{2.5}$ would be expected to result in visibility improvements in the eastern U.S. at both urban and regional scales, but little or no change in the western U.S. except in and near selected urban areas.

The Administrator also considered whether establishment of a more stringent national secondary standard or standards would be effective and efficient in providing increased visibility protection in the western U.S. Table VIII–4 of the Staff Paper indicates

[35] Visual range can be defined as the maximum distance at which one can identify a black object against the horizon sky. It is typically described in miles or kilometers. Light extinction is the sum of light scattering and absorption by particles and gases in the atmosphere. It is typically expressed in terms of inverse megameters (Mm^{-1}), with larger values representing poorer visibility. The deciview metric describes perceived visual changes in a linear fashion over its entire range, analogous to the decibel scale for sound. A deciview of 0 represents pristine conditions. Under many scenic conditions, a change of 1 deciview is considered perceptible by the average person.

[36] Estimates of annual average visibility improvements assume (1) that the % reduction for each fine particle constituent is equal to the % reduction in the mass of fine particles, and (2) the overall light extinction efficiency of the fine particle pollutant mix does not change. (Damberg and Polkowsky, 1996)

[37] IMPROVE (Interagency Monitoring of PROtected Visual Environments) is a visibility monitoring network managed cooperatively by EPA, Federal land management agencies, and State representatives. An analysis of IMPROVE data for 1992–1995 is found in Sisler et al. (1996).

that the current level of annual average light extinction (resulting from both anthropogenic *and* background sources of PM) in several western locations, such as the Colorado Plateau, is about equal to the level of *background* light extinction (i.e., the level representing nonanthropogenic sources only) in the East. This regional difference is due to higher background particle concentrations in the East, the greater light scattering associated with higher humidity levels in the East, and significantly lower concentrations of anthropogenic PM in remote western locations as compared with remote eastern sites.

Because of these regional differences, it is the Administrator's judgment that national secondary standards intended to maintain or improve visibility conditions on the Colorado Plateau would have to be set at or even below natural background levels in the East, the attainment of which would effectively require elimination of all eastern anthropogenic emissions. Conversely, national secondary standards that would achieve an appropriate degree of visibility improvement in the East would permit further degradation in the West. Due to this regional variability in visibility conditions created by differing background fine particle levels and the effect of humidity on these background levels, the Administrator concludes that proposing more stringent national secondary standards would not be an effective or appropriate means to protect the public welfare from adverse impacts of PM on visibility in all parts of the country.

The Administrator then considered the potential effectiveness of a regional haze program in addressing regional differences in visibility impairment and thereby supplementing the protection that would be achieved by setting the secondary standards identical to the suite of proposed primary standards. A program to address this widespread, regionally uniform type of haze caused by a multitude of sources is required by sections 169A and 169B of the Act. In 1977, Congress established as a national goal ''the prevention of any future, and the remedying of any existing, manmade impairment of visibility in mandatory Class I areas.'' EPA is required by section 169A(b)(2) of the Act to ensure that ''reasonable progress'' is achieved toward meeting the national goal. The structure and requirements of sections 169A and 169B, to be implemented by the States, make it clear that visibility protection programs can be specific to each affected region, in contrast with the national applicability of a secondary NAAQS. The EPA is currently engaged in efforts to develop a regional haze program, and will have the benefit of the June 1996 recommendations from the Grand Canyon Visibility Transport Commission as well as recommendations from the Federal Advisory Committee Act (FACA) Subcommittee on Ozone, Particulate Matter, and Regional Haze Implementation Programs which are expected by the end of the year.

An important factor considered in this review is whether a regional haze program, in conjunction with secondary standards set identical to the suite of proposed primary standards for PM, would provide appropriate protection for visibility in non-Class I areas. Based on the following recommendation from the 1993 report of the National Research Council, Protecting Visibility in National Parks and Wilderness Areas, the Administrator believes such protection would be provided:

> Efforts to improve visibility in Class I areas also would benefit visibility outside these areas. Because most visibility impairment is regional in scale, the same haze that degrades visibility within or looking out from a national park also degrades visibility outside it. Class I areas cannot be regarded as potential islands of clean air in a polluted sea.

The Administrator recognizes, however, that people living in certain urban areas may place a high value on unique scenic resources in or near these areas, yet could have visibility problems attributable to local sources that would not necessarily be addressed by the combined effects of a regional haze program and secondary standards identical to the proposed suite of primary standards for PM. This may be particularly true of certain cities located near scenic vistas in the West. In the Administrator's judgment, State or local regulatory approaches, such as recent action by Colorado to establish a local visibility standard for the city of Denver, would be more appropriate and effective in addressing these special situations because of the localized and unique characteristics of the problems involved. Visibility in an urban area located near a Class I area can also be improved through State implementation of the current visibility regulations, by which emission limitations can be imposed on a source or group of sources found to be contributing to ''reasonably attributable'' impairment in the Class I area.

Based on the above considerations, the Administrator proposes to set secondary standards identical to the proposed suite of primary standards, in conjunction with a regional haze program under sections 169A and 169B of the Act, as the most appropriate and effective means of addressing the welfare effects associated with visibility impairment. Together, the two programs and associated control strategies should provide appropriate protection against the effects of PM on visibility and allow all regions of the country to make reasonable progress toward the national visibility goal.

B. Materials Damage and Soiling Effects

Annual and 24-hour secondary standards for PM_{10} effects on materials damage and soiling were established in 1987 at levels equal in all respects to the primary standards. As discussed in the Criteria Document and Staff Paper, particles affect materials by promoting and accelerating the corrosion of metals, by degrading paints, and by deteriorating building materials such as concrete and limestone. Soiling is found to reduce the aesthetic quality of buildings and objects of historical or social interest. Past studies have found that residential properties in highly polluted areas typically have lower values than those in less polluted areas. Thus, at high enough concentrations, particles become a nuisance and result in increased cost and decreased enjoyment of the environment.

After reviewing the extent of relevant studies and other information provided since the 1987 review of the PM standards, the Administrator concurs with staff and CASAC conclusions that the available data do not provide a sufficient basis for establishing a secondary standard based on soiling or materials damage alone. In the Administrator's judgment, however, setting secondary standards identical to the suite of proposed $PM_{2.5}$ and PM_{10} primary standards, as discussed above, would provide increased protection against the effects of fine particles and retain an appropriate degree of control on coarse particles. Accordingly, the Administrator proposes to set the secondary standards identical to the suite of proposed primary standards to protect against materials damage and soiling effects of PM.

C. Proposed Decision on the Secondary Standards

The Administrator proposes to set secondary standards identical to the suite of proposed primary standards, in conjunction with establishment of a regional haze program. In her judgment, such an approach would provide appropriate protection against the welfare effects associated with particle pollution.

If at the time of final promulgation the most stringent approach to setting the $PM_{2.5}$ primary standards were to be adopted, the Administrator would propose to set the secondary standards identical to the final suite of primary standards. However, even if the levels of the $PM_{2.5}$ standards were to be set as low as 12 μg/m³ and 25 μg/m³, respectively, for the annual and 24-hour $PM_{2.5}$ standards, the Administrator would still foresee the need for a regional haze program to supplement the visibility protection afforded by such standards. If, on the other hand, the levels of the $PM_{2.5}$ primary standards were to be set at up to 20 μg/m³, annual average, and up to 65 μg/m³, 24-hour average, the Administrator would find it necessary to re-examine whether a separate lower secondary standard would have to be established to protect against the welfare effects associated with particle pollution. Based on the above discussion, the Administrator would consider setting separate secondary standards for $PM_{2.5}$ at 15 μg/m³, annual average, and 50 μg/m³, 24-hour average, with PM_{10} standards set identical to the final primary PM_{10} standards. In her judgment, such a suite of secondary standards, in conjunction with the establishment of a regional haze program, would appropriately protect public welfare from the effects of particle pollution.

IV. Revisions to Appendix K—Interpretation of the PM NAAQS

The EPA is proposing to revise Appendix K to 40 CFR part 50 to reflect the proposed forms for the annual and 24-hour standards for $PM_{2.5}$ and PM_{10}. The proposed revisions to Appendix K explain the computations necessary for determining when the proposed primary and secondary standards are met. More specifically, the proposed revisions address data reporting, handling, and rounding conventions, with example calculations. The proposed revisions do not address the treatment of exceptional events data. Policies for addressing exceptional and natural events are part of the standards implementation process.

Key elements of the proposed revisions to Appendix K are outlined below.

A. $PM_{2.5}$ Computations and Data Handling Conventions

As discussed in section II.F above, EPA is proposing a spatially averaged annual mean as the form of the annual $PM_{2.5}$ and a 98th percentile concentration form of the 24-hour $PM_{2.5}$ standard. The proposed Appendix K explains the data handling conventions and computations for the annual and 24-hour forms of the $PM_{2.5}$ standards in sections 2.1 and 2.2, respectively; data rounding conventions in section 2.3; monitoring considerations in section 2.4; and formulas for calculating the annual and 24-hour forms in sections 2.5 and 2.6, respectively.

With regard to the annual $PM_{2.5}$ standard, EPA is proposing to spatially average the annual mean values in areas designated to represent population exposures. The spatial average is to be carried out using data from monitoring sites designated in a State monitoring plan in accordance with the proposed revisions to 40 CFR Part 58. Also, EPA is proposing that the requirements for 3 years of data for comparison with the standard be fulfilled by the spatial averaging network as a whole, not by individual monitors within the network. The EPA also proposes that intermediate averaging over calendar quarters be retained for the annual average form of the standard. Quarterly averages may be important to ensure representative sampling in areas with extreme seasonal variation; however, this extra calculation has little effect on the calculated 3-year average value (SAI, 1996, pp. 6–9). Thus, EPA solicits comments on whether or not the calculation of quarterly means as an intermediate step in deriving the annual mean should be retained.

With regard to the 24-hour $PM_{2.5}$ standard, the proposed Appendix K defines the 98th percentile as the daily value out of a year of monitoring data below which 98 percent of all values in the group fall.

State and local agencies are expected to report daily $PM_{2.5}$ concentrations to the nearest 0.1 μg/m³ for concentrations less than 100 μg/m³ and to the nearest 1 μg/m³ for higher values. The incremental sensitivity of proposed $PM_{2.5}$ monitors is better than that for PM_{10}, and $PM_{2.5}$ measurements can be reported to 3 significant digits.

In addition to instrument sensitivity, the number of measured values used to calculate an averaged value affects the precision of the value to be compared with the level of the standard. In calculating a 3-year average of annual means, many values (typically 144 values to as many as 1095 values) are used to calculate the annual mean, whereas only 3 values are averaged to calculate the 24-hour standard. As a result, the annual and 24-hour standards are expressed with different degrees of precision and, thus, different rounding conventions are appropriate. Specifically, when calculating a 3-year average of annual mean values, the second decimal place shall be rounded (0.05 to be rounded up) to fall within the ±15% precision goal for the $PM_{2.5}$ measurements. When calculating the 3-year average of the 98th percentile values, only two significant digits are retained at levels near the standard, with the non-significant first decimal place rounded (0.5 μg/m³ to be rounded up to the next highest 1 μg/m³).

To determine whether the proposed standards are met, the calculated value of the 3-year average of the annual means and the 3-year average of the 98th percentile values would be compared to the level of the relevant standard. The proposed annual standard of 15.0 μg/m³ is expressed to the nearest 0.1 μg/m³, while the 24-hour standard of 50 μg/m³ is expressed to the nearest 1 μg/m³, reflective of the quantitative uncertainties in the health effects evidence upon which these standards are based. More specifically, these uncertainties include the measurement uncertainty inherent in the ambient $PM_{2.5}$ concentrations used in epidemiological studies upon which consideration of the levels of the standards have been based. Because the measurement precision is expressed as a percentage of the measured value (±15%), the magnitude of the target concentration affects the appropriate number of significant digits for the purpose of comparison to the standard. The EPA believes that expressing the proposed annual standard to the nearest 0.1 μg/m³ and the 24-hour standard to the nearest 1 μg/m³ is consistent with the quality assurance goal for $PM_{2.5}$ measurements, as stated in the proposed Appendix A of 40 CFR Part 58, to be within ±15%.

B. PM_{10} Computations and Data Handling Conventions

As discussed in section II.H above, the EPA is proposing to retain the annual mean as the form of the annual PM_{10} standard, and to revise the form of the 24-hour PM_{10} standard to a 98th percentile form. The 98th percentile for the 24-hour PM_{10} standard would be calculated in the same manner as described in section A above for the $PM_{2.5}$ standard. The proposed Appendix K explains the data handling conventions and computations for the annual and 24-hour forms of the PM_{10} standards in sections 3.1 and 3.2, respectively; rounding conventions in section 3.3; monitoring considerations in section 3.4; and formulas for calculating the annual and 24-hour forms in sections 3.5 and 3.6, respectively.

State and local agencies report daily PM_{10} concentrations to the nearest 1 μg/

m^3 since the typical incremental sensitivity of currently PM_{10} monitors is 1 μg/m^3. As with the $PM_{2.5}$ standards, the number of measured values used to calculate an averaged value affects the precision of the value to be compared with the level of the standard. As a result, the annual and 24-hour standards are expressed with different degrees of precision and different rounding conventions. Specifically, when calculating the annual mean concentration (i.e., typically with 144 values or greater), the non-significant first decimal place shall be rounded (with 0.5 rounded up) to preserve the number of significant digits in the reported data. When calculating the 3-year average of the annual 98th percentile values (i.e., 3 values are averaged), only two significant digits are retained at levels near the standard, with the non-significant units digit rounded (5 μg/m^3 to be rounded up to the next highest 10 μg/m^3).

To determine whether the proposed standards are met, the calculated value of the 3-year average of the annual means and the 3-year average of the annual 98th percentile values would be compared to the levels of the respective standards. The proposed annual standard of 50 μg/m^3 is expressed to the nearest 1 μg/m^3, while the 24-hour standard of 150 μg/m^3 is expressed to the nearest 10 μg/m^3, reflective of the quantitative uncertainties in the health effects evidence upon which these standards are based. More specifically, these uncertainties include the measurement uncertainty inherent in the ambient PM_{10} concentrations used in epidemiological studies upon which consideration of the levels of the standards have been based. Because the measurement precision is expressed as a percentage of the measured values (±15%), the magnitude of the target concentration affects the number of significant digits for the purpose of comparison to the standard. The EPA believes that expressing the proposed annual standard to the nearest 1 μg/m^3 and the 24-hour standard to the nearest 10 μg/m^3 is consistent with the quality assurance guidelines that indicate that the precision for PM_{10} measurements shall be within ±15%.

V. Reference Methods for the Determination of Particulate Matter as $PM_{2.5}$ and PM_{10} in the Atmosphere

A. Revisions to Appendix J—Reference Method for PM_{10}

During the course of this review, EPA has received a number of comments regarding the appropriateness of the current practice of adjusting measured PM_{10} concentrations to reflect standard conditions of temperature and pressure (25 °C and 760 mm Hg, respectively), as required by Appendix J to Part 50. The practice was originally adopted to provide a standard basis for comparing all pollutants measured in terms of mass per unit volume (e.g., μg/m^3). As EPA has reviewed the ambient standards for gaseous pollutants, however, technical changes have been made to express them on a pollutant volume/air volume basis (i.e., ppm) that is insensitive to differences in altitude and temperature. Such an approach is not applicable to particulate pollutants. The question arises whether continuing the past practice of making temperature and pressure adjustments for PM is appropriate or necessary.

Information in the Criteria Document on the health and welfare effects of PM provides no clear basis for making such adjustments. Recent health effects studies have been conducted in cool and warm climates, and in cities at high altitude (e.g., Denver) as well as near sea level (e.g., Philadelphia) (U.S. EPA, 1996a). These studies provide no evidence that risk associated with PM exposures is affected by variations in altitude. Accordingly, any effect that would be accounted for by temperature and pressure adjustments would be below the detection limits of epidemiological studies. While extremes of altitude might be expected to increase the delivered dose of PM in those not acclimatized to such locations, the dosimetric studies summarized in the Criteria Document provide no clear support for any quantitative adjustment to standard conditions. With respect to welfare effects, visibility is directly related to the actual mass of fine particles in the atmosphere. Adjustment of PM concentrations collected at higher altitudes to standard conditions would therefore lead to an overstatement of the effect of PM on visibility in such locations. Similarly, there is no evidence in the Criteria Document suggesting that effects on materials damage and soiling are dependent on altitude.

Based on this assessment, EPA concludes that a continuation of the practice of adjusting PM_{10} concentrations to standard conditions of temperature and pressure is not warranted or appropriate. Accordingly, EPA proposes to delete this requirement from Appendix J and to make corresponding revisions in 40 CFR Part 50.3. In addition, EPA proposes to make minor modifications to update Appendix J.

B. Appendix L—New Reference Method for $PM_{2.5}$

A new reference method for the measurement of fine particles (as $PM_{2.5}$) in the ambient air has been developed for the primary purpose of determining attainment of the new $PM_{2.5}$ standards. The proposed method is described in a new Appendix L to part 50, and would join the other reference methods (or measurement principles) specified for other criteria pollutants in other appendices to part 50.

In developing a new reference method for $PM_{2.5}$, EPA staff consulted with a number of individuals and groups in the monitoring community, including instrument manufacturers, academics, consultants, and experts in State and local agencies. The approach and key specifications were submitted to the CASAC Technical Subcommittee for Fine Particle Monitoring, which held a public meeting to discuss the FRM and related monitoring issues on March 1, 1996. Comments on the proposed method were provided orally and in writing by interested parties. The Technical Subcommittee indicated their overall satisfaction with the FRM approach in a letter (Price, 1996) forwarded by CASAC to the Administrator.

1. Approach

In addition to the primary purpose of the new $PM_{2.5}$ reference method (determining attainment of the standards), the EPA considered a variety of possible secondary goals and objectives that this measurement method might also fulfill. Subsequently, various alternative $PM_{2.5}$ measurement techniques were evaluated. From this analysis, the EPA determined that the new reference method should be based on a conventional type ambient air sampler that collects 24-hour integrated $PM_{2.5}$ samples on a filter that is subsequently moisture and temperature equilibrated and analyzed gravimetrically.

This type of sampler is relatively inexpensive and easy to use by monitoring agency personnel, operates over a wide range of ambient conditions, produces a measurement that is comparable to large sets of previously collected PM data in existing data bases, and provides a physical sample that can be further analyzed for chemical composition. The proposed $PM_{2.5}$ sampler is a low volume sampler operating at 1 cubic meter per hour, for a total sample volume of 24 m^3 for the specified 24-hour sample collection period. The sample is collected on a 47 mm Teflon® filter.

2. PM Concentrations Based on Actual Air Volume

In accordance with the proposed change to the PM_{10} reference method in Appendix J, ambient concentrations measured with the new reference method would be expressed as micrograms of PM mass per actual cubic meter of air sampled ($\mu g/m^3$), rather than mass per cubic meter of air adjusted to standard temperature and pressure (25 °C and 760 mm Hg, respectively). This convention would provide PM concentration measurements that are more representative of the actual mass of $PM_{2.5}$ present in conditions of cold temperatures and for monitoring sites at high altitude.

3. Sampler

Although the sampler is conventional in configuration, its design is more sophisticated than previous samplers used for collection of PM samples. This more sophisticated sampler, together with improved manufacturing and operational quality assurance, is necessary to achieve the more stringent data quality objectives established for $PM_{2.5}$ monitoring data.

To meet precision requirements, the critical mechanical components of the inlet, particle size separator, downtube, and upper filter holder are proposed to be specified by design, in the form of manufacturing drawings. Performance specifications for these components would be quite extensive, and the performance tests that would be required are difficult and require very costly test facilities. All other aspects of the sampler would be described by performance-based specifications. Sample air flow rate would have to be carefully controlled and accurately measured. Ambient temperature and barometric pressure sensors would be required for accurate measurement of actual volumetric sample flow rate and to provide archival documentation of these conditions associated with the $PM_{2.5}$ measurements. Loss of semi-volatile components of $PM_{2.5}$ would be reduced by temperature control of the sample filter. The allowable rise of the temperature of the filter above ambient temperature is proposed to be limited to 3 degrees C above ambient temperature during sampling as well as after sample collection while the sample is retained in the sampler awaiting retrieval.

The sampler would be required to have a variety of other timing, control, and diagnostic functions and to report any abnormal operational conditions to the sampler operator. Flow rate, sample volume, sample time, and other sample, site, and diagnostic information would also be downloadable to a portable data retrieval device through an electronic port connection for fast and accurate documentation of the sample parameters and site conditions. A built-in sampler leak-check capability would allow frequent checking of this potentially important source of measurement error. Filters would be mounted in filter cassettes to facilitate protected installation and retrieval from the sampler, and sampler manufacturers would be free to develop innovative filter holder opening/closing mechanisms to make filter changing fast and reliable.

VI. Implementation Program

Recognizing that potential adoption of new or revised NAAQS for PM and O_3, as well as potential new regulations for regional haze, could have profound implications for existing State implementation programs, EPA established a subcommittee under the Clean Air Act Advisory Committee (CAAAC) in 1995 to consider how such actions might be implemented. The Subcommittee, comprised of some 58 members representing environmental organizations, State and local air pollution control agencies, Federal agencies, academia, industry, and other public interests, was asked to provide advice and recommendations to EPA on developing new, integrated approaches for implementing potential new NAAQS for PM and O_3, as well as a potential new regional haze reduction program. The Subcommittee, through several work groups made up of Subcommittee members and other designees recommended by the Subcommittee, is examining key aspects of the existing implementation programs for PM and O_3, to provide for more effective implementation of the potential new NAAQS, as well as to provide new approaches to better integrate broad regional and national control strategies with more localized efforts.

Upon completion of its work, the Subcommittee will present its findings and recommendations to the CAAAC. These recommendations will then assist EPA's development of appropriate policies and regulations for implementing the potential new PM and O_3 NAAQS and regional haze regulations in the most efficient and environmentally effective manner. These policies and regulations will then be published in the Federal Register for further input from the public.

As discussed in the advance notice of proposed rulemaking, EPA also intends to release an interim implementation policy that would take effect at the time the new or revised NAAQS for PM and O_3 are promulgated. The interim implementation policy is intended to provide for an effective transition from the existing implementation requirements and control strategies for PM and O_3 to new ones that are under development. Among other things, the policy will address such issues as the continuation of existing control requirements during the transition period, continued classification of areas, substitution of progress requirements, as well as the timing of the applicability of certain provisions of new source review requirements.

VII. Regulatory and Environmental Impact Analyses

The EPA has judged this proposal to be a significant action, and has prepared a draft Regulatory Impact Analysis (RIA) for it as discussed below. Neither the draft RIA nor the associated contractor reports have been considered in issuing this proposal. Judicial decisions make clear that the economic and technological feasibility of attaining ambient standards are not to be considered in setting them, although such factors may be considered to a degree in the development of State plans to implement the standards.

As discussed above, EPA has established a Subcommittee of the CAAAC to examine the existing implementation programs for PM and O_3, and provide advice and recommendations to assist EPA in developing new, integrated approaches for implementing potential new or revised NAAQS for PM and O_3, as well as a potential new regional haze reduction program. Because the work of the Subcommittee is still in progress, the draft RIA and associated regulatory flexibility assessment that accompany this notice do not reflect its advice and recommendations or any resulting implementation strategies for PM. The EPA anticipates that such strategies will be more efficient and environmentally effective than the ones analyzed. While the draft RIA and flexibility assessment should be useful in generally informing the public about potential costs and benefits associated with implementation of the proposed revisions, they do not reflect any new implementation requirements or policies that may be proposed after consideration of the Subcommittee's advice and recommendations. As EPA develops and elaborates such requirements or policies, it will continue to consult with the Subcommittee and will prepare further regulatory analyses as appropriate.

A. Executive Order 12866

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

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations or recipients thereof; or

(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

In view of its important policy implications, this proposal has been judged to be a ''significant regulatory action'' within the meaning of the Executive Order, and EPA has submitted it to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public docket and made available for public inspection at EPA's Air and Radiation Docket Information Center (Docket No. A–95–54).

The EPA has prepared and entered into the docket a draft RIA entitled ''Regulatory Impact Analysis for Proposed Particulate Matter National Ambient Air Quality Standard (November 1996).'' This draft RIA assesses the costs, economic impacts, and benefits associated with the implementation of the current and several alternative NAAQS for PM as discussed above. As discussed in the draft RIA, there are an unusually large number of limitations and uncertainties associated with the analyses and resulting cost impacts and benefit estimates. Below are the estimated costs and benefits associated with partial attainment of the alternative levels in 2007. Because judicial decisions make clear that cost can not be considered in setting NAAQS, the results of the draft RIA have not been considered in developing this proposal.

COMPARISON OF ANNUAL BENEFITS AND COSTS OF $PM_{2.5}$ ALTERNATIVES IN 2007 [a] (BILLIONS 1990$)

$PM_{2.5}$ alternative (μg/m³)	Monetized annual benefits of partial attainment[b c]	Annual costs of partial attainment
*20/65	22–44	2
15/50[d]	58–119	6
12.5/50	94–192	14

*Does not include the reductions in costs and benefits associated with revised PM_{10} studies. This alternative requires less reductions than current PM_{10} standards.

[a] All estimates are measured incremental to the baseline PM_{10} alternative (PM_{10} μg/m³ annual/150 μg/m³ daily, 1 expected exceedance per year).

[b] Lower and upper end of benefit range reflects benefits of including the short-term and long-term mortality risk reduction measure, respectively.

[c] Partial attainment benefits based upon post-control air quality as defined in the control cost analysis.

[d] Proposed $PM_{2.5}$ alternative.

As discussed in the RIA itself, there are a large number of limitations and uncertainties inherent in estimating these national costs and benefits over extended periods of time. Results are limited by the inability to monetize certain health or welfare benefits for comparison with projections of control costs that are usually more complete, but are sometimes overstated due to an inability to forecast advances in pollution prevention and control. The approaches used for the RIA did not attempt to take advantage of flexibilities and savings possible in consideration of combined air quality management programs for PM and O_3. Further, they were limited by availability of emissions, air quality monitoring, and related information. Indeed, the suite of control measures available to be considered in the cost analysis was not sufficient to achieve full attainment in 2007. It is for this reason we have only presented the costs and benefits for this ''partial attainment'' scenario. In the partial attainment scenario, there would be 57 residual nonattainment counties representing 29 million people in 2007 for the proposed level. One implication of this scenario is that more time will be needed to attain the standards in the areas remaining in nonattainment. Moreover, based on past experience, improvements in technologies and creative implementation programs are likely to result in more effective programs than can now be forecasted. The EPA is planning to improve and expand its analysis of the integrated costs and benefits of attaining both the PM and ozone standards in association with developing implementation guidance.

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., provides that, whenever an agency is required to publish a general notice of rulemaking for a proposed rule, the agency must prepare regulatory flexibility analyses for the proposed and final rule unless the head of the agency certifies that it will not have a significant economic impact on a substantial number of small entities. In judging what kinds of economic impacts are relevant for this determination, it is appropriate to consider the purposes and requirements of the RFA. *Mid-Tex Electrical Co-op v. FERC*, 773 F.2d 327, 341–42 (D.C. Cir. 1985).

Review of the findings and purposes section of the RFA makes clear that Congress enacted the RFA to address the economic impact of rules on small entities *subject to the rule's requirements.* Pub. L. 96–354, section 2 (1980); *see also* 126 Cong. Rec. 21,452, 21,453 (1980). In explaining the need for the RFA, Congress generally expressed concern about the problematic consequences of applying regulations uniformly to large and small entities. Specifically, Congress stated that ''laws and regulations designed for application to large scale entities have been applied uniformly to small [entities] even though the problems that gave rise to government action may not have been caused by those small entities,'' that ''uniform Federal regulatory and reporting requirements have in numerous instances imposed unnecessary and disproportionately burdensome demands . . . upon small [entities] with limited resources,'' that ''the failure to recognize differences in the scale and resources of regulated entities has in numerous instances adversely affected competition in the marketplace,'' and that ''the practice of treating all regulated [entities] as equivalent may lead to inefficient use of regulatory agency resources.'' *Id.* To address these concerns, Congress enacted the RFA ''to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the [entity] *subject to regulation*'' (emphasis added). *Id.*

The statutory requirements for regulatory flexibility analyses confirm that the economic impact to be analyzed is the impact of the rule on small entities that will have to comply with the rule's requirements. In both initial

and final regulatory flexibility analyses, for example, the agency issuing the rule is required to describe and (where feasible) estimate the number of small entities ''to which the proposed rule will apply''; describe the reporting, recordkeeping and other ''compliance requirements'' of the proposed rule; and estimate the classes of small entities that ''will be subject to the requirement.'' *See* RFA sections 603 and 604. The agency must also discuss and address significant regulatory alternatives that are consistent with the applicable statutes and would minimize any significant economic impact on small entities. Among the possible alternatives listed by the RFA are the establishment of differing compliance and reporting requirements that take into account the resources available to small entities and partial or total exemptions from the rule for small entities. *See* RFA section 603(c). The RFA's requirements for regulatory flexibility analyses thus establish that the focus of such analyses are the regulatory requirements small entities will be required to meet as a result of the rule and ways to tailor those requirements to reduce the burden on small entities. *Mid-Tex Electrical Co-op,* 773 F.2d at 342 (''[I]t is clear that Congress envisioned that the relevant 'economic impact' was the impact of compliance with the proposed rule on regulated small entities'').

The scope of regulatory flexibility analyses in turn informs the scope of the analysis necessary to support a certification that a rule will not have ''a significant economic impact on a substantial number of small entities.'' Thus, ''an agency may properly certify that no regulatory flexibility analysis is necessary when it determines that the rule will not have a significant economic impact on a substantial number of small entities *that are subject to the requirements of the rule.'' Id.* (emphasis added); *see also United Distribution Companies* v. *FERC,* 88 F.3d 1105, 1170 (D.C. Cir. 1996).

In view of the RFA's purposes and the requirements it establishes for regulatory flexibility analyses, EPA believes that today's proposal to revise the PM NAAQS will not have a significant economic impact on small entities within the meaning of the RFA. The proposed rule, if promulgated, will not establish requirements applicable to small entities. Instead, it will establish a standard of air quality that other Clean Air Act provisions will call on states (or in case of state default, the federal government) to achieve by adopting implementation plans containing specific control measures for that purpose. In other words, state (or federal) regulations implementing the NAAQS might establish requirements applicable to small entities, but the NAAQS itself would not.[38]

For these reasons, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

While the statutory requirements for regulatory flexibility analyses are thus inapplicable to NAAQS standard-setting, EPA is nonetheless interested in assessing to the extent possible the potential impact on small entities of implementing a revised PM NAAQS. EPA has accordingly conducted a more general analysis of the potential cost impacts on small entities of control measures that states might adopt to attain and maintain a revised NAAQS, and has included that analysis in the RIA cited above.

That analysis examines industry-wide cost and economic impacts for those sectors likely to be affected when the proposed revisions to the PM NAAQS are implemented by States. As part of the draft RIA, the EPA has analyzed various industries for the existence of small entities to ascertain whether small entities within a given industry category are likely to be differentially affected when compared to the industry category as a whole. This information will serve to inform potentially affected small entities, thus enabling them to participate more effectively in EPA's review and potential revision of existing implementation requirements and policies and in development of any necessary State implementation plan revisions. As indicated previously, EPA will prepare further analyses as appropriate as it develops new implementation requirements or policies.

EPA's finding that today's proposal will not have a significant economic impact on small entities also entails that the new small-entity provisions in Section 244 of the Small Business Regulatory Enforcement Fairness Act (SBREFA) do not apply. Nevertheless, EPA intends to fulfill the spirit of SBREFA on a voluntary basis. To accomplish this, following the proposal of new air quality standards for O_3 and PM, EPA intends to work with the Small Business Administration (SBA) to hold two separate panel exercises to collect comments, advice and recommendations from representatives of small businesses, small governments, and other small organizations. The first panel, soliciting comments on the new standards themselves, will be held shortly after proposal. The second panel, covering implementation of the standards, will be held a few months later. Both panel exercises will be carried out using a panel process modeled on the ''Small Business Advocacy Review Panel'' provisions in Section 244 of SBREFA. We are also adding a number of small-entity representatives to our Federal advisory committee focusing on NAAQS implementation; we expect the small-entity advice from this committee will help the aforementioned implementation panel accomplish its purpose.

C. Impact on Reporting Requirements

There are no reporting requirements directly associated with an ambient air quality standard proposed under section 109 of the Act (42 U.S.C. 7400). There are, however, reporting requirements associated with related sections of the Act, particularly sections 107, 110, 160, and 317 (42 U.S.C. 7407, 7410, 7460, and 7617). In EPA's proposed revisions to the air quality surveillance requirements (40 CFR part 58) for PM, the associated RIA addresses the Paperwork Reduction Act requirements through an Information Collection Request.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. This requirement does not apply if EPA is prohibited by law from considering section 202 estimates and analyses in adopting the rule in question. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. These requirements do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective,

[38] Because the proposed rule would not establish requirements applicable to small entities, EPA cannot in fact perform the analyses contemplated by the RFA.

or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

As indicated previously, EPA cannot consider in setting a NAAQS the economic or technological feasibility of attaining ambient air quality standards, although such factors may be considered to a degree in the development of State plans to implement the standards. Moreover, the proposed revisions to the PM NAAQS, if adopted, will not in themselves impose any new expenditures on governments or on the private sector, or establish any new regulatory requirements affecting small governments. Accordingly, EPA has determined that the provisions of sections 202, 203, and 205 of the UMRA do not apply to this proposed decision. The EPA acknowledges, however, that any corresponding revisions to associated State implementation plan requirements and air quality surveillance requirements, 40 CFR part 51 and 40 CFR part 58, respectively, might result in such effects. Accordingly, EPA has addressed unfunded mandates in the notice that announces the proposed revisions to 40 CFR part 58, and will, as appropriate, when it proposes any revisions to 40 CFR part 51.

E. Environmental Justice

Executive Order 12848 requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. These requirements have been addressed to the extent practicable in the draft RIA cited above.

List of Subjects in 40 CFR Part 50

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

Dated: November 27, 1996.

Carol M. Browner,

Administrator.

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For the reasons set forth in the preamble, Part 50 of Chapter I of Title 40 of the Code of Federal Regulations is proposed to be amended as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

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

Authority: Secs. 109 and 301(a), Clean Air Act, as amended (42 U.S.C. 7409, 7801(a)).

2. Section 50.3 is revised to read as follows:

§ 50.3 Reference conditions.

All measurements of air quality that are expressed as mass per unit volume (e.g., micrograms per cubic meter) other than for particulate matter (PM_{10} and $PM_{2.5}$) shall be corrected to a reference temperature of 25 °C and a reference pressure of 760 millimeters of mercury (1,013.2 millibars). Measurements of PM_{10} and $PM_{2.5}$ shall be reported based on actual air volume measured at the actual temperature and pressure at the monitoring site during the measurement period.

3. Section 50.6 is revised to read as follows:

§ 50.6 National primary and secondary ambient air quality standards for particulate matter.

(a) The national primary and secondary ambient air quality standards for particulate matter are:

(1) 15.0 micrograms per cubic meter ($\mu g/m^3$) annual arithmetic mean concentration, and 50 $\mu g/m^3$ 24-hour average concentration measured in the ambient air as $PM_{2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers) by:

(i) A reference method based on Appendix L and designated in accordance with Part 53 of this chapter, or

(ii) An equivalent method designated in accordance with Part 53 of this chapter.

(2) 50 micrograms per cubic meter (μg/m³) annual arithmetic mean concentration, and 150 μg/m³ 24-hour average concentration measured in the ambient air as PM_{10} (particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers) by:

(i) A reference method based on Appendix J and designated in accordance with Part 53 of this chapter, or

(ii) An equivalent method designated in accordance with Part 53 of this chapter.

(b) The annual primary and secondary $PM_{2.5}$ standards are met when the annual arithmetic mean concentration, as determined in accordance with Appendix K to this part, is less than or equal to 15.0 micrograms per cubic meter.

(c) The 24-hour primary and secondary $PM_{2.5}$ standards are met when the 98th percentile 24-hour concentration, as determined in accordance with Appendix K to this part, is less than or equal to 50 micrograms per cubic meter.

(d) The annual primary and secondary PM_{10} standards are met when the annual arithmetic mean concentration, as determined in accordance with Appendix K of this part, is less than or equal to 50 micrograms per cubic meter.

(e) The 24-hour primary and secondary PM_{10} standards are met when the 98th percentile 24-hour concentration, as determined in accordance with Appendix K of this part, is less than or equal to 150 micrograms per cubic meter.

4. Appendix J is amended as follows:

a. Section 2.2 is revised.

b. The last sentence of Section 3.1 is revised.

c. The first sentence of Section 7.3 is revised.

d. The last sentence of Section 8.1.2 is removed.

e. Section 8.2.1 is revised.

f. The first sentence of Section 8.2.2 is revised.

g. Section 11.1 is revised.

h. Section 11.2 is revised.

i. Section 11.3 is removed.

Appendix J to Part 50—Reference Method for the Determination of Particulate Matter as PM_{10} in the Atmosphere

* * * * *

2.2 Each filter is weighed (after moisture equilibration) before and after use to determine the net weight (mass) gain due to collected PM_{10}. The total volume of air sampled, measured at the actual ambient temperature and pressure, is determined from the measured flow rate and the sampling time. The mass concentration of PM_{10} in the ambient air is computed as the total mass of collected particles in the PM_{10} size range divided by the volume of air sampled, and is expressed in micrograms per actual cubic meter (μg/m³).

* * * * *

3.1 * * * Nevertheless, all samplers should be capable of measuring 24-hour PM_{10} mass concentrations of at least 300 μg/m³ while maintaining the operating flow rate within the specified limits.

* * * * *

7.3 *Flow Rate Transfer Standard.* The flow rate transfer standard must be suitable for the sampler's operating flow rate and must be calibrated against a primary flow or volume standard that is traceable to the National Institute of Standards and Technology (NIST).

* * * * *

8.2.1 PM_{10} samplers employ various types of flow control and flow measurement devices. The specific procedure used for flow rate calibration or verification will vary depending on the type of flow controller and flow rate indicator employed. Calibration is in terms of actual volumetric flow rates (Q_a) to meet the requirements of section 8.1. The general procedure given here serves to illustrate the steps involved in the calibration. Consult the sampler manufacturer's instruction manual and Reference 2 for specific guidance on calibration. Reference 14 provides additional information on various other measures of flow rate and their interrelationships.

8.2.2 Calibrate the flow rate transfer standard against a primary flow or volume standard traceable to NIST.

* * * * *

11.1 Calculate the total volume of air sampled as:

$$V=Q_a \times t$$

Where:

V=total air sampled, at ambient temperature and pressure, m³,

Q_a=average sample flow rate at ambient temperature and pressure, m³/min, and

t=sampling time, min.

11.2 Calculate the PM_{10} concentration as:

$$PM_{10}=(W_f - W_i) \times 10^6/V$$

Where:

PM_{10}=mass concentration of PM_{10}, μg/m³,

W_f, W_i=final and initial weights of filter collecting PM_{10} particles, g, and

10^6 = conversion of g to μg.

Note: If more than one size fraction in the PM_{10} size range is collected by the sampler, the sum of the net weight gain by each collection filter [$\sum S(W_f - W_i)$] is used to calculate the PM_{10} mass concentration.

* * * * *

5. Appendix K is revised in its entirety to read as follows:

Appendix K to Part 50—Interpretation of the National Ambient Air Quality Standards for Particulate Matter

1.0 General

This appendix explains the data handling conventions and computations necessary for determining whether the annual and 24-hour primary and secondary national ambient air quality standards for particulate matter specified in part 50.6 of this chapter are met. Particulate matter is measured in the ambient air as PM_{10} and $PM_{2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 10 and 2.5 micrometers, respectively) by a reference method based on appendix J of this part for PM_{10} and on appendix L for $PM_{2.5}$, as applicable, and designated in accordance with part 53 of this chapter, or by an equivalent method designated in accordance with part 53 of this chapter. Data reporting, data handling, and computation procedures to be used in making comparisons between reported PM_{10} and $PM_{2.5}$ concentrations and the levels of the PM standards are specified in the following sections.

Several terms used throughout this appendix are defined here. A ''daily value'' for PM refers to the 24-hour average concentration of PM calculated or measured from midnight to midnight (local time) for PM_{10} or $PM_{2.5}$. The term ''98th percentile'' means the daily value out of a year of monitoring data below which 98% of all values in the group fall. The terms ''average'' and ''mean'' refer to an arithmetic mean. All particulate matter standards are expressed in terms of 3-year averages of annual values: the 3-year average of the annual means for the annual standards, and the 3-year average of the 98th percentile values for each year for the 24-hour standards. The term ''year'' refers to a calendar year. ''Designated monitors'' are those monitoring sites designated in a State monitoring plan for spatial averaging in areas designated for spatial averaging in accordance with part 58 of this chapter.

2.0 Comparisons With the $PM_{2.5}$ Standards

2.1 Annual $PM_{2.5}$ Standard

The annual $PM_{2.5}$ standard is met when the 3-year average of the spatially averaged annual means is less than or equal to 15.0 μg/m³. The 3-year average of the spatially averaged annual means is determined by averaging quarterly means at each monitor to obtain the annual mean $PM_{2.5}$ concentrations at each monitor, then averaging across all designated monitors, and finally averaging for three consecutive years.

The steps can be summarized as follows:

(a) Average 24-hour measurements to obtain quarterly means at each monitor,

(b) Average quarterly means to obtain annual means at each monitor,

(c) Average across designated monitoring sites to obtain an annual spatial mean for an area, and

(d) Average 3 years of annual spatial means to obtain a 3-year average of spatially averaged annual means.

For the annual $PM_{2.5}$ standard, a year meets data completeness requirements when at

least 75 percent of the scheduled sampling days for each quarter have valid data. Three years of spatial averages are required to demonstrate that the standard has been met. Sites with less than 3 years of data shall be included in spatial averages for those years that data completeness requirements are met. The formulas for calculating the 3-year average annual mean of the $PM_{2.5}$ standard are given in Section 2.5.

Although 3 complete years of data are required to demonstrate that the standard has been met, years with high concentrations shall not be ignored just because they have less than complete data. Thus, in computing annual spatially averaged means, sites with less than 75 percent data completeness for each quarter in a year shall be included in the computation if the resulting annual mean concentration is greater than the level of the standard.

2.2 24–Hour $PM_{2.5}$ Standard

The 24-hour $PM_{2.5}$ standard for is met when the 3-year average of the 98th percentile values at each monitoring site is less than or equal to 50 μg/m³. This comparison shall be based on three consecutive, complete years of air quality data. A year meets data completeness criteria when at least 75 percent of the scheduled sampling days have valid data for each quarter. The formula for calculating the 3-year average of the annual 98th percentile values is given in Section 2.6.

Although three complete years of data are required to demonstrate that the standard has been met, years with high concentrations shall not be ignored just because they have less than complete data. Thus, in computing the 3-year average 98th percentile value, years with less than 75 percent data completeness shall be included in the computation if the annual 98th percentile value is greater than the level of the standard.

2.3 Rounding Conventions

For the purposes of comparing calculated values to the applicable level of the standard, it is necessary to round the final results of the calculations described in sections 2.5 and 2.6. For the annual $PM_{2.5}$ standard, the 3-year average of the spatially averaged annual means shall be rounded to the nearest 0.1 g/m³ (decimals 0.05 and greater are rounded up to the next 0.1, and any decimal lower than 0.05 is rounded down to the nearest 0.1). For the 24-hour $PM_{2.5}$ standard, the 3-year average of the annual 98th percentile values shall be rounded to the nearest 1 μg/m³ (decimals 0.5 and greater are rounded up to nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

2.4 Monitoring Considerations

Part 58.13 of this chapter specifies the required minimum frequency of sampling for $PM_{2.5}$. Part 58 also specifies which monitors shall be used in making comparisons with the particulate matter standards.

For the annual $PM_{2.5}$ standard, when designated monitors are located at the same site and are reporting $PM_{2.5}$ values for the same time periods, their concentrations shall be averaged before an area-wide spatial average is calculated, and such monitors will then be considered as one monitor.

2.5 Formulas for the Annual $PM_{2.5}$ Standard

(a) An annual mean value for $PM_{2.5}$ is determined by first averaging the daily values of a calendar quarter.

$$\overline{X}_{q,y,s} = \frac{1}{n_q}\sum_{i=1}^{n_q} X_{i,q,y,s} \quad [1]$$

Where:

$x_{q,\,y,\,s}$=the mean for quarter q of year y for site s,

n_q=the number of monitored values in the quarter, and

$x_{i,\,q,\,y,\,s}$=the ith value in quarter q for year y for site s.

(b) The following formula is then to be used for calculation of the annual mean:

$$\overline{X}_{y,s} = \frac{1}{4}\sum_{q=1}^{4} \overline{X}_{q,y,s} \quad [2]$$

Where:

$x_{y,\,s}$=the annual mean concentration for year y (y=1, 2, or 3) and for site s, and

$x_{q,\,y,\,s}$=the mean for quarter q of year y for site s.

(c) The spatially averaged annual mean for year y is computed by first calculating the annual mean for each site designated to be included in a spatial average, $x_{y,s}$ and then computing the average of these values across sites:

$$\overline{x}_y = \frac{1}{n_s}\sum_{s=1}^{n_s} \overline{x}_{y,s} \quad [3]$$

Where:

x_y=the spatially averaged mean for year y,

$x_{y,s}$=the annual mean for year y and site s, and

n_s=the number of sites designated to be averaged.

In the event that an area designated for spatial averaging has one or more sites at the same location producing data for the same time periods, the sites are averaged together before using formula [3] by:

$$\overline{x}_{y,s*} = \frac{1}{n_c}\sum_{s=1}^{n_c} \overline{x}_{y,s} \quad [4]$$

Where:

$x^{y,s*}$=the annual mean for year y for the sites at the same location (which will now be considered one site),

n_c=the number of sites at the same location designated to be included in the spatial average, and

$x_{y,s}$=the annual mean for year y and site s.

(d) The 3-year average of the spatially averaged annual means is calculated by using the following formula:

$$\overline{x} = \frac{1}{3}\sum_{y=1}^{3} \overline{x}_y \quad [5]$$

Where:

x=the 3-year average of the spatially averaged annual means, and

x_y=the spatially averaged annual mean for year y.

Example 1. Area designated for spatial averaging that meets the primary annual $PM_{2.5}$ standard.

In an area designated for spatial averaging, four designated monitors recorded data in at least 1 year of a particular 3-year period. Using formulas [1] and [2], the annual means for $PM_{2.5}$ at each site are calculated for each year. The following table can be created from the results. Data completeness percentages are also shown.

		Site #1	Site #2	Site #3	Site #4	Spatial mean
Year 1	Annual mean (μg/m³)	12.7				12.7
	% data completeness	80	0	0	0	
Year 2	Annual mean (μg/m³)	13.3	17.4	9.8		15.35
	% data completeness	90	63	40	0	
Year 3	Annual mean (μg/m³)	12.9	16.7	12.3	20.1	15.50
	% data completeness	90	80	85	50	
3-year mean						14.52

The data from these sites are averaged in the order described in section 2.1. Note that the annual mean from site #3 in year 2 does not enter in the spatial mean since the data completeness criteria are not met. However, the annual means from site #2 in year 2 and from site #4 in year 3 are included, even though the data completeness criteria are not met, since they are above the level of the standard. The 3-year mean is rounded to 14.5 μg/m³, indicating that this area meets the annual $PM_{2.5}$ standard.

Example 2. Area with two monitors at the same location that meets the primary annual $PM_{2.5}$ standard.

In an area designated for spatial monitoring, six designated monitors, with

two monitors at the same location (#5 and #6), recorded data in a particular 3-year period.

Using formulas [1] and [2], the annual means for PM2.5 at each site are calculated for each year. The following table can be created from the results.

Annual mean (μg/m³)	Site #1	Site #2	Site #3	Site #4	Site #5	Site #6	Average of #5 and #6	Spatial mean
Year 1	14.2	11.5	8.7	10.9	16.9	14.5	15.70	12.21
Year 2	16.4	13.3	10.3	12.3	15.5	13.8	14.65	13.39
Year 3	12.9	12.4	9.5	11.2	15.1	13.3	14.20	12.04
3-Year mean								12.55

The annual means for sites #5 and #6 are averaged together using formula [4] before the spatial average is calculated using formula [3] since they are in the same location. The 3-year mean is rounded to 12.6 μg/m³, indicating that this area meets the annual $PM_{2.5}$ standard.

Example 3. Area with a single monitor that meets the primary annual $PM_{2.5}$ standard.

Given data from a single monitor in an area designated for spatial averaging, the calculations are as follows. Using formulas [1] and [2], the annual means for $PM_{2.5}$ are calculated for each year. If the annual means are 10.28, 17.38, and 12.25 μg/m³, then the 3-year mean is:

$X=(1/3)\times(10.28+17.38+12.25)=13.303$ μg/m³.

This value is rounded to 13.3, indicating that this area meets the annual $PM_{2.5}$ standard.

2.6 Formulas for the 24-Hour $PM_{2.5}$ Standard

When the data for a particular site and year meet the data completeness requirements in section 2.2, calculation of the 98th percentile is accomplished by the following steps. All the daily values from a particular site and year comprise a series of values (X_1, X_2, X_3, . . ., X_n), that can be sorted into a series where each number is equal to or larger than the preceding number ($X_{[1]}$, $X_{[2]}$, $X_{[3]}$, . . ., $X_{[n]}$). In this case, $X_{[1]}$ is the smallest number and $X_{[n]}$ is the largest value. The 98th percentile is found from the sorted series of daily values which is ordered from the lowest to the highest number. Compute (0.98)×(n) as the number ''i.d'', where ''i'' is the integer part of the result and ''d'' is the decimal part of the result. The 98th percentile value for year y, $P_{0.98,\,y}$, is given by formula [6]:

$$P_{0.98,y} = X_{[j+1]} \text{ if } d \neq 0 \text{ and}$$

$$P_{0.98,y} = \frac{X_{[j]} + X_{[j+1]}}{2} \text{ if } d = 0 \qquad [6]$$

where:

$P_{0.98,y}$=98th percentile for year y,

$X_{[j]}$=the jth number in the ordered series of numbers,

''i''=the integer part of the product of 0.98 and n (the number of values in the series), and

''d''=the decimal part of the product of 0.98 and n.

The 3-year average 98th percentile is then calculated by averaging the annual 98th percentiles:

$$P_{0.98} = \frac{\sum_{y=1}^{3} P_{0.98,y}}{3} \qquad [7]$$

The 3-year average 98th percentile is rounded according to the conventions in section 2.3 before a comparison with the standard is made.

Example 4. Ambient monitoring site with every-day sampling that meets the primary 24-hour $PM_{2.5}$ standard.

In each year of a particular 3 year period, varying numbers of daily $PM_{2.5}$ values (e.g., 278, 300, and 293) out of a possible 365 values were recorded at a particular site with the following ranked values (in μg/m³):

Year 1		Year 2		Year 3	
j rank	X_j value	j rank	X_j value	j rank	X_j value
* * *	* * *	* * *	* * *	* * *	* * *
272	44.1	293	41.4	287	50.3
273	45.0	294	43.5	288	52.1
274	47.4	295	48.0	289	53.2
* * *	* * *	* * *	* * *	* * *	* * *

Using formula [6], the 98th percentile values for each year are calculated as follows:

$$0.98*278 = 272.44 \Rightarrow P_{0.98,1} = X_{[273]} = 45.0\mu g/m^3$$

$$0.98*300 = 294 \Rightarrow P_{0.98,2} = \frac{X_{[294]} + X_{[295]}}{2} = \frac{(43.5+48.0)}{2} = 45.75$$

$$0.98*293 = 287.14 \Rightarrow P_{0.98,3} = X_{[288]} = 52.1\mu g/m^3.$$

Using formula [7], the 3-year average 98th percentile is calculated as follows:

$$P_{0.98} = \frac{45.0+45.75+52.7}{3} = 47.6\mu g/m^3, \text{ which rounds to } 48\mu g/m^3$$

Therefore, this site meets the 24-hour $PM_{2.5}$ standard.

3.0 Comparisons with the PM_{10} Standards

3.1 Annual PM_{10} Standard

The annual PM_{10} standard is met when the 3-year average of the annual mean PM_{10} concentrations at each monitoring site is less than or equal to 50 μg/m³. The 3-year average of the annual means is determined by averaging quarterly means to obtain annual mean PM_{10} concentrations for 3 consecutive, complete years at each monitoring site. The steps can be summarized as follows:

(a) Average 24-hour measurements to obtain a quarterly mean,

(b) Average quarterly means to obtain an annual mean, and

(c) Average annual means to obtain a 3-year mean.

For the annual PM_{10} standard, a year meets data completeness requirements when at least 75 percent of the scheduled sampling days for each quarter have valid data. The formulas for calculating the 3-year average annual mean of the PM_{10} standard are given in Section 3.5.

Although 3 complete years of data are required to demonstrate that the standard has been met, years with high concentrations shall not be ignored just because they have less than complete data. Thus, in computing the 3-year average annual mean concentration, years with less than 75 percent data completeness shall be included in the computation if the annual mean concentration is greater than the level of the standard.

3.2 24-Hour PM_{10} Standard

The 24-hour PM_{10} standard is met when the 3-year average of the annual 98th percentile values at each monitoring site is less than or equal to 150 μg/m³. This comparison shall be based on 3 consecutive, complete years of air quality data. A year meets data completeness criteria when at least 75 percent of the scheduled sampling days have valid data each quarter. The formula for calculating the 3-year average of the annual 98th percentile values is given in Section 3.6.

Although 3 complete years of data are required to demonstrate that the standard has been met, years with high concentrations shall not be ignored just because they have less than complete data. Thus, in computing the 3-year average of the annual 98th percentile values, years with less than 75 percent data completeness shall be included in the computation if the annual 98th percentile value is greater than the level of the standard.

3.3 Rounding Conventions

For the annual PM_{10} standard, the 3-year average of the annual PM_{10} means shall be rounded to the nearest 1 μg/m³ (decimals 0.5 and greater are rounded up to the next whole number, and any decimal less than 0.5 is rounded down to the nearest whole number). For the 24-hour PM_{10} standard, the 3-year average of the annual 98th percentile values of PM_{10} shall be rounded to the nearest 10 μg/m³ (155 μg/m³ and greater would be rounded to 160 μg/m³ and 154 μg/m³ and less would be rounded to 150 μg/m³).

3.4 Monitoring Considerations

Part 58.13 of this chapter specifies the required minimum frequency of sampling for PM_{10}. For making comparisons with the PM_{10} NAAQS, all sites meeting applicable requirements in part 58 of this chapter would be used.

3.5 Formulas for the Annual PM_{10} Standard

(a) An annual arithmetic mean value for PM_{10} is determined by first averaging the 24-hour values of a calendar quarter using the following formula:

$$\overline{X}_{q,y} = \frac{1}{n_q}\sum_{i=1}^{n_q} X_{i,q,y} \quad [9]$$

Where:

$\bar{X}_{q,y}$=the mean for quarter q of year y,

n_q=the number of monitored values in the quarter, and

$x_{i,q,y}$=the ith value in quarter q for year y.

(b) The following formula is then to be used for calculation of the annual mean:

$$\overline{X} = \frac{1}{4}\sum_{q=1}^{4} \overline{X}_{q,y} \quad [10]$$

Where:

X_y=the annual mean concentration for year y, (y=1, 2, or 3), and

$x_{q,y}$=the mean for a quarter q of year y.

(c) The 3-year average of the annual means is calculated by using the following formula:

$$\overline{x} = \frac{1}{3}\sum_{y=1}^{3} \overline{x}_y \quad [11]$$

Where:

$\tilde{x}$=the 3-year average of the annual means, and

$\tilde{x}_y$=the annual mean for calendar year y.

Example 5. Ambient monitoring site that does not meet the annual PM_{10} standard.

Given data from a PM_{10} monitor and using formulas [9] and [10], the annual means for PM_{10} are calculated for each year. If the annual means are 52.42, 82.17, and 63.23 μg/m³, then the 3-year average annual mean is

$\tilde{x}$=(⅓) • (52.42 + 82.17 + 63.23)=65.94 which is rounded to 66 μg/m³. Therefore, this site does not meet the annual PM_{10} standard.

3.6 Formula for the 24-Hour PM_{10} Standard

When the data for a particular site and year meet the data completeness requirements in section 3.2, calculation of the 98th percentile is accomplished by the following steps. All the daily values from a particular site and year comprise a series of values (X_1, X_2, X_3, . . ., X_n) that can be sorted into a series where each number is equal to or larger than the preceding number ($X_{[1]}$, $X_{[2]}$, $X_{[3]}$, . . ., $X_{[n]}$). In this case, $X_{[1]}$ is the smallest number and $X_{[n]}$ is the largest value. The 98th percentile is found from the sorted series of daily values which is ordered from the lowest to the highest number. Compute (0.98) × (n) as the number ''i.d'', where ''i'' is the integer part of the result and ''d'' is the decimal part of the result. The 98th percentile value for year y, $P_{0.98,y}$, is given by formula [12]:

$$P_{0.98,y} = X_{[j+1]} \text{ if } d \neq 0 \text{ and}$$

$$P_{0.98,y} = \frac{X_{[j]} + X_{[j+1]}}{2} \text{ if } d = 0 \quad [12]$$

Where:

$P_{0.098,y}$=the 98th percentile for year y,

$X_{[j]}$=the jth number in the ordered series of numbers,

''i''=the integer part of the product of 0.98 and n (the number of observations in the series), and

''d''=the decimal part of the product of 0.98 and n.

The 3-year average 98th percentile value is then calculated by averaging the annual 98th percentiles:

$$P_{0.98} = \frac{\sum_{y=1}^{3} P_{0.98,y}}{3} \quad [13]$$

The 3-year average 98th percentile is rounded according to the conventions in section 3.3 before a comparison with the standard is made.

Example 6. Ambient monitoring site with sampling every sixth day that meets the primary 24-hour PM_{10} standard.

In each year of a particular three year period, varying numbers of PM_{10} daily values (e.g., 55, 49, and 50) out of a possible 61 daily values were recorded at a particular site with the following ranked values (in μg/m³):

Year 1		Year 2		Year 3	
j rank	X_j value	j rank	X_j value	j rank	X_j value
* * *	* * *	* * *	* * *	* * *	* * *
53	120	47	143	48	140
54	128	48	148	49	144
55	130	49	150	50	147
* * *	* * *	* * *	* * *	* * *	* * *

Using formula [12], the 98th percentile values for each year are calculated as follows:

$$0.98 * 55 = 53.9 \Rightarrow P_{0.98,1} = X_{[54]} = 128 \mu g/m^3$$

$$0.98 * 49 = 48.02 \Rightarrow P_{0.98,2} = X_{[49]} = 150 \mu g/m^3$$

$$0.98 * 50 = 49 \Rightarrow P_{0.98,3} = \frac{X_{[49]} + X_{[50]}}{2} = \frac{144 + 147}{2} = 145.5 \mu g/m^3$$

Using formula [3], the 3-year average 98th percentile is calculated as follows:

$$\frac{128 + 150 + 145.5}{3} = 141.2 \mu g/m^3 \text{ rounds to } 140 \mu g/m^3.$$

Therefore, this site meets the 24-hour PM_{10} standard.

6. Appendix L is added to read as follows:

Appendix L—Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere

1.0 Applicability.

1.1 This method provides for the measurement of the mass concentration of fine particulate matter having an aerodynamic diameter less than or equal to a nominal 2.5 micrometers ($PM_{2.5}$) in ambient air over a 24-hour period for purposes of determining whether the primary and secondary national ambient air quality standards for fine particulate matter specified in Sec. 50.6 of this chapter are met. The measurement process is considered to be nondestructive, and physical or chemical analyses. Quality assessment procedures are provided in part 58, Appendices A and B, of this chapter and quality assurance procedures and guidance are provided in References 1 and 2.

1.2 This method will be considered a reference method for purposes of part 58 of this chapter only if:

(a) the associated sampler meets the requirements specified in this appendix and the applicable requirements in part 53 of this chapter,

(b) the method and associated sampler have been designated as a reference method in accordance with part 53 of this Chapter, and

(c) the national operating performance of the associated sampler, as determined in accordance with part 58, Appendix A, section 6 of this chapter, continue to meet the specifications set forth in part 58, Appendix A, section 6.3.3 of this chapter.

1.3 $PM_{2.5}$ samplers that meet all specifications set forth in this method but have minor deviations and/or modifications of the reference method sampler necessary to obtain sequential operation will be designated as ''Class I'' equivalent methods for $PM_{2.5}$ in accordance with part 53 of this Chapter.

2.0 Principle

2.1 An electrically powered air sampler draws ambient air at a constant volumetric flow rate into a specially shaped inlet and through an inertial particle size separator (impactor) where the suspended particulate matter in the $PM_{2.5}$ size range is separated for collection on a polytetrafluoroethylene (PTFE) filter over the specified sampling period. The air sampler and other aspects of this reference method are specified either explicitly in this appendix or generally with reference to other applicable regulations or quality assurance guidance.

2.2 Each filter is weighed (after moisture and temperature equilibration) before and after sample collection to determine the net weight (mass) gain due to collected $PM_{2.5}$. The total volume of air sampled is determined by the sampler from the measured flow rate at actual ambient temperature and pressure and the sampling time. The mass concentration of $PM_{2.5}$ in the ambient air is computed as the total mass of collected particles in the $PM_{2.5}$ size range divided by the actual volume of air sampled, and is expressed in micrograms per actual cubic meter of air ($\mu g/m^3$).

3.0 $PM_{2.5}$ Measurement Range

3.1 Lower concentration limit. The lower limit of the mass concentration range should be 1 $\mu g/m^3$ or less and is determined primarily by the repeatability (precision) of filter blanks, based on the 24 m^3 nominal total air sample volume specified for the 24-hour sample.

3.2 Upper concentration limit. The upper limit of the mass concentration range is determined by the filter mass loading beyond which the sampler can no longer maintain the operating flow rate within specified limits due to increased pressure drop across the loaded filter. This upper limit cannot be specified precisely because it is a complex function of the ambient particle size distribution and type, humidity, the individual filter used, the capacity of the sampler flow rate control system, and perhaps other factors. Nevertheless, all samplers should be capable of measuring 24-hour $PM_{2.5}$ mass concentrations of at least 200 $\mu g/m^3$ while maintaining the operating flow rate within the specified limits.

3.3 Sample period. The required sample period for $PM_{2.5}$ concentration measurements by this method shall be 1380 to 1500 minutes (23 to 25 hours). However, when a sample period is less than 1380 minutes, the measured concentration (as determined by the collected $PM_{2.5}$ mass divided by the actual sampled air volume), multiplied by the actual number of minutes in the sample period and divided by 1440, may be used as a valid concentration measurement for purposes of determining violations of the NAAQS. This number represents the minimum concentration that would have been measured for the full 24-hour sample period. When reported to AIRS, this data value should receive a special code.

4.0 Accuracy

4.1 Because the size and volatility of the particles making up ambient particulate matter vary over a wide range and the mass concentration of particles varies with particle size, it is difficult to define the accuracy of $PM_{2.5}$ samplers in an absolute sense. The accuracy of $PM_{2.5}$ measurements is therefore defined in a relative sense, referenced to measurements provided by this reference method. Accordingly, accuracy for other (equivalent) methods for $PM_{2.5}$ shall be defined as the degree of agreement between a subject field $PM_{2.5}$ sampler and a collocated $PM_{2.5}$ reference method audit sampler operating simultaneously at the monitoring site location of the subject sampler. This field sampler audit procedure is set forth in section 6 of part 58, Appendix A of this chapter.

4.2.1 Test of concordance (reproducibility). Annual assessment of reproducibility for each designated reference

method sampler is required under the provisions of Appendix A of Part 58 of this chapter. This assessment is based on the concordance correlation, using 6 measurements per year at regular intervals of each reference method sampler operated in a SLAMS network to a collocated audit reference sampler. The assessment audits may be performed by either the reporting agency itself or by a third party and must meet criteria specified in Appendix A of part 58 of this Chapter. A test procedure is described in section 6.1 of part 58, Appendix A that determines the bias in the primary sampler as compared to the reference method sampler under actual network operational sampling conditions. The lower 95 percent probability limit of the concordance correlation for $PM_{2.5}$ samplers, as determined by this procedure, must be equal to or greater than 0.94 for each designated reference method sampler to retain its designation.

4.2.2 Annual assessment of the bias of each designated reference method sampler is required under the provisions of part 58 of this chapter. This assessment is based on comparisons made six times per year at regular intervals of each reference method sampler operated in a SLAMS network to a collocated audit sampler. The assessment audits may be performed by either the reporting agency itself or by a third party and must meet criteria specified in Appendix A of part 58 of this chapter. A screening test procedure is described in section 6.2 of part 58, Appendix A that examines for bias between the primary sampler and the reference method sampler under actual network operational sampling conditions. The test uses a simple counting procedure and leads to a conclusion of bias only when the evidence is quite strong (p=0.01).

4.3 In addition, part 58, Appendix A of this chapter requires that the flow rate accuracy of $PM_{2.5}$ samplers used in SLAMS monitoring networks be assessed periodically via audits of the sampler's operational flow rate.

5.0 Precision.

5.1 Tests to establish initial operational precision for each reference method sampler are specified as a part of the requirements for designation as a reference method under part 53 of this chapter (§ 53.56).

5.2 Annual assessments of routine operational precision are also required.

5.2.1 Annual assessment of the pooled operational precision of each designated reference method sampler is required under the provisions of part 58 of this chapter. This assessment is based on comparisons made six times per year at regular intervals of each reference method sampler operated in a SLAMS network to a collocated audit sampler. The assessment audits may be performed by either the reporting agency itself or by a third party and must meet criteria specified in Appendix A of part 58 of this Chapter. A test procedure is described in section 6.1 of part 58, Appendix A that determines the variation in the $PM_{2.5}$ concentration measurements of reference method samplers under the actual network operational sampling conditions. The pooled operational precision of $PM_{2.5}$ samplers, as determined by this procedure, must meet the specification in section 6 of Appendix A, part 58 for each designated reference method sampler to retain its designation.

5.2.2 A screening test for bias and excessive imprecision is required under the provisions of part 58 of this chapter. This assessment is based on comparisons made six times per year at regular intervals of each reference method sampler operated in a SLAMS network to a collocated audit sampler. The assessment audit may be performed by either the reporting agency itself or by a third party and must meet criteria specified in Appendix A section 6.2 of part 58 of this Chapter. A screening test procedure is described in section 6 of part 58, Appendix A that examines for excessive imprecision (>15%) in one or both of the samplers. The test uses a simple counting procedure and leads to a conclusion of excessive imprecision only when evidence is quite strong ($p - 0.01$) under the actual network operational sampling conditions.

6.0 Filter for $PM_{2.5}$ Sample Collection

6.1 Size: Circular, 47 mm diameter.

6.2 Medium: Polytetrafluoroethylene (PTFE) with integral 0.38 ±0.04 mm thick polymethylpentene (PMP) or equivalent support ring.

6.3 Pore size: 2 µm as measured by ASTM F 316–80

6.4 Thickness: 20–60 µm

6.5 Maximum pressure drop: 30 cm H_2O column @ 16.67 L/min clean air flow.

6.6 Maximum moisture pickup: 0.0% weight increase after 24-hour exposure at 48% relative humidity at 23 °C.

6.7 Collection efficiency. Greater than 99.7 percent, as measured by the DOP test (ASTM D 2986–91) with 0.3 µm particles at the sampler's operating face velocity.

6.8 Filter weight stability. Filter weight loss ≤ 20 µg, measured as specified in the following two tests. Filter weight loss shall be the average difference between the initial and the final weights of a random sample of test filters selected from each lot prior to shipment. The number of filters tested shall be not less than 0.1% of the filters of each manufacturing lot, or 10 filters, whichever is greater. The filters shall be weighed under laboratory conditions and shall have had no air sample passed through them (i.e., filter blanks). Each test procedure must include initial equilibration and weighing, the test, and final equilibration and weighing. Equilibration and weighing shall be in accordance with section 8 and guidance provided in Reference 2.

6.8.1 Test for surface particle contamination. Install each test filter in a filter cassette (Drawing numbers L–25, L–26) and drop the cassette from a height of 25 cm to a flat hard surface, such as a particle-free wood bench. Repeat three times. Remove the test filter from the cassette and weigh the filter. The average change in weight must be less than 20 µg.

6.8.2 Test of temperature stability. Place randomly selected test filters in a drying oven set at 40°C ±2 °C for not less than 48 hours. Remove, equilibrate, and reweigh each test filter. The average change in weight must be less than 20 µg.

6.9 Alkalinity. Less than 25 microequivalents/gram of filter, as measured by the procedure given in Reference 2.

6.10 Supplemental Requirements. Although not required for determination of $PM_{2.5}$ mass concentration under this reference method, additional specifications for the filter must be developed by users who intend to subject $PM_{2.5}$ filter samples to subsequent chemical analysis. These supplemental specifications include background chemical contamination of the filter and any other filter parameters that may be required by the method of chemical analysis. All such supplemental filter specifications must be compatible with and secondary to the primary filter specifications given in this section 6.

7.0 $PM_{2.5}$ Sampler.

7.1 Configuration. The sampler shall consist of a sample air inlet, downtube, particle size separator (impactor), filter holder assembly, air pump and flow rate control system, flow rate measurement device, ambient and filter temperature monitoring system, timer, outdoor environmental enclosure, and suitable mechanical, electrical, or electronic control capability to provide the design and functional performance as specified in this section 7. The performance specifications require that the sampler:

(a) provide automatic control of sample flow rate and other operational parameters,

(b) monitor these operational parameters as well as ambient temperature and pressure, and

(c) provide this information to the sampler operator at the end of each sample period in digital form, either visually or as electronic data available for output through a data output port connection.

7.2 Nature of specifications. The $PM_{2.5}$ sampler is specified by a combination of design and performance requirements. The sample inlet, downtube, particle size discriminator, and the internal configuration of the filter holder assembly are specified explicitly by design drawings and associated mechanical dimensions, tolerances, materials, surface finishes, assembly instructions, and other necessary specifications. All other aspects of the sampler are specified by required operational function and performance, and the design of these other aspects (including the design of the lower portion of the filter holder assembly) is optional, subject to acceptable operational performance. Test procedures to demonstrate compliance with both the design and performance requirements are set forth in subpart E of part 53 of this Chapter.

7.3 Design specifications. These components must be manufactured or reproduced exactly as specified in an ISO 9001-registered facility, with registration initially approved and subsequently maintained.

7.3.1 Sample inlet assembly. The sample inlet assembly, consisting of the inlet, downtube, and impactor shall be assembled as indicated in drawing No. L–1 and shall meet all associated requirements. A portion of this assembly shall also be subject to the maximum overall sampler leak rate specification (see section 7.4.6).

7.3.2 Inlet. The sample inlet shall be fabricated as indicated in drawing Nos. L–2 through L–18 and shall meet all associated requirements.

7.3.3 Downtube. The downtube shall be fabricated as indicated in drawing No. L–19 and shall meet all associated requirements.

7.3.4 Impactor.

7.3.4.1 The impactor (particle size separator) shall be fabricated as indicated in drawing Nos. L–20 through L–24 and shall meet all associated requirements.

7.3.4.2 Impactor filter specifications:

(a) Size: Circular, 35 to 37 mm diameter

(b) Medium: Borosilicate glass fiber, without binder

(c) Pore size: 1 to 1.5 micrometer, as measured by ASTM F 316–80

(d) Thickness: 300 to 500 micrometers

7.3.4.3 Impactor oil specifications:

(a) Composition: Tetramethyltetraphenyltrisiloxane, single compound diffusion oil

(b) Vapor pressure: Maximum 2×10^{-8} mm Hg at 25 °C

(c) Viscosity: 36 to 40 centistokes at 25 °C

(d) Density: 1.06 to 1.07 g/cm^3 at 25 °C

(e) Quantity: 1 mL

7.3.5 Filter holder assembly. The sampler shall have a sample filter holder assembly to adapt and seal to the down tube and to hold and seal the specified filter (section 6) in the sample air stream in a horizontal position below the downtube such that the sample air passes downward through the filter at a uniform face velocity. The upper portion of this assembly shall be fabricated as indicated in drawing Nos. L–25 and L–26 and shall accept and seal with the filter cassette, which shall be fabricated as indicated in drawing Nos. L–27 through L–29.

(a) The lower portion of the filter holder assembly shall be of a design and construction that:

(1) mates with the upper portion of the assembly to complete the filter holder assembly,

(2) completes both the external air seal and the internal filter cassette seal such that all seals are reliable over repeated filter changings, and

(3) facilitates repeated changing of the filter cassette by the sampler operator.

(b) Leak-test performance requirements for the filter holder assembly are included in section 7.4.6 below.

7.3.6 Flow rate measurement adapter. A flow rate measurement adapter as specified in drawing No. L–30 shall be furnished with each sampler.

7.3.7 Surface finish. All internal surfaces exposed to sample air prior to the filter shall be treated electrolytically in a sulfuric acid bath to produce a clear, uniform anodized surface finish of not less than 1000 mg/ft^2 (1.08 mg/cm^2) in accordance with military standard specification (mil. spec.) 8625F, Type II, Class 1 (Reference 3). This anodic surface coating shall not be dyed or pigmented. Following anodization, the surfaces shall be sealed by immersion in boiling deionized water for 15 minutes.

7.4 Performance specifications.

7.4.1 Sample flow rate. Proper operation of the impactor requires that specific air velocities be maintained through the device. Therefore, the sample air flow rate through the inlet, downtube, impactor, and filter shall be 16.67 L/min (1.000 m^3/hour) ±5%, measured as actual volumetric flow rate at the temperature and pressure of the sample air entering the impactor.

7.4.2 Sample air flow rate control system. The sampler shall have a sample air flow rate control system which shall be capable of providing a sample air volumetric flow rate within the specified range (section 7.4.1) for the specified filter (section 6), at any atmospheric conditions specified (section 7.4.7), at a filter pressure drop equal to that of a clean filter plus up to 75 cm water column (55 mm Hg), and over the specified range of supply line voltage (section 7.4.15.1). This flow control system shall allow for operator adjustment of the operational flow rate of the sampler over a range of at least ±10 percent of the flow rate specified in section 7.4.1.

7.4.3 Sample flow rate regulation. The sample flow rate shall be regulated such that for the specified filter (section 6), at any atmospheric conditions specified (section 7.4.7), at a filter pressure drop equal to that of a clean filter plus up to 75 cm water column (55 mm Hg), and over the specified range of supply line voltage (section 7.4.15.1), the flow rate is regulated as follows:

7.4.3.1 The volumetric flow rate, measured or averaged over intervals of not more than 5 minutes over a 24-hour period, shall not vary more than ±5 percent from the specified 16.67 L/min flow rate over the entire sample period; and

7.4.3.2 The coefficient of variation (sample standard deviation divided by the average) of the flow rate, measured at intervals of not more than 5 minutes over a 24-hour period, shall not be greater than 4 percent.

7.4.4 Flow rate cut off. The sampler's sample air flow rate control system shall terminate sample collection and stop all sample flow for the remainder of the sample period in the event that the sample flow rate deviates by more than 10 percent from the nominal (or cumulative average) sampler flow rate specified in section 7.4.1 for more than 60 seconds. However, this sampler cut-off provision shall not apply during periods when the sampler is inoperative due to a temporary power interruption and the elapsed time of the inoperative period will not be included in the total sample time measured and reported by the sampler (see section 7.4.13).

7.4.5 Flow rate measurement.

7.4.5.1 The sampler shall provide a means to measure and indicate the instantaneous sample air flow rate, which shall be measured as volumetric flow rate at the temperature and pressure of the sample air entering the impactor, with an accuracy of ±2 percent. The sampler shall also provide a simple means by which the sampler operator can manually start the sample flow temporarily during non-sampling modes of operation, for the purpose of checking the sample flow rate or the flow rate measurement system.

7.4.5.2 During each sample period, the sampler's flow rate measurement system shall automatically monitor the sample volumetric flow rate, obtaining flow rate or average flow rate measurements at intervals of not greater than 5 minutes.

(a) Using these interval flow rate measurements, the sampler shall determine or calculate the following flow-related parameters, scaled in the specified engineering units:

(1) the instantaneous or interval-average flow rate, in L/min;

(2) the value of the average sample flow rate for the sample period, in L/min;

(3) the value of the coefficient of variation (sample standard deviation divided by the average) of the sample flow rate for the sample period, in percent;

(4) any time during the sample period in which the sample flow rate measured exceeds a range of ±5 percent of the average flow rate for the sample period for more than 5 minutes, in which case a warning flag indicator shall be set; and

(5) the value of the integrated total sample volume for the sample period, in m^3.

(b) Determination or calculation of these values shall properly exclude periods when the sampler is inoperative due to temporary interruption of electrical power (see section 7.4.13). These parameters shall be accessible to the sampler operator as specified in Table L–1, section 7.4.19.

7.4.6 Leak test capability.

7.4.6.1 External leakage: The sampler shall include components, accessory hardware, operator interface controls, a written procedure in the associated Operation/Instruction Manual (section 7.4.18), and all other necessary functional capability to permit and facilitate the sampler operator to conveniently carry out a leak test of the sampler at a field monitoring site without additional equipment.

(a) The suggested technique for this leak test is as follows: The operator:

(1) removes the sampler inlet and installs the flow rate measurement adapter supplied with the sampler (see section 7.3.6),

(2) closes the valve on the flow rate measurement adapter and uses the sampler air pump to draw a partial vacuum in the sampler, including (at least) the impactor, filter holder assembly (filter in place), flow measurement device, and interconnections between these devices, of at least 55 mm Hg (75 cm water column),

(3) plugs the flow system downstream of these components to isolate the components under vacuum from the pump, such as with a built-in valve,

(4) stops the pump,

(5) measures the trapped vacuum in the sampler with a built-in pressure measuring device, and

(6) measures the vacuum in the sampler with the built-in pressure measuring device again at a later time at least 10 minutes after the first pressure measurement, and

(7) removes the plugs and restores the sampler to the normal operating configuration.

(b) The associated leak test procedure shall require that for successful passage of this test, the difference between the two pressure measurements shall not be greater than either:

(1) 10 mm Hg or

(2) an alternative number of mm of Hg specified for the sampler by the manufacturer based on the actual internal volume of the sampler that indicates a leak of less than 80 mL/min.

(c) The specific proposed external leak test procedure, or particularly a proposed alternative leak test technique such as may be required for samplers whose design or configuration would make the suggested technique impractical, may be described and submitted for specific individual acceptability either as part of a reference or equivalent method application under part 53 of this chapter or in writing in advance of such application.

7.4.6.2 Internal (filter bypass) leakage: The sampler shall include components, accessory hardware, operator interface controls, a written procedure in the Operation/Instruction Manual, and all other necessary functional capability to permit and facilitate the sampler operator to conveniently carry out a test for internal filter bypass leakage in the sampler at a field monitoring site without additional equipment.

(a) The suggested technique for this leak test is as follows: The operator:

(1) Carries out an external leak test as provided under the paragraph 7.4.6.1 which indicates successful passage of the prescribed external leak test,

(2) Installs a flow-impervious membrane material in the filter cassette, either with or without a filter, as appropriate, which effectively prevents air flow through the filter holder,

(3) Uses the sampler air pump to draw a partial vacuum in the sampler, downstream of the filter holder assembly, of at least 55 mm Hg (75 cm water column),

(4) Plugs the flow system downstream of the filter holder to isolate the components under vacuum from the pump, such as with a built-in valve,

(5) Stops the pump,

(6) Measures the trapped vacuum in the sampler with a built-in pressure measuring device,

(7) Measures the vacuum in the sampler with the built-in pressure measuring device again at a later time at least 10 minutes after the first pressure measurement, and

(8) removes the membrane and plugs and restores the sampler to the normal operating configuration.

(b) The associated leak test procedure shall require that for successful passage of this test, the difference between the two pressure measurements shall not be greater than either 10 mm Hg or an alternative number of mm of Hg specified for the sampler by the manufacturer based on the actual internal volume of the portion of the sampler under vacuum that indicates a leak of less than 80 mL/min. The specific proposed internal leak test procedure, or particularly a proposed alternative internal leak test technique such as may be required for samplers whose design or configuration would make the suggested technique impractical, may be described and submitted for specific individual acceptability either as part of a reference or equivalent method application under part 53 of this chapter or in writing in advance of such application.

7.4.7 Range of Operational Conditions. The sampler is required to operate properly and meet all requirements specified herein over the following operational ranges:

7.4.7.1 Ambient temperature: −30 to +45 degrees Celsius (Note: Although for practical reasons, the temperature range over which samplers are required to be tested under part 53 of this chapter is −20 to +40 degrees Celsius, the sampler should be designed to operate properly over this wider temperature range.);

7.4.7.2 Ambient relative humidity: 0 to 100 percent;

7.4.7.3 Barometric pressure range: 600 to 800 mm Hg.

7.4.8 Ambient temperature sensor. The sampler shall have capability to measure the temperature of the ambient air surrounding the sampler over the range of −20 to +40 , with a resolution of 0.1 C and accuracy of ±2.0º C (referenced to National Weather Service (NWS) requirements; see part 53, subpart E), with or without maximum solar insolation. This ambient temperature measurement shall be updated at least every 5 minutes during both sampling and standby (non-sampling) modes of operation. A visual indication of the current (most recent) value of the ambient temperature measurement shall be available to the sampler operator during both sampling and standby (non-sampling) modes of operation, as specified in Table L–1. This ambient temperature measurement shall be used for the purpose of monitoring filter temperature deviation from ambient temperature, as required by section 7.4.11.4, and may be used for purposes of effecting filter temperature control (section 7.4.10) or computation of volumetric flow rate (sections 7.4.1 to 7.4.5). Following the end of each sample period, the sampler shall report the maximum, minimum, and average temperature for the sample period, as specified in Table L–1.

7.4.9 Ambient barometric sensor. The sampler shall have capability to measure the barometric pressure of the air surrounding the sampler over a range of 600 to 800 mm Hg (referenced to National Weather Service (NWS) requirements; see part 53, subpart E). (The barometric pressure of the air entering the impactor when sampling will be assumed to be the same as the barometric pressure of the air surrounding the sampler.) This barometric pressure measurement shall have a resolution of 5 mm Hg and an accuracy of ±10 mm Hg and shall be updated at least every 5 minutes. A visual indication of the value of the current (most recent) barometric pressure measurement shall be available to the sampler operator during both sampling and standby (non-sampling) modes of operation, as specified in Table L–1. This barometric pressure measurement may be used for purposes of computation of volumetric flow rate (sections 7.4.1 to 7.4.5), if appropriate. Following the end of a sample period, the sampler shall report the maximum, minimum, and average barometric pressures for the sample period, as specified in Table L–1.

7.4.10 Filter temperature control (sampling and post-sampling). The sampler shall provide a means to limit the temperature rise of the sample filter, from insolation and other sources, to no more than 3 °C above the temperature of the ambient air surrounding the sampler, during both sampling and post-sampling periods of operation. The post-sampling period is the non-sampling period between the end of the active sampling period and the time of retrieval of the sample filter by the sampler operator.

7.4.11 Filter temperature sensor. The sampler shall have the capability to monitor the sample filter temperature via a temperature sensor located within 1 cm of the center of the filter downstream of the filter and to provide a visual indication of the filter temperature to the operator, as specified in Table L–1. The sampler shall also provide a warning flag indicator following any occurrence in which the filter temperature exceeds the ambient temperature by more than 3 °C for more than 10 consecutive minutes during either the sampling or post-sampling periods of operation, as specified in Table L–1. It is further recommended (not required) that the sampler be capable of recording the maximum differential between the measured filter temperature and the ambient temperature and its time and date of occurrence during both sampling and post-sampling (non-sampling) modes of operation and providing those data to the sampler operator following the end of the sample period, as suggested in Table L–1.

7.4.12 Clock/Timer System. (a) The sampler shall have a programmable real-time clock timing/control system that:

(1) Is capable of maintaining local time and date, including year, month, day-of-month, hour, minute, and second to an accuracy of ±1.0 minute per month;

(2) Provides a visual indication of the current system time, including year, month, day-of-month, hour, and minute, updated at least each minute, for operator verification;

(3) Provides appropriate operator controls for setting the correct local time and date; and

(4) Is capable of starting the sample collection period and sample air flow at a specific, operator-settable time and date, and stopping the sample air flow and terminating the sampler collection period 24 hours (1440 minutes) later, or at a specific, operator-settable time and date.

(b) These start and stop times shall be readily settable by the sampler operator to within ±1.0 minute. The system shall provide a visual indication of the current start and stop time settings, readable to ±1.0 minute, for verification by the operator, and the start and stop times shall also be available via the data output port, as specified in Table L–1. Upon execution of a programmed sample period start, the sampler shall automatically reset all sample period information and warning indications pertaining to a previous sample period. Refer also to section 7.4.15.4 regarding retention of current date and time and programmed start and stop times during a temporary electrical power interruption.

7.4.13 Sampling sample time determination. The sampler shall be capable of determining the elapsed sample collection time for each $PM_{2.5}$ sample, accurate to

within ±1.0 minute, measured as the time between the start of the sampling period (sec. 7.4.12) and the termination of the sample period (sec. 7.4.12 or sec. 7.4.4). This elapsed sample time shall not include periods when the sampler is inoperative due to a temporary interruption of electrical power (section 7.4.15.4). In the event that the elapsed sample time determined for the sample period is not within the range specified for the required sample period in section 3.3, the sampler shall set a warning flag indicator. The date and time of the start of the sample period, the value of the elapsed sample time for the sample period, and the flag indicator status shall be available to the sampler operator following the end of the sample period, as specified in Table L–1.

7.4.14 Outdoor environmental enclosure. The sampler shall have an outdoor enclosure (or enclosures) suitable to protect the filter and other non-weatherproof components of the sampler from precipitation, wind, dust, extremes of temperature and humidity; to help maintain temperature control of the filter; and to provide reasonable security for sampler components and settings.

7.4.15 Electrical power supply.

7.4.15.1 The sampler shall be operable and function as specified herein when operated on an electrical power supply voltage of 105 to 125 volts AC (RMS) at a frequency of 59 to 61 Hz. Optional operation as specified at additional power supply voltages and/or frequencies shall not be precluded by this requirement.

7.4.15.2 The design and construction of the sampler shall comply with all applicable National Electrical Code and Underwriters Laboratories electrical safety requirements.

7.4.15.3 The design of all electrical and electronic controls shall be such as to provide reasonable resistance to interference or malfunction from ordinary or typical levels of stray electromagnetic fields (EMF) as may be found at various monitoring sites and from typical levels of electrical transients or electronic noise as may often or occasionally be present on various electrical power lines.

7.4.15.4 In the event of temporary loss of electrical supply power to the sampler, the sampler shall not be required to sample or provide other specified functions during such loss of power, except that the internal clock/timer system shall maintain its local time and date setting within ±1 minute per week, and the sampler shall retain all other time and programmable settings and all data required to be available to the sampler operator following each sample period for at least 7 days without electrical supply power. When electrical power is absent at the operator-set time for starting a sample period or is interrupted during a sample period, the sampler shall automatically start or resume sampling when electrical power is restored, if such restoration of power occurs before the operator-set stop time for the sample period.

7.4.15.5 The sampler shall have the capability to record and retain a record of the year, month, day-of-month, hour, and minute of the start of each power interruption of more than 1 minute duration, up to 10 such power interruptions per sample period. (More than 10 such power interruptions shall invalidate the sample, except where an exceedance is measured see section 3.3.) The sampler shall provide for these power interruption data to be available to the sampler operator following the end of the sample period, as specified in Table L–1.

7.4.16 Control devices and operator interface. The sampler shall have mechanical, electrical, or electronic controls, control devices, electrical or electronic circuits as necessary to provide the timing, flow rate measurement and control, temperature control, data storage and computation, operator interface, and other functions specified. Operator-accessible controls, data displays, and interface devices shall be designed to be simple, straightforward, reliable, and easy to learn, read, and operate under field conditions. The sampler shall have provision for operator input and storage of up to 64 characters of numeric (or alphanumeric) data for purposes of site, sampler, and sample identification. This information shall be available to the sampler operator for verification and change and for output via the data output port along with other data following the end of a sample period, as specified in Table L–1. All data required to be available to the operator following a sample collection period or obtained during standby mode in a post-sampling period shall be retained by the sampler until reset, either manually by the operator or automatically by the sampler upon initiation of a new sample collection period.

7.4.17 Data output port requirement. The sampler shall have a standard RS–232C data output connection through which digital data may be exported to an external data storage or transmission device. All information which is required to be available at the end of each sample period shall be accessible through this data output connection. The information that shall be accessible though this output port is summarized in Table L–1.

7.4.18 Operation/Instruction Manual. The sampler shall include an associated comprehensive operation or instruction manual, as required by part 53 of this chapter, which includes detailed operating instructions on the setup, operation, calibration, and maintenance of the sampler. This manual shall provide complete and detailed descriptions of the operational and calibration procedures prescribed for field use of the sampler and all instruments utilized as part of this reference method. The manual shall include adequate warning of potential safety hazards that may result from normal use or malfunction of the method and a description of necessary safety precautions. The manual shall also include a clear description of all procedures pertaining to installation, operation, periodic and corrective maintenance, and troubleshooting, and shall include parts identification diagrams.

TABLE L–1.—SUMMARY OF INFORMATION TO BE PROVIDED BY THE SAMPLER

Information to be provided	Appendix L section reference	Availability				Format	
		Anytime [1]	End of period [2]	Visual display [3]	Data output [4]	Digital reading [5]	Units
Flow rate, instantaneous.	7.4.5.1	✔		✔		XX.X	L/min
Flow rate, average for the sample period.	7.4.5.2	*	✔	*	✔	XX.X	L/min
Flow rate, CV, for sample period.	7.4.5.2	*	✔	*	✔■	XX.X	%
Flow rate, 5-min average out of spec. (FLAG [6]).	7.4.5.2	✔	✔	✔	✔■	On/Off	
Sample volume, total	7.4.5.2	*	✔	✔	✔■	XX.X	m^3
Temperature, ambient, instantaneous or 5-minute average.	7.4.8	✔		✔		XX.X	°C
Temperature, ambient, min., max., average for the sample period.	7.4.8	*	✔	✔	✔■	XX.X	°C

TABLE L–1.—SUMMARY OF INFORMATION TO BE PROVIDED BY THE SAMPLER

Information to be provided	Appendix L section reference	Availability				Format	
		Anytime [1]	End of period [2]	Visual display [3]	Data output [4]	Digital reading [5]	Units
Baro pressure, ambient, instantaneous or 5-minute average.	7.4.9	✔		✔		XXX	mm Hg
Baro pressure, ambient, min, max, average for the sample period.	7.4.9	*	✔	✔	✔■	XXX	mm Hg
Filter temperature, instantaneous.	7.4.11	✔		✔		XX.X	°C
Filter temperature, instantaneous differential out of spec. (FLAG [1]).	7.4.11	*	✔	✔	✔■	On/Off	
Filter temp, maximum differential from ambient, date, time of occurrence.	7.4.11	*	*	*	*	X.X, YY/MM/DD HH.mm.	°C, Yr/Mon/Day Hrs.min
Date and Time	7.4.12	✔		✔		YY/MM/DD HH.mm	Yr/Mon/Day Hrs.min
Sample start and stop time settings.	7.4.12	✔	✔	✔	✔	YY/MM/DD HH.mm	Yr/Mon/Day Hrs.min
Sample period start time.	7.4.12		✔	✔	✔■	YYYY/MM/DD HH.mm	Yr/Mon/Day Hrs.min
Elapsed sample time	7.4.13	*	✔	✔	✔■	HH.mm	Hrs.min
Elapsed sample time, out of spec. (FLAG[6]).	7.4.13		✔	✔	✔■	On/Off	
Power interruptions >1 min, start time of first 10.	7.4.15.5	*	✔	*	✔	1HH.mm 2HH.mm	Hrs.min
User-entered information, such as sampler and site identification.	7.4.16	✔	✔	✔	✔■	As entered	

[1] Information is required to be available to the operator at any time the sampler is operating, whether sampling or not.
[2] Information relates to the entire sampler period and must be provided following the end of the sample period until reset manually by the operator or automatically by the sampler upon the start of a new sample period.
[3] Information shall be available to the operator visually.
[4] Information is to be available as digital data at the sampler's data output port specified in section 7.4.16 following the end of the sample period until reset manually by the operator or automatically by the sampler upon the start of a new sample period.
[5] Digital readings, both visual and data output, shall have not less than the number of significant digits and resolution specified.
[6] Flag warnings may be displayed to the operator by a single flag indicator or each flag may be displayed individually. Only a set (on) flag warning must be indicated; an off (unset) flag may be indicated by the absence of a flag warning. The occurrence of a flag warning during a sample period shall not *necessarily* indicate an invalid sample but shall indicate the need for specific review of the QC data by a quality assurance officer to determine sample validity.
* Provision of this information is optional. If information related to the entire sample period is optionally provided prior to the end of the sample period, the value provided should be the value calculated for the portion of the sampler period completed up to the time the information is provided.
■ Indicates that this information is also required to be provided to the AIRS data bank; see § 58.26 and § 58.35 of part 58 of this Chapter.

7.4.19 Data reporting requirements. The various information that the sampler is required to provide and how it is to be provided is summarized in Table L–1.

8.0 Filter weighing.

See Reference 2 for additional, more detailed guidance.

8.1 Analytical balance. The analytical balance used to weigh filters must be suitable for weighing the type and size of filters specified (section 6) and have a readability of ±1 µg. The balance shall be calibrated as specified by the manufacturer at installation and recalibrated immediately prior to each weighing session, but not less often than once per year. See Reference 2 for additional guidance.

8.2 Filter conditioning/equilibration. All filters used are to be conditioned or equilibrated immediately before both the pre- and post-sampling weighings as specified below. See Reference 2 for additional guidance.

8.2.1 Mean temperature: 20–23 °C.

8.2.2 Temperature control: ±2 °C over 24 hours.

8.2.3 Mean humidity: 30–40 percent relative humidity.

8.2.4 Humidity control: ±5 relative humidity percent over 24 hours.

8.2.5 Conditioning time: not less than 24 hours.

8.3 Weighing procedure.

8.3.1 New filters should be placed in the conditioning environment immediately upon arrival and stored there until the pre-sampling weighing. See Reference 2 for additional guidance.

8.3.2 The analytical balance shall be located in the same environment in which the filters are conditioned or equilibrated, such that the filters can be weighed immediately following the conditioning period without intermediate or transient exposure to nonequilibration conditions.

8.3.3 Filters must be equilibrated at the same conditions before both the pre- and post-sampling weighings.

8.3.4 Both the pre- and post-sampling weighings should be carried out by the same analyst on the same analytical balance, using an effective technique to neutralize static charges on the filter.

8.3.5 The pre-sampling (tare) weighing shall be within 30 days of the sampling period.

8.3.6 The post-sampling equilibration and weighing shall be completed within 240 hours (10 days) after the end of the sample period.

8.3.7 New blank filters shall be weighed along with the pre-sampling (tare) weighing of each lot of $PM_{2.5}$ filters. These blank filters shall be transported to the sampling site, installed in the sampler, retrieved from the sampler without sampling, and reweighed as a quality control check.

8.3.8 Additional guidance for proper filter weighing is provided in Reference 2. See also section 10.17 concerning filter archiving.

9.0 Calibration

See Reference 2 for additional guidance.

9.1 General Requirements

9.1.1 Multipoint calibration and single-point verification of the sampler's flow rate measurement device must be performed periodically to establish traceability of subsequent flow measurements to a flow rate standard.

9.1.2 An authoritative flow rate standard shall be used for calibrating or verifying the sampler's flow rate measurement device with an accuracy of ±2 percent. The flow rate standard shall be a separate stand-alone device designed to connect to the flow rate measurement adapter, drawing L–30. This flow rate standard must have its own certification and be traceable to National Institute of Standards and Technology (NIST) primary standards for volume or flow rate. If adjustments to the sampler's flow calibration are to be made in conjunction with an audit of the sampler, such adjustments shall be made following the audit. See Reference 2 for additional guidance.

9.1.3 The sampler's flow rate measurement device shall be re-calibrated after electromechanical maintenance or transport of the sampler.

9.2 Flow Rate Calibration/Verification Procedure

9.2.1 $PM_{2.5}$ samplers may employ various types of flow control and flow measurement devices. The specific procedure used for calibration or verification of the flow rate measurement device will vary depending on the type of flow rate controller and flow rate measurement employed. Calibration shall be in terms of actual ambient volumetric flow rates (Q_a). The generic procedure given here serves to illustrate the general steps involved in the calibration of a $PM_{2.5}$ sampler. The sampler operation/instruction manual (required under section 7.4.18) and the Quality Assurance Handbook (Reference 2) provide more specific and detailed guidance for calibration.

9.2.2 The flow rate standard used for flow rate calibration shall have its own certification and be traceable to National Institute of Standards and Technology (NIST) primary standards for volume or flow rate. A calibration relationship for the flow rate standard (*e.g.*, an equation, curve, or family of curves) shall be established that is accurate to within 2 percent over the expected range of ambient temperatures and pressures at which the flow rate standard may be used. The flow rate standard must be re-calibrated or re-verified at least annually.

9.2.3 The sampler flow rate measurement device shall be calibrated or verified by removing the sampler inlet and connecting the flow rate standard to the sampler in accordance with the operation/instruction manual, such that the flow rate standard accurately measures the sampler's flow rate. The sampler operator shall verify that no leaks exist between the flow rate standard and the sampler.

9.2.4 The calibration relationship between the flow rate (in actual L/min) indicated by the flow rate standard and by the sampler's flow rate measurement device shall be established or verified in accordance with the sampler operation/instruction manual. Temperature and pressure corrections to the flow rate indicated by the flow rate standard may be required for certain types of flow rate standards. Calibration of the sampler's flow rate measurement device shall consist of at least three separate flow rate measurements (multipoint calibration) evenly spaced within the range of −10% to +10% of the sampler's operational flow rate (see section 7.4.1). Verification of the sampler's flow rate shall consist of one flow rate measurement at the sampler's operational flow rate. The sampler operation/instruction manual and Reference 2 provide additional guidance.

9.2.5 If during a flow rate verification the reading of the sampler's flow rate indicator or measurement device differs by ±4 percent or more from the flow rate measured by the flow rate standard, a new multipoint calibration shall be performed and the flow rate verification must then be repeated.

9.2.6 Following the calibration or verification, the flow rate standard shall be removed from the sampler and the sampler inlet shall be reinstalled. Then the sampler's normal operating flow rate (in L/min) shall be determined with a clean filter in place. If the sampler flow rate differs by ±2 percent or more from the required sampler flow rate, the sampler flow rate must be adjusted to the required flow rate (see section 7.4.1).

10.0 $PM_{2.5}$ Measurement Procedure

The detailed procedure for obtaining valid PM2.5 measurements with each specific sampler designated as part of a reference method for $PM_{2.5}$ under part 53 of this chapter shall be provided in the sampler-specific operation or instruction manual required by section 7.4.18. Supplemental guidance is provided in section 2.12 of the QA Handbook (Reference 2). The generic procedure given here serves to illustrate the general steps involved in the $PM_{2.5}$ sample collection and measurement, using a $PM_{2.5}$ reference method sampler.

10.1 The sampler shall be set up, calibrated, and operated in accordance with the specific, detailed guidance provided in the specific sampler's operation or instruction manual and in accordance with a specific quality assurance program developed and established by the user, based on applicable supplementary guidance provided in Reference 2.

10.2 Each new filter shall be inspected for correct type and size and for pinholes, particles, and other imperfections. A filter information record shall be established for, and an identification number assigned to, each filter.

10.3 Each filter shall be equilibrated in the conditioning environment in accordance with the requirements specified in section 8.2.

10.4 Following equilibration, each filter shall be weighed in accordance with the requirements specified in section 8 and the presampling weight recorded with the filter identification number.

10.5 A numbered and preweighed filter shall be installed in the sampler following the instructions provided in the sampler operation or instruction manual.

10.6 The sampler shall be checked and prepared for sample collection in accordance with instructions provided in the sampler operation or instruction manual and with the specific quality assurance program established for the sampler by the user.

10.7 The sampler's timer shall be set to start the sample collection at the beginning of the desired sample period and stop the sample collection 24 hours later.

10.8 Information related to the sample collection (site location or identification number, sample date, filter identification number, and sampler model and serial number) shall be recorded and, if appropriate, entered into the sampler.

10.9 The sampler shall be allowed to collect the $PM_{2.5}$ sample during the set 24-hour time period.

10.10 Within 96 hours of the end of the sample collection period, the filter, while still contained in the filter cassette, shall be carefully removed from the sampler, following the procedure provided in the sampler operation or instruction manual and the quality assurance program, and placed in a protective container. The protective container shall hold the filter cassette securely. The cover shall not come in contact with the filter's surfaces. The protective container shall be made of metal and contain no loose material that could be transferred to the filter. (See reference 2 for additional information.)

10.11 The total sample volume in actual m^3 for the sampling period and the elapsed sample time shall be obtained from the sampler and recorded in accordance with the instructions provided in the sampler operation or instruction manual. All sampler warning flag indications and other information required by the local quality assurance program shall also be recorded.

10.12 All factors related to the validity or representativeness of the sample, such as sampler tampering or malfunctions, unusual meteorological conditions, construction activity, fires or dust storms, etc. shall be recorded as required by the local quality assurance program.

10.13 After retrieval from the sampler, the exposed filter containing the $PM_{2.5}$ sample should be transported to the filter conditioning environment as soon as possible—ideally within 24 hours—for equilibration and subsequent weighing. During the period between filter retrieval

from the sampler and the start of the conditioning or equilibration, the filter shall not be exposed to temperatures over 32 °C.

10.14 The exposed filter containing the $PM_{2.5}$ sample shall be re-equilibrated in the conditioning environment in accordance with the requirements specified in section 8.2.

10.15 The filter shall be reweighed immediately after equilibration in accordance with the requirements specified in section 8, and the postsampling weight shall be recorded with the filter identification number.

10.16 The $PM_{2.5}$ concentration shall be calculated as specified in section 12.

10.17 Filter archiving. Following the post-sampling weighing or other non-destructive analysis, air pollution control agencies shall archive all routinely collected $PM_{2.5}$ filter samples from all SLAMS sites, as well as appropriate, associated laboratory and field blanks and other quality assurance replicate samples, for a period of not less than 1 year after collection. All $PM_{2.5}$ filters from core NAMS sites shall be archived for a period of not less than 5 years after collection. These archived filters shall be made available for supplemental analyses at the request of the EPA or to provide information to State and local agencies on the composition and trends for $PM_{2.5}$. Archived filter samples shall be stored in clean, dust-proof, covered containers at a temperature of 4 ±3 °C; see Reference 2 for additional guidance.

11.0 Sampler Maintenance

The sampler shall be maintained as described by the sampler's manufacturer in the sampler-specific operation or instruction manual required under section 7.4.18 and in accordance with the specific quality assurance program developed and established by the user based on applicable supplementary guidance provided in Reference 2.

12.0 Calculations.

12.1 The $PM_{2.5}$ concentration is calculated as:

$$PM_{2.5} = (W_f - W_i)/V_a$$

Where:

$PM_{2.5}$ = mass concentration of $PM_{2.5}$, $\mu g/m^3$;

W_f, W_i = final and initial weights, respectively, of the filter used to collect the $PM_{2.5}$ particle sample, µg;

V_a = total air volume sampled in actual volume units, as provided by the sampler, m^3.

Note: Total sample time must be between 1380 and 1500 minutes (23 and 25 hrs) for a fully valid $PM_{2.5}$ sample; however, see also section 3.3.

13.0 References

1. Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I, Principles. EPA/600/R–94/038a, April 1994. Available from CERI, ORD Publications, U.S. Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, Ohio 45268.

2. Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods (Interim Edition), section 2.12. EPA/600/R–94/038b, April 1994. Available from CERI, ORD Publications, U.S. Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, Ohio 45268. [Section 2.12 is currently under development and will not be available from the previous address until it is published as an addition to EPA/600/R–94/038b. Prepublication draft copies of section 2.12 will be available from Department E (MD–77B), U. S. EPA, Research Triangle Park, NC 27711 or from the contact identified at the beginning of this proposed rule].

3. Military standard specification (mil. spec.) 8625F, Type II, Class 1 as listed in Department of Defense Index of Specifications and Standards (DODISS), available from DODSSP-Customer Service, Standardization Documents Order Desk, 700 Robbins Avenue, Building 4D, Philadelphia, PA 1911–5094.

14.0 Figures

Figures L–1 through L–30 are included as part of this appendix L.

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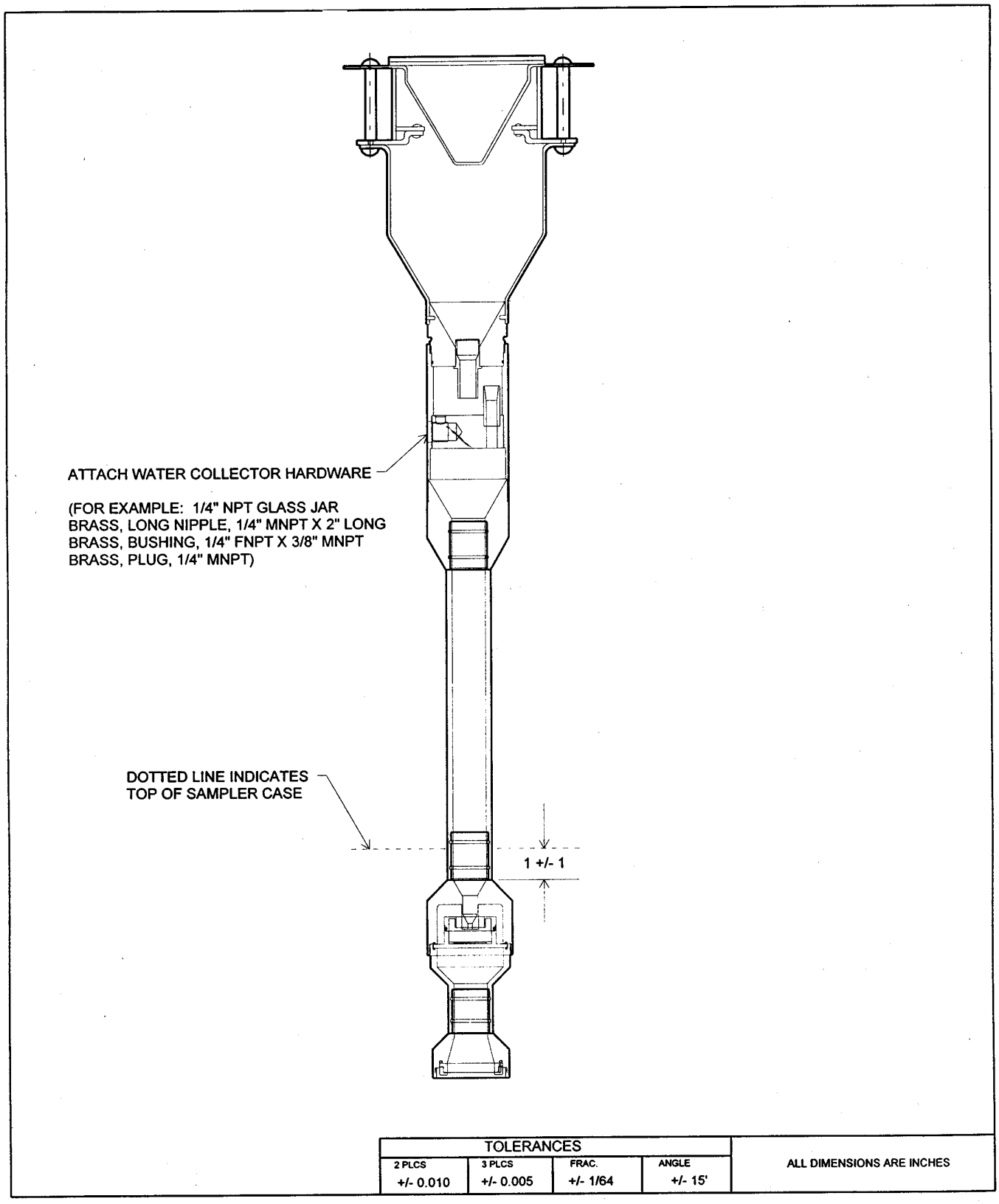

Figure L-1. PM2.5 Sampler, Assembly

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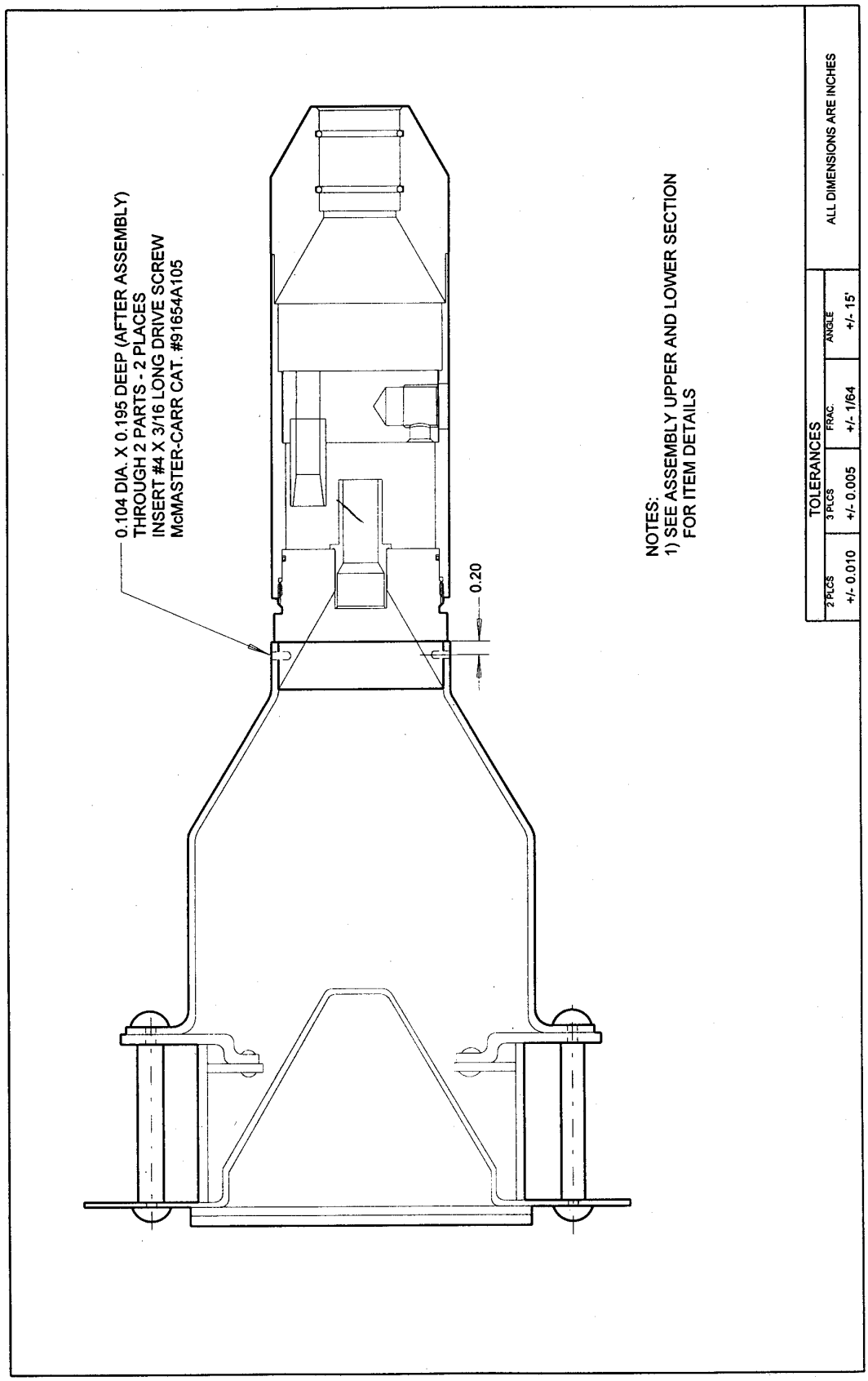

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Figure L-2. 10-Micron Inlet Assembly

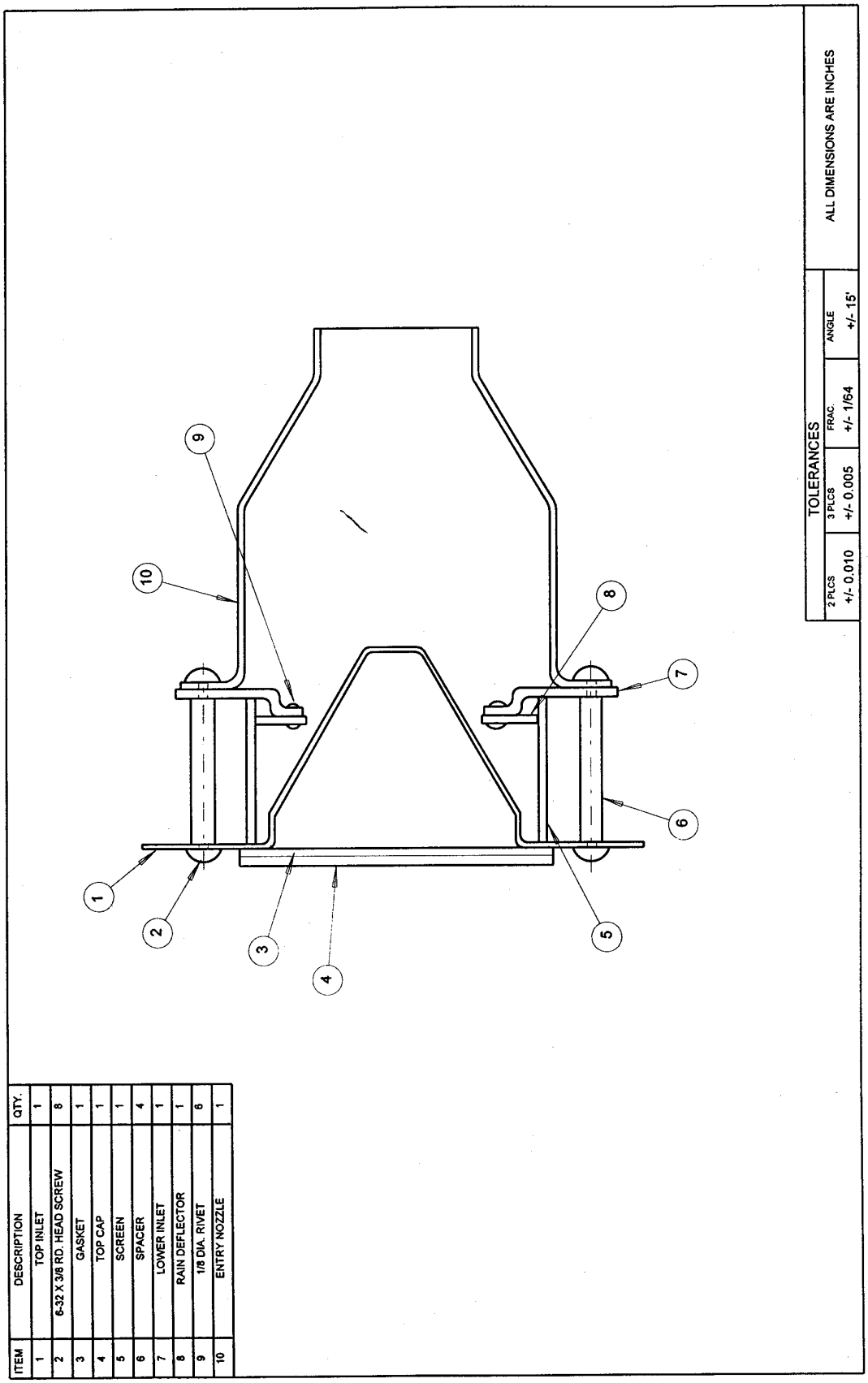

Figure L-3. 10-Micron Assembly, Upper Section

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Version 3

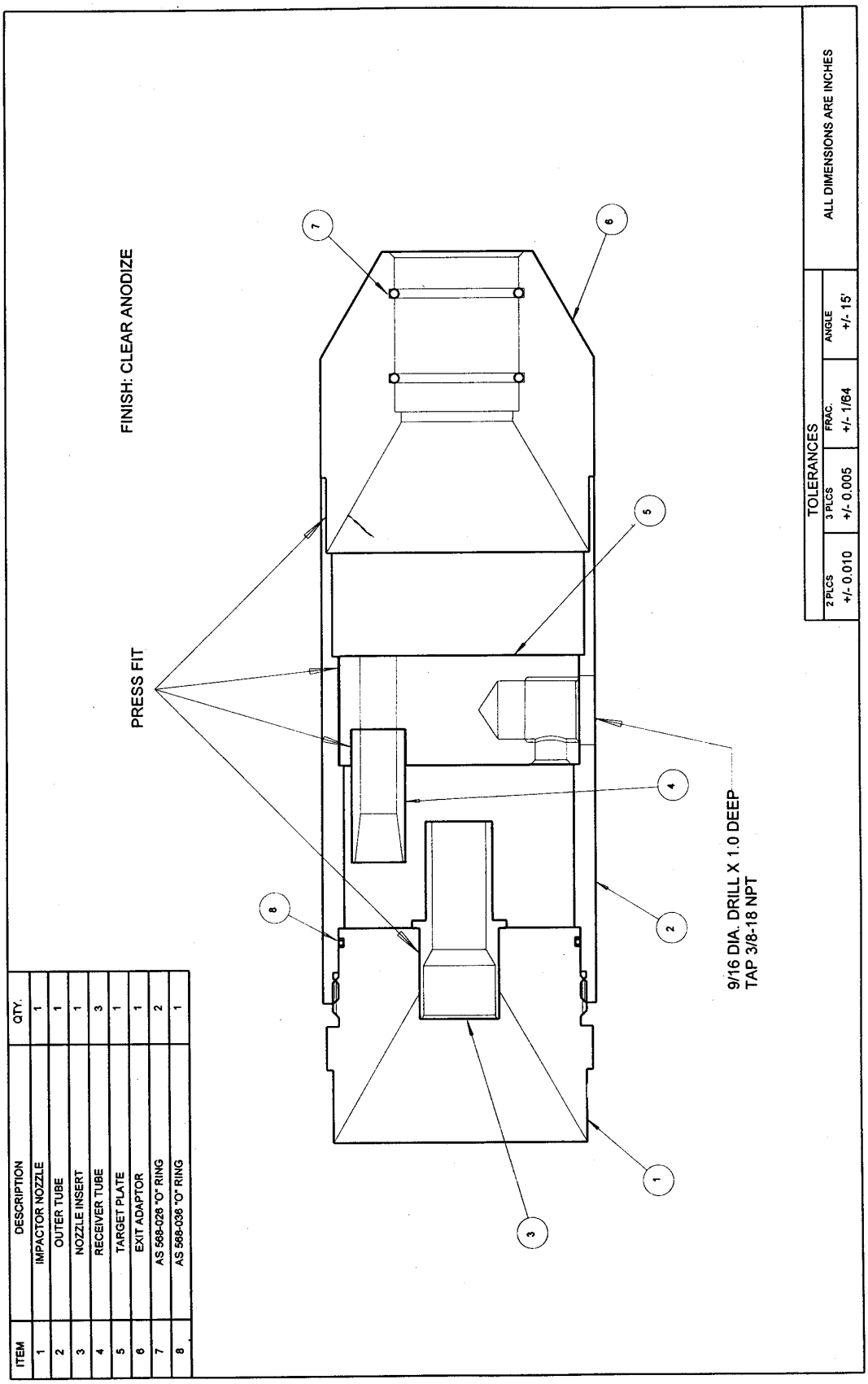

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Figure L-4. 10-Micron Assembly, Lower Section

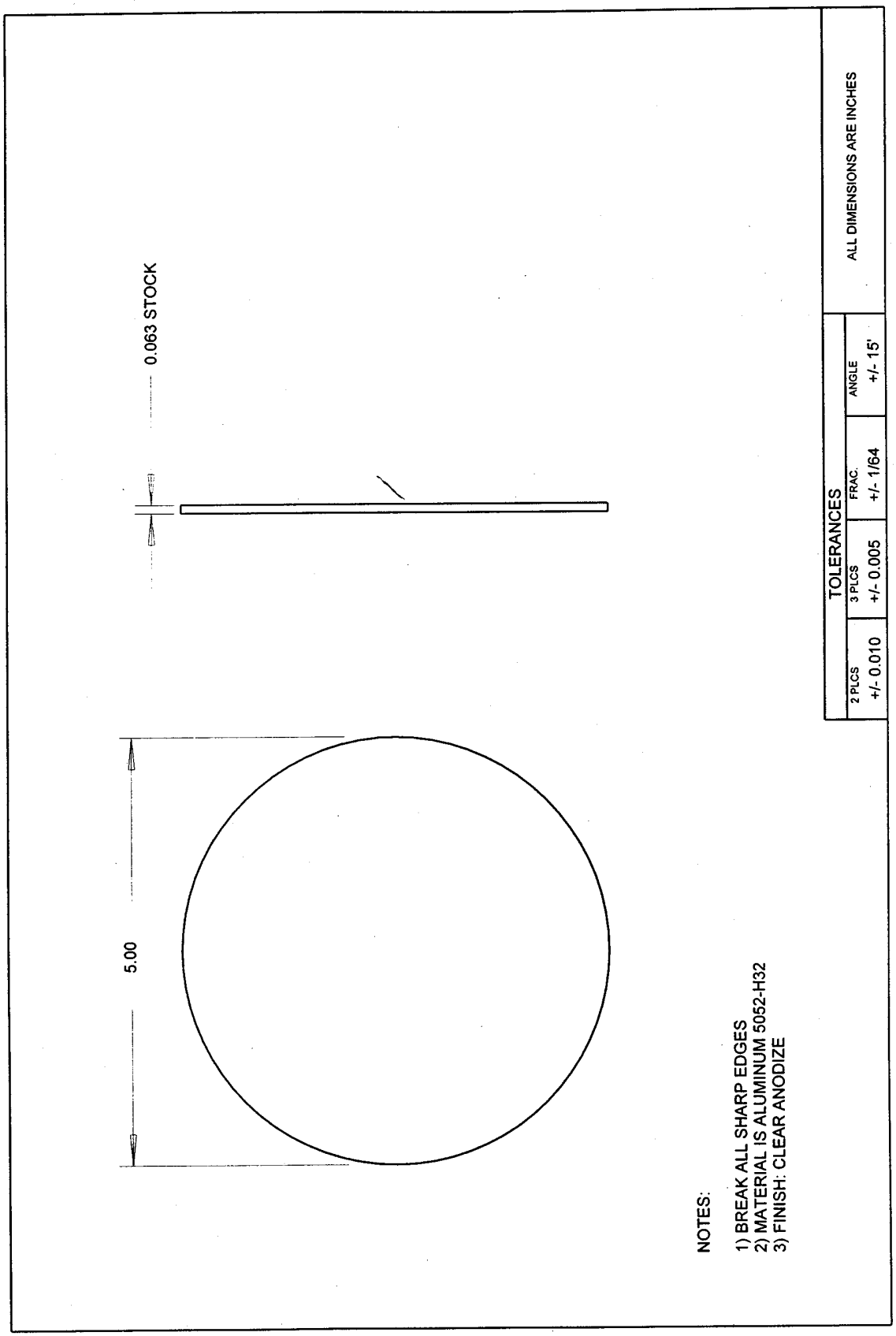

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Figure L-5. 10-Micron Top Cap

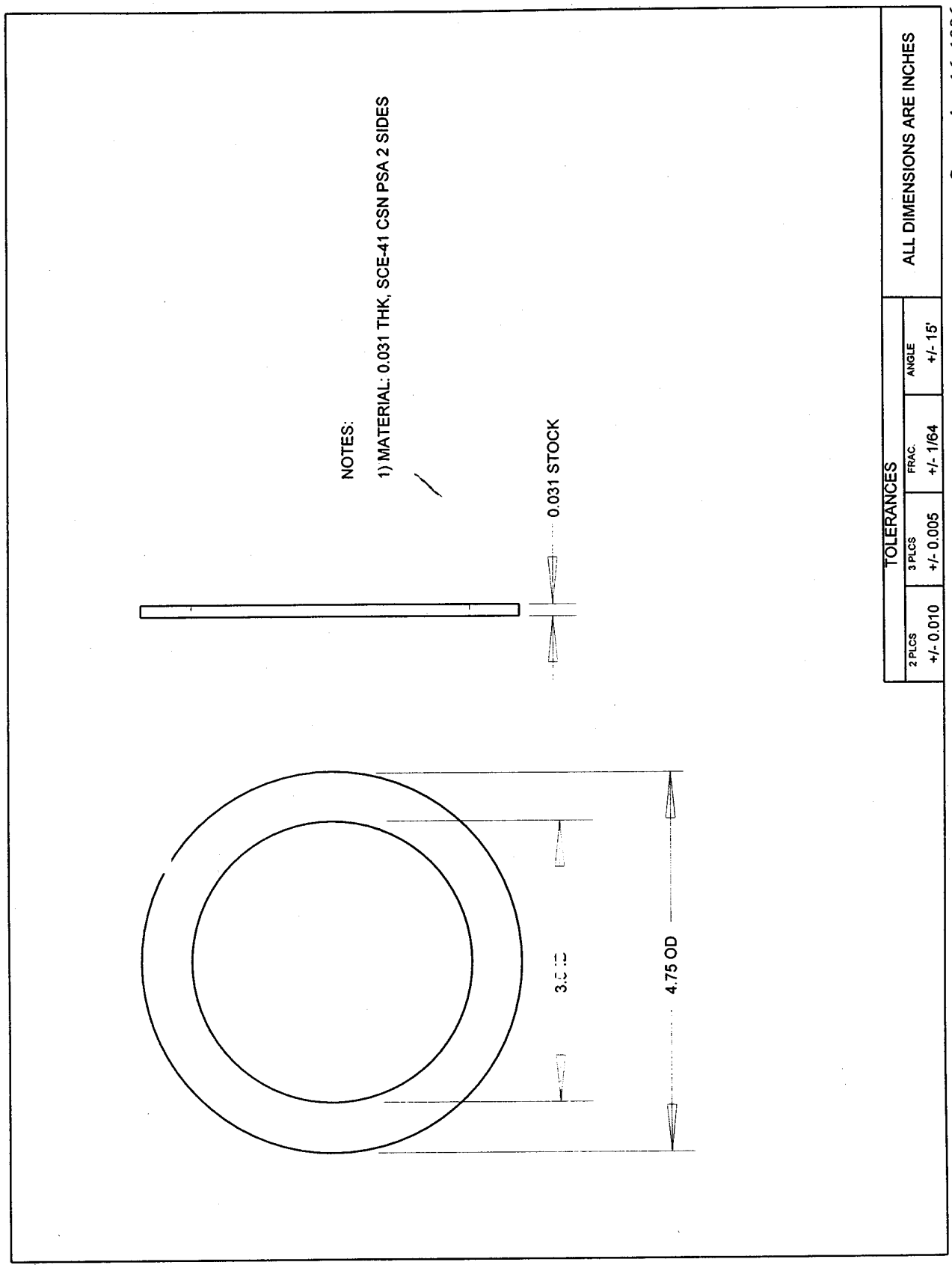

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Figure L-6. 10-Micron Gasket

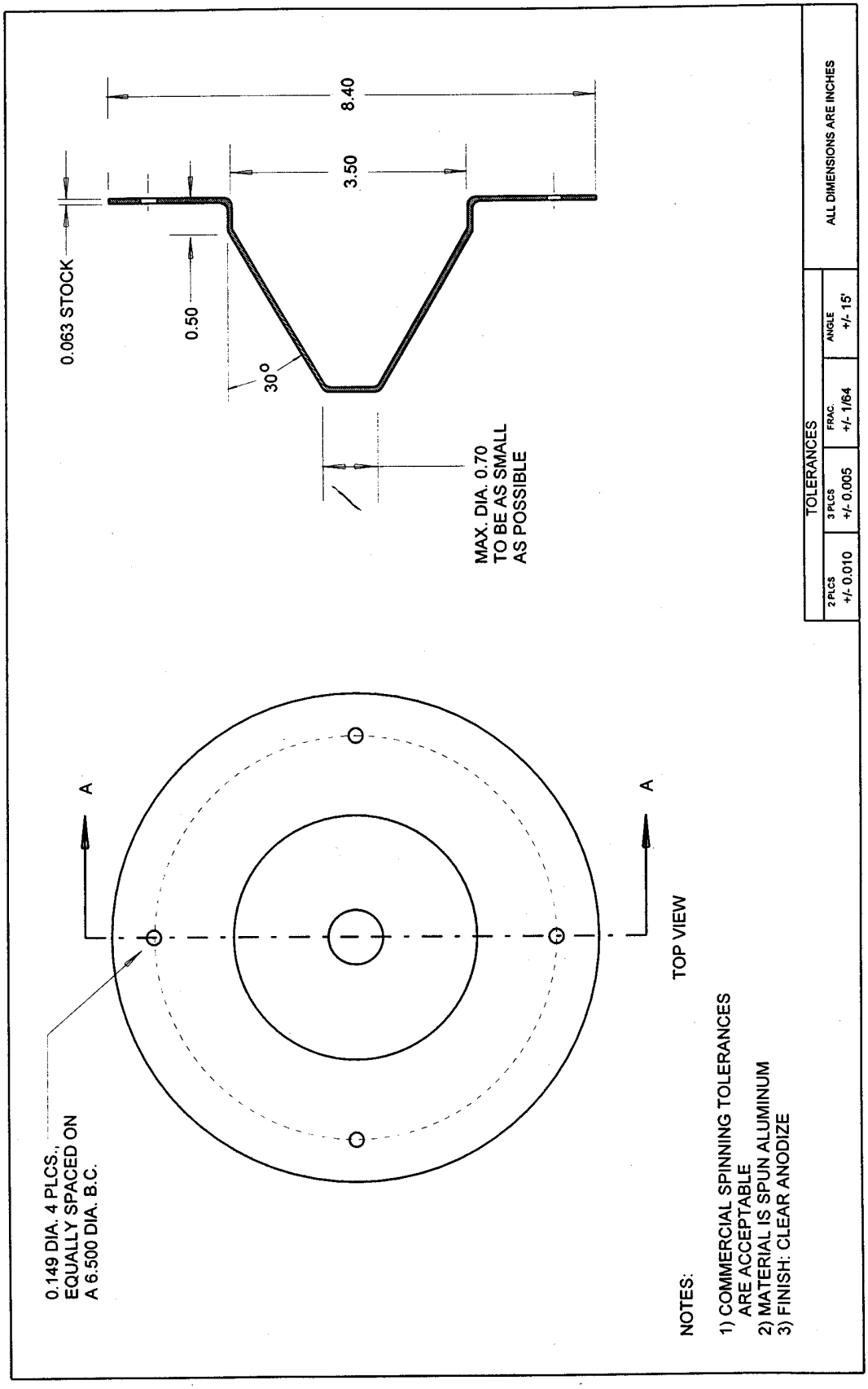

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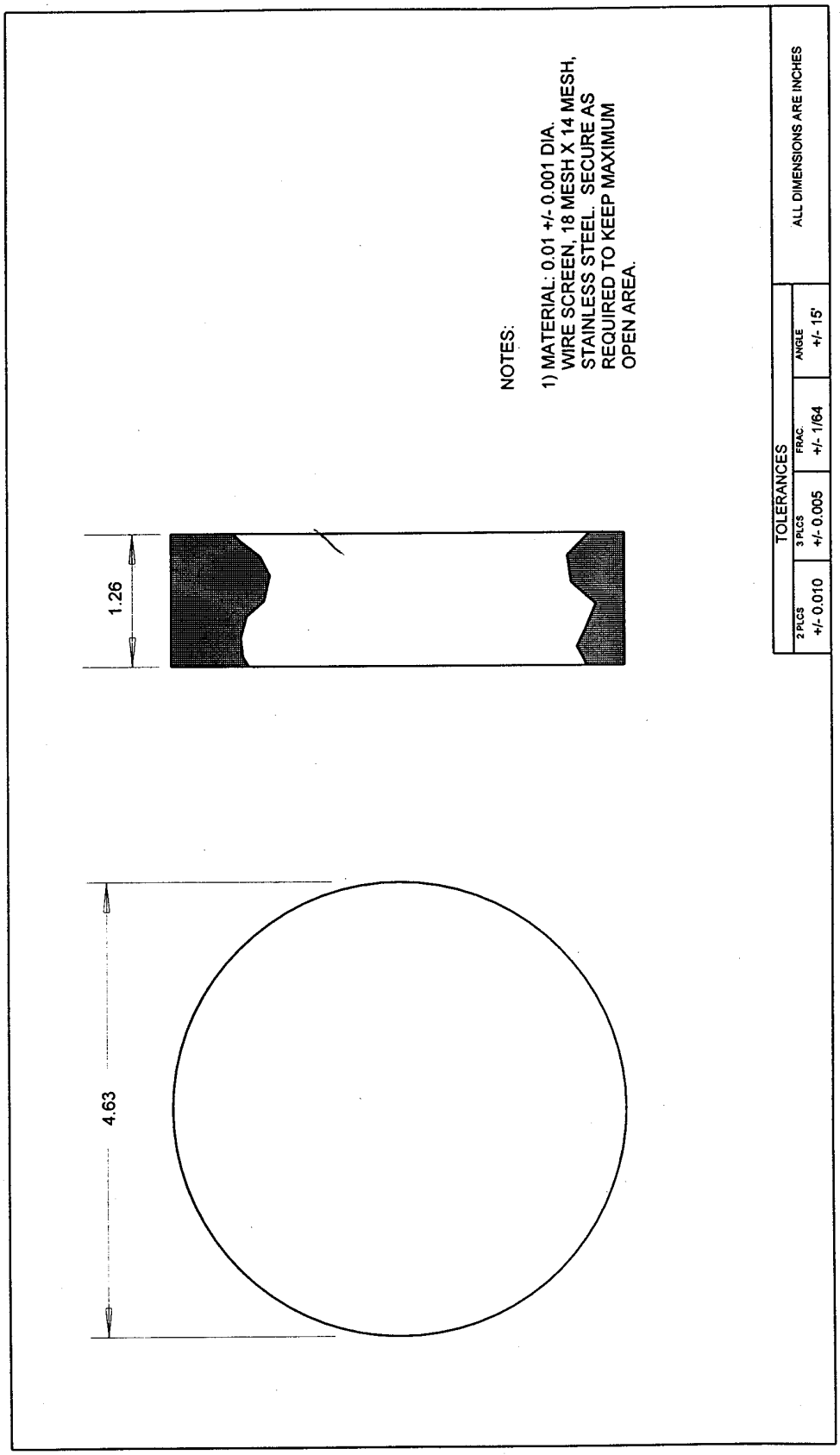
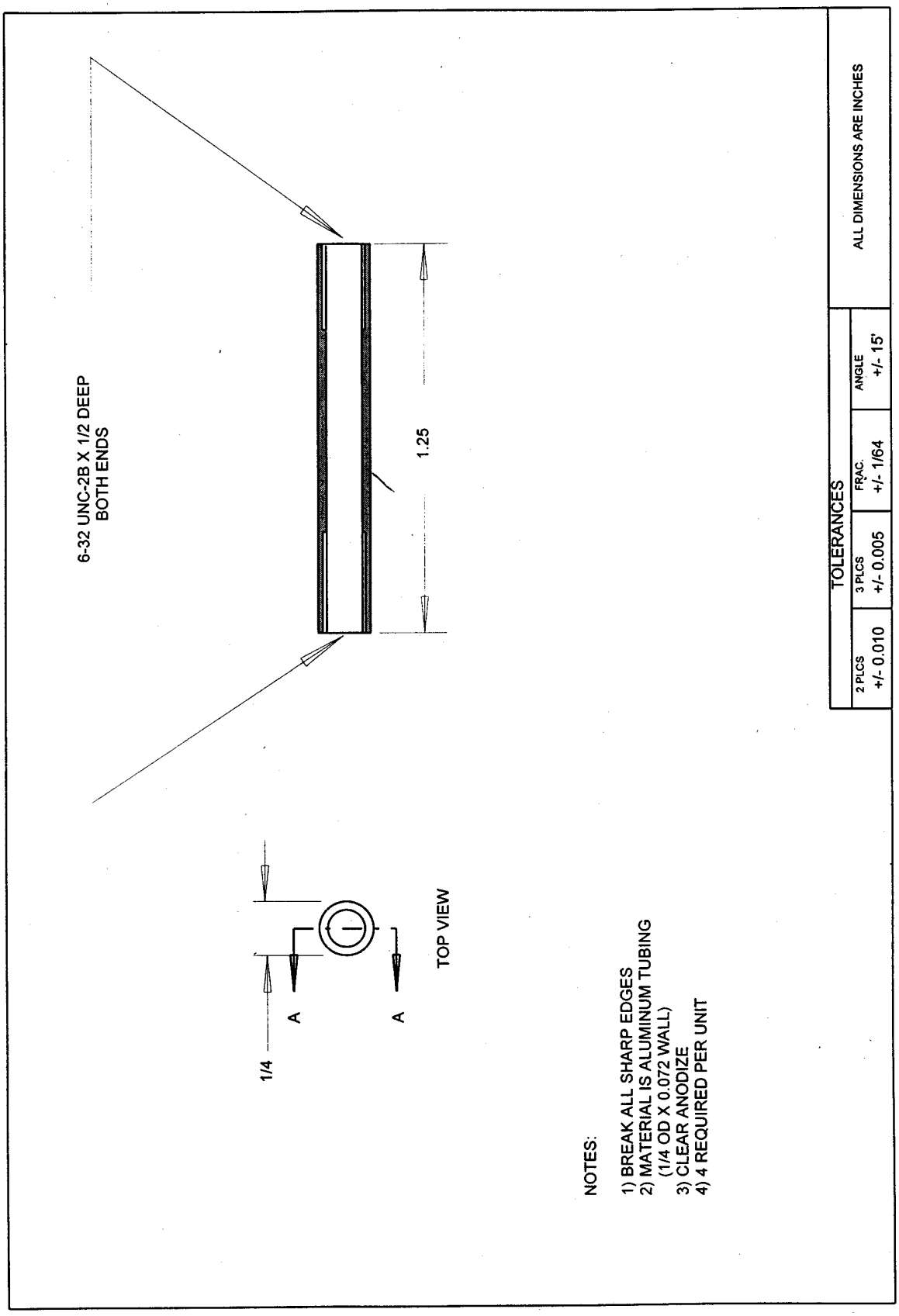
Figure L-7. 10-Micron Inlet, Top



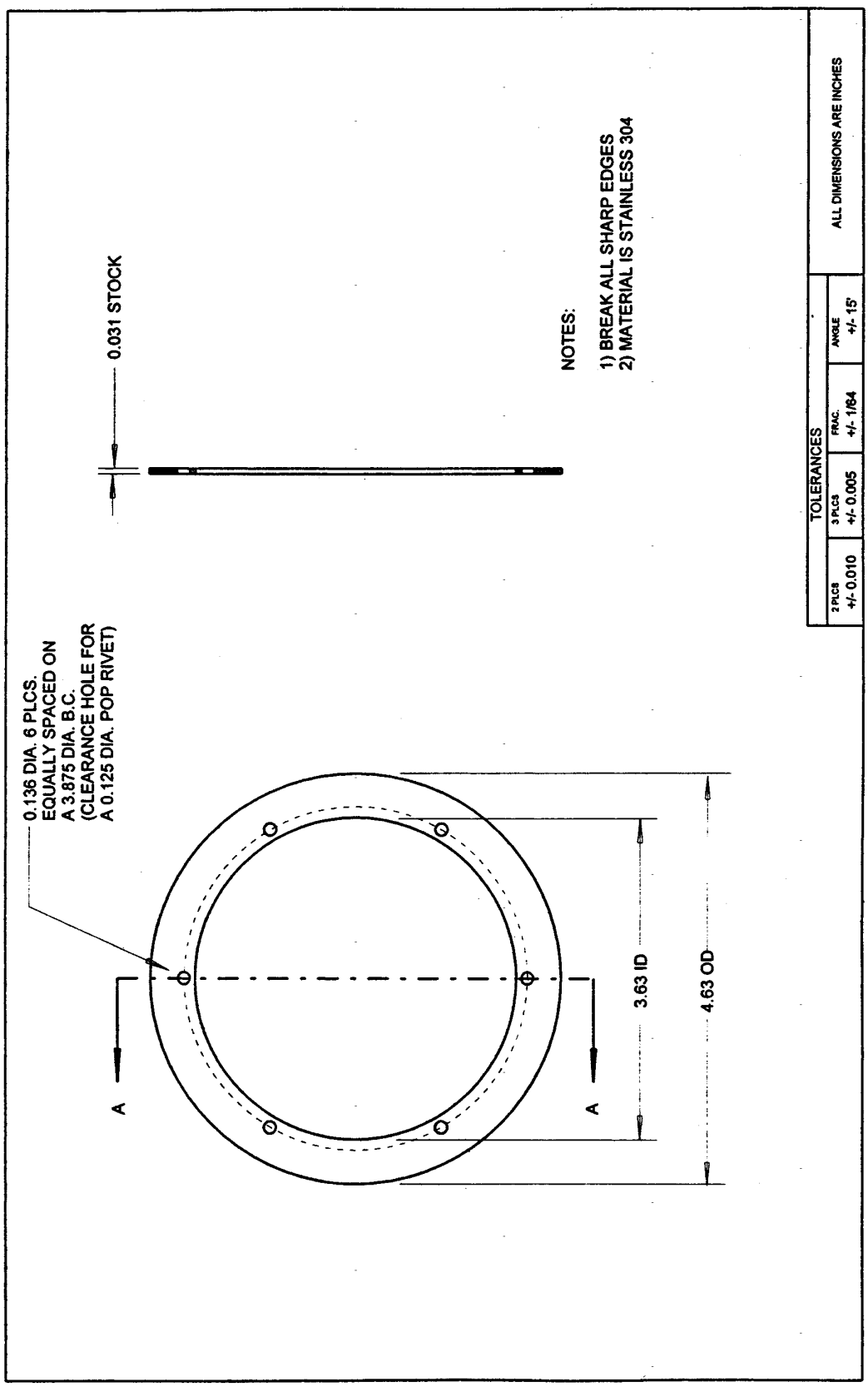
September 16, 1996
Version 4

Figure L-8. 10-Micron Screen



November 4, 1996
Version 5

Figure L-9. 10-Micron Spacer



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Version 5

Figure L-10. 10-Micron Rain Deflector

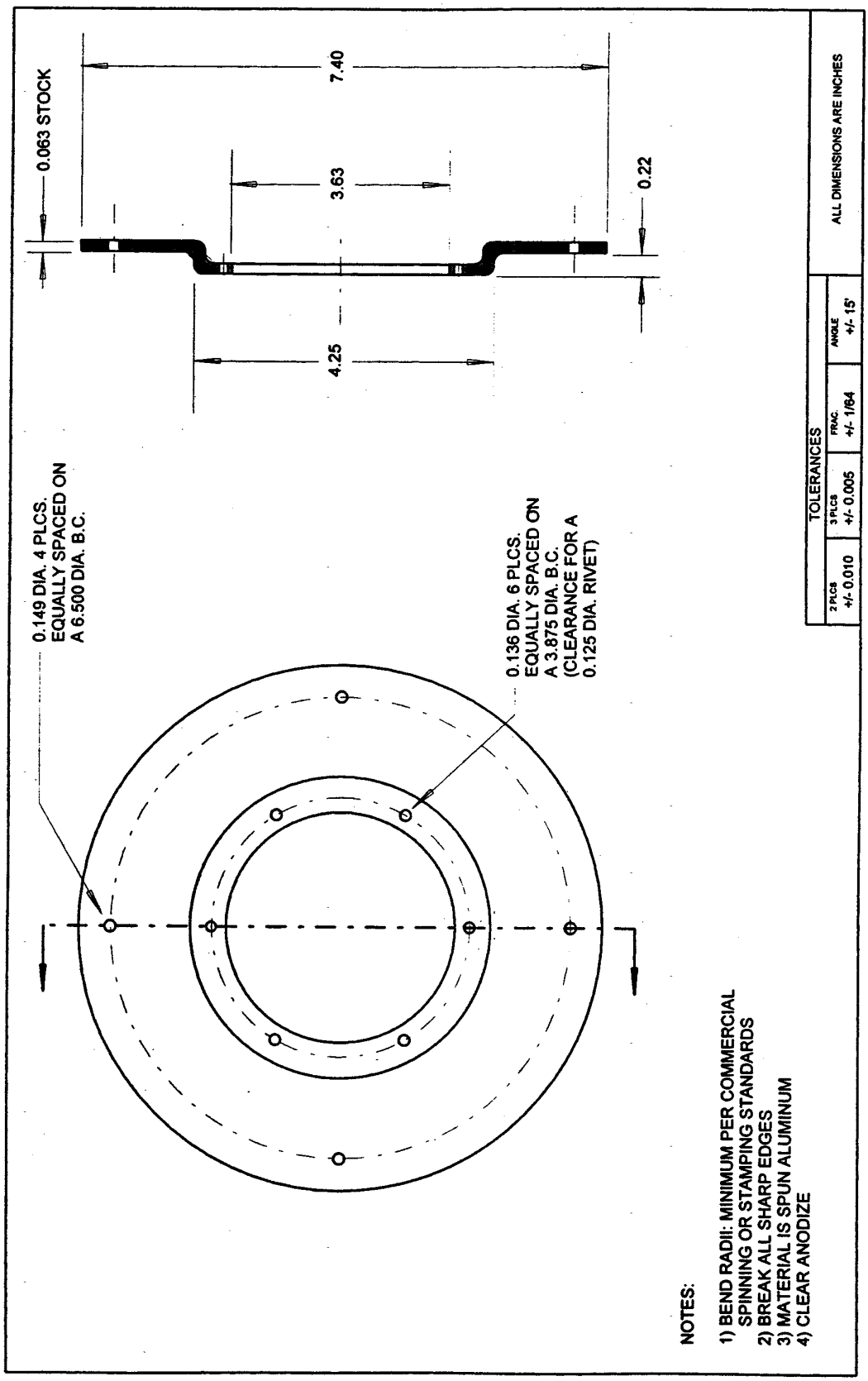

Figure L-11. 10-Micron Inlet, Lower

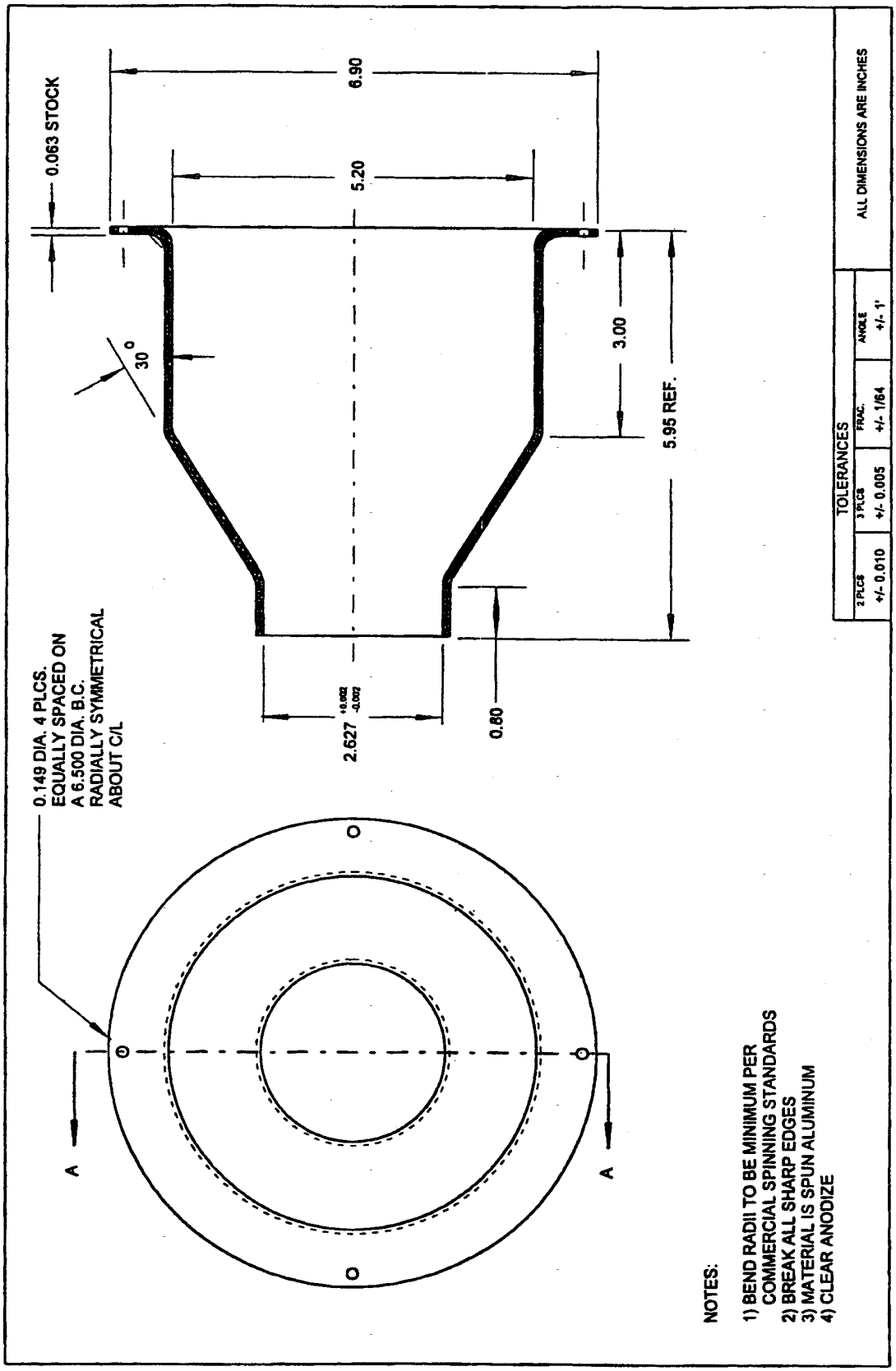

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Figure L-12. 10-Micron Nozzle Entry Section

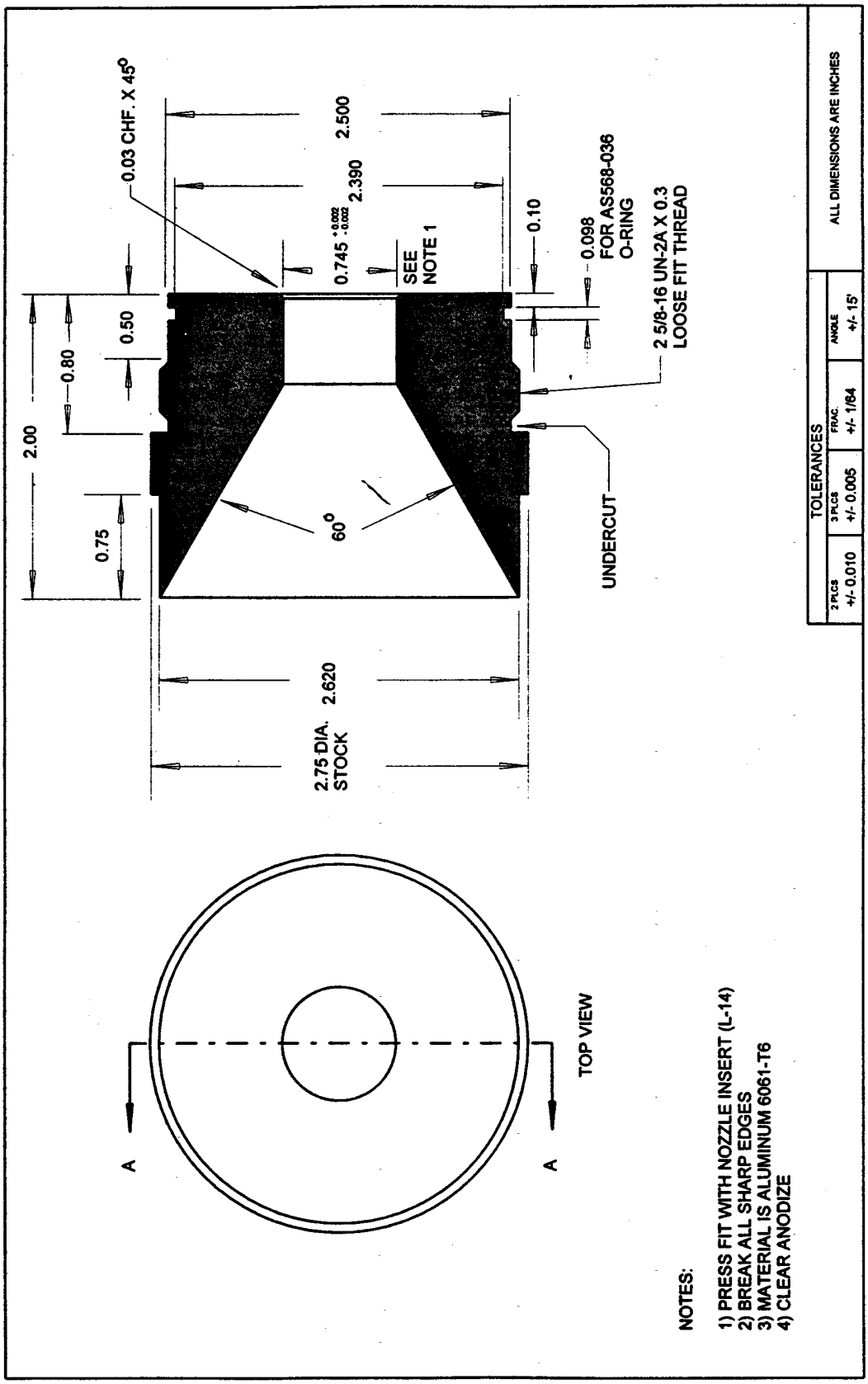

Figure L-13. 10-Micron Impactor Nozzle

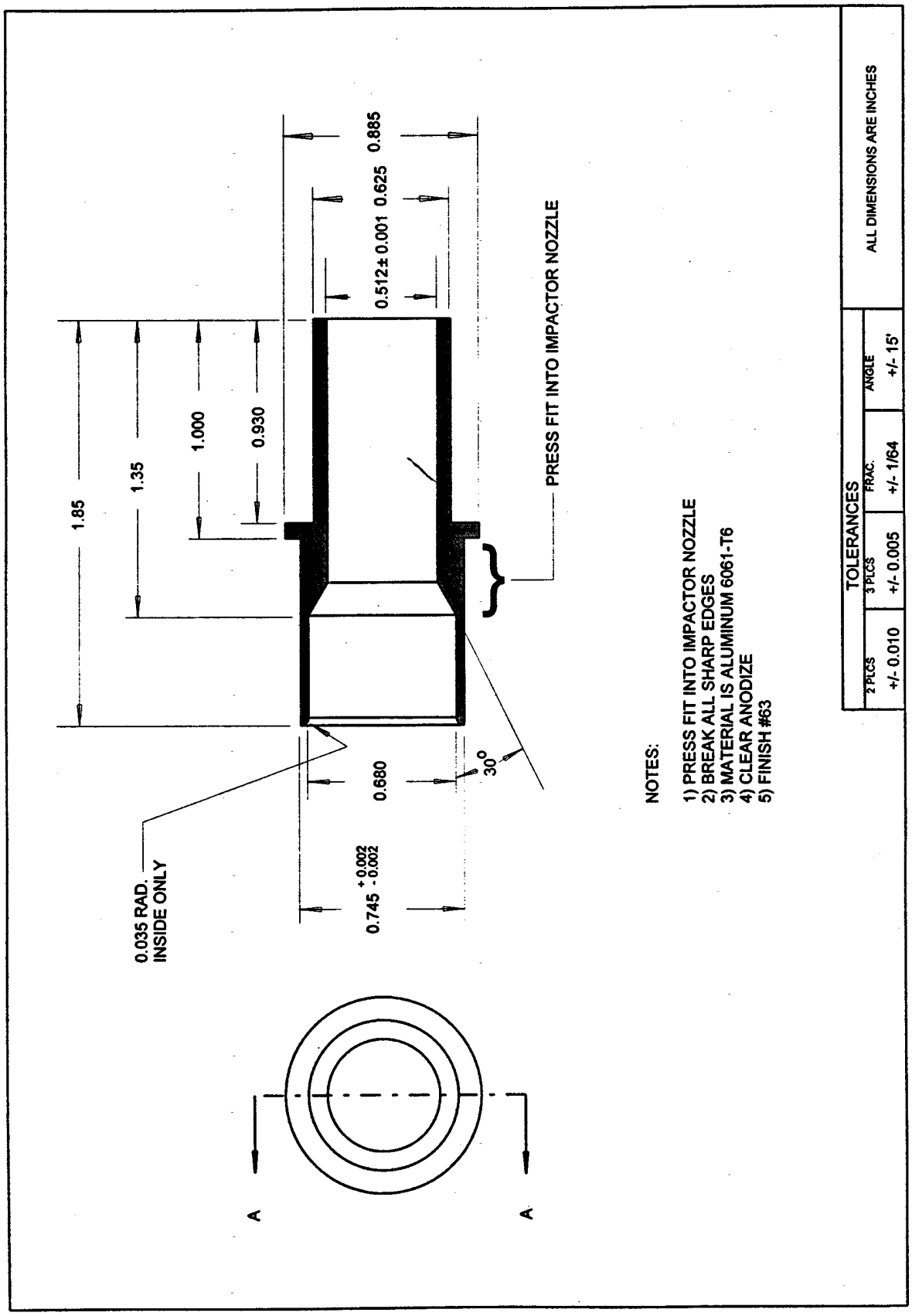

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Figure L-14. 10-Micron Nozzle Insert

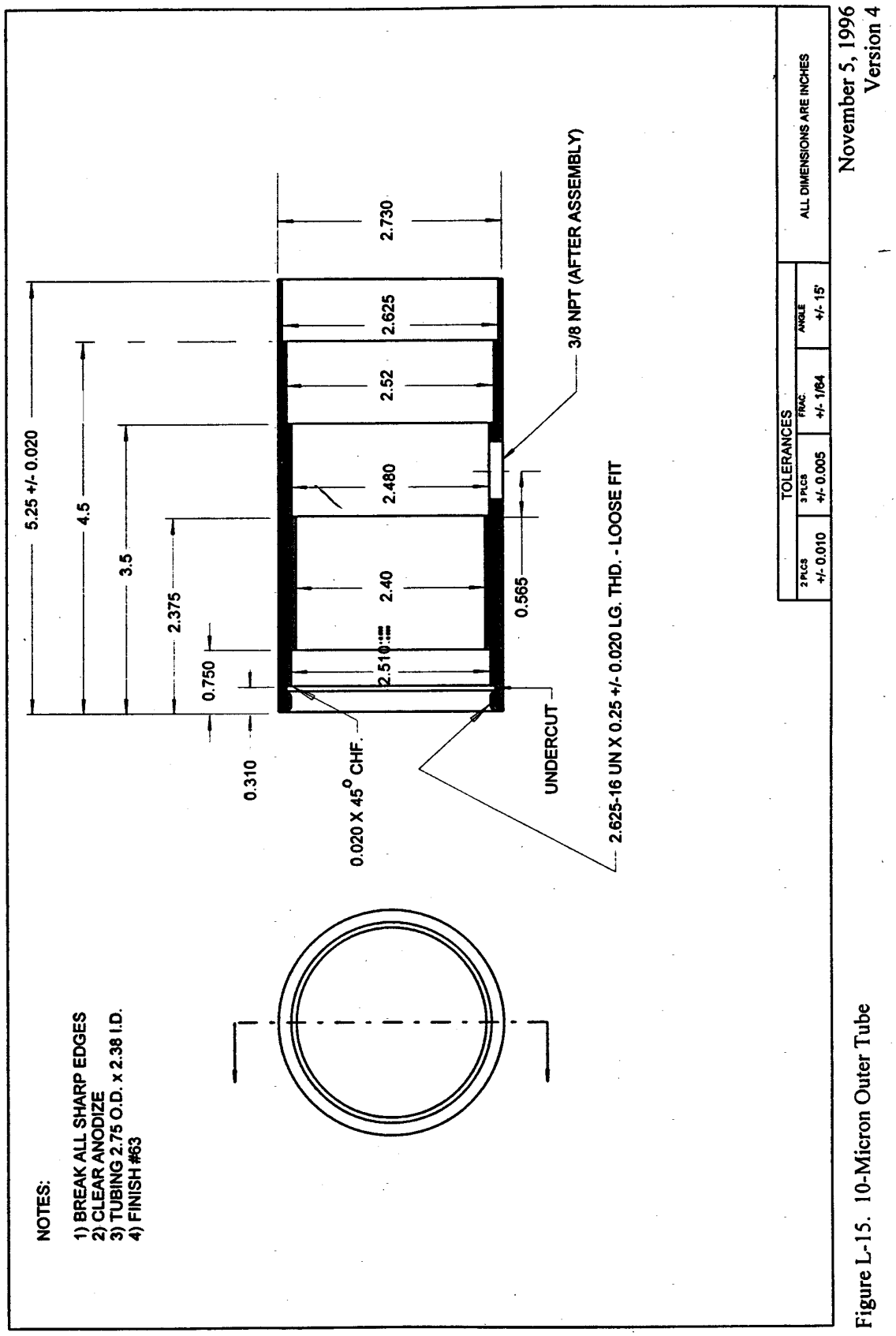

Figure L-15. 10-Micron Outer Tube

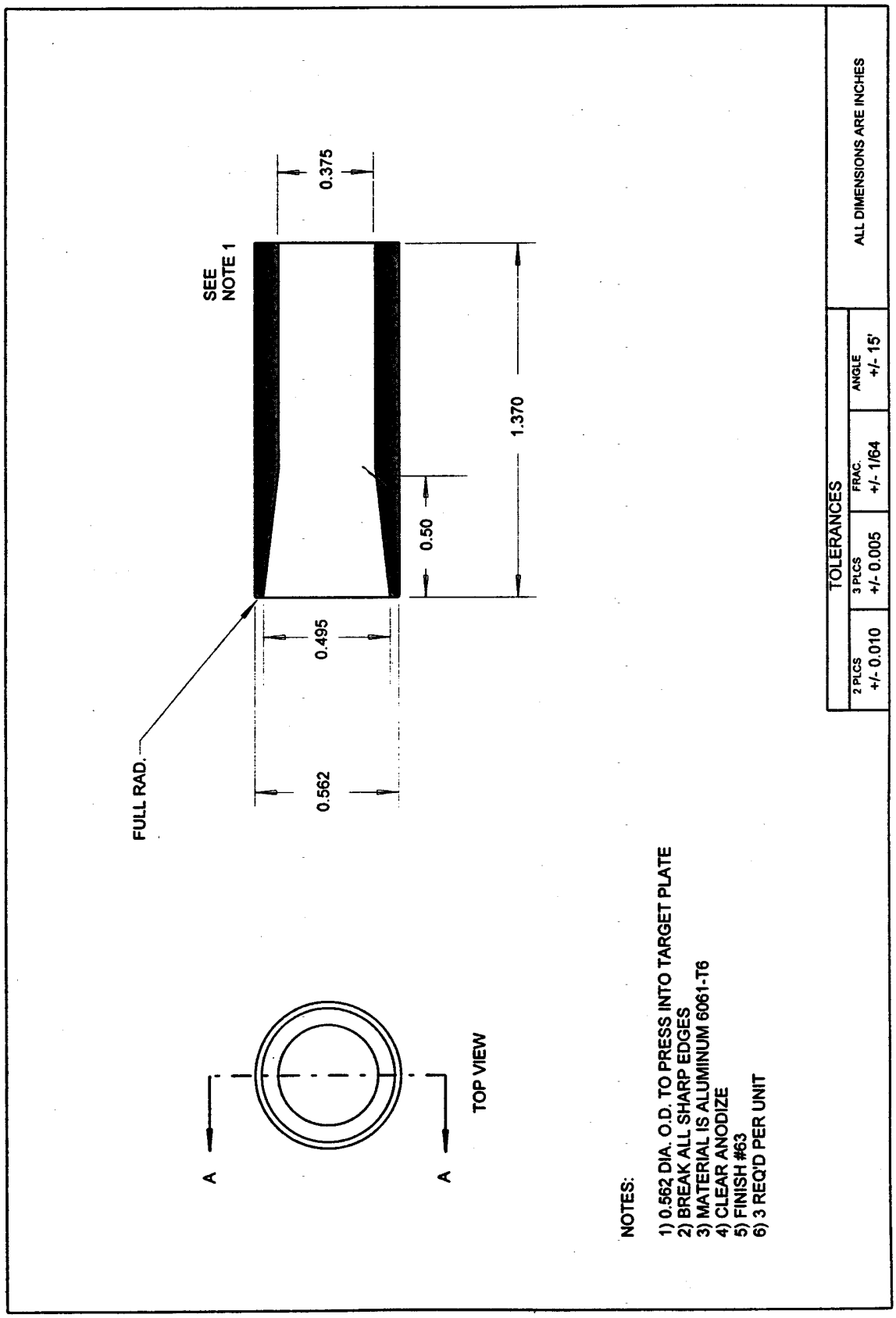

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Figure L-16. 10-Micron Receiver Tube

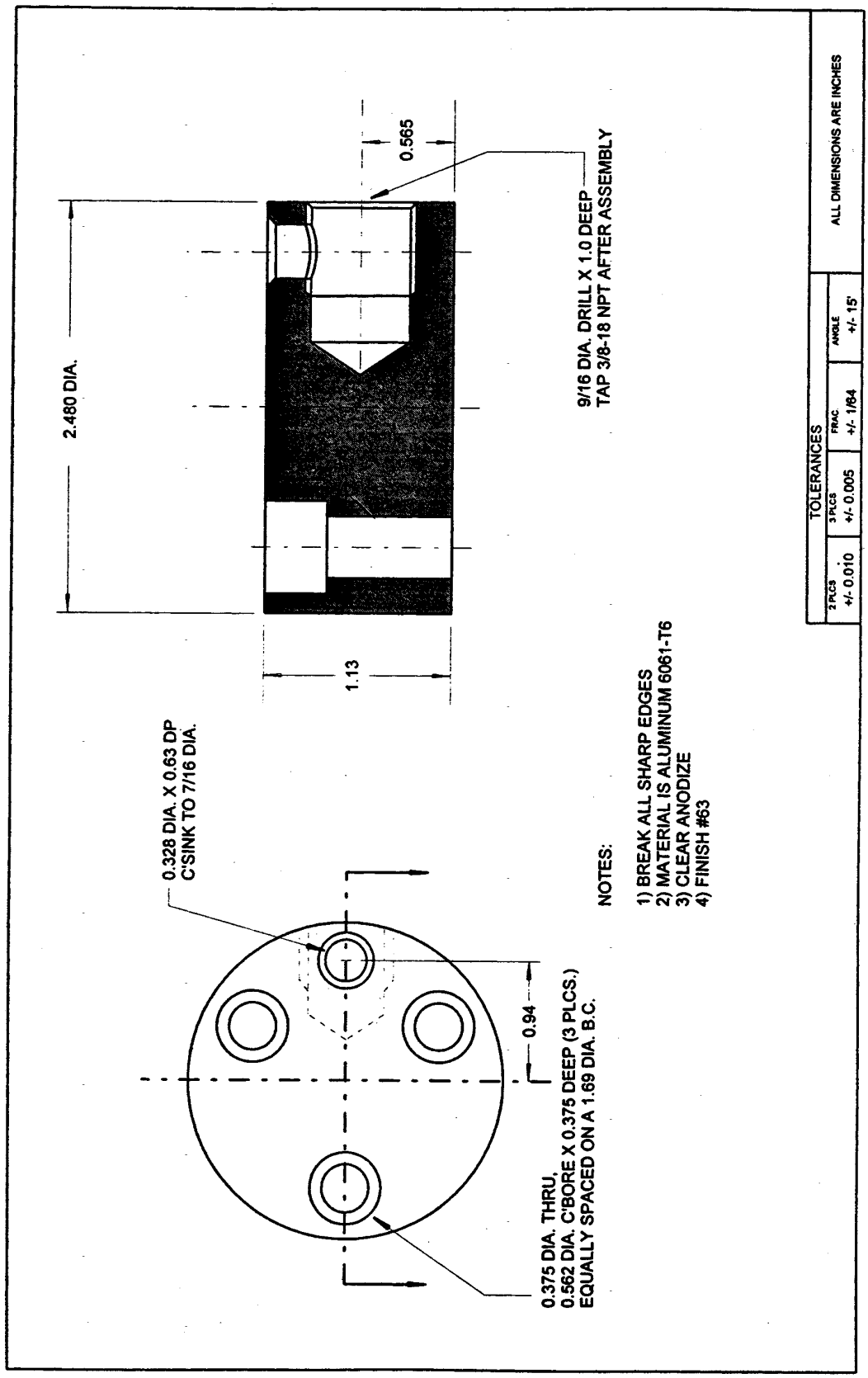

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Figure L-17. 10-Micron Target Plate

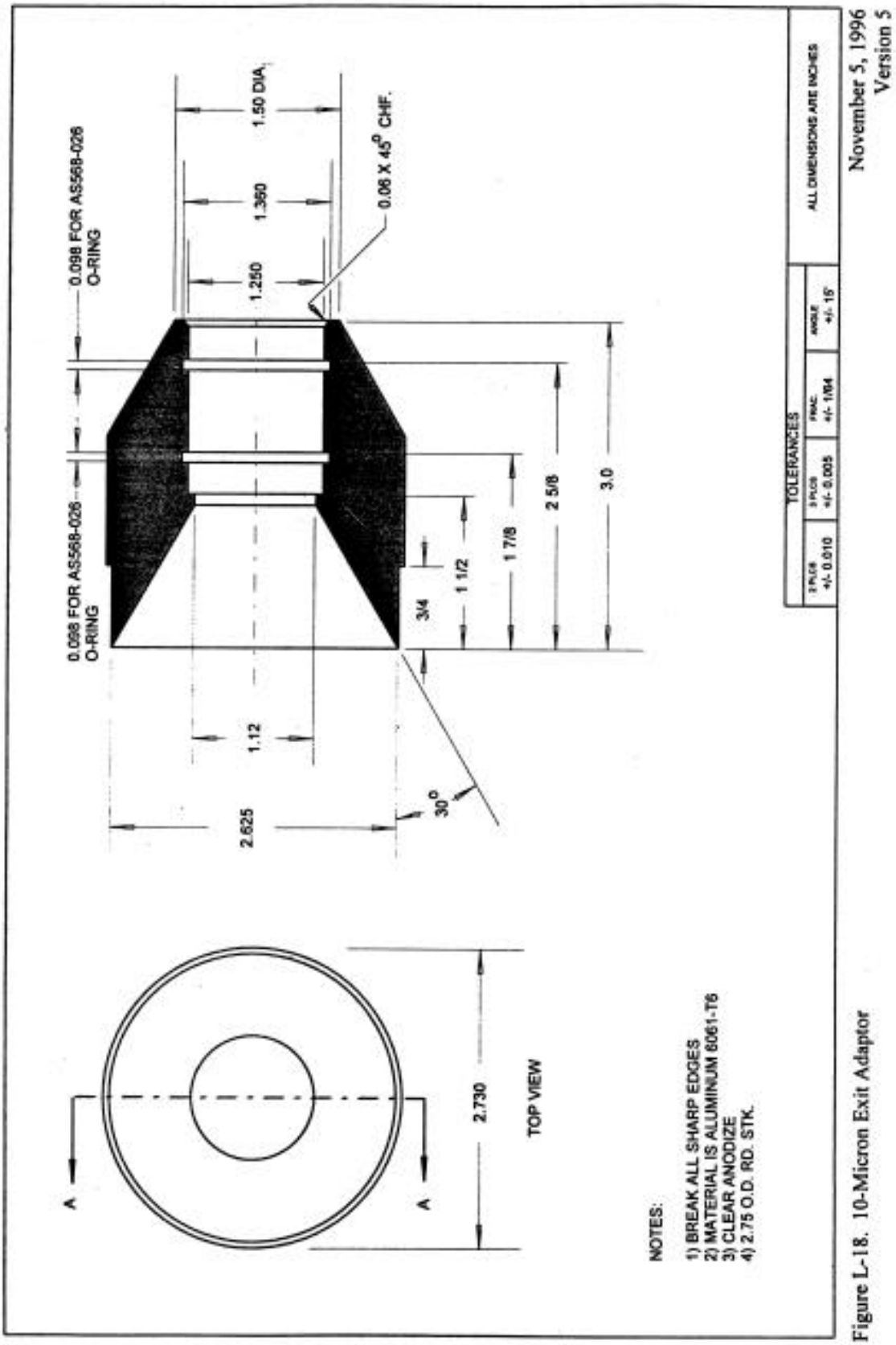

Figure L-18. 10-Micron Exit Adaptor

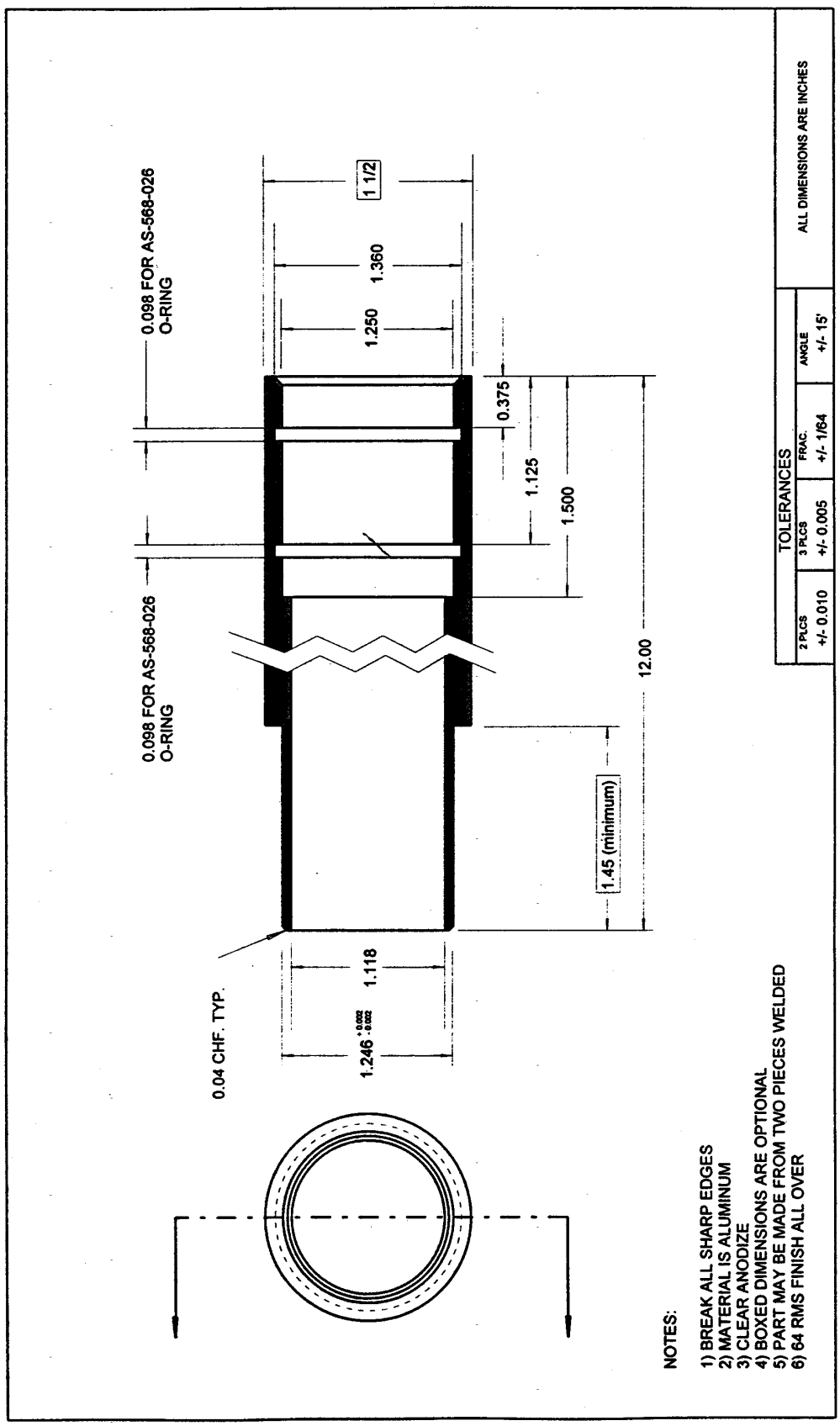

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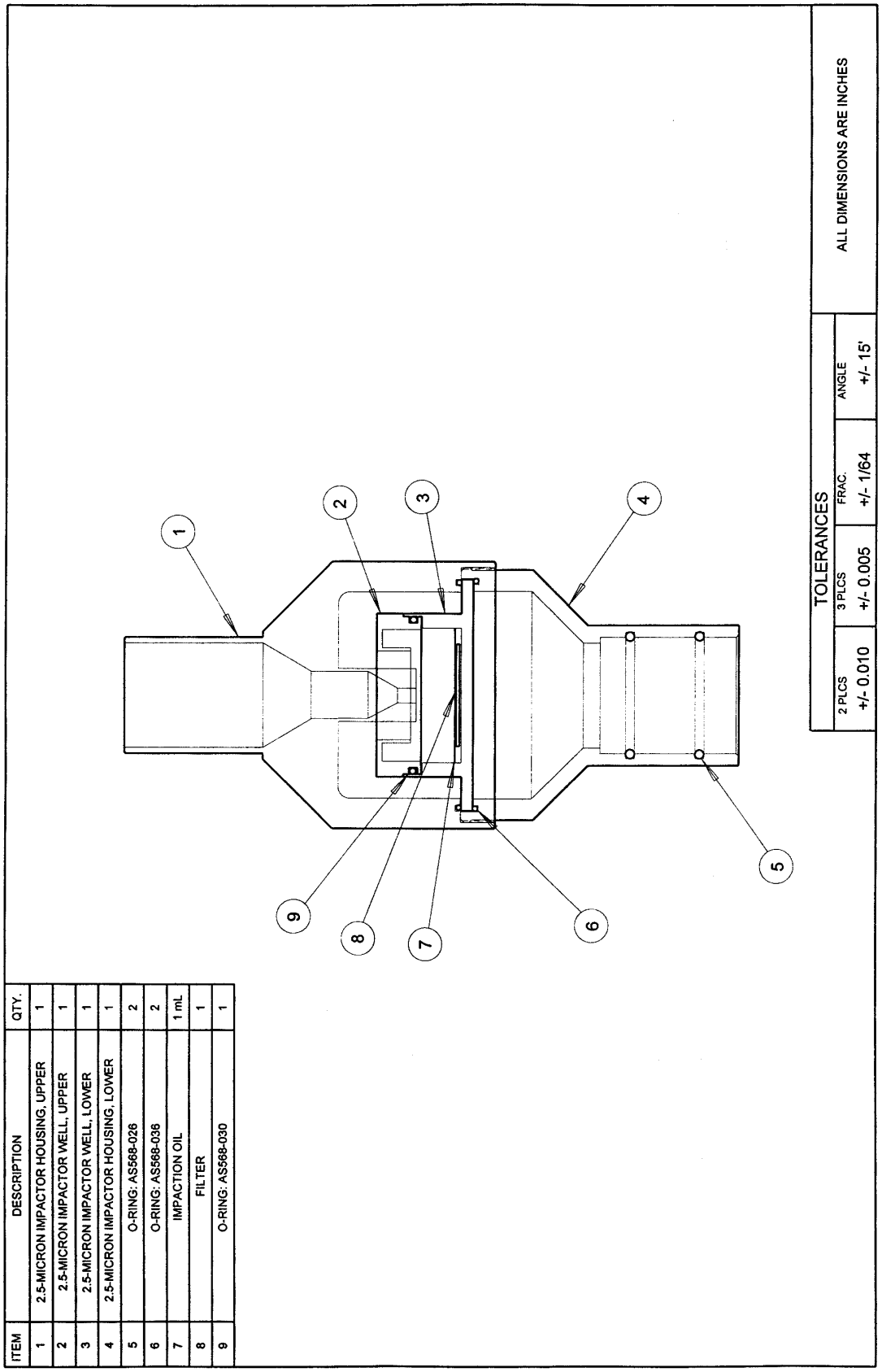
Figure L-19. 10-Micron Down Tube



ITEM	DESCRIPTION	QTY.
1	2.5-MICRON IMPACTOR HOUSING, UPPER	1
2	2.5-MICRON IMPACTOR WELL, UPPER	1
3	2.5-MICRON IMPACTOR WELL, LOWER	1
4	2.5-MICRON IMPACTOR HOUSING, LOWER	1
5	O-RING: AS568-026	2
6	O-RING: AS568-036	2
7	IMPACTION OIL	1 mL
8	FILTER	1
9	O-RING: AS568-030	1

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Figure L-20. 2.5-Micron Impactor Assembly

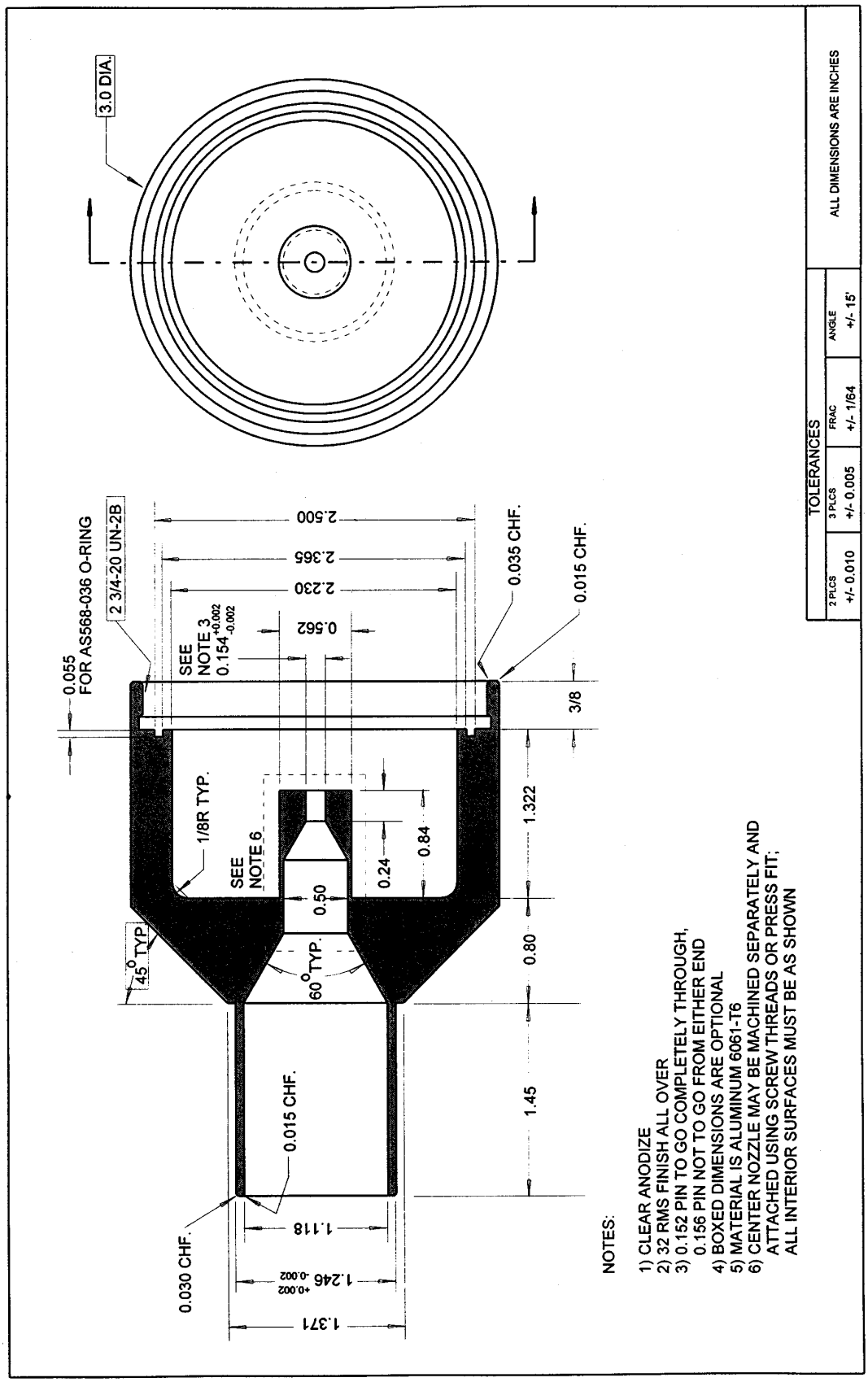

Figure L-21. 2.5-Micron Impactor Housing, Upper

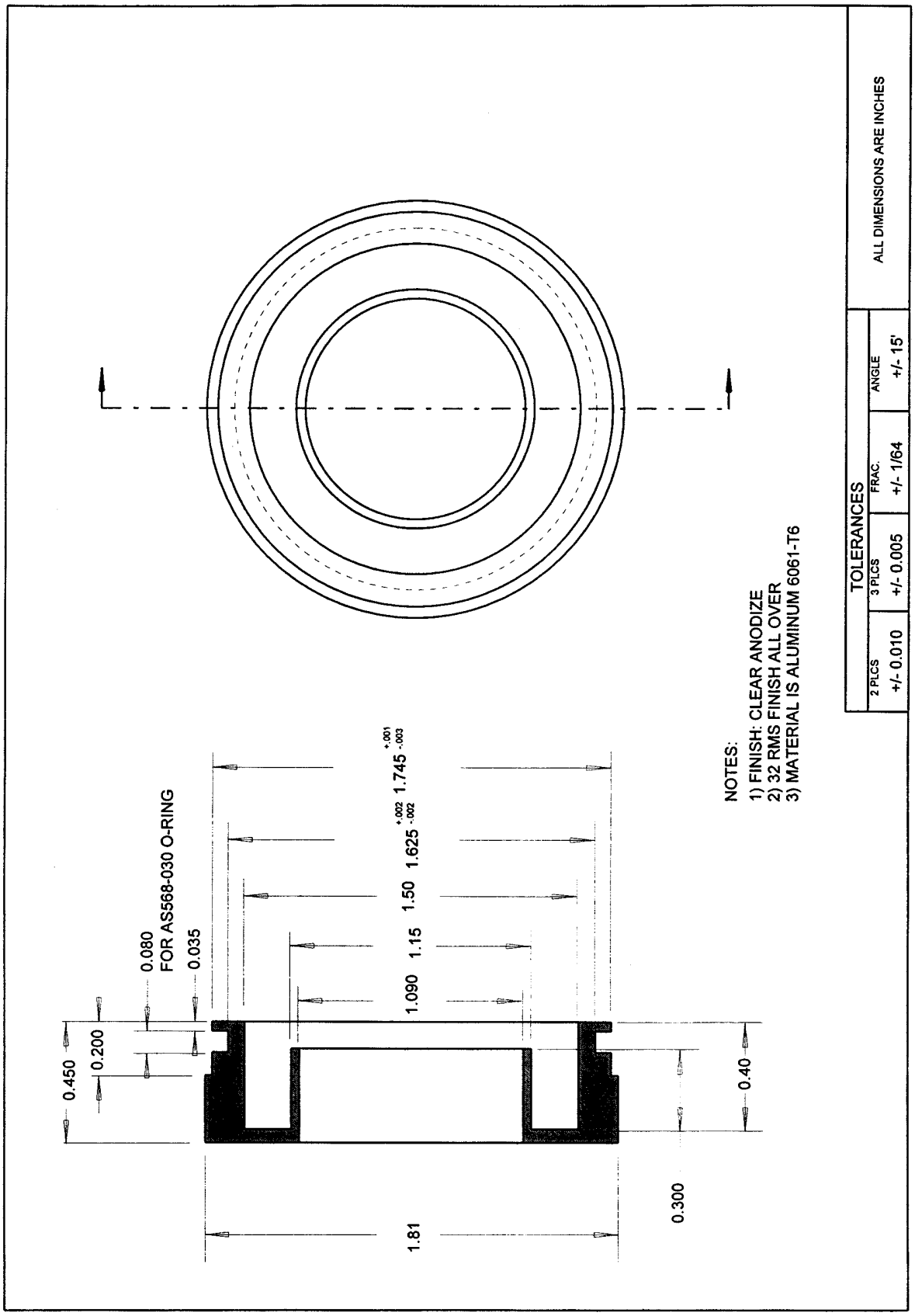

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Figure L-22. 2.5-Micron Impactor Well, Upper Section

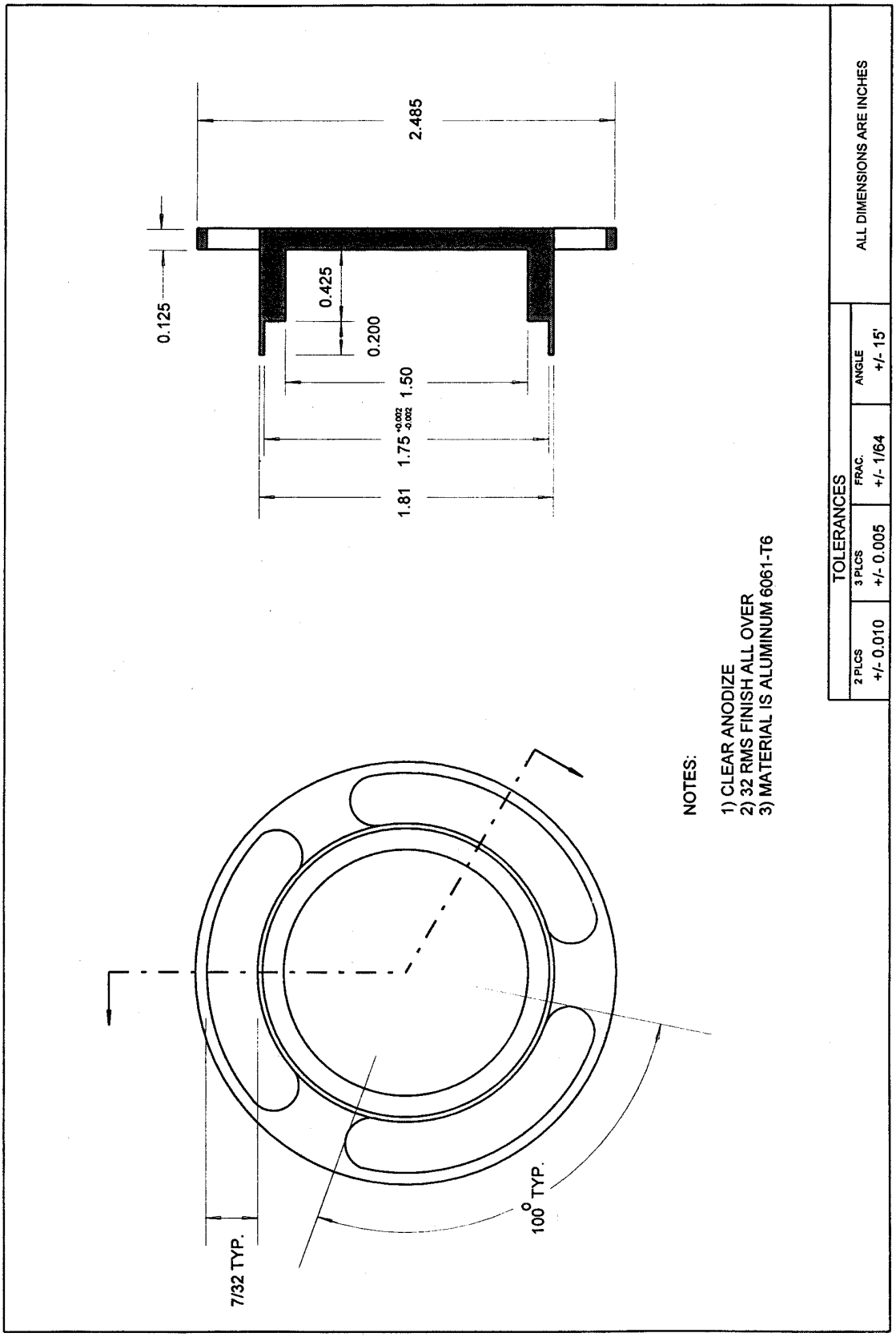

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Figure L-23. 2.5-Micron Impactor Well, Lower Section

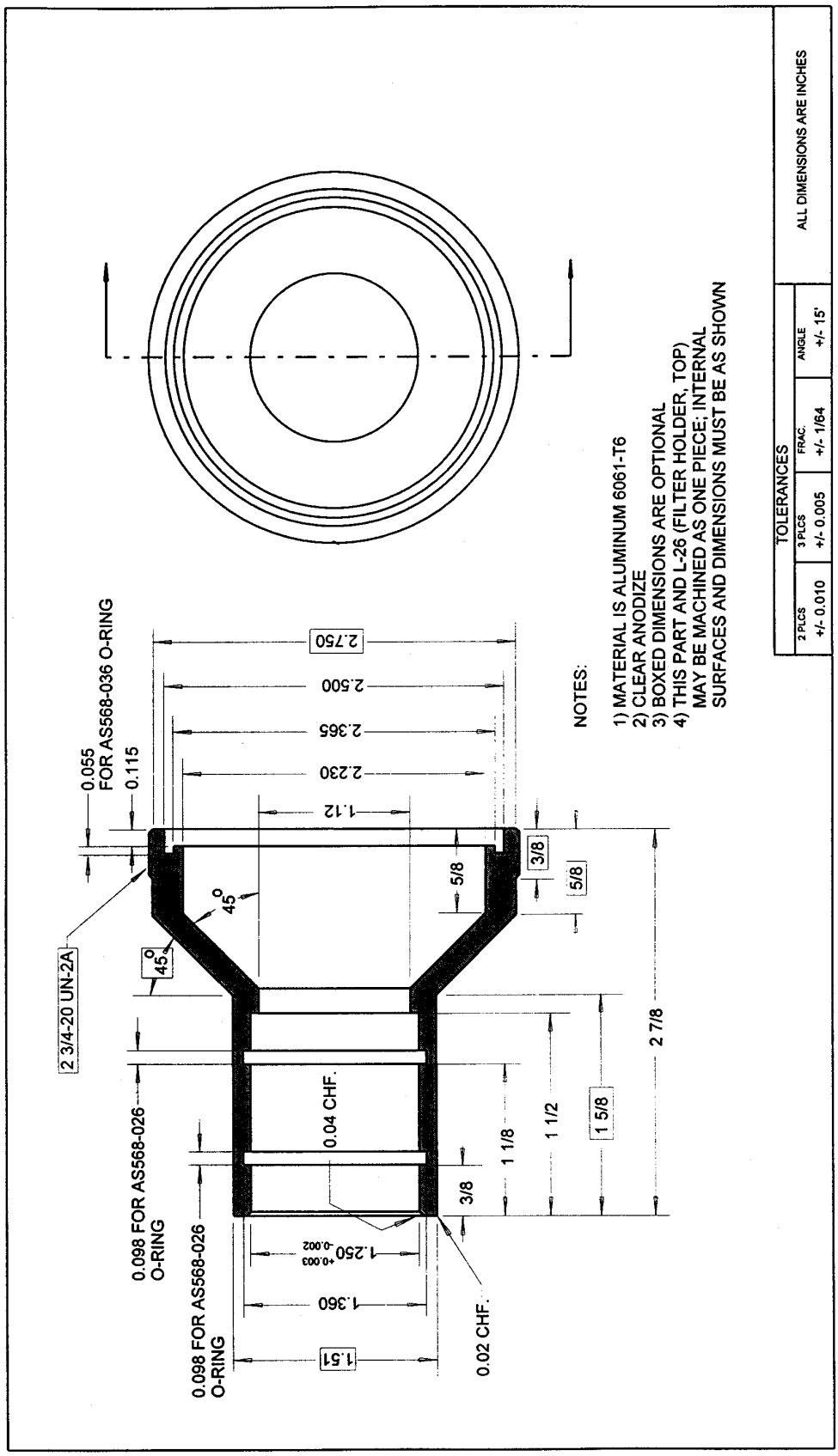

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Figure L-24. 2.5-Micron Impactor Housing, Lower

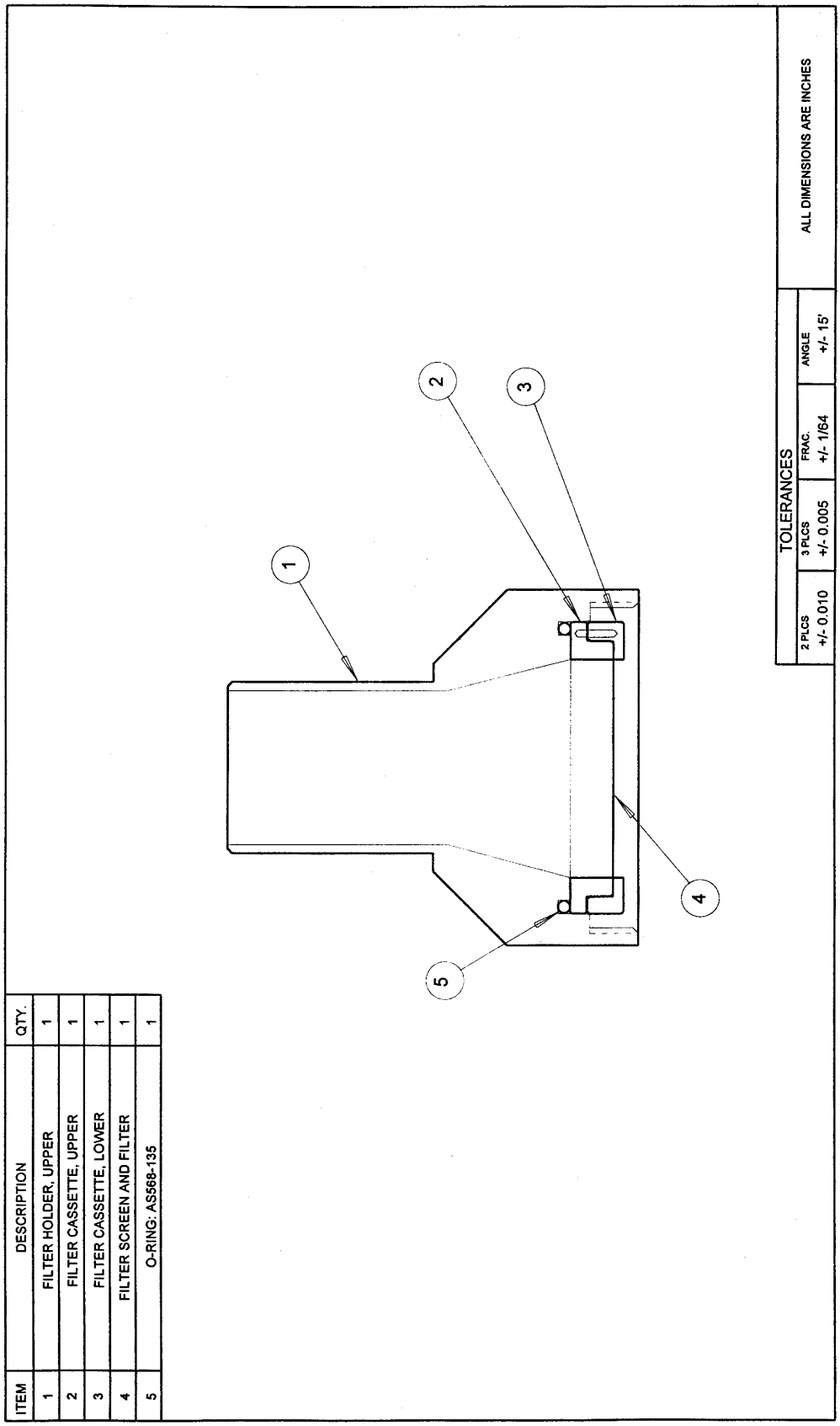

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Figure L-25. Filter Holder, Assembly

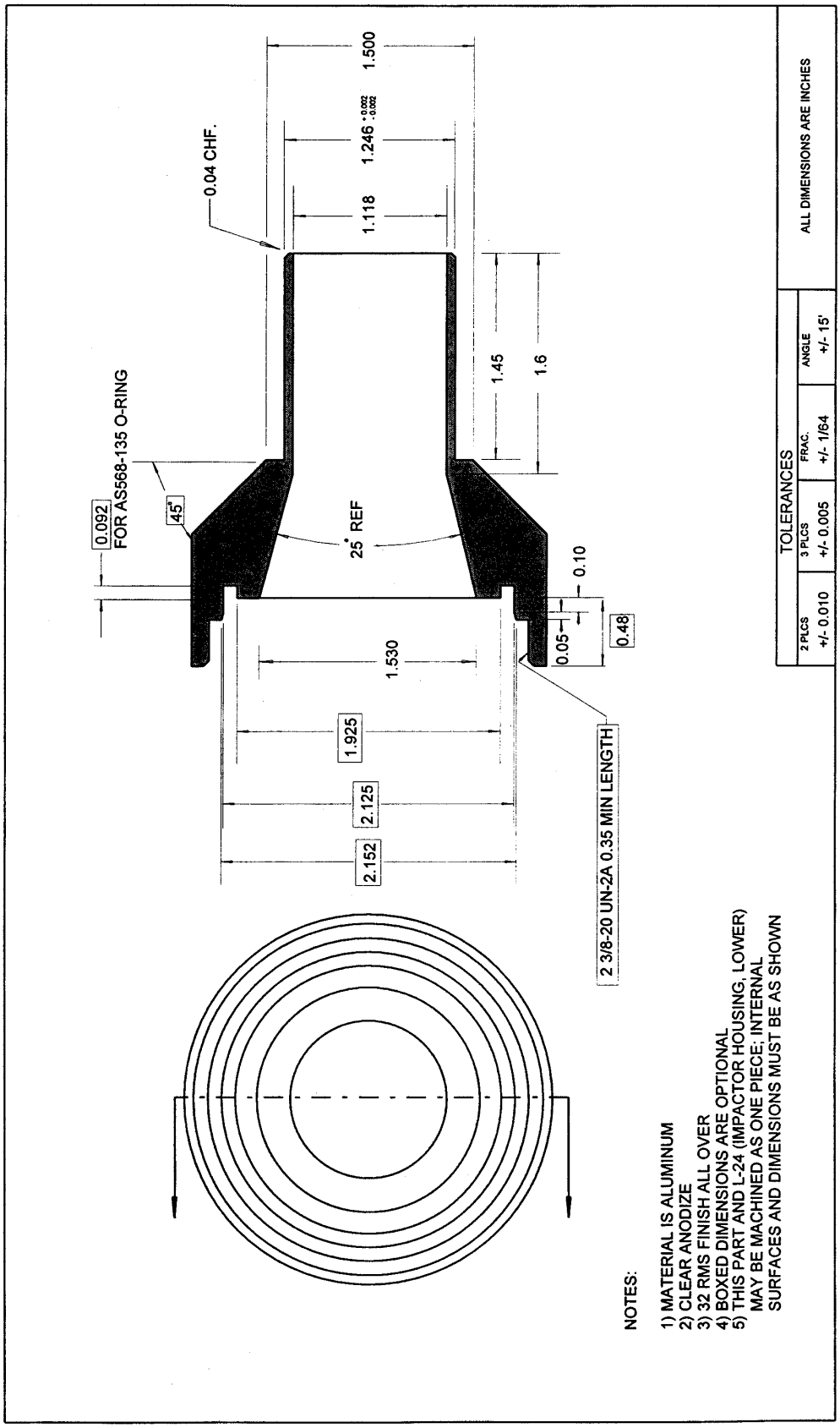

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Figure L-26. Filter Holder, Top

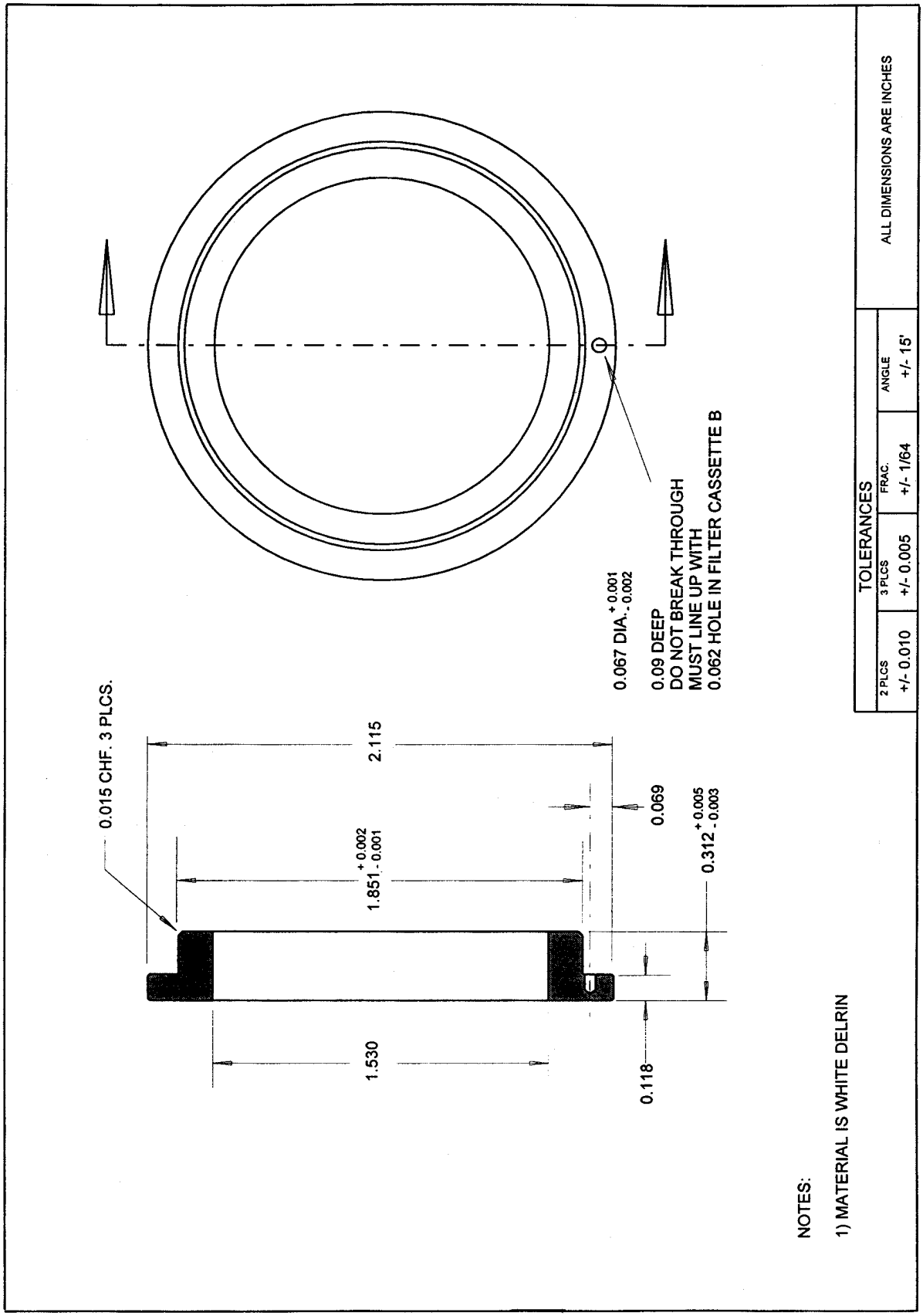

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Figure L-27. Filter Cassette, Upper Section

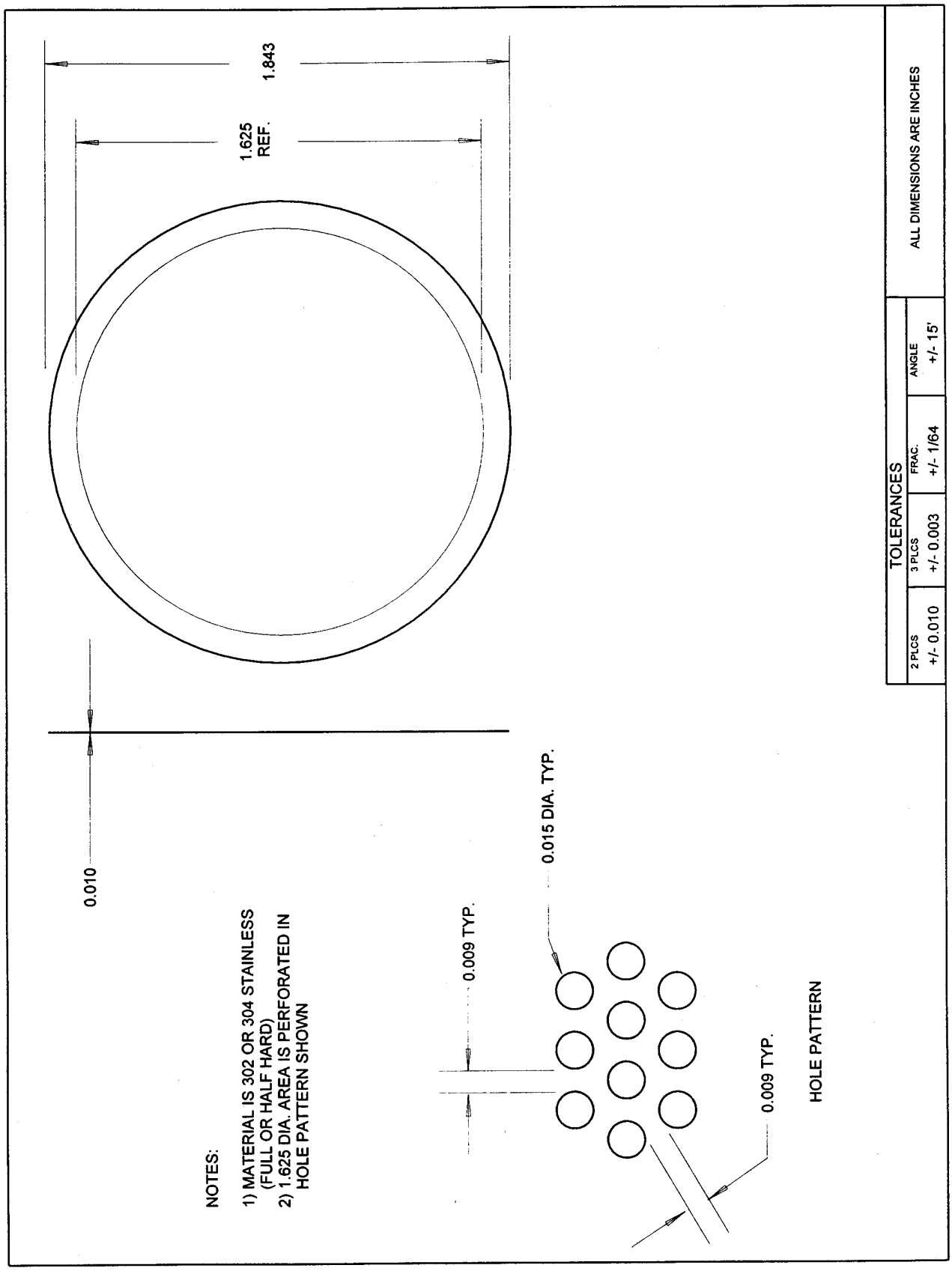

Figure L-28. Filter Screen

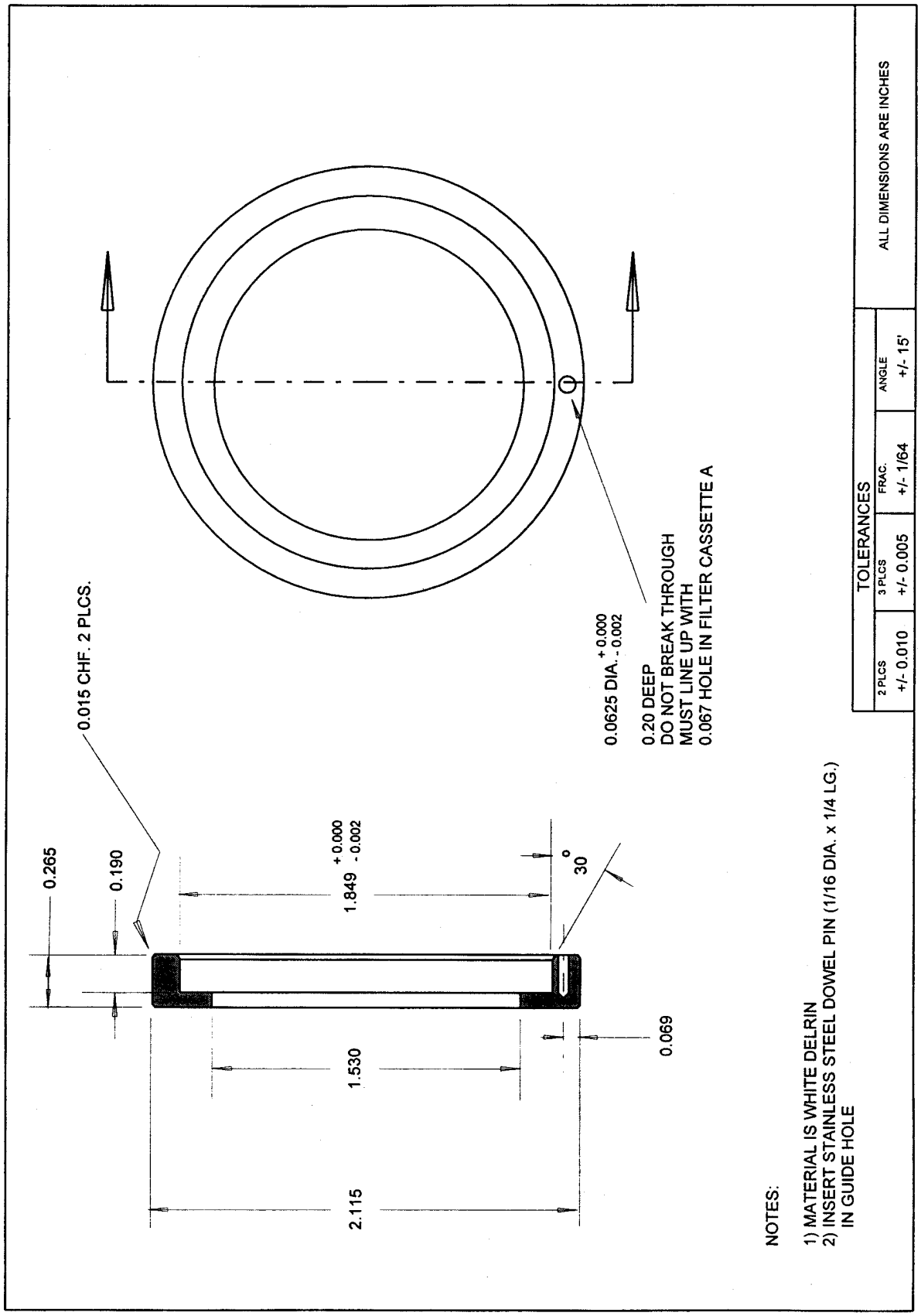

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Figure L-29. Filter Cassette, Lower Section

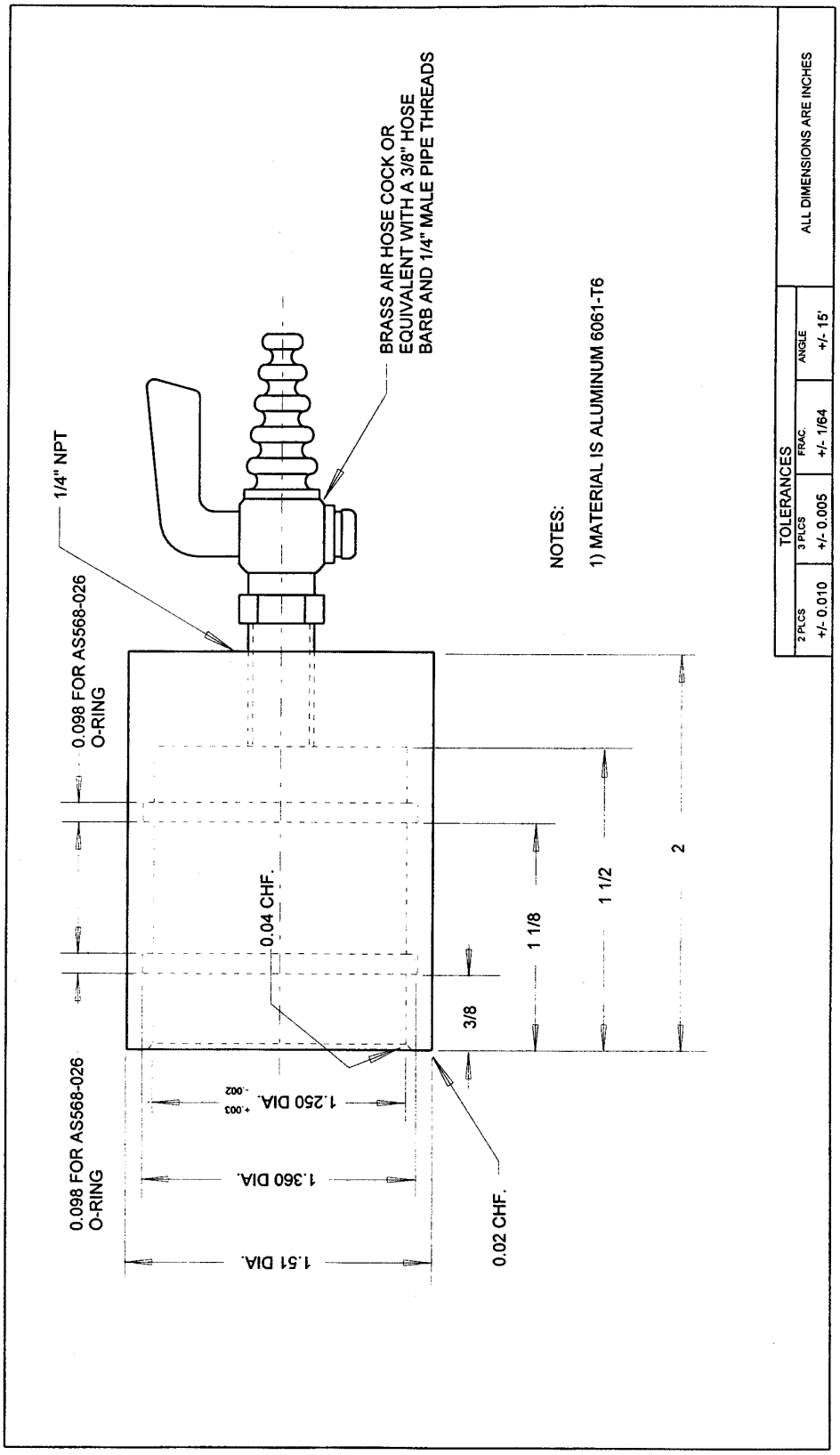

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Figure L-30. Flow Rate Measurement Adapter

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BILLING CODE 6560–50–C