

GAO

Report to the Chairman, Subcommittee on
Oversight and Investigations, Committee
on Energy and Commerce
House of Representatives

December 1986

AIR QUALITY STANDARDS

EPA's Standard Setting Process Should Be More Timely and Better Planned



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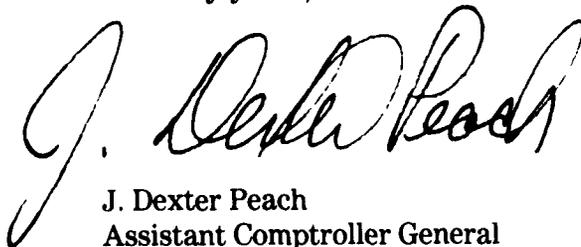
The Honorable John D. Dingell
Chairman, Subcommittee on
Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

As requested in your letter of October 3, 1984, and subsequent discussions with your office, we have reviewed the Environmental Protection Agency's (EPA's) efforts to review and update its national air quality standards. This report discusses the current status and cost of EPA's efforts in reviewing and updating the standards and the extent to which additional research is needed to support the standards and EPA plans for addressing the research needs.

As arranged with your office, unless you publicly release its contents earlier, we will make this report available to other interested parties 30 days after the date of this letter. At that time copies of the report will be sent to appropriate congressional committees; the Administrator, EPA; and the Director, Office of Management and Budget.

Sincerely yours,



J. Dexter Peach
Assistant Comptroller General

Executive Summary

Purpose

Watering eyes, burning throat, dizziness, and chest discomfort are some of the symptoms that people suffer because of air pollution. These symptoms are often precursors to more serious health problems, such as lung and heart diseases and cancer. The Clean Air Act of 1970 required the Environmental Protection Agency (EPA) to identify the highest level of an air pollutant's concentration that would not endanger public health and establish national air quality standards at or below that level.

Concern over EPA's progress in updating the national air quality standards and the adequacy of the scientific information supporting the standards prompted the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, to ask GAO to examine

- the current status and cost of EPA's efforts in reviewing and updating the standards, and
- the extent to which the standards require additional supporting research and EPA's plans for addressing these research needs.

Background

The Clean Air Act, as amended in 1977, requires EPA to review and update the national air quality standards by the end of 1980 and every 5 years thereafter. Currently, standards exist for six pollutants: carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter, and sulfur dioxide.

EPA must set air quality standards despite questions about the precise harm that a pollutant causes or the precise levels at which the pollutant may be harmful.

Results in Brief

EPA has not met its Congressional mandate for reviewing and updating the national air quality standards. Initial reviews of three pollutants are not expected to be completed until 1989, and only one was completed by the end of 1980. Factors contributing to EPA delays include 1) the length of time it takes to perform internal and external reviews, 2) EPA managers waiting on the re-examination of existing science or publication of new studies, and 3) turnover of top EPA administrators. EPA officials believe that measures can be taken to overcome these obstacles and that the standards can be reviewed and updated as required. EPA has developed milestones to accomplish this.

EPA is aware that questions exist about the scientific information supporting each of the six air pollutant standards. However, these questions are not systematically identified and matched with planned and ongoing research projects for each pollutant. A plan matching questions with research has been prepared for only one pollutant, but in GAO's opinion would be valuable for all six.

EPA has not kept records on the actual cost of reviewing and updating the national air quality standards. However, EPA estimates that it has spent about \$348 million on the standards since fiscal year 1978.

Principal Findings

EPA was able to review and update only one of the six national air quality standards by the end of 1980 as required by the Clean Air Act. EPA reviews for two others were not completed until 4 years after the 1980 deadline. Reviews of the standards for the remaining three pollutants and a second review of a previously updated standard are expected to be completed in 1989.

Delays in the Standard Setting Process

In 1982, EPA developed a 5-year planning schedule which included milestones for reviewing and updating the standards. The schedule identifies 18 key steps in the standard setting process and establishes the number of months required to complete each step. However, increased review time both inside and outside the EPA have caused delays in the standard setting process. For example, EPA allows 60 to 90 days for public comments on documents supporting proposed standards. However, in the case of the particulate matter standard, it extended the comment period for an additional 11 months. According to EPA, the volume of comments required the extension.

Delays in the standard setting process are sometimes caused by EPA waiting for additional research to be completed. When the research is completed, additional reviews and comment periods may be required, creating a new cycle of delays. While it is hard to fault EPA for wanting to consider new research results, the Clean Air Act requires EPA to review and update the national air quality standards every 5 years using available scientific evidence.

Questions Remain About Health Effects

Numerous questions remain about the health effects caused by pollutants for which national air quality standards have been established. While such questions exist for each of the six pollutants, EPA believes

the scientific support is stronger for some standards than others. For example, EPA considers health effects from exposure to ozone to have been more definitively shown than the effects of nitrogen dioxide.

Identifying and Matching Health Effects Questions With Research

Although EPA is aware of many unanswered questions concerning the health effects caused by the six pollutants, the questions are not systematically identified and matched with planned and ongoing research. Questions are not always documented by EPA officials most knowledgeable about the pollutants. Further, a research plan matching unanswered questions with planned and ongoing research has been prepared for only one pollutant—nitrogen dioxide. GAO believes that a process that systematically identifies research needs and documents the extent to which ongoing and planned research addresses such needs would be helpful to EPA managers in updating the air quality standards.

Costs of the Standards

EPA's standard setting process emphasizes the soundness of the science supporting the air quality standards and not the cost of reviewing and updating the air quality standards. In fact, EPA does not maintain records of such costs. However, in response to a GAO request, EPA estimated that it has spent about \$320 million since 1980 on research to support the air quality standards. Further, EPA estimates that it has spent about \$28 million on the review process and that it will spend at least another \$1.5 million on the four standards which are still being updated. Because EPA does not compile cost data, it cannot determine how much it spends on any particular standard or how much delays in the standard setting process costs. EPA could implement procedures for recording costs in updating and reviewing the air quality standards to provide EPA officials, as well as the Congress, with information useful for budgeting, cost control, and other financial management functions.

Recommendations

GAO recommends that the Administrator of the Environmental Protection Agency:

Adhere to the milestones in EPA's schedule for reviewing and updating the standards in order to meet the 5-year timetable established by the Congress. (See p. 33.)

Implement a formal process that identifies research needs for each pollutant and matches planned and ongoing research with these needs. (See p. 39.)

Implement procedures to record costs to review and update each air quality standard. (See p. 33.)

Agency Comments

GAO discussed the national air quality standards program with EPA officials and included their comments in the report where appropriate. As requested, GAO did not obtain official agency comments on this report.

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Abbreviations

CASAC	Clean Air Scientific Advisory Committee
EPA	Environmental Protection Agency
GAO	General Accounting Office
NAAQS	National Ambient Air Quality Standards
OMB	Office of Management and Budget
SAB	Scientific Advisory Board

Introduction

Watering eyes, burning throat, dizziness, and chest discomfort are among the more common symptoms experienced by people exposed to air pollution. More serious health conditions associated with air pollution include lung diseases, kidney disorders, cancer, and impairment of the circulatory and nervous systems.

Because of Congressional concern over declines in air quality, the Congress passed the Clean Air Act Amendments of 1970. The amendments made the Environmental Protection Agency (EPA) the focal point for federal efforts to control air pollution. EPA is required to identify the highest levels of air pollutants that will not endanger public health and to establish air quality standards at or below these levels. The standards are to be based on the latest available science and must protect the public from known and anticipated adverse health effects. While the standards must be stringent enough to protect public health, they should not be so stringent as to require unnecessary costs for potential polluters.

In passing the 1970 amendments, the Congress envisioned that EPA would periodically review and update the air quality standards to ensure that they remain as accurate and current as possible. Because of concern over EPA's failure to review and update the standards, the Congress again amended the Clean Air Act in 1977. The 1977 amendments required EPA to review and revise, as necessary, each standard before December 31, 1980, and at 5-year intervals. However, the act specifies that the standards may be changed less frequently than every 5 years. As a result, EPA established an extensive process for reviewing and making needed changes in the standards.

In carrying out its responsibilities under the Clean Air Act, EPA (1) identifies air pollutants that may be anticipated to cause adverse health effects; (2) establishes, reviews, and updates standards to protect the public from such effects; (3) monitors the progress states are making in attaining the standards; and (4) enforces compliance with the standards through various means. This report addresses one of the responsibilities: EPA's efforts to establish, review, and update air quality standards.

Pollutants Covered by Air Quality Standards

In response to the Clean Air Act, EPA has established air quality standards for six air pollutants: carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter, and sulfur dioxide. These pollutants appear in many different forms, are widely dispersed in the atmosphere, are caused by a variety of sources, and cause or contribute to a number of

adverse health effects. While some commonalities exist, to a great extent each pollutant has unique characteristics and requires individual control strategies.

Carbon Monoxide

Carbon monoxide is a colorless, odorless gas produced by incomplete fuel combustion. EPA estimates that over two-thirds of the carbon monoxide released into the air comes from motor vehicle exhausts. This is especially true when automobile engines are starting or idling, or when automobiles are moving slowly through traffic. Other sources of carbon monoxide include fuel burned in homes, incinerators, and industrial processes. When inhaled, carbon monoxide replaces oxygen in the bloodstream and adversely affects vision, alertness, and other mental and physical capacities. Carbon monoxide presents a special health concern for individuals with heart and lung diseases.

Lead

Lead is a heavy metal that exists as an air pollutant when it is found in the atmosphere. The more significant contributors to atmospheric lead are leaded gasoline used in older automobiles, non-ferrous smelters, and battery plants. Transportation sources are estimated to contribute up to 80 percent of all lead emissions. Decreases in the use of leaded gasoline have resulted in a 64 percent reduction in concentration of lead in the air between 1975 and 1982. Lead enters the body through ingestion and inhalation and accumulates in the blood, bone, and soft tissue. Lead adversely affects the kidneys, the nervous system, and other organs. Infants and children are especially susceptible to lead, as it damages their central nervous systems.

Nitrogen Dioxide

Nitrogen dioxide is a gaseous air pollutant generated by high temperature combustion processes from automobiles, power plants, and industrial boilers. Nitrogen dioxide can irritate the lungs, cause bronchitis and pneumonia, and lower resistance to respiratory infections such as influenza.

Ozone

Ozone, which is the principal component of "smog," results from a complex series of chemical reactions involving sunlight, volatile organic compounds, and nitrogen oxides. A major source of ozone is motor vehicle emissions. Consequently, ozone levels are the highest during the day, usually after heavy morning traffic has released heavy emission levels and when sunlight is abundant. In addition to automobiles, other

sources such as dry cleaners, paint manufactureres, and gasoline stations contribute to the ozone problem. Scientific research links ozone to reduced lung functions, difficulties in breathing, asthma, eye irritation, nasal congestion, and reduced resistance to infection.

Particulate Matter

Particulate matter is a generic term for a broad class of chemically and physically different particles that exist in the atmosphere. They exist as solid particles or liquid droplets small enough to remain suspended in the air. Some particles are large enough to be visible as soot, smoke, or dust. Other particles are so small they are only detected by an electron microscope. Fine particles, about the size of cigarette smoke particles, can cause permanent damage when inhaled and become deeply lodged in the lungs. Some particles, such as those from diesel engines, are suspected of causing cancer. Other particles, such as wind-blown dust, carry pesticides and other toxic substances.

Sulfur Dioxide

Sulfur dioxide is a corrosive, poisonous, gaseous pollutant produced primarily from the burning of coal and oil by electric utilities. Other sources include petroleum refineries, pulp and paper mills, steel plants, and chemical factories. Home furnaces and coal-burning stoves are sources that more directly affect neighborhoods. After entering the atmosphere, sulfur dioxide forms other compounds such as sulfuric acid, sulfate, and sulfites, which can be more irritating to the respiratory system than sulfur dioxide alone. Excessive levels of sulfur dioxide contribute to acute and chronic respiratory diseases. Sulfur dioxide also bonds with particles of dust, smoke, and aerosols, often resulting in acid rain problems for areas long distances from the original sulfur dioxide source.

Determining Health Effects of Air Pollution Is Difficult

It is difficult to determine the extent to which air pollutants cause adverse health effects. Reactions to medications or to contaminated food or water are among the many alternative causes of such effects. Therefore, isolating health effects caused by air pollutants is an elusive process.

Despite the difficulty of identifying adverse health effects, the Clean Air Act requires that air quality standards protect the public health. EPA must deal with considerable uncertainties in establishing and updating the standards. For example, standards established by EPA must protect the public against known health effects as well as health effects not yet

identified by scientific research and those identified but not fully understood.

As soon as EPA identifies adverse health effects from exposure to air pollutants at certain levels, it must begin searching for scientific evidence suggesting that adverse health effects start at even lower concentrations of the pollutant. The lower the pollutant level examined, the more subtle the health effects and the fewer people affected.

Types of Evidence Used in Standard Setting

In setting air quality standards EPA relies on three types of indirect scientific evidence—clinical studies, epidemiological studies, and animal studies. While each type provides useful information, each has its own peculiar shortcoming.

Clinical studies generally expose relatively limited numbers of healthy individuals to various levels of a pollutant over short periods of time. To make the findings useful for standard setting, researchers must project what might occur if individuals with various medical conditions were exposed to similar levels of the pollutant over an extended time period. These projections often involve a series of judgments on the part of researchers and managers.

Epidemiological studies examine large numbers of individuals living and working in areas with different pollution levels. The studies include people with medical problems as well as healthy individuals. Researchers study people who have been exposed to pollution and other environmental stresses over long periods of time. While epidemiological studies may address the questions facing managers more directly than clinical studies, their reliability is even more questionable. Researchers have little control over the people being studied and the results are often affected by factors unrelated to pollution exposure. Sometimes there is little assurance that the correct pollutants are even being measured.

Along with clinical and epidemiological evidence, researchers and managers often rely on evidence produced by studying laboratory animals. Animal studies have several advantages. Because of different ethical considerations, animals are generally exposed to higher pollution levels than humans. Also, larger numbers of animals can be studied at a lower cost. The short life spans of rats, mice, and other animals allow researchers to examine the effects of lifetime exposure to pollutants. Projecting the results of animal studies to humans, however, is even more difficult than projecting from clinical evidence. Again, this

requires considerable judgment on the part of researchers and managers.

Although EPA is faced with uncertainties, the Clean Air Act requires the Agency to set air quality standards based on the best available scientific evidence. This is important, considering that where EPA sets the standards can cause significant economic and health consequences. For example, if EPA's interpretation of the scientific evidence and subsequent decisions result in more stringent standards, additional control cost may be imposed on the economy—estimated by the Clean Air Scientific Advisory Committee and others to be in the billions of dollars. On the other hand, if EPA's interpretation of the scientific evidence and its decisions result in standards becoming less stringent, concern over public health becomes an issue.

Evolution of the Standard Setting Process

In requiring EPA to establish national air quality standards, the Congress may not have envisioned that the standard setting process would become as complex as it is today. The 1970 Clean Air Act required that the original standards be issued by EPA within 120 days of enactment. The standards were established on schedule using a 12-step process. EPA officials reviewed the few health studies available on each pollutant, discussed whether noted health effects were considered adverse, and issued the standards with minimal outside input and explanation.

In passing the 1977 amendments to the Clean Air Act, the Congress expressed its desire for better science, more public participation, and more frequent reviews of the standards. Since that time, EPA's standard setting process has become more complex. EPA officials, outside interest groups, independent scientists, and others now spend years debating proposed new standards and revisions to existing standards. Additionally, EPA now provides extensive documentation in support of its proposed and final standards.

EPA and other researchers, analysts, reviewers, and regulators go through approximately 57 steps in setting the air quality standards. Steps added to the process include reviews of proposed and final standards by the Clean Air Scientific Advisory Committee, an independent group of scientists who advise EPA; public hearings on proposed standards; and reviews of EPA decisions by the Office of Management and Budget (OMB). Appendix I shows these and various other steps in EPA's standard setting process.

EPA Offices Involved in the Standard Setting Process

Two EPA offices have primary responsibility for decisions regarding air quality standards: the Environmental Criteria and Assessment Office, within the Office of Research and Development, and the Office of Air Quality Planning and Standards, within the Office of Air and Radiation. These offices evaluate the scientific information on which standards are based, arrange public hearings, perform technical analyses and suggest ranges within which air quality standards could be established.

The Environmental Criteria and Assessment Office initiates the standard setting process by performing or contracting with scientists outside of EPA to perform an extensive review of all scientific information concerning a pollutant, including its potential health effects. The results are published in what is termed a "criteria document." This document critically reviews the health evidence from a scientific point of view. It provides an assessment of the scientific credibility of research projects for standard setting purposes. Typical questions addressed may include: Were the studies properly designed and conducted? Were appropriate statistical techniques used? Did researchers rule out other possible explanations of the results? Do studies on the same health effects tend to support or contradict each other?

The criteria document receives intensive review by the scientific and medical communities and is usually reviewed at least twice by the Clean Air Scientific Advisory Committee. Part of the Committee's review involves public hearings which allow all interested parties to voice their opinions on the document. The criteria document is complete only after the Committee is satisfied that it contains an adequate assessment of the scientific knowledge available for standard setting.

As soon as the criteria document appears substantially complete, the Office of Air Quality Planning and Standards begins preparing what is termed a "staff paper." The staff paper includes interpretations of the key studies and scientific evidence contained in the criteria document. It also identifies critical information to be addressed in the standard setting process. In effect, the staff paper helps bridge the gap between the science contained in the criteria document and the judgments required of the EPA Administrator in setting air quality standards. Like the criteria document, the staff paper is subjected to Clean Air Scientific Advisory Committee and public review to assure that EPA interpretations are consistent with available scientific information.

At the same time the criteria document and staff paper are being prepared, the Office of Air Quality Planning and Standards conducts a

number of technical analyses to aid the standard setting process. These include regulatory impact analyses, risk assessments, and exposure analyses.

Once the technical analyses are complete, the proposed standard and supporting documents are sent to the Administrator for approval. After an initial review, the Administrator sends the proposed standard and documents to OMB for their review. (Executive Order 12291 requires all standards be submitted to OMB for review.)

After EPA considers OMB comments, it publishes a proposed standard in the Federal Register and solicits public comments. If there are no public comments, the standard becomes final. If public comments are received, however, EPA must consider any new information and make any needed changes in the proposed standard. The proposed standard must then be reviewed again by EPA managers, the Administrator, and OMB. After completing the second review cycle, EPA publishes the final standard.

Objectives, Scope, and Methodology

As agreed with the Office of the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, we examined

- the current status and cost of EPA's efforts in reviewing and updating the standards and
- the extent to which additional research is needed to support the standards and EPA plans for addressing these research needs.

We performed our work between October 1985 and October 1986 at EPA Headquarters in Washington, D.C.; the Environmental Criteria and Assessment Office in Research Triangle Park, North Carolina; and the Office of Air Quality Planning and Standards in Durham, North Carolina. Our work covered EPA efforts from 1977 to the present.

We examined EPA efforts to review and update each of the six national air quality standards and compared the results with the prescribed standard setting process. In doing so, we interviewed EPA officials responsible for and directly involved in setting the standards. These included the Director and Deputy Director of the Environmental Criteria and Assessment Office, the branch chief at the Office of Air Quality Planning and Standards responsible for updating the standards, and project officers and managers at both offices responsible for criteria development and standard setting for individual pollutants. We also

reviewed and extracted information from EPA's public file, or docket, on the standards. Finally, we reviewed and discussed EPA-conducted or -sponsored studies of the standard setting process with EPA officials.

To determine the costs EPA incurred in reviewing and updating the air quality standards, we obtained information from the Environmental Criteria and Assessment Office and the Office of Air Quality Planning and Standards on salary, contract, and support costs for each standard. Because neither office maintains actual cost information, estimates of the number of staff years and the equivalent costs were obtained. Likewise, estimates of contractor and support costs were provided by both offices.

The Environmental Criteria and Assessment Office relies on numerous individuals from other EPA offices and laboratories to write, review, and edit chapters of the criteria documents. We obtained the names of these individuals, contacted their respective EPA offices and laboratories, and obtained estimates of the amount of time they spent working on each criteria document. We provided this information to the Environmental Criteria and Assessment Office for inclusion in their cost estimates.

As previously discussed, the Clean Air Scientific Advisory Committee plays a significant role in the air quality standards review process. Accordingly, we obtained estimates of the costs incurred by the Committee for each of the six standards. Specifically, we obtained salary, consultant, travel, and contractor costs.

Finally, we obtained from the Office of Research and Development research costs to support the standards for the period fiscal year 1980 through fiscal year 1986. This data included both EPA in-house and extramural research costs.

To obtain information on the uncertainties in the scientific information supporting the air quality standards and EPA plans for addressing them, we held numerous discussions with officials at the Environmental Criteria and Assessment Office. Specifically, we talked with the Office's Director, Deputy Director, and with individual project managers. We also talked with officials at the Office of Air Quality Planning and Standards.

We attended several public meetings on setting national air quality standards. The meetings were led by the Chairman of the Clean Air Scientific Advisory Committee. During the meetings, the completeness,

accuracy, and relevancy of criteria documents, staff papers, and proposed standards were discussed. Participants included members of the Committee, EPA managers and researchers, and representatives from such organizations as the National Park Service, the California Air Resources Board, the American Petroleum Institute, E.I. duPont deNemours and Co., the Texas Chemical Council, and General Motors. Representatives of environmental groups such as the Natural Resources Defense Council also participated in the meetings.

We obtained and reviewed copies of written statements presented by these groups and obtained and reviewed transcripts of the Committee meetings. We also met with a representative of the California Air Resources Board to obtain the organization's views on the quality of the scientific information supporting the air quality standards. We also talked specifically about research the organization has done on the health effects caused by exposure to selected levels of carbon monoxide.

We discussed the national air quality standards program with EPA officials and have incorporated their comments where appropriate. However, as requested, we did not obtain official EPA comments on a draft of this report. Except as noted above, our review was performed in accordance with generally accepted government audit standards.

Review and Update of the National Air Quality Standards Is Slow and Costly

While EPA has made extensive efforts toward reviewing and updating the national air quality standards in accordance with the 1977 Amendments to the Clean Air Act, the results achieved have not met Congressional intent. Reviews both inside and outside EPA, as well as frequent changes in the scientific evidence, contribute to delays in the review and update of the air quality standards.

Other causes of delays include difficulties in obtaining acceptable products from contractors who prepare various documents related to the process, and turnover in top EPA management. EPA recognizes these delays and has initiated a number of changes to improve the standard setting process.

Ensuring the soundness of the air quality standards is the primary emphasis of EPA's standard setting process. EPA does not consider cost a major factor in its review and update of the standards. While EPA does not maintain data on the cost of updating the standards, it estimates that it has spent about \$348 million since fiscal year 1978. Of this amount, EPA estimates that \$320 million was spent on research to support the standards and \$28 million was spent on the review and update process.

Delays in Updating the National Air Quality Standards

EPA has experienced numerous delays and failed to meet the initial review requirement of December 31, 1980, for all but one of the six standards—ozone. For two other standards, EPA did not complete the review until more than 4 years after the December 1980 date. Furthermore, based on EPA's planning schedule, it will be 1989 before EPA completes the review and update of the remaining three air quality standards. We also estimate that the second review of the ozone standard will be completed about 5 years behind schedule. Table 2.1 shows the time frames and delays of EPA's review of the standards.

**Table 2.1: Time Frames and Delays for
 EPA's Review of the National Air
 Quality Standards**

Standards	Review		Elapsed time (years)	Delays ^a (years)
	Start	Complete ^b		
Ozone	10/76	2/79	2.3	.0
	9/81	4/89	7.6	5.2
Nitrogen Dioxide	9/77	6/85	7.8	4.5
Carbon Monoxide	12/77	9/85	7.8	4.8
Sulfur Dioxide	10/79	6/89	9.7	8.5
Particulate Matter	10/79	6/89	9.7	8.5
Lead	1/82	11/89	7.8	6.1

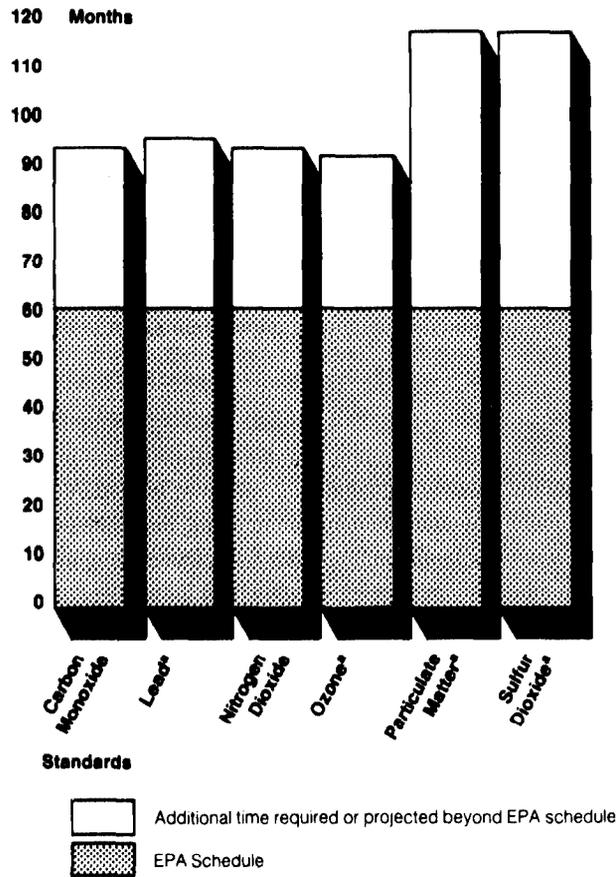
^aDelays for the ozone standard are based on it being updated in 2/79 and a subsequent update being due in 2/84. The lead standard delays are based on it being issued in 10/78 and an update being due by 10/83. All other delays are based on the updates being due by 12/80.

^bCompletion dates beyond 1985 are based on EPA's 5-year planning schedule.

Because of EPA's need to identify its workload in future years, the Office of Air Quality Planning and Standards developed a 5-year planning schedule in 1982 for reviewing and updating the standards. The schedule identified 18 key steps in the standard setting process and established the number of months required to complete each of the steps. The schedule allows 28 months for the scientific phase of the standard setting process and 32 months for the decision phase. According to the Chief of the Ambient Standards Branch, Office of Air Quality Planning and Standards, the schedule assumed the process would go smoothly without any problems.

EPA has been unable to meet this schedule. The standard setting process has been drawn out beyond the EPA schedule milestones because of EPA's decision to repeatedly review the scientific evidence. Figure 2.1 compares EPA's schedule to the actual/projected time required to review and update the standards.

Figure 2.1: Number of Months for EPA to Complete the Review of National Air Quality Standards

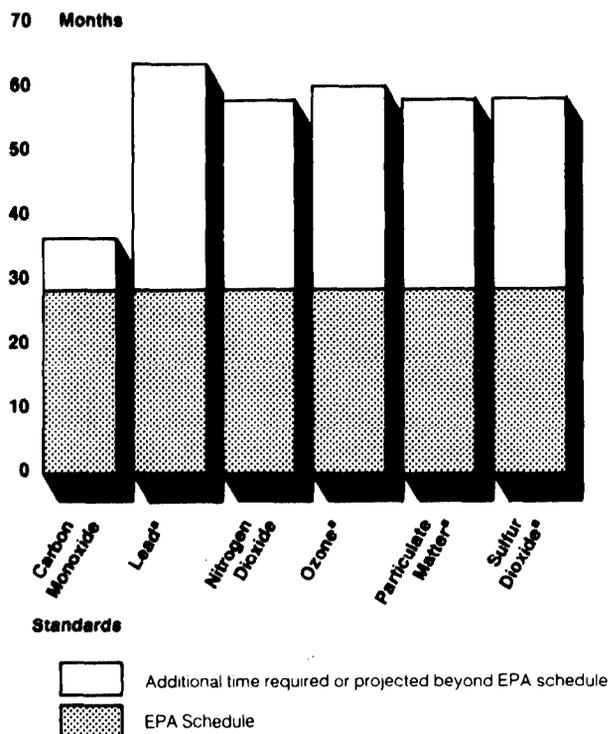


*Represents projected time to complete the overall review based on EPA's 5-year planning schedule.

Delays in the Scientific Review of the National Air Quality Standards

Significant delays in the standard setting process are attributable to the review and analysis of the scientific research related to the standards. The scientific phase of the process begins with EPA identifying available scientific information and ends with the Clean Air Scientific Advisory Committee's approval of the staff paper. Based on its planning schedule, EPA should complete the scientific phase within 28 months; however, its experience in completing this phase of the process ranges from 32 to 58 months. Figure 2.2 compares the EPA schedule to the actual/projected time required to complete the scientific phase of the standard setting process.

Figure 2.2: Number of Months for EPA to Complete the Scientific Phase of the National Air Quality Standards



*Represents projected time to complete the overall review based on EPA's 5-year planning schedule.

**Technical Analyses and Reviews
 Take Longer Than Planned**

Technical analyses and reviews by EPA staff and others lengthen the standard setting process. The entire standard setting process has increased from 12 steps in 1971 to approximately 57 steps. Included are a number of technical analyses, such as regulatory impact analyses and health risk assessments. Also, staff members from the Environmental Criteria and Assessment Office and the Office of Air Quality Planning and Standards are involved in the preparation, review, and approval of the criteria documents and staff papers. Additionally, the involvement by the Clean Air Scientific Advisory Committee and the public has increased.

Solicitation of public comments on the criteria documents and staff papers is one example of delays in the standard setting process. Traditionally, EPA allows 60 to 90 days for the public to submit comments on drafts of the criteria documents and staff papers. However, in the case of one pollutant—particulate matter—EPA extended the comment period

for another 11 months. The volume of comments required the extension, according to the particulate matter project officer.

Another example of delays is the Clean Air Scientific Advisory Committee's reviews of the criteria documents and staff papers. EPA's schedule provides for three Committee meetings during a 5-month period to review the criteria documents and staff papers. However, because of concern over the scientific evidence by the Committee and EPA, the Committee's involvement in the review process has exceeded the three meetings and has taken several years. For example, during EPA's review and update of the carbon monoxide standard, the Committee met five times during a 56-month period to review and comment on various drafts of the criteria document and staff paper. Similarly, the Committee met five times during a 43-month period to review and comment on the nitrogen dioxide criteria document and staff paper.

EPA Delays Scientific Review to Consider New Data

Changes in the scientific evidence delay EPA's review and update of the national air quality standards. In developing the criteria documents, EPA uses the latest published research related to each of the standards. New research is sometimes published after the criteria documents have been developed. In some instances, EPA and the Clean Air Scientific Advisory Committee decided that the newly published research was germane to the review and update of the standards. Thus, EPA delayed its decisions on issuing the standards until it considered the new research, as shown in the following examples.

1) EPA received approval of the particulate matter criteria document in January 1982. However, EPA did not propose a particulate matter standard until March 1984. (This delay was caused by administrative changes; see p. 27.) In December 1985 the Clean Air Scientific Advisory Committee again reviewed the criteria document and recommended that EPA prepare an addendum to the document to incorporate newly published research. Subsequently, EPA prepared an addendum and based on EPA's planning schedule, an updated standard will be issued in June 1989.

2) EPA released a first draft of the lead criteria document in October 1983 with plans to issue an updated standard by early 1988. After incorporating the Clean Air Scientific Advisory Committee's comments as well as comments from the public into the criteria document, EPA released a second draft in October 1984. By May 1985, when the Committee again reviewed the criteria document, newly published science

was available which could potentially affect EPA's decision about reviewing and updating the lead standard. The Committee recommended that EPA prepare an addendum to the criteria document. In August 1986 the Committee gave formal approval to the addendum. Thus, the various criteria document reviews delayed the scheduled review and update of the lead standard by more than a year beyond the projected completion date.

Use of Contractors Delayed the Review of Scientific Evidence

EPA experienced delays of as much as a year in developing criteria documents, due to difficulties in receiving acceptable and timely products from contractors. For example, EPA awarded a contract in September 1981 which required a contractor to develop the ozone criteria document. According to the ozone project manager, after spending \$669,000, EPA realized that the contractor could not deliver an acceptable product. Therefore, in late 1982 EPA discontinued the contract and obtained all the scientific materials and drafts of the chapters which had been prepared. An EPA team then completed the criteria document.

In another example, EPA experienced delays with the contractor who prepared the joint particulate matter/sulfur dioxide criteria document. EPA planned for the contractor to complete the criteria document by May 1980, according to an official of the Environmental Criteria and Assessment Office. However, according to the official it was mid-1981 before the contractor delivered the product. The official said that, for the particulate matter/sulfur dioxide criteria document, the Environmental Criteria and Assessment Office had to extensively revise the document after receiving it from the contractor.

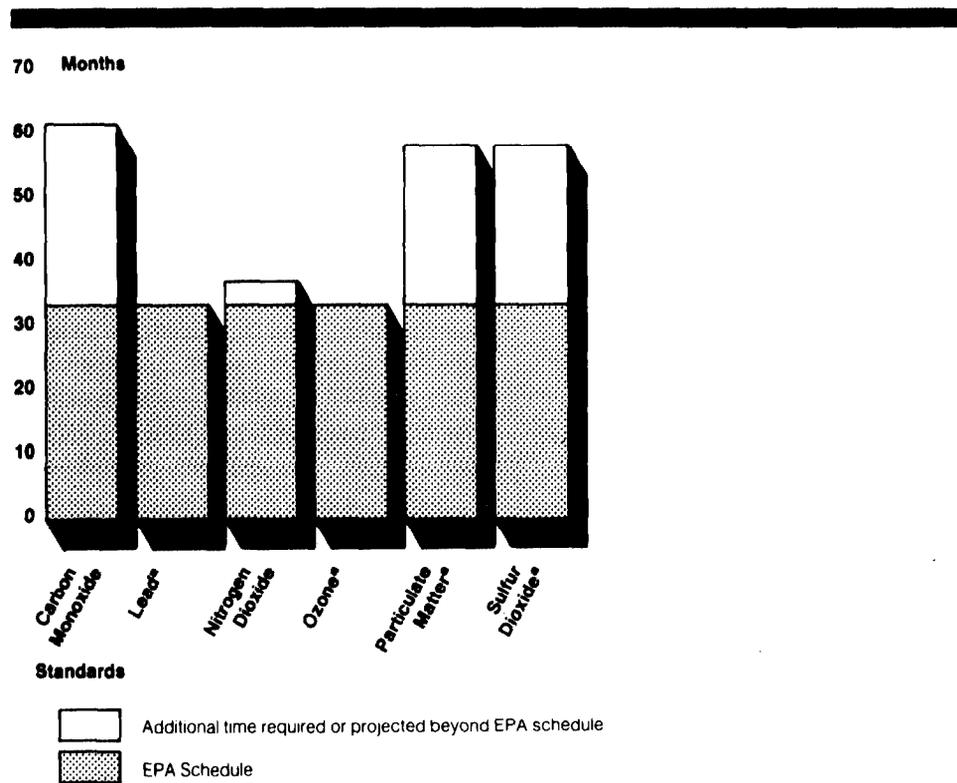
EPA decided in 1982 to no longer assign contractors the primary responsibility for preparing criteria documents, according to the Deputy Director of the Environmental Criteria Assessment Office.

Delays in Decisionmaking for the National Air Quality Standards

The decision phase begins with the completion of the staff paper and ends with the EPA Administrator announcing a decision on the standard. EPA's schedule allows 32 months for the completion of this phase. However, EPA's actual experience was 35 and 61 months for the nitrogen dioxide and carbon monoxide standards, respectively. Further, the projected completion of the decision phases for the four standards still

being updated ranges from 32 to 58 months.¹ Figure 2.3 compares the EPA schedule to the actual/projected time required to complete this phase of the standard setting process.

Figure 2.3: Number of Months for EPA to Complete the Decision Phase of the National Air Quality Standards



*Represents projected time to complete the overall review based on EPA's 5-year planning schedule.

Reviews of Proposed Standards Contribute to Delays

EPA's solicitation of public comments on the proposed standards, as well as reviews by the Clean Air Scientific Advisory Committee, OMB, and various EPA management levels, is time-consuming. For example, in March 1984 EPA initially solicited public comments on the proposed changes to the particulate matter standard for 90 days. Because of the public interest and volume of comments on the proposed standard, the EPA Administrator extended the comment period another 11 months—until June 1985. EPA received over 1,400 comments on the proposed particulate matter standard, according to officials in the Office of Air

¹We determined these times by subtracting the amount of time expended for the scientific phase from EPA's total estimated time to complete the standard setting process.

Quality Planning and Standards. Because of the volume of comments, EPA used a contractor to analyze and summarize the comments, at a cost of \$43,000. The contractor required 3 months to complete the task.

Executive Order 12291, dated February 1981, requires all regulatory agencies to submit regulations and standards to OMB for approval before issuance. In complying with the executive order, EPA includes 90 days in its standard setting schedule for two OMB reviews. In two instances in which OMB reviewed the proposed standards it took longer than 90 days. For example, OMB's review of the proposed nitrogen dioxide and particulate matter standards took approximately 10 months longer than scheduled, according to the project officers.

**Questions About Health Effects
Delay Decisions**

As discussed in Chapter 3, the research supporting the air quality standards continues to leave questions unanswered for each standard. The EPA Administrator and senior EPA officials sometimes postpone decisions to update the standards while waiting for more research, even though the Clean Air Act requires EPA to set the standards using the latest available scientific information.

Information presented to top EPA management by industry and environmental groups sometimes appears to conflict with the scientific evidence identified by EPA. Further, according to the Director, Environmental Criteria and Assessment Office, information included in various EPA analytical documents, such as benefit analyses, occasionally appears to be at odds with the science in the criteria documents and staff papers.

Unanswered health questions and conflicts in the science supporting the standards often cause the EPA Administrator to wait for re-examination of existing information or publication of new science before deciding on air quality standards, according to the Director, Environmental Criteria and Assessment Office. The Director expressed concern over this practice, since the science supporting some standards is substantial enough that it is unlikely that any new study would significantly affect the level at which the standards would be set.

EPA's review of the carbon monoxide standard illustrates how questions about health effects caused delays. As of March 1983, EPA was prepared to issue an updated carbon monoxide standard which relied heavily on the studies of one researcher. The reliability of that researcher's work was later questioned. Subsequently, EPA required approximately 10

months to delete these studies from the carbon monoxide scientific evidence and re-evaluate the remaining studies. The remaining studies included four studies of how low-level carbon monoxide exposure affects people's health. One study showed adverse health effects at low carbon monoxide levels and three studies showed impaired exercise ability of healthy people at low exposure levels. Because of the limited scientific evidence showing adverse health effects from low-level carbon monoxide exposure, the EPA Administrator waited for additional research to become available before updating the standard. However, in June 1985 the federal courts ordered EPA to announce its decision on the carbon monoxide standards. Thus, in September 1985, 2.5 years after discounting results of the researcher whose studies were questioned and identifying no new information that would justify a change, the EPA Administrator reaffirmed the original standard.

The review of the nitrogen dioxide standard further illustrates how questions about health effects have caused EPA to delay its standard setting decisions. In reviewing the nitrogen dioxide science, EPA and the Clean Air Scientific Advisory Committee concluded that the scientific evidence demonstrated adverse health effects from nitrogen dioxide exposure, but EPA was unable to identify the lowest level at which adverse health effects occurred. EPA concluded that this imprecision prevented it from making a decision on whether the standard should be revised. Thus, after more than 7 years of reviewing the nitrogen dioxide science, the EPA Administrator decided in June 1985 to retain the current long-term nitrogen dioxide standard and to defer a decision on issuing a short-term standard.²

The sulfur dioxide standard provides an example of where questions about the supporting science caused the EPA Administrator to delay his decision to issue a proposed standard. In September 1984 the Assistant Administrator for the Office of Air and Radiation recommended that EPA retain the existing sulfur dioxide standard. However, during a February 1985 meeting of the Administrator and assistant administrators, questions were raised about information in one of the documents supporting the proposed standard. In November 1985, the Administrator met with a group of environmentalists who pointed out several sulfur dioxide studies that EPA had not considered. The Administrator agreed to revise the criteria document to incorporate these studies. The combination of these events resulted in the review and update of the sulfur dioxide

²The long-term standard is an annual average of the nitrogen dioxide levels. The short-term standard, if issued, would have been an average of not more than 3 hours of the nitrogen dioxide levels.

standard being delayed more than a year. Based on EPA's planning schedule, the final decision on the sulfur dioxide standard will not be made until June 1989.

Turnover of Top EPA Officials Contributes to Additional Delays

Turnover among top EPA officials has contributed to delays in the standard setting process. Different regulatory philosophies as well as different levels of knowledge among incoming and outgoing administrators have contributed to the problem.

For example, the review and update of the carbon monoxide standard was completed in December 1980 except for the EPA Administrator's approval of the proposed standard. However, he decided to defer the decision to the new EPA Administrator for the incoming Administration. The new EPA Administrator and other EPA managers considered several alternatives for the carbon monoxide standard. Various public and environmental groups criticized EPA for trying to relax the standard. Thus, in March 1983 the previously proposed standard was submitted to the assistant administrators for review. Because of questions about the scientific evidence (discussed on p. 25) which occurred after March 1983, EPA did not update the carbon monoxide standard until September 1985.

In another example, the particulate matter criteria document and staff paper were completed in January 1982. However, a proposed standard was not released for public comment until March 1984. According to the particulate matter project officer, the delay was due in part to the Administrator deferring a decision until after the 1982 Congressional elections and the change of EPA Administrators in April 1983. According to the particulate matter project officer, the new Administrator required additional time to clarify and understand the issues surrounding the proposed standard.

EPA Officials Believe Deadlines Can Be Met

Despite the various reasons for delays in the standard setting process, the Chief of the Ambient Standards Branch, Office of Air Quality Planning and Standards—the office responsible for recommending levels at which the standards should be set—believes that EPA is capable of completing the process within the 5 years mandated by the Clean Air Act. In his opinion, this can be achieved by adhering to the milestones in EPA's 5-year schedule for reviewing and updating the standards. Reviews and analyses would be limited to those provided for in the 5-year schedule. Additional reviews and analyses would be completed during the next 5-

year review cycle. Further, the Clean Air Act provides for EPA to incorporate new scientific information into the standard setting process as it becomes available and allows EPA to change the standards more frequently than every 5 years.

The Director and Deputy Director of the Environmental Criteria and Assessment Office told us that criteria documents can be completed within the 2 years allowed by EPA's schedule. However, most criteria documents have not been completed within 2 years because of repeated efforts to amend the documents to incorporate new scientific evidence or re-examine existing evidence.

According to the Director, Environmental Criteria and Assessment Office, one possibility for dealing with the delays is to require the EPA Administrator to make a decision within a specified time or the air quality standard will automatically be reaffirmed or removed. However, such action would require a change in the Clean Air Act.

EPA's Efforts to Improve the Standard Setting Process

EPA and others performed several studies which identified problems with the standard setting process and recommended ways to improve the process.³ Generally, the studies recommended streamlining the criteria document by emphasizing the more important issues and including only the significant research. Further, the studies stated that the criteria document should place more emphasis on evaluating and interpreting the important studies.

Other recommendations of the studies included:

- assigning a key EPA official as project manager to oversee the development and revision of the criteria document for each standard;
- expanding the staff paper to include ranges of numerical values for future standards, as well as identifying sensitive individuals and population groups at risk;
- expanding the use of various analyses as part of the standard setting process to address the uncertainties of the science; and
- increasing the involvement of the Clean Air Scientific Advisory Committee and making it more responsive to EPA.

³EPA, National Ambient Air Quality Standard: A Review of the Process, May 1985; Clean Air Scientific Advisory Committee, Setting Ambient Air Quality Standards: Improving the Process, September 1981; Clean Air Scientific Advisory Committee, Improving the Process for Setting National Ambient Air Quality Standards: An Update, July 1985; R.M. Dowd Company, Recommendations to Improve the Process of Preparing Air Quality Criteria Documents, August 1984.

Based on the recommendations from these reports and EPA's own recognized need to improve the standard setting process, EPA initiated a number of changes. These changes relate to improvements implemented by the Environmental Criteria and Assessment Office, the Office of Air Quality Planning and Standards, and the Clean Air Scientific Advisory Committee.

In an effort to improve the development of the criteria documents as recommended by the studies, the Environmental Criteria and Assessment Office initiated several changes. For example, the Environmental Criteria and Assessment Office assigns a project manager to coordinate the preparation of a criteria document. Further, the criteria documents currently focus on evaluation and interpretation of the scientific evidence and also concentrate on science that shows significant effects rather than including all the science regardless of the quality. For example, the ozone criteria document states that the scientific evidence is intended to present current science on probable consequences of exposure rather than including a complete literature review.

Based on the recommendation to improve the staff papers, the Office of Air Quality Planning and Standards includes information on the ranges of numerical values for standards. For example, the ozone draft staff paper recommends that the standards be set at a level ranging between .08 and .14 parts of ozone per million parts of air. Staff papers for the other standards also included recommended ranges for setting the standards.

In response to recommendations for expanded use of various analyses in the standard setting process, the Office of Air Quality Planning and Standards is increasing its use of various analyses. To the extent analyses are used, EPA has agreed to provide them for the Clean Air Scientific Advisory Committee and public review. According to EPA, this should insure that the analyses are technically sound and have made appropriate use of the science contained in the criteria document.

The Office of Air Quality Planning and Standards also increased its emphasis on analyses such as exposure and health risk analyses. Such analyses are prepared by the Office of Air Quality Planning and Standards and are now included as part of the standard setting process.

In response to recommendations to increase the Clean Air Scientific Advisory Committee's involvement in the standard setting process, EPA expanded the Committee's review responsibility to include submitting

the proposed standard to the Committee for review and comment. For example, the Committee reviewed the proposed nitrogen dioxide standard before EPA reaffirmed the standard in 1985. Similarly, the Committee also reviews and comments on various documents such as the risk assessment and exposure analysis. For example, during the April 1986 Committee meeting on the ozone criteria document and staff paper, the staff of the Office of Air Quality Planning and Standards presented the exposure analysis and health risk assessment information to the Committee for comment. The Committee also agreed to respond to EPA with formal conclusions and recommendations on the criteria documents and staff papers within 90 days.

Cost Estimates for Updating the Standards

A primary emphasis of EPA's standard setting process is ensuring the defensibility of its regulatory decisions, according to the Assistant Director of the Strategies and Air Standards Division, Office of Air Quality Planning and Standards. Potential or actual costs are not a major consideration, even though such information would allow EPA officials to identify phases of the standard setting process which are costly and may need their attention.

While EPA does not maintain data on the cost of updating the standards, it estimates that it has spent about \$348 million on the standards since fiscal year 1978. EPA estimates it has spent nearly \$320 million to conduct research in support of the air quality standards. An estimated \$197 million of this amount was awarded to contractors to conduct research for EPA. Additionally, based on EPA estimates, about \$28 million have been expended to review and update the standards.

The estimated cost for reviewing and updating a standard ranges from \$2.1 million for the carbon monoxide standard to \$6.2 million for the particulate matter standard. The estimated costs covered the period from the start of the standard setting process for each standard (see Table 2.1) through fiscal year 1986. Table 2.2 shows the estimated costs which EPA has incurred for each of the air quality standards.

**Table 2.2: Estimated EPA Expenditures
for Reviewing the National Air Quality
Standards**

Standard	Cost (million)
Carbon Monoxide	\$2.1
Lead	4.4
Nitrogen Dioxide	3.3
Ozone	6.1
Particulate Matter	6.2
Sulfur Dioxide	5.5
Total	27.6

**EPA Uses Contractors to
Review the National Air
Quality Standards**

EPA makes extensive use of contractors in its review and update of the air quality standards. Of the estimated \$28 million that EPA has spent on setting air quality standards, approximately \$12 million was spent on over 700 contracts. For example, over 250 contracts, costing about \$2.6 million, were awarded in the review and update of the particulate matter standard. In other instances, EPA awarded a single contract to prepare key documents. For example, the contract for preparing the ozone criteria document cost \$669,000 even though an acceptable product was not delivered. (See p. 23 for additional detail.) The three contracts awarded for developing the joint particulate matter/sulfur dioxide criteria document totaled \$530,000. Contracts were also awarded to perform segments of the standard setting process such as preparing analyses and summarizing public comments. For example, a contract was awarded to summarize the public comments received on the proposed particulate matter standard at a cost of \$43,000. Table 2.3 shows the number of contracts awarded and the cost incurred by EPA for the review and update of the standards.

Table 2.3: Number and Cost of Contracts Used for the Standard Setting Process^a

Standard	Number of contracts	Cost (millions)
Carbon Monoxide	32	\$0.9
Lead	219	2.1
Nitrogen Dioxide	45	1.3
Ozone	114	2.6
Particulate Matter ^b	256	2.6
Sulfur Dioxide ^b	257	2.3
Applicable to all standards	15	0.4
Total		\$12.2

^aDoes not include the contract costs for the Clean Air Scientific Advisory Committee because the data were not available.

^bOnly one criteria document was developed for the standards; therefore, 234 of the contracts were the same. The costs of the contracts were allocated equally.

EPA Has Not Projected Costs for Completing Some Standards

EPA has not projected the costs to complete the review and update of the four air quality standards which are still being updated. One office—the Office of Air Quality Planning and Standards—estimates that it will spend at least \$1.5 million to complete its review of the four standards. While not included in this estimate, additional contract costs will be incurred to complete the process. Other EPA offices have not estimated additional costs to complete their review of these standards. According to the Assistant Director of the Strategies and Air Standards Division, Office of Air Quality Planning and Standards, these offices probably will not incur significant contract costs because much of the additional efforts will be by his office.

Conclusions

EPA has failed to meet the legislative mandate for reviewing and updating the national air quality standards by December 31, 1980, and every 5 years thereafter. Factors contributing to EPA's failure to meet this mandate include (1) the length of time it takes to perform internal and external reviews, (2) EPA managers waiting on the re-examination of existing science or publication of new studies, and (3) turnover of top EPA officials. Even though these factors have contributed to delays in the past, some EPA officials responsible for evaluating the scientific evidence and recommending the levels at which standards should be set believe that in the future, standards can be reviewed and updated within the 5 years established by the Congress.

Although EPA has not been successful in meeting the legislative mandate for reviewing and updating the standards every 5 years, we believe that it can be met if EPA adheres to its 5-year planning schedule and utilizes the latest available scientific information without waiting for additional studies and analyses to be completed. We do not believe such changes would compromise the quality of the standards because new information can be considered by EPA and the standards revised at any time. In fact, the Clean Air Act specifies that the standards may be changed more frequently than every 5 years.

EPA management's attention is directed primarily at improving the quality of the scientific evidence supporting the air quality standards and not on the costs of reviewing and updating the standards. Consequently, EPA does not maintain records of such costs. Without compiling cost data, EPA cannot determine how much it spends on any particular standard or how much delays in the standard setting process cost. We believe that EPA's management of its standard setting process would be enhanced by recording costs for updating and reviewing the air quality standards. Both the Congress and EPA could use such information for budgeting, cost control, and other financial management functions.

Recommendations to the Administrator, EPA

In order to meet the timetable established by the Congress, we recommend that the EPA Administrator adhere to the milestones in EPA's 5-year schedule for reviewing and updating the standards. To meet the milestones, the Administrator will need to limit technical analyses and reviews in the standard setting process to those provided for in EPA's 5-year planning schedule. Additional analyses and reviews should be done during the next 5-year review cycle.

We also recommend that the EPA Administrator implement procedures to record costs to review and update each air quality standard.

Questions Remain in the Science Supporting the National Air Quality Standards

Although EPA estimates that it has spent about \$320 million since 1980 on research supporting the national air quality standards, questions remain concerning each of the six pollutants' health effects. The number and significance of these questions—and thus, the quality of the scientific evidence supporting the air quality standards—varies considerably. Consequently, EPA's ability to assure the Congress and the public that the air quality standards reasonably protect public health is limited.

While EPA is aware that many questions exist concerning the health effects for each of the six pollutants, the questions are not systematically documented by EPA officials most knowledgeable of the science supporting each standard. Further, a formal research plan matching unanswered questions with planned and ongoing research has been prepared for only one of the six pollutants—nitrogen dioxide. Similar plans for the other pollutants could be useful to EPA officials responsible for standard setting by highlighting the more significant health effects questions for each pollutant and the extent to which planned and ongoing research will address the questions.

As of October 1986, EPA had not developed formal research plans similar to the nitrogen dioxide plan for the other five pollutants. Some EPA officials believe that such plans would be useful. However, EPA has not determined which office would have lead responsibility for preparing the plans, according to the Acting Director of the Office of Health Research.

Questions Remain About Health Effects of Each Pollutant

According to EPA officials, considerable improvements have been made in the science supporting some of the air quality standards. However, examinations by EPA and others have identified further research needs common to all six air quality standards. These research needs involve questions related to the health effects of the six pollutants. Additionally, questions unique to each of the six pollutants also remain.

In December 1983 the Clean Air Scientific Advisory Committee reported that some questions common to all six of the air quality standards remained unanswered. The Committee stated that EPA's research program had failed to provide EPA regulators with the information they needed to make sound standard setting decisions. The Committee identified the following five critical research needs, or areas with continuing questions:

- health effects experienced by individuals exposed to specific pollutants over extended periods,
- models to infer human reactions based on animal reactions to pollutants,
- the relationship between air pollution concentrations at air monitoring sites and the levels to which humans are actually exposed,
- relating human exposure to actual doses of inhaled pollutants, and
- the body's reaction to exposure from more than one pollutant.

EPA officials responsible for identifying and reviewing the scientific information used for standard setting told us that many of the research needs reported by the Committee were identified by their offices.

Other questions are unique to individual pollutants and the accompanying standards. In its 1983 report, the Committee identified and ranked a total of 46 research needs for four of the six standards—carbon monoxide, nitrogen dioxide, particulate matter, and sulfur dioxide. The Committee considered 34 of the 46 needs to be of high priority to EPA.

EPA officials have identified questions about health effects for each of the six standards. For example, in its assessment of the scientific information for nitrogen dioxide, EPA's Office of Air Quality Planning and Standards stated that research does not consistently show that people suffer adverse health effects from breathing nitrogen dioxide at levels normally found in the air. The Office concluded that no rigorous rationale exists for a specific nitrogen dioxide standard. The Acting Deputy Director of EPA's Health Effects Research Laboratory told us that, in her opinion, so many questions exist concerning the health effects of nitrogen dioxide that if the standard was not already in place, the scientific evidence would not support its establishment. On the other hand, adverse health effects from exposure to ozone have been more definitively shown. For example, studies show adverse health effects of breathing ozone at levels equal to or above the minimum set by the standard.

Research needs (or continuing questions) for the pollutants range from determining effects on fetal development to problems with projecting animal data to humans. As stated previously, the number and significance of remaining questions varies for all the pollutants and their standards. Table 3.1 shows examples of some research needs identified by the Clean Air Scientific Advisory Committee and EPA for each air quality standard; however, it does not reflect the variance of research needs among the six standards.

Table 3.1: Examples of Research Needs for Each National Air Quality Standard*

Standard	Information needed
Carbon monoxide	The effects of carbon monoxide on fetal development
	The effects of carbon monoxide on the central nervous system
	The effects of carbon monoxide on the circulatory system
Lead	The effects of lead on brain wave patterns
	The effects of lead on the body's metabolism of vitamin D
	The effects of lead on blood pressure in adults
Nitrogen dioxide	The effects of nitrogen dioxide on people who are more sensitive to it
	The effects of high hourly peak exposure of nitrogen dioxide
	The dose responses for asthmatics exposed to nitrogen dioxide for relatively short periods
Ozone	The effects of ozone on certain species or people that are more sensitive to ozone
	A model which will better enable EPA and others to project animal data to humans
	Additional research on the effects of ozone on animals
Particulate Matter	Development of a reading monitor for small particles
	The effects of exposure to wood and coal smoke from domestic fires
	Development of a more extensive ambient acid aerosol data base
Sulfur dioxide	Continued studies on the effects of sulfur dioxide on asthmatics
	Identification of other groups of people excessively sensitive to sulfur dioxide
	The effects of high sulfur dioxide concentrations for short time periods

*The table does not show all needs or their relative importance for each standard.

EPA's Process for Identifying Scientific Questions

Although EPA officials are aware of many questions concerning the health effects of the six pollutants, the questions are not systematically documented by EPA officials most knowledgeable of the research needs. Instead, health effects questions, or research needs, are identified and reported on an ad hoc basis by various EPA officials involved in the standard setting process. The information is provided to such groups as EPA's Air and Radiation Research Committee and the Clean Air Scientific Advisory Committee for their consideration.

An EPA task force established to review the standard setting process reported in May 1985 that EPA's documentation of health effects questions could be improved. The task force recommended that the EPA officials who develop a detailed awareness of such questions during preparation of the criteria documents and staff papers jointly prepare research needs papers for each standard. Further, the task force recommended that the research needs papers be prepared after identification and assessment of available scientific evidence is documented in EPA criteria documents and staff papers. The Director of EPA's Environmental Criteria and Assessment Office told us that formal research needs papers have not been prepared for the four pollutants for which criteria documents and staff papers have been completed. In his opinion, when EPA provided the Clean Air Scientific Advisory Committee information on research needs for its 1983 report, the agency complied with the task force's recommendation.

Matching Health Effects Questions With Research Efforts

EPA relies primarily on the efforts of its Air and Radiation Research Committee and the Clean Air Scientific Advisory Committee to formally document health effects questions for the pollutants and to recommend research projects to address these questions. Some EPA laboratories also prepare 5-year plans showing anticipated research on the health effects of the pollutants. However, this information is not presented in a systematic fashion that directly matches the questions with research projects for specific pollutants.

At the request of EPA's Office of Air and Radiation, in October 1984 EPA's Office of Research and Development did publish a formal research plan for nitrogen dioxide. The plan, which was updated in December 1985, contains information on (1) specific questions regarding health effects, (2) EPA's planned and ongoing research addressing specific questions, and (3) related research being done by the Health Effects Institute and other EPA research programs.

The plan matches eight broad areas of health effects questions for nitrogen dioxide with approximately 20 specific planned research projects. For example, questions concerning the role that nitrogen dioxide plays in development of chronic conditions in humans will, according to the plan, be addressed by six separate research projects. The question of how nitrogen dioxide affects the body's defense mechanisms and immune systems will be addressed by seven separate projects.

The plan can be effectively used to show what questions remain about health effects for nitrogen dioxide and provides a logical description of EPA's approach toward addressing those questions, according to the Assistant Administrator for EPA's Office of Research and Development. He also said that the plan attempts to respond to information needs of EPA's Office of Air and Radiation, which is responsible for setting the air quality standards. The Acting Deputy Director of EPA's Health Effects Research Laboratory told us that the plan enables EPA managers to quickly assess research plans for addressing questions that remain about health effects in the science supporting the standard. Additionally, the Acting Director, Office of Health Research and the Chief of the Ambient Standards Branch, Office of Air Quality Planning and Standards, believe that formal research plans similar to the nitrogen dioxide plan would provide EPA managers better oversight over the research needs for each of the standards and what research is planned and ongoing to address these needs.

EPA has not developed formal research plans similar to the nitrogen dioxide plan for the other five pollutants. According to the Acting Director, Office of Health Research, it is unclear whether his office or the Air and Radiation Research Committee would have the lead responsibility for preparing the plans. The Acting Director told us he planned to clarify which EPA office should be responsible for preparing the plans and initiate actions to have them prepared. As of October 1986, no plans had been developed.

Conclusions

Although improvements have been made in the scientific evidence on which the national air quality standards are based, questions about pollutants' health effects remain for each of the six standards. Therefore, it is difficult for EPA to assure the Congress and the public that national air quality standards protect public health.

While EPA officials are aware of many unanswered questions about adverse health effects caused by the pollutants, such questions are not systematically documented by those EPA officials most knowledgeable about the pollutants. We believe that EPA's process of relying on various individuals involved in the standard setting process to identify and report on additional research needs could be improved. Specifically, we agree with the EPA task force which recommended that those EPA officials most knowledgeable about the scientific information needed to support the air quality standards prepare research needs papers after

identification and assessment of available scientific information is documented in the criteria documents and staff papers.

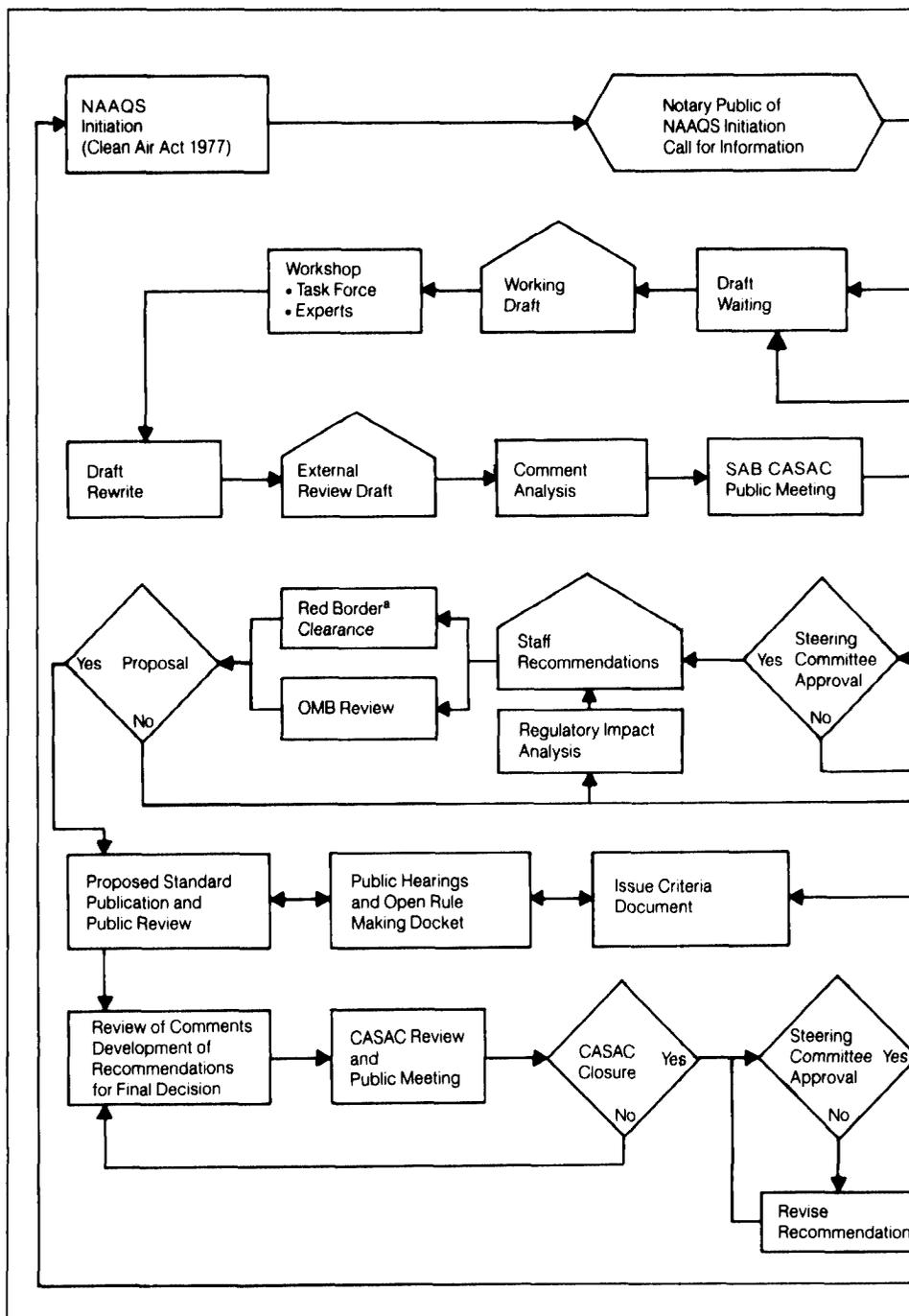
Further, we agree with EPA officials who believe that the current process for matching unanswered questions on adverse health effects with planned and ongoing research could be improved. Specifically, we believe that the preparation of formal research plans, similar to the nitrogen dioxide plan, for each of the six pollutants would be a more effective way of highlighting the more critical health effects questions for each pollutant and the extent to which planned and ongoing research will address the questions. Although research plans for individual pollutants would not, in themselves, improve the science supporting the standards, they could be useful to EPA officials responsible for standard setting.

Recommendations to the Administrator, EPA

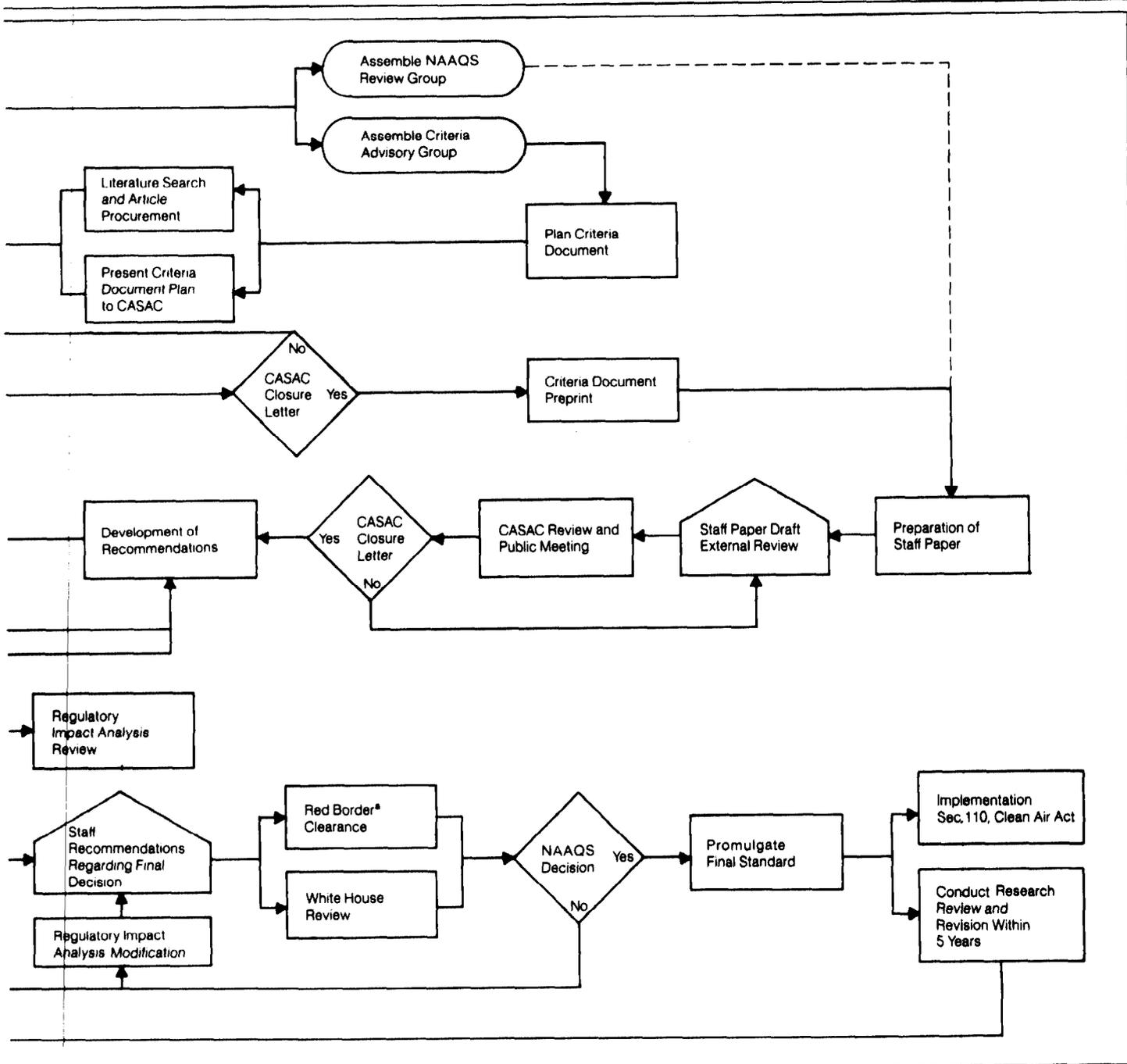
To assist EPA managers in setting national air quality standards, we recommend that the EPA Administrator implement a formal process for identifying and documenting research questions and matching these questions with planned and ongoing research for each of the six pollutants. Specifically, formal research plans should be prepared highlighting questions about health effects for each pollutant and the extent to which planned and ongoing research will address them. The identification of research questions should be done by those EPA officials most knowledgeable of the science supporting each standard and should be done after identification and assessment of available scientific evidence is documented in the criteria documents and staff papers.

Description of EPA's Air Quality Standard Setting Process

Description of EPA's Air Quality Standard Setting Process



**Appendix I
Description of EPA's Air Quality Standard
Setting Process**



*Formal senior management review of options for setting standards and their supporting documentation.

Source: "Research and Development: A Method for Examining Policy Implementation: A Study of Decisionmaking for the National Ambient Air Quality Standards, 1964-1984," Michael Berry, Deputy Director, Environmental Criteria and Assessment Office, Research Triangle Park, North Carolina, 1984.



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