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October 18, 1984

Honorable William Ruckelshaus
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Dear Mr. Ruckelshaus:

On July 19-20, 1984, the Clean Air Scientific Advisory Committee (CASAC) met to consider the Agency's proposal regarding revisions to the National Ambient Air Quality Standards (NAAQS) for Nitrogen Dioxide. Included in this proposal is the reaffirmation of the existing annual average standards for nitrogen dioxide at 0.053 ppm (100 ug/m³), and solicitation of public comments on both the need to set a separate short-term standard and the need to use an alternative form of the standard (statistical instead of deterministic). The Committee has prepared this closure letter to advise you of its major conclusions and recommendations concerning the scientific and technical aspects of these and other issues associated with the Agency's proposal for the revision of the NAAQS for nitrogen dioxide.

Through previous closure letters dated June 19, 1981 and July 6, 1982, respectively, the CASAC advised that the revised Air Quality Criteria Document for Nitrogen Oxides was scientifically adequate for standard setting and that the Office of Air Quality Planning and Standards (OAQPS) Staff Paper represented a balanced and thorough interpretation of the scientific evidence contained in the criteria document. The Committee has reviewed relevant research which has been published since those documents were prepared, and concludes that the scientific conclusions reached in those documents are still satisfactory.

The CASAC has concluded that the existing annual average primary standard for nitrogen dioxide adequately protects against adverse health effects associated with long-term exposure and provides some measure of protection against short-term health effects. Therefore, the Committee concurs with the Agency's recommendation to retain the current annual average primary standard of 0.053 ppm. The Committee further concludes that, while short-term effects from nitrogen dioxide are documented in the scientific literature, the available information was insufficient



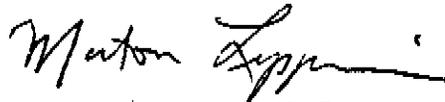
to provide an adequate scientific basis for establishing any specific short-term standard, or for determining an acceptable number of exceedances, a concentration limit, and an averaging time for such a standard. Indeed, the scientific basis for setting a separate short-term standard appears to be less firm than it was at the time of the Committee's previous review. We recommend that the Agency vigorously pursue a research program designed to address and resolve the issues related to short-term effects of nitrogen dioxide.

The Committee reaffirms its conclusion from two years ago that a secondary standard set at a level equivalent to the annual primary standard would offer sufficient protection against the identified welfare effects of nitrogen dioxide.

Members of the Committee who held a view on the issue of the form of the standard favored retaining the present deterministic form rather than adopting a statistical form for the annual standard.

A more extended analysis of the factors leading to the Committee's recommendations is contained in the enclosed report. Thank you for the opportunity to present the Committee's views on this important public health issue.

Sincerely,



Morton Lippmann, Ph.D.
Chairman, Clean Air Scientific
Advisory Committee

Enclosure

cc: Mr. Alvin Alm
Mr. Joseph Cannon
Dr. Bernard Goldstein
Dr. Terry Yosie



CASAC Findings and Recommendations on the Scientific Basis for
a Revised NAAQS for Nitrogen Dioxide

Options Presented by the Agency

Agency staff presented for CASAC review and comment three options that the Agency could pursue in concluding its current review of the NAAQS for nitrogen dioxide. These are as follows:

1. Reaffirm the annual standard at the current level and propose a short-term standard, or
2. Reaffirm the annual standard at the current level and conclude that a short-term standard is not needed, or
3. Reaffirm the annual standard at the current level, defer a decision on a short-term standard, and perform high priority research on short-term effects of nitrogen dioxide.

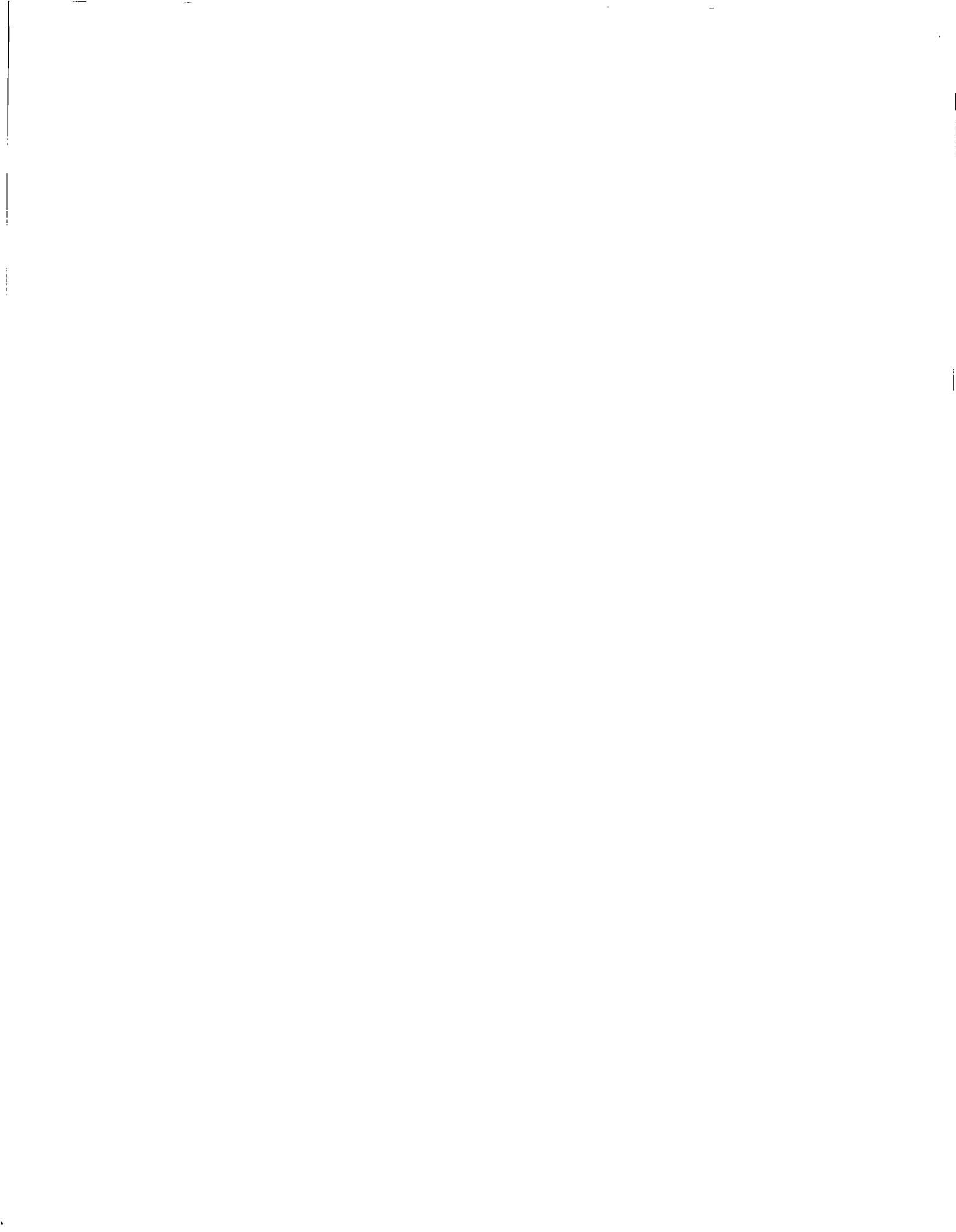
Based on the Committee's review of the scientific issues associated with the reaffirmation of the annual standard and the possible short-term standard as discussed below, the Committee believes: 1) that there is an insufficient scientific basis for action on option 1; and, 2) that options 2 and 3 are functionally equivalent, i.e. a vigorous program of research into the short-term effects of nitrogen dioxide is needed and can be accomplished under either option.

Scientific Issues in Revising the Standards

In CASAC's closure letter of July 6, 1982, the Committee discussed its review of the nitrogen oxides staff paper, noting that no single study provided the scientific basis for a decision on revising the primary standard for nitrogen dioxide. Rather, it could be based on a "weight of evidence" approach, using animal studies, controlled human exposure studies and epidemiology studies to provide both quantitative (i.e. exposure/effect) and qualitative (mechanistic) support for such a decision. Since that time new studies have been completed and, along with previously discussed studies, form the basis for the Committee's conclusions and recommendations concerning the critical issues associated with reaffirming the annual standard and evaluating a short-term standard for nitrogen dioxide.

1. Animal Toxicology Studies.

The results from recent animal studies provide further substantiation of the effects of nitrogen dioxide exposure on immune functions and increased susceptibility to infection. Some of these studies also examine patterns of exposure to nitrogen dioxide that are closer simulations of what may be actually occurring in, for example, gas stove homes. An example of this



is superimposing repeated short-term higher levels of exposure to nitrogen dioxide (e.g. 0.4 to 5.0 ppm, or more) on relatively low background levels of nitrogen dioxide, such as found in gas stove homes.

2. Controlled Human Exposure Studies.

The more recent controlled human exposure studies (mostly unpublished) present rather mixed and often contradictory results concerning respiratory effects in asthmatic and normal subjects exposed to concentrations in the range of 0.1 to 4.0 ppm nitrogen dioxide. Kagawa and Tsuru (1979) reported results possibly suggestive of short-term nitrogen dioxide effects on pulmonary function in normal subjects without combined provocative challenge by other agents (such as carbachol). Although they reported no significant differences for mean pulmonary function changes for a group of six subjects exposed to 0.15 ppm nitrogen dioxide, there were small significant decreases in airway conductance in three of the six subjects. However, the smallness of these decrements and questions regarding the statistical analyses used suggest caution in accepting the reported findings as demonstrating nitrogen dioxide effects on pulmonary function at 0.15 ppm. More recently, Bauer et al. (1984 - abstract) exposed asthmatics to 0.3 ppm nitrogen dioxide and observed effects on both pulmonary function after exercise and airway reactivity following cold air challenge.

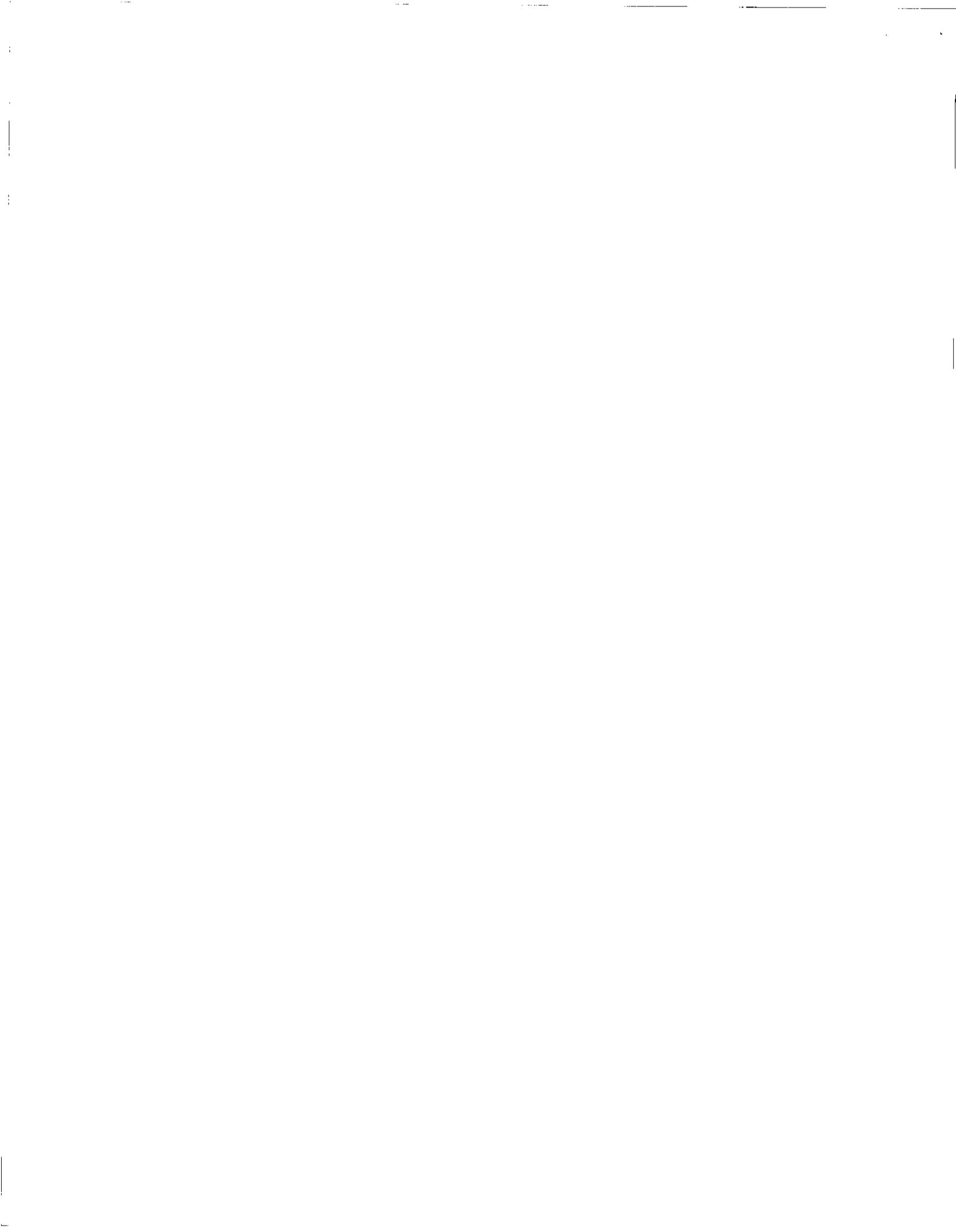
3. Epidemiological Studies.

The most recent epidemiological studies indicate less conclusive findings of an association between nitrogen dioxide and respiratory effects than previously reported. The first report of the Harvard Six Cities Study, published several years ago, noted one positive result -- an association between both lung function changes and respiratory illnesses in children under age two and exposure to gas stoves -- among a number of associated variables. More recent analyses, published in Ferris et al. (1983) and Ware et al. (1984) made adjustment for the socio-economic status of the children under age two and reported that the association between their living in homes with gas stoves and their incidence of respiratory illness is no longer statistically significant. From these results, as well as those reported by other investigators studying people living in homes with gas stoves, CASAC concludes that the scientific evidence supporting an association between living in homes with gas stoves and increases in respiratory illnesses and symptoms is insufficient to support specific limits for either short-term or long-term standards for nitrogen dioxide.

Annual Standards

1. Primary Standard.

The CASAC reviewed the results of animal, controlled human exposure, and epidemiological studies to determine if such evidence provided a scientific basis for retention of the annual standard and scientific support



for establishment of a short-term standard. The most serious effects associated with nitrogen dioxide exposures that are reported in the scientific literature result from animal studies conducted at concentrations well above those permitted by the current annual standard. Although there are large uncertainties in extrapolating these results directly to humans, the seriousness of these effects coupled with the biological similarities between animals and humans suggests that there is risk to human health from long-term exposure to nitrogen dioxide. This set of factors, widely accepted within the scientific community, leads the Committee to conclude that there is a continuing need for a long-term nitrogen dioxide standard.

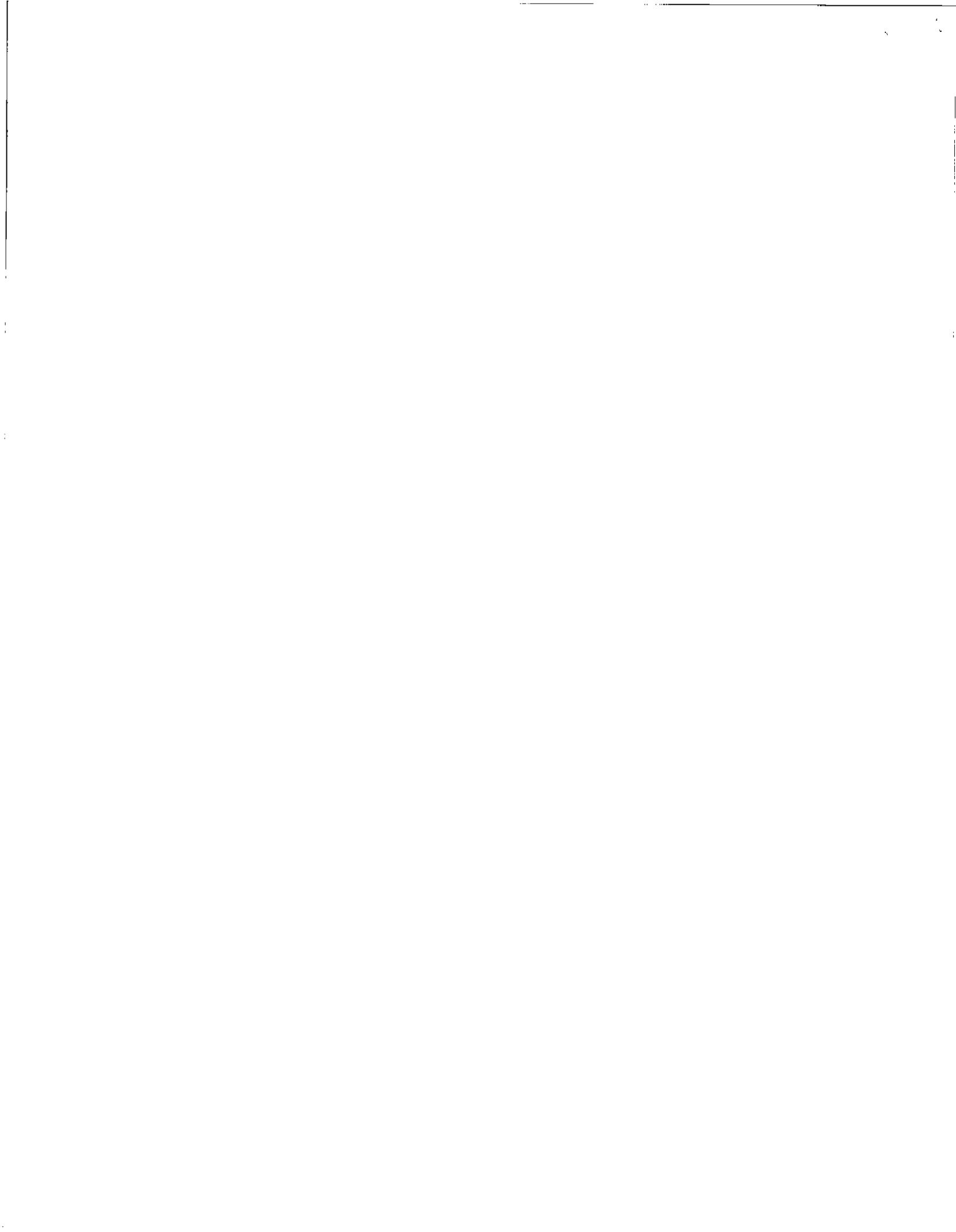
The results from recent studies showing some evidence of detectable health effects due to short-term nitrogen dioxide exposures do not provide sufficient evidence to develop a concentration level, an averaging time, or a number of exceedences for a short-term standard. For example, the gas stove studies were originally used in support of the rationale for a short-term standard; however, recent reassessments by the authors of these studies led them to reduce the level of statistical significance of their reported results. Moreover, the results of the recent clinical studies have been inconsistent. As a result, the overall scientific support for a short-term standard is more equivocal than previously thought. If the CASAC were to make a recommendation favoring a short-term standard, the Committee would also have to take into account the need to determine the number of allowable exceedences, the establishment of a concentration level, and the identification of an averaging time. At the present time, the Committee is unable to make such recommendations due to the absence of a sufficient body of information on such factors.

2. Secondary Standard.

The CASAC has not identified any further information to change its conclusion from two years ago that a secondary standard set equivalent to the annual primary standard would offer sufficient protection against the identified welfare effects of exposures to nitrogen dioxide. Although the issue of visibility impairment was raised, several members noted that, given the present state of knowledge, it is difficult to identify the degree to which nitrogen dioxide concentrations may contribute to this phenomenon. The Agency indicated that further work on this complex, multi-pollutant issue has been assigned a high priority in relation to the task and that the issue will be addressed further at subsequent CASAC meetings. The Committee is looking forward to reviewing the results of the Agency's force on visibility, progress on this important issue.

Form of the Standard

The Committee did not reach a consensus on the desirability of changing the form of the standard from the present deterministic form to a statistical form which uses the available arithmetic averages from



the last three-years to determine compliance. Although most members of the Committee took no position, one member suggested that there is a stronger argument for a statistical approach to short-term standards than for annual standards. Two others favored the retention of the current deterministic form for the annual standard.

Research Efforts

The CASAC was encouraged to learn that the Agency is currently pursuing research which addresses some of the issues raised in our December 30, 1983 report to you on Research Needed to Support the Development of NAAQS. We look forward to continued reports from the Agency on the progress of this important research. The Committee feels compelled to reiterate that without an adequately funded research program aimed at assessing the significance of the health effects associated with short-term nitrogen dioxide exposures, the Agency cannot make scientifically informed decisions concerning the need for a short-term standard, its concentration level, averaging time or an acceptable number of exceedances.

Summary of CASAC Recommendations

For the reasons stated, the Committee recommends that you reaffirm the annual standard at the current level, and that you defer a decision on the short-term standard while pursuing an aggressive research program on short-term effects of nitrogen dioxide.

