RULE	STATUS	ANNUAL (RECURRING) COST (millions of dollars)	INVESTMENT (ONE-TIME) COST (millions of dollars)	COMMENTS
Test Vehicle Exemption Requirements				
used for testing purposes. EPA intends to relax both the reporting requirements and the requirements for qualifications for an exemption to reduce administrative burdens.				
Emission averaging scheme for manufacturers to meet the NOx emission requirement for light and heavy trucks				
EPA has been investigating the possibility of allowing manufacturers to meet the NOx standards for trucks "on the average" rather than requiring that each vehicle meet a specific NOx standard.	EPA has published a NPRM for NOx averaging (45 FR 79382) and intends to propose an averaging scheme by May 1982, in conjunction with the NOx rulemaking.	NA	NA	
Intention to provide sufficient leadtime for compliance with emission regulations				
In setting various emission standards, EPA must take into account the time that the industry will need to either develop the necessary control technology or to make other changes in order to meet the standards. EPA intends to provide this necessary leadtime, as measured from the date of promulgation of regulations.	EPA's position will be made clear in future notices and appropriate contacts with the manufacturers.	NA	NA	

EPA DRAFT STAFF PAPERS SUMMARIZING RECOMMENDED REVISIONS TO PARTICULATE NAAQS, CRITICAL ISSUES IN SULFUR DIOXIDE CRITERIA

Issued June 13, 1981

Summary of Staff Conclusions and Recommendations for the Primary Standards

The major staff conclusions and recommendations made in Section VI are briefly summarized below:

1. A separate general particulate standard remains a reasonable public health policy choice.

2. Inclusion of particles deposited in the extrathoracic region in TSP misdirects control efforts towards particles of low risk to health. A new particle indicator representing total thoracic deposition (TTP) is recommended. A choice should be made with regard to the two ISO definitions (<10 um, <15 um).

3. Short-term (24-hour) statistical form and annual arithmetic means standards are recommended.

4. Based on a staff assessment of the epidemiology data, the numerical levels of the TTP standards should be in the vicinity of the levels of the current TSP standards. Specifically, the recommended ranges are:

24-Hours	150-350 $\mu g/m^3$
Annual	55-120 $\mu g/m^3$

To a greater or lesser extent, these ranges incorporate reasonable "margins of safety" for sensitive groups and for potential hazards not yet evaluated in quantitative studies. When selecting a level within these ranges, consideration must also be given to the particle size chosen for TTP.

5. Factors to be considered in evaluating risks in the ranges are discussed in Section VI. An additional consideration in choosing a size cut and level is the nature of potential secondary standards for visibility and/or soiling damage.

The above ranges of TTP standards represent varying degrees of relaxation when compared to the current primary TSP standard. In the lower portions of the range, the major portion of the relaxation results from the more restrictive size range. Thus, a city where exceedance of the TSP standard was largely dominated by coarse mode dust would be less likely to violate a comparable TTP standard than would an area where exceedance of the TSP standard was dominated by fine and smaller coarse particles. In the upper portion of the above range, relaxation occurs for TTP as well as larger particles.

Summary of Staff Conclusions and Recommendations for the Secondary Standards

Major staff conclusions and recommendations are made in Section VII and are summarized below:

1. Impairment of visibility over urban to multistate regions clearly affects public welfare. The staff recommends development of a fine particle secondary standard. If the standard is based on aircraft operations, a short-term (24 hours or less) fine mass standard in the range of 70 $\mu g/m^3$ to 220 $\mu g/m^3$ is indicated. Consideration of aesthetic effects would suggest lower concentration and seasonal or annual averaging times. Linking the fine mass standard to a more direct indication of longer path visibility (observation,

extinction) is advisable to account for uncertainties in the fine particle/humidity/visibility relationships.

2. Although effects on climate support the desirability of a fine particle standard, quantitative relationships are not well enough developed to provide the principal basis for selecting the level of the standard.

3. Consideration should be given to soiling and nuisance effects in determining whether a secondary standard for TSP or other large particle indicator is desirable to supplement whatever benefits accrue from the primary and secondary fine standards. Ancillary support for such a standard may be found in the limited data on effects of large particles on personal comfort.

4. While chemically active fine mode and hygroscopic coarse mode particles have been qualitatively associated with materials damage, the available data do not suggest major effects of particles on materials for concentrations and sizes at or below the ranges recommended for the primary health and secondary visibility standards. Therefore, a secondary standard based on materials damage is not recommended.

5. The staff concludes that a secondary particle standard is not needed to protect vegetation.

6. The acid deposition issue will not be addressed in the review of the particulate matter standards.

Preliminary Staff Summary of Critical Elements in the Review of Primary SO_2 Standard

Preparation of the staff paper for sulfur oxides is being deferred until results of ongoing controlled human exposure studies of SO_2 are available. This preliminary staff assessment is based on available information and is intended to assist in the review of key studies included in the criteria document. Because the effects of sulfuric acid and other sulfates are included in the draft staff paper for particulate matter, this summary will focus on SO_2.

1. Epidemiological studies suggest that SO_2 in combination with particulates may be associated with a number of health effects. By themselves, these studies may support continuation of 24-hour and annual standard(s) for SO_2, perhaps indexed according to existing particle levels. Many of these studies are discussed in the draft staff paper for particulate matter. The staff intends to evaluate the following additional epidemiology studies in the SO_2 staff paper for qualitative or quantitative evidence: Aubry *et al.* (1979); Becklake *et al.* (1979); Carnow *et al.* (1969); Cohen *et al.* (1972); Kerrebijn *et al.* (1975); and Neri *et al.* (1975).*

2. Animal and human studies suggest that the most common response to SO_2 is a relatively rapid reflex bronchoconstriction (Nadel *et al.*, 1965). Under resting conditions, SO_2 is largely removed by the moist lining of the upper respiratory tract, limiting the amount reaching the more sensitive areas (Speizer and Frank, 1966). Particles may enhance effects of SO_2 through increased penetration of sorbed SO_2 or irritant reaction products (McJilton and Frank, 1976); Admur and Underhill, 1968).

3. The more important controlled human exposure studies of SO_2 are summarized in Table I. The staff believes these studies may suggest the need for a one hour SO_2 standard.

In summary, the data indicate that most healthy adult subjects respond to short-term SO_2 exposures of 5 ppm or more. At lower levels (1-4 ppm) results are more mixed, with a number of studies reporting otherwise normal individual "hyperreactors." At 1 ppm, Frank *et al.* (1962) reported a significant increase in pulmonary flow resistance in 1 of 11 subjects during exposures lasting 15 minutes. Also at 1 ppm, Andersen *et al.* (1974) found a progressive decrease in forced expiratory flow (FEF25-75%) and forced expiratory volume (FEV) and an increase in nasal flow resistance in 15 adults exposed for six hours. Exercise appears to increase the response in normal subject, probably through increased dose to tracheobronchial receptors. With intermittent exericse, levels of 0.75 ppm SO_2 have resulted in significant decreases in several functional parameters in free-breathing health adults (Bates and Hazucha, 1973, Stacy *et al.*, 1981). No significant symptomatic effects were reported in these studies.

Asthmatic subjects appear to respond to SO_2 at levels an order of magnitude lower than do healthy adults. Several studies report marked changes in functional measurements after short-term (- 1 hour) oral (mouthpiece) exposure at rest and during exercise at levels of 1-5 ppm with symptoms such as wheezing, shortness of breath increasing with concentration. A number of subjects were reportedly unable to tolerate these exposures. Symptomatic responses are reported at levels as low as 0.5 ppm for 10 minutes (Sheppard *et al.*, 1981). Decreased functional measurements can occur for oral (mouthpiece) exposures of 0.25 to 0.5 ppm with exercise. For the two most sensitive asthmatic subjects, increased airway resistance (without symptoms) was reported for oral breathing and exercise at levels of 0.1 ppm, comparable to the lowest pulmonary effects level for guinea pigs (0.16 ppm, Amdur and Underhill, 1970).

At issue is at what levels would symptomatic and functional responses occur in asthmatics under free breathing conditions and with less steep temporal gradients in pollutant exposure. The results of ongoing controlled human studies should be of significant value in addressing these issues. It is, therefore, advisable to defer preparation of the SO_2 staff paper at least until preliminary results are available.

4. As noted in the criteria document, the evidence for mutagenicity/cocarcinogenicity of SO_2 is equivocal. Nevertheless, the available evidence for these important health endpoints must be carefully evaluated.

Table I. EFFECTS OF SO_2 ON RESPIRATORY MECHANICS, SYMPTOMS

Exposure	Observations	References
Healthy Subjects		
0.4-.75 ppm SO_2, 2 hours, various routes, activity	5 studies - No effects on function, symptoms 2 studies - Decreased in MEFR, FVC, $FEV_{1.0}$, MMFR @ .75 ppm, free breathing with exercise	Bates and Hazucha, 1973 Bedi et al., 1979 Bell et al., 1977 Horvath and Folinsbee, 1977 Jaeger et al., 1979 Snell and Luchsinger, 1969 Stacy et al., 1981
1-4 ppm SO_2, 3-30 minutes, mostly resting, various routes	Mixed results; some subjects appear more sensitive; some changes in function measurements indicating bronchoconstriction (e.g., increased airway resistance, decreased MEFR, MMFR; some subjects report symptoms such as throat irritation; usually greater response with oral breathing, exercise	Amdur et al., 1953 Burton et al., 1969 Frank et al., 1962 Kriesman et al., 1976 Lawther et al., 1975 Melville, 1970 Nadel et al., 1965 Sim and Pattle, 1957 Sheppard et al., 1980 Snell and Luchsinger, 1969 Tomono, 1961
5 ppm SO_2, 3-180 minutes, mostly resting, various routes	Most studies report changes in function measurements, bronchoconstriction. Increased symptoms: throat irritation cough, dryness	Amdur et al., 1953 Anderson et al., 1974 Frank et al., 1962 Kreisman et al., 1976 Lawther et al., 1975 Melville, 1970 Nadel et al., 1965 Newhouse et al., 1978 Sheppard et al., 1980 Sim and Pattle, 1957 Snell and Luchsinger, 1969 Tomono, 1961
Asthmatic Subjects		
.1-.5 ppm SO_2, 10-180 minutes various activity levels, oral exposures	Incremental airway resistance in some subjects at all levels, slight change in MMFR, resting subjects; wheezing, shortness of breath in some subjects; potentiated by exercise	Jaeger et al., 1979 Sheppard et al., 1981
1-5 ppm SO_2, 3-150 minutes, mostly at rest, oral exposures	Marked changes in respiratory function in most subjects (airway resistance, others). Numbers reporting wheezing, shortness of breath, dyspnea increase with dose, exercise; some require medication	Kriesman et al., 1976 Sheppard et al., 1980 Sheppard et al., 1981
1 ppm SO_2 + 1 mg/m^3 NaCl (0.9 m) droplets, RH 75%, oral, rest and exercise 1 hour	Decreased flow, other parameters suggesting effects in central and small airways; with exercise 5 of 8 experienced wheezing, 3 of 8 shortness of breath	Koenig et al., 1981

EPA REPORTING, RECORDKEEPING FORMS UNDER REVIEW BY OMB

(46 FR 30926, June 11, 1981)

OFFICE OF MANAGEMENT AND BUDGET

Agency Forms Under Review

Background

June 8, 1981.

When executive departments and agencies propose public use forms, reporting, or recordkeeping requirements, the Office of Management and Budget (OMB) reviews and acts on those requirements under the Paperwork Reduction Act (44 USC, Chapter 35). Departments and agencies use a number of techniques including public hearings to consult with the public on significant reporting requirements before seeking OMB approval. OMB in carrying out its responsibility under the Act also considers comments on the forms and recordkeeping requirements that will affect the public.

List of Forms Under Review

Every Monday and Thursday OMB publishes a list of the agency forms