ORAL ARGUMENT NOT YET SCHEDULED

No. 08-1200 (Lead) and Consolidated Cases

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

STATE OF MISSISSIPPI, *ET AL.*,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

On Petitions for Review of Final Agency Action of the United States Environmental Protection Agency

JOINT OPENING BRIEF OF PETITIONER STATE OF MISSISSIPPI AND INDUSTRY PETITIONERS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), Petitioner State of Mississippi and Industry Petitioners state as follows:

A. Parties, Intervenors, and Amici

Because these consolidated cases involve direct review of final agency action, the requirement to furnish a list of parties, intervenors, and *amici* that appeared below is inapplicable. These cases involve the following parties:

Petitioners:

Case No. 08-1200: State of Mississippi

Case No. 08-1202: State of New York; State of California, by and through Arnold Schwarzenegger, Governor of the State of California; California Air Resources Board; State of Connecticut; State of Delaware; State of Illinois; State of Maine; State of Maryland; Commonwealth of Massachusetts; State of New Hampshire; State of New Jersey; State of New Mexico; State of Oregon; State of Rhode Island; District of Columbia; City of New York

Case No. 08-1203: American Lung Association; Environmental Defense Fund; Natural Resources Defense Council; National Parks Conservation Association; Appalachian Mountain Club

Case No. 08-1204: Ozone NAAQS Litigation Group; Utility Air Regulatory Group

Case No. 08-1206: National Association of Home Builders

Respondent

The United States Environmental Protection Agency is the Respondent in all of these consolidated cases.

Intervenors and *Amici*

The County of Nassau is an Intervenor-Petitioner.

American Lung Association, Appalachian Mountain Club, Environmental Defense Fund, National Association of Home Builders, Natural Resources Defense Council, Ozone NAAQS Litigation Group, and Utility Air Regulatory Group are Intervenor-Respondents.

The Province of Ontario is an *amicus curiae* in support of Petitioners.

B. Rulings Under Review

These consolidated cases involve final agency action of the United States Environmental Protection Agency entitled "National Ambient Air Quality Standards for Ozone," published on March 27, 2008, at 73 Fed. Reg. 16436.

C. Related Cases

These consolidated cases have not previously been before this Court or any other court.

DISCLOSURE STATEMENTS

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, the following Petitioners provide the following disclosures:

Ozone NAAQS Litigation Group **–** Ozone NAAQS Litigation Group ("ONLG") is a coalition of not-for-profit trade associations whose member companies represent a broad cross-section of American industry. The ONLG's purpose is to advance the interests of the companies represented by its member associations in the regulatory and judicial arenas. The ONLG has no outstanding shares or debt securities in the hands of the public and has no parent company. No publicly held company has a 10% or greater ownership interest in the ONLG.

Utility Air Regulatory Group **–** Utility Air Regulatory Group ("UARG") is a not-for-profit association of individual electric generating companies and national trade associations that participates on behalf of its members collectively in administrative proceedings under the Clean Air Act, and in litigation arising from those proceedings, that affect electric generators. UARG has no outstanding shares or debt securities in the hands of the public and has no parent company. No publicly held company has a 10% or greater ownership interest in UARG.

National Association of Home Builders **–** National Association of Home Builders ("NAHB") is a not-for- profit trade association organized for the purposes of promoting the general commercial, professional, and legislative interests of its

approximately 140,000 builder and associate members throughout the United States. NAHB's membership includes entities that construct and supply single family homes, as well as apartment, condominium, multi-family, commercial and industrial builders, land developers, and remodelers. NAHB does not have any parent companies that have a 10% or greater ownership interest in NAHB, and no publicly held company has a 10% or greater ownership interest in NAHB.

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MISCELLANEOUS

GLOSSARY OF TERMS

Act	Clean Air Act
Agency	U.S. Environmental Protection Agency
CAA	Clean Air Act
CASAC	Clean Air Scientific Advisory Committee
CD	Criteria Document
EPA	U.S. Environmental Protection Agency
FEV	Forced Expiratory Volume
IQA	Information Quality Act
NAAQS	National Ambient Air Quality Standard
NOx	Nitrogen Oxides
OMB	Office of Management and Budget
PM	Particulate Matter
$PM_{2.5}$	Fine Particulate Matter
PM_{10}	Coarse Particulate Matter
ppm	parts per million
RTC	Response to Comments
SIP	State Implementation Plan
Standard	National Ambient Air Quality Standard
VOCs	Volatile Organic Compounds

JURISDICTIONAL STATEMENT

Petitioners seek review of a final rule of the U.S. Environmental Protection Agency ("EPA" or "Agency") entitled "National Ambient Air Quality Standards for Ozone." 73 Fed. Reg. 16436 (Mar. 27, 2008), Joint Appendix ("JA") __-__. Petitions for review of this rule were filed within the 60-day period prescribed by § 307(b)(1) of the Clean Air Act[1] ("CAA" or "Act"). This Court has jurisdiction under that provision.

STATEMENT OF ISSUES

1. Whether EPA's decision to revise the primary national ambient air quality standard ("NAAQS" or "standard") for ozone is arbitrary, capricious, or contrary to law for failure to, *inter alia*:

(a) Apply the "requisite to protect" standard of CAA § 109(b)(1);

(b) Explain adequately how new evidence justifies a revision of the ozone NAAQS; or

(c) Consider important aspects of the issue, including how current risks compare with risks EPA previously found acceptable.

[1] All citations are to the CAA; the Table of Authorities provides parallel citations to the U.S. Code.

2. Whether EPA's reliance on data and analyses that violate §§ 108 and 109 of the CAA, as well as the Information Quality Act ("IQA"), renders its decision to revise the ozone NAAQS unlawful.

3. Whether, if the revised primary ozone standard is vacated, the revised secondary ozone NAAQS must also be set aside.

STATUTES AND REGULATION

Pertinent statutes and regulations are reproduced in the Statutory and Regulatory Addendum.

STATEMENT OF THE CASE AND FACTS

This case involves EPA's 2008 revision to the ozone NAAQS. 73 Fed. Reg. 16436/1,[2] JA__. EPA first established NAAQS for ozone in 1971 and, pursuant to CAA §§ 108 and 109, has periodically reviewed and revised those NAAQS. *See, e.g.*, 44 Fed. Reg. 8202/1 (Feb. 8, 1979), JA__-__; 58 Fed. Reg. 13008/1 (Mar. 9, 1993), JA__-__.

In 1997, EPA revised the ozone NAAQS, finding that an 8-hour average standard of 0.08 parts per million ("ppm") was "requisite" to protect public health with an "adequate margin of safety," within the meaning of CAA § 109(b)(1), taking into account "uncertainties associated with inconclusive scientific and

[2] For the Court's convenience, the Federal Register column number in which cited material can be found is provided after the diagonal.

technical information" and "provid[ing] a reasonable degree of protection against hazards that research has not yet identified." 62 Fed. Reg. 38856, 38857/1 (July 18, 1997) ("the 1997 NAAQS"), JA__, __. EPA promulgated a secondary NAAQS identical to the primary one. *Id.* at 38871/1, JA__. The 1997 NAAQS were controversial and resulted in challenges being heard in the Supreme Court and twice in this Court. *See Am. Trucking Ass'ns v. EPA*, 175 F.3d 1027 (D.C. Cir.) ("*ATA I*"), *modified in part on reh'g*, 195 F.3d 4 (D.C. Cir. 1999) ("*ATA II*"), *aff'd in part, rev'd in part, and remanded sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001) ("*Whitman*"), *on remand*, 283 F.3d 355 (D.C. Cir. 2002) ("*ATA III*"). The Supreme Court held that EPA must set primary NAAQS at the level that is "requisite," meaning the level that is "sufficient, but not more than necessary" to protect public health. *Whitman*, 531 U.S. at 473 (quotation omitted). On remand, this Court held that the 0.08 ppm primary ozone NAAQS met the "requisite" standard of *Whitman*. *ATA III*, 283 F.3d at 379 ("Although we think Petitioners' individual criticisms have some force, we are satisfied that in selecting a level of 0.08 rather than 0.07 (or, for that matter, 0.09), EPA 'engage[d] in reasoned decision-making.'") (quoting *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 392 (D.C. Cir. 1998)). The Court also upheld the secondary NAAQS. *Id.* at 380.

This litigation addresses whether EPA's 2008 determination that further revision of the 1997 NAAQS was "requisite" comports with the legal obligation to

set standards that are neither more nor less stringent than necessary to protect public health and welfare.

I. The CAA and IQA

CAA § 108(a)(1)(A) provides for regulation of air pollution that "endanger[s]" public health or welfare. EPA must base primary and secondary NAAQS on "[a]ir quality criteria … [that] accurately reflect the *latest scientific knowledge* useful in indicating the kind and extent of all identifiable effects on public health or welfare…." CAA § 108(a)(2) (emphasis added).

The Act requires EPA to set "primary" NAAQS at the level "requisite to protect the public health … [with] an adequate margin of safety." CAA § 109(b)(1). The CAA also directs EPA to establish "secondary" NAAQS at the level "requisite to protect the public welfare from any known or anticipated adverse effects." *Id.* § 109(b)(2). As explained by the Supreme Court, "requisite … mean[s] sufficient, but not more than necessary." *Whitman*, 531 U.S. at 473 (quotation omitted). Thus, NAAQS need not eliminate all risk, but only those public health and welfare risks that are unacceptable. Whether a risk is unacceptable requires consideration of, among other things, "background circumstances." *Id*. at 495 (Breyer, J., concurring).

The Act also requires EPA to review NAAQS and the underlying air quality criteria every five years and to "make such revisions … as may be appropriate in

accordance with section 108 … and … [section 109]." CAA § 109(d)(1). Accordingly, a decision to revise an existing NAAQS must "accurately reflect" the latest science regarding "identifiable effects" on public health and welfare, *id.* § 108(a)(2), and must be founded on a record showing that the existing NAAQS is no longer "requisite" (i.e., no longer "sufficient, but not more than necessary").

Although EPA has "no obligation … to quantify precisely the pollutant's risks prior to setting primary NAAQS," *ATA III*, 283 F.3d at 378, EPA must do more when it revises a NAAQS than engage in an "analysis of the relative protection expected from the recommended standards." *See Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 530 (D.C. Cir. 2009). It must justify why a new level of protection is "requisite" for its decision-making to satisfy the CAA and have a "reasoned basis." *Id.*

Moreover, because NAAQS revision must "accurately reflect the latest scientific knowledge," CAA § 108(a)(2), the IQA must inform EPA's analysis. The IQA requires federal agencies including EPA to ensure the quality, objectivity, utility, and integrity of information they use. Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153 to -154 (2000). The IQA requires that information EPA uses for decisionmaking must be (1) objective and (2) useful for the purpose for which it was intended. 67 Fed. Reg. 8452 (Feb. 22, 2002) (Office of Management and Budget ("OMB") guidelines for IQA) ("OMB IQA Guidelines"), JA__-__; *see*

also EPA, EPA/260R-02-008, GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED BY THE ENVIRONMENTAL PROTECTION AGENCY (Oct. 2002) ("EPA IQA Guidelines"), JA__-__. The IQA and EPA's data quality rules therefore provide standards for evaluating whether NAAQS revision "accurately" reflects the latest scientific knowledge.

II. Ozone in the Ambient Air

NAAQS regulate pollutants whose "presence … in the ambient air results from numerous or diverse mobile or stationary sources." CAA § 108(a)(1)(B). EPA defines ambient air as "that portion of the atmosphere, external to buildings, to which the general public has access." 40 C.F.R. § 50.1(e). Ozone is present in the ambient air as a result of both natural and anthropogenic emissions. EPA has explained that "[n]aturally occurring [ambient ozone] can result from biogenic organic precursors reacting with naturally occurring nitrogen oxides (NOx) and by stratospheric [ozone] intrusion into the troposphere." 73 Fed. Reg. 16437/3, JA__. Anthropogenic activities that result in emissions of NOx and volatile organic compounds ("VOCs") also contribute to ambient ozone. *Id.* Although emissions from anthropogenic activities in the United States contribute to ambient ozone in this country, EPA recognizes that emissions from as far away as Asia also contribute. *See* EPA, EPA/600/R-05/004aF, AIR QUALITY CRITERIA FOR OZONE

AND RELATED PHOTOCHEMICAL OXIDANTS, VOLUME I OF III, at 2-13 (Feb. 2006) ("2006 Criteria Document" or "2006 CD"), JA__.

As a result, even eliminating all anthropogenic sources of NOx and VOCs in the United States would not eliminate ozone in the ambient air. As part of the rulemaking on the 1997 NAAQS, EPA estimated "background" concentrations of ozone to be 0.040 ppm based on monitored data. EPA, EPA-452/R-96-007, REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION: OAQPS STAFF PAPER at 20-21, 116 (June 1996) ("1996 Staff Paper"), JA__-__, __. Reflecting this reality, one of "EPA's three justifications" for setting the level of the 1997 NAAQS at the 0.08 ppm level was that a lower NAAQS "would be too close to peak background levels." *ATA III*, 283 F.3d at 379.

Emissions of NOx and VOCs in the United States have decreased significantly over the past thirty years. EPA reported decreases in NOx and VOC emissions of 52% and 63%, respectively, between 1980 and 2010, resulting in an overall 28% improvement in 8-hour ozone levels. EPA, Air Quality Trends, *available at* http://epa.gov/airtrends/aqtrends.html, JA__.

III. The 1997 NAAQS

In 1997, EPA reviewed the then-existing ozone NAAQS of 0.12 ppm (1-hour average) to determine whether revisions were appropriate. EPA identified a

wide-range of possible health effects as relevant to its decision. Evidence for these effects was taken from three types of scientific studies: human clinical studies (also called human exposure or controlled-exposure studies), epidemiological studies, and toxicological studies. 62 Fed. Reg. 38859/2, JA__.

First, EPA concluded that human clinical studies demonstrated associations between ozone exposure and "effects of concern." *Id.* at 38863/3, JA__. For example, these studies reported lung function decrements, respiratory symptoms (such as cough and pain on deep respiration), nonspecific bronchial responsiveness, and respiratory inflammation in humans resulting from short-term (1 to 3 hours) and prolonged (6 to 8 hours) ozone exposures at concentration levels as low as 0.08 ppm. *Id*. at 38863/3-38864/1, JA__-__. These studies, however, covered only a limited number of subjects and reported a wide range of responses at these concentration levels, such that it was impossible to draw broadly applicable conclusions concerning adversity. *Id.* at 38864/1-2, JA__.

Second, EPA found that epidemiological studies provided "evidence of similar functional and symptomatic effects at ambient [ozone] exposures that are consistent with the clinical findings." *Id*. at 38864/1, JA__. According to EPA, these studies suggested possible associations between exposures to ambient levels of ozone and excess hospital admissions and emergency department visits for respiratory causes, both for sensitive populations and the general public. *Id*. EPA

also noted that the epidemiological literature suggested an association between ozone exposure and mortality, but determined this evidence was of such a limited nature it could not be relied upon for decisions regarding the ozone NAAQS. *See* 73 Fed. Reg. 16446/2, JA__; *see also* EPA, EPA/600/P-93/004cF, AIR QUALITY CRITERIA FOR OZONE AND RELATED PHOTOCHEMICAL OXIDANTS, VOLUME III OF III at 7-143 (July 1996) ("1996 Criteria Document" or "1996 CD"), JA __.

Third, EPA considered the results of toxicological studies of animals or cell systems. EPA found these studies shed light on the potential mechanisms of action for respiratory inflammation, lung function changes, and increased risks of respiratory infection examined in the human clinical and epidemiological studies. 62 Fed. Reg. 38864/1, JA__. This information regarding potential mechanisms for the effects observed, EPA concluded, supported its use of the clinical and epidemiological studies for decisions regarding the NAAQS. *Id.*

EPA also examined evidence regarding the impact of ozone exposure on different segments of the population. Based on that evidence, EPA identified active children, outdoor workers, and people with increased responsiveness to ozone, including asthmatics, as the sensitive population for NAAQS decisions. *Id.* at 38859/3, JA__.

After considering this evidence, EPA identified the possibility of the following "acute health effects" associated with ozone exposure: "transient

pulmonary function responses, transient respiratory symptoms, effects on exercise performance, increased airway responsiveness, increased susceptibility to respiratory infection, increased hospital admissions and emergency room visits, and transient pulmonary inflammation." *Id.* According to EPA, some individuals would be at risk of such effects due to short-term (1-hour) ozone exposures at concentrations as low as 0.12 ppm, and by longer (8-hour) exposures at concentrations as low as 0.08 ppm. *Id*. Based on the toxicological studies, EPA also expressed concern with even less certain possible "chronic" effects, consisting of "damage to respiratory tissue such that individuals later in life may experience a reduced quality of life." *Id.* According to EPA, such chronic effects were "at least … biologically plausible" over a lifetime of ozone exposure. *Id*.

Given the uncertainties that exist when regulating at very low exposure levels, EPA "put [its] judgments about health effects that are adverse for individuals into a broader public health context … [by] conduct[ing] quantitative assessments." *Id.* at 38860/2, JA__. These assessments analyzed ozone exposures and related risks in nine representative U.S. urban areas for the then-existing 0.12 ppm 1-hour standard and for various alternative standards, *id*. at 38860/3 to 38861/1, JA__-__, and showed that statistically significant reductions in risks associated with various adverse health outcomes would result from alternative 8-hour NAAQS as compared to the then-existing standard, *id*. at 38864/3, JA__.

Based on this information, EPA set the 1997 primary ozone NAAQS at 0.08 ppm (8-hour average), finding this level would prevent not only "pollution levels … demonstrated to be harmful," but also "lower pollutant levels that … may pose *an unacceptable risk of harm*." *Id.* at 38857/1, JA__ (emphasis added). EPA rejected arguments asking it to set the 1997 ozone NAAQS at 0.07 ppm. *Id.* at 38868/2, JA__. EPA observed that although risks of adverse effects existed at exposures *below* 0.08 ppm, "the most certain [ozone]-related effects, while judged to be adverse, are *transient and reversible* (particularly at [ozone] exposures below 0.08 ppm) and the more serious effects with greater immediate and potential long-term impacts on health are less certain." *Id*. (emphasis added); *see also id*. at 38861/3 (EPA also considered "the possibility of long-term effects in selecting the level of an 8-hour standard, which will provide protection against any such effects to the extent they may occur in humans, by lowering overall air quality distributions and, thus, reducing cumulative long-term exposures."), JA__. EPA also noted that 0.08 ppm was close enough to peak background concentrations to justify not lowering the standard further. *Id.* at 38868/3, JA__; *see ATA III*, 283 F.3d at 379 (EPA properly considered the "relative proximity [of 0.08 ppm] to peak background ozone concentrations" in deciding not to set a lower standard).

Thus, EPA determined in 1997 that a primary standard set below 0.08 ppm was not "requisite to protect the public health with an adequate margin of safety,"

62 Fed. Reg. 38868/3, JA__, and determined that the 0.08 ppm standard would "*reduce risks sufficiently* to protect public health with an adequate margin of safety," *id*. at 38867/3 (emphasis added), JA__. This Court upheld EPA's determination, noting the proximity of 0.08 ppm to background levels and "the absence of *any* human clinical studies at ozone concentrations below 0.08 [ppm]." *ATA III*, 283 F.3d at 379 (emphasis in original).

For the secondary NAAQS, EPA focused on effects of ozone on vegetation, including "effects such as visible foliar injury, growth reductions and yield loss in annual crops, growth reductions in tree seedlings and mature trees, and effects that can have impacts at the forest stand and ecosystem level." 62 Fed. Reg. 38875/1, JA__. Noting that "significant uncertainties remain with respect to exposure dynamics, air quality relationships, and estimates in increased vegetation protection," *id.* at 38877/1, JA__, and that a standard equivalent to the new primary standard would "provide substantially improved protection for vegetation from [ozone]-related adverse effects," *id*. at 38877/3, JA_, EPA established a new secondary ozone NAAQS "identical in all respects to the new primary standard," *id.* This Court upheld that standard. *ATA III*, 283 F.3d at 380.

IV. The 2008 Decision To Revise the 1997 NAAQS

EPA's review of the 1997 primary NAAQS, which led to the promulgation of the 2008 primary ozone NAAQS at issue here, addressed the same types of health evidence considered in 1997. 73 Fed. Reg. 16440/2-3, JA__.

First, EPA again examined the clinical evidence. As EPA observed, this evidence still suggested associations between ozone exposures and "lung function decrements, respiratory symptoms, pulmonary inflammation, and increased airway responsiveness" – the same health endpoints such studies identified in 1997. *Id*. at 16445/1, JA__; *see also id.* at 16476/1 (noting studies examining exposure at 0.08 and above form "the large bulk" of clinical evidence), JA__. According to EPA, clinical studies remain the "most compelling" evidence examined during the review. *Id*. at 16444/3, JA__.

EPA paid particular attention to the *only* two new clinical studies that examined exposures to ozone concentrations below 0.08 ppm, the lowest level examined in 1997. *Id.* at 16454/1, 16507/2, JA__, __ (citing Adams, W.C., *Comparison of Chamber and Face-Mask 6.6-Hour Exposures to Ozone on Pulmonary Function and Symptoms Responses*, 14 INHALATION TOXICOLOGY 745-64 (2002) ("Adams 2002"), JA__-__; Adams, W.C., *Comparison of Chamber 6.6-Hour Exposures to 0.04-0.08 ppm Ozone via Square-wave and Triangular Profiles on Pulmonary Responses*, 18 INHALATION TOXICOLOGY 127-36 (2006) ("Adams

2006"), JA__-__). Dr. Adams, the author of these two studies, explained that his studies "do[] not demonstrate a significant mean effect by ordinarily acceptable statistical analysis" from exposure to ozone levels below 0.08 ppm. Adams, William C., Comment on EPA Memorandum: The Effects of Ozone on Lung Function at 0.06 ppm in Healthy Adults, at 4 (Oct. 9, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4783 ("Adams Comments"), JA__. EPA disagreed, describing these studies as providing "very limited evidence" of lung function decrements and respiratory symptoms at concentrations below 0.08 ppm, based on an EPA reanalysis of the data used in one of these studies, unpublished at the time of the 2008 NAAQS revision. 73 Fed. Reg. 16445/1, JA__. *But see* Adams, William C., Email to U.S. EPA, at 1 (Aug. 22, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-1811 ("I believe that EPA has misinterpreted the statistics contained in my published, peer-reviewed paper.") ("Adams Email"), JA__.

Second, EPA considered the epidemiological evidence, which also largely paralleled that considered in the 1997 review. Once again, EPA cited the epidemiological studies as additional evidence of associations between ozone exposures and the types of lung function decrements and respiratory symptoms identified in the clinical studies, 73 Fed. Reg. 16440/2, JA__, and as evidence that ozone exposures are associated with excess hospital admissions and emergency department visits for respiratory causes, *id*. at 16471/1, JA__. EPA also noted that

limited epidemiological evidence suggested associations between ozone exposures and school absenteeism, *id.* at 16440/2, JA__, but found these associations required additional study before any conclusions could be drawn, 2006 CD at 7-65 (noting "further replication is needed before firm conclusions can be drawn"), JA__. Similarly, although EPA pointed to new epidemiological evidence concerning effects on "cardiac-related physiological endpoints," 73 Fed. Reg. 16440/2, EPA explained that the evidence remains "limited" and "much needs to be done to more fully integrate links between ambient [ozone] exposures and adverse cardiovascular outcomes," *id.* at 16457/1, JA__. EPA also acknowledged limitations in other epidemiological evidence. *See, e.g.*, *id.* at 16461/1 ("[T]he epidemiological association cannot be interpreted with confidence as providing evidence that the observed health effects can be attributed to [ozone] alone."), JA__; *id.* at 16479/3 ("[T]he epidemiological studies are not themselves direct evidence of a causal link between exposure to [ozone] and the occurrence of the effects."), JA__.

As in 1997, EPA observed the epidemiological literature indicated possible mortality associated with ozone exposures but, due to uncertainties in the data, concluded only that such an association was "highly suggestive." *Id*. at 16446/3, JA__. Because EPA determined (as it had in 1997) that the NAAQS should be revised based only on health effects "for which the Criteria Document concluded

that the associations are *causal or likely to be causal*," *id*. at 16439/3 (emphasis added), JA__, it "did *not* focus on mortality as a basis for proposing that the current [ozone] standard was not adequate," *id*. at 16460/2 (emphasis added), JA__.

Third, EPA again considered evidence from toxicological studies regarding biological mechanisms for associations between ozone exposures and respiratory infection, respiratory inflammation, and the other lung function effects identified in the clinical and epidemiological studies, *id.* at 16457/1, JA__, and again identified sensitive populations, essentially consistent with the findings made in 1997, *see id.* at 16440/3 (active people, children, older people, those with pre-existing lung disease (such as asthmatics) or heart disease, and "people with increased responsiveness to [ozone]"), JA__.

Finally, as in 1997, because "[t]he CAA does not require … zero-risk," *id.* at 16437/2, JA__, EPA undertook risk assessments "to help inform [its] evaluation of the adequacy of the current standard," *id*. at 16471/2, JA__. Given the "uncertainties associated with inconclusive scientific and technical information … [and] hazards that research has not yet identified," *id*. at 16437/1, JA__, these assessments were designed "to provide some perspective on the extent to which at-risk groups would likely experience 'exposures of concern,'" and regarding "the potential magnitude of the risk of experiencing various adverse health effects," *id.*

at 16450/2-3, JA__. As EPA explained, its task was to determine "a [concentration] level that *reduces risk sufficiently* so as to protect public health with an adequate margin of safety." *Id.* at 16437/2 (emphasis added), JA__.

In performing this risk evaluation, EPA altered certain parameters of its 2008 assessments such that (according to EPA) it would be "factually inappropriate to compare the quantitative risks estimated in 1997 with those estimated in the current rulemaking." *Id*. at 16466/3, JA__; *see e.g., id*. at 16466/3-16467/1 (selecting different geographic areas to include in the assessments), JA__-__; *id.* at 16467/1 (selecting different sensitive populations subgroups), JA__; EPA, EPA-452/R-07-007, REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE: POLICY ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION at 2-55 (July 2007) ("2007 Staff Paper") (selecting different level of background concentration), JA__. On this basis, EPA refused to compare the risks it determined acceptable in 1997 with the risks predicted by the assessments in 2008, as requested by commenters. *See, e.g.*, American Petroleum Institute Comments on National Ambient Air Quality Standards for Ozone: Proposed Rule, at 30 (Oct. 9, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4141 ("API Comments"), JA__; ExxonMobil Corporation, Detailed Comments on EPA's Proposed Rule on the Ozone National Ambient Air Quality Standard, at 82 (Oct. 9, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4163 ("ExxonMobil

Comments"), JA__; Comments of the Utility Air Regulatory Group on National Ambient Air Quality Standards for Ozone: Proposed Rule at 28 (Oct. 9, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4183 ("UARG Comments"), JA__.

Despite the criticism of the risk analysis and the limited new scientific information on exposures below 0.08 ppm, EPA concluded that "important new evidence demonstrat[es] that exposures to [ozone] at levels below the level of the current standard are associated with a broad array of adverse health effects." *Compare* 73 Fed. Reg. 16471/1, JA__, *with* 62 Fed. Reg. 38859/3 (noting that "new information available since the last review" showed a variety of effects at ozone concentrations as low as 0.08 ppm),[3] JA__. EPA also concluded in 2008 that the public health risks that remain at the 0.08 ppm level are "important from a public health perspective." 73 Fed. Reg. 16472/1, JA__; *see also id.* at 16449/2, 16452/1, JA__, __; *compare* 62 Fed. Reg. 38868/2 (noting the most certain ozone-related effects "are transient and reversible (particularly at [ozone] exposures below 0.08 ppm")), JA__. On this basis, EPA determined that standard "revision [from 0.08 ppm to 0.075 ppm] is needed to provide increased public health protection." 73 Fed. Reg. 16472/2, JA__; *see id.* at 16449/1, JA__.

[3] EPA considered the previous 1-hour standard of 0.12 ppm to be approximately equivalent to an 8-hour standard of 0.09 ppm. 61 Fed. Reg. 65716, 65729/1 (Dec. 13, 1996), JA__-__.

In reviewing the secondary NAAQS in 2008, EPA focused – as it had in 1997 – on "the broad array of vegetation effects." *Id*. at 16485/2, JA__. Concluding a secondary standard identical to the new primary standard "would provide a significant degree of additional protection for vegetation as compared to that provided by the current secondary standard," *id.* at 16499/3, JA__, EPA revised the secondary NAAQS to be identical to the primary NAAQS, *id.* at 16500/2, JA__.

SUMMARY OF ARGUMENT

In 2002, this Court affirmed EPA's 0.08 ppm ozone NAAQS as "requisite" to protect public health and welfare. *ATA III*, 283 F.3d at 358. EPA now asserts that "important new evidence" suggests that health risk exists below 0.08 ppm, 73 Fed. Reg. 16471/1, JA__, and that those risks are "important from a public health perspective," *id.* at 16472/1, JA__. As a result, EPA now concludes that the 0.08 ppm NAAQS is not "requisite" and that revision of the ozone NAAQS "is needed to provide increased public health protection." *Id.* at 16472/2, JA__. Several legal and factual errors underlie EPA's revision of the ozone NAAQS – errors that independently and collectively warrant vacatur of the rule.

First, EPA applied an erroneous legal standard in promulgating the revised NAAQS. Under the plain language of the CAA, *see Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842-43 (1984), EPA should have asked whether the existing

NAAQS levels were no longer "requisite" to protect public health and welfare, and whether the revised NAAQS levels were "requisite." CAA § 109(b)(1), (2); *see Whitman*, 531 U.S. at 473 ("requisite" means "sufficient, but not more than necessary") (quotation omitted). Instead, EPA stated that a revised NAAQS would provide "increased protection." A finding that a revised standard would provide "increased protection" fails to satisfy the CAA.

Second, the "new information" cited by EPA does not establish that revision of the 1997 primary NAAQS is "requisite." At most, the scientific evidence continues to support the public health judgments this Court affirmed in 2002 and nothing more.

Third, EPA erred by refusing to place its risk estimates in context by comparing them to the risks it found acceptable in 1997. If EPA had compared the current level of health risk associated with ambient ozone exposure with the level of health risk it found acceptable in its last NAAQS review, the lack of any increase in risk would have been revealed, and EPA would be unable to justify revision of the primary NAAQS as "requisite" to protect public health and welfare.

Fourth, EPA's mistaken characterization of the findings of the key new human clinical studies, unwarranted reliance on epidemiological studies that lack personal exposure measurements, and selective reliance on studies without adequate control of alternative explanations for reported associations means that

EPA has inaccurately characterized the scientific record. This inaccuracy and lack of objectivity violate both the CAA and EPA's guidelines implementing the IQA that should inform this Court's interpretation of the CAA.

Finally, because EPA did not justify its revision of the secondary NAAQS independently of the primary NAAQS revision, EPA lacks any basis for revision of the secondary NAAQS.

For these reasons, EPA's decision to revise the ozone NAAQS must be vacated, with the result that the prior 1997 NAAQS of 0.08 ppm would continue in place.

STANDARD OF REVIEW

The Court sets aside final EPA action under the CAA if that action is "arbitrary, capricious, [or] an abuse of discretion," or exceeds statutory authority. CAA § 307(d)(9).[4] EPA must establish a "rational connection between the facts found and the choices made." *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962). Agency action is arbitrary and capricious when the agency: (1) relies on factors that Congress did not intend it to consider; (2) fails to consider an important aspect of the issue; or (3) offers an explanation for its decision that runs counter to the evidence before it. *Id.*

[4] EPA's promulgation of the ozone NAAQS is subject to CAA § 307(d)(9). *See* CAA § 307(d)(1)(A).

STANDING

Petitioner State of Mississippi satisfies each element of Article III standing. The 2008 ozone NAAQS impose obligations on Mississippi under the CAA, including the requirement to designate areas, CAA § 107, and to revise its state implementation plan ("SIP") to "provide[] for implementation, maintenance, and enforcement" of the revised NAAQS, *id.* § 110(a). Some areas of Mississippi may be designated nonattainment as a result of the ozone NAAQS, *see* EPA Response To State Recommendations on Area Designations for the 2008 Ozone Standards – December 9, 2011 & January 31, 2012, *available at* http://www.epa.gov/ozonedesignations/2008standards/documents/20120130RecommendationsMatrix.pdf, JA__, a designation with severe consequences under the CAA, *see, e.g.*, *id.* §§ 181-185. As a result of the revised ozone NAAQS, Mississippi therefore has (1) suffered an actual injury that is (2) "fairly traceable" to the revised ozone standards and is (3) "likely" to be redressed by "a favorable decision." *Allen v. Wright*, 468 U.S. 737, 751 (1984) (quotations omitted).

Petitioners Ozone NAAQS Litigation Group, Utility Air Regulatory Group, and National Association of Home Builders ("Industry Petitioners") also have standing in that the ozone NAAQS will cause them injury that would be redressed by a favorable decision. The various industries and specific facilities represented by Industry Petitioners are subject to extensive CAA regulation, including

regulation to reduce their NOx and VOC emissions for the purpose of attaining and maintaining the NAAQS. The changes to the level of the ozone NAAQS affect the business operations of Industry Petitioners both directly and indirectly through the CAA's requirement that states impose additional emission controls in their SIPs to meet a more stringent NAAQS. *See* CAA § 110. The revised, more stringent ozone standards will increase costs for Industry Petitioners, significantly impact business decisions, and will require substantial planning and implementation measures to ensure compliance with new requirements. EPA, EPA-452/R-08-003, FINAL OZONE NAAQS REGULATORY IMPACT ANALYSIS at 5-1, 5-23 to 5-26 (Mar. 2008) (estimating the "costs of purchasing, installing, and operating" control technology to attain the NAAQS will be over $7.6 billion annually), JA__, __-__. Industry Petitioners' standing is confirmed by the many NAAQS challenges in which industry has participated as a petitioner. *See, e.g.*, *Whitman*, 531 U.S. at 457; *Am. Farm Bureau*, 559 F.3d at 512; *ATA III*, 283 F.3d at 355; *ATA I*, 175 F.3d at 1027; *Am. Petroleum Inst. v. Costle*, 665 F.2d 1176, 1187 (D.C. Cir. 1981).

ARGUMENT

In addressing EPA's authority under CAA §§ 108 and 109, the Supreme Court has stated that "[r]equisite … means sufficient, but not more than necessary … to protect public health." *Whitman*, 531 U.S. at 473 (quotation omitted). This standard "does not compel the elimination of *all* risk; and it grants the

Administrator sufficient flexibility to avoid setting … [NAAQS] ruinous to industry." *Id*. at 494 (Breyer, J., concurring) (emphasis in original). Thus, EPA does not have unfettered discretion to revise or to establish NAAQS, nor is EPA required to impose a standard that is "free of all risk." *Id.* Rather, EPA must set NAAQS at a level that avoids unacceptable public health risk.

In exercising this authority, "the words 'requisite' and 'public health' … [cannot] be understood independent of context." *Id.* In determining what level of risk is "requisite," EPA "can consider … background circumstances … [and] comparative health risks" to decide "'what risks are acceptable in the world in which we live.'" *Id.* at 494-95 (quoting *NRDC v. EPA*, 824 F.2d 1146, 1165 (D.C. Cir. 1987) (en banc)). Indeed, putting risk in the context of earlier NAAQS decisions (and other risk-based decisions) is essential to explaining why further risk reduction is "requisite."[5] Strict adherence to these principles is important, given "the scope of the power congressionally conferred" for "setting air standards that affect the entire national economy." *Id.* at 475.

Applying these statutory requirements here requires that EPA's decision to revise the NAAQS be set aside.

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[5] In setting the 1997 ozone NAAQS, for example, EPA took pains to explain the consistency of its 1993 and 1997 risk judgments. 62 Fed. Reg. 38860/1-2 (stating that EPA's 1993 judgments are "in fact, consistent with judgments presented in the 1996 proposal"), JA__.

I. A Finding That Increased Protection Results From a Lower Standard Is Insufficient, as a Matter of Law, To Establish That NAAQS Revision Is "Requisite."

In support of the 1997 NAAQS, EPA observed that the risk of adverse effects associated with ozone extend to exposures below 0.08 ppm, and indeed down to background levels. 62 Fed. Reg. 38863/3 ("[I]t is likely that '[ozone] may elicit a continuum of biological responses down to background concentrations.'") (quoting Letter from George T. Wolff, Chair, Clean Air Scientific Advisory Committee ("CASAC") to Carol M. Browner, Adm'r, EPA, at 2 (Nov. 30, 1995), EPA-SAB-CASAC-LTR-96-002), JA__. In fact, EPA explained, because most people experience exposures below 0.08 ppm, "a significant portion" of the population risk addressed by the 1997 NAAQS was associated with exposures below 0.08 ppm. EPA, EPA-452/R-96-007, REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION: OAQPS STAFF PAPER at 131 (June 1996) ("1996 Staff Paper"), JA__. EPA nevertheless concluded that, while public health risks were "important and sufficiently large as to warrant a standard set at a level of 0.08 ppm," they were neither sufficiently important nor large enough to warrant a standard below that level. 62 Fed. Reg. 38868/2-3, JA__.

This Court upheld the 1997 NAAQS in 2002 as "requisite" based on EPA's reasoning that: (1) no CASAC member supported a standard below 0.08 ppm; (2)

health effects at ozone levels below 0.08 ppm are transient and reversible; and (3) 0.07 ppm would be too close to peak background levels. *ATA III*, 283 F.3d at 379. According to the Court, "[m]ost convincing" in EPA's rationale was the "absence of *any* human clinical studies at ozone concentrations below 0.08." *Id.* (emphasis in original). This provided "an eminently rational reason to set the primary standard at [0.08 ppm] … at least until additional studies become available." *Id.*

Now, EPA says, there are new studies that provide "strong support … for consideration of an [ozone] standard that is *at least as protective* as the current standard." 73 Fed. Reg. 16444/2 (emphasis added), JA__. EPA says this new information provides "increased certainty in the risks … [presented] in the last review," *id.* at 16466/3, JA__, and has led EPA to conclude the risks that remain at exposures of 0.08 ppm that were previously unimportant, are now "important." *Id.* at 16449/1, 16472/1, JA__, __. This, EPA says, supports a decision to revise the current NAAQS to provide "increased public health protection," making the 0.08 ppm NAAQS no longer "requisite." *Id.* at 16472/1-2, JA__.

As discussed below, the "new" studies on which EPA relies show that little has changed since this Court affirmed the 1997 NAAQS: the most certain effects below 0.08 ppm are transient and reversible, and the author of the two clinical studies addressing exposures below 0.08 ppm found no significant association between ozone and such effects. As a matter of law, however, studies supporting a

standard "at least as protective" as the current standard, and a conclusion that standard revision based on those studies would provide an "increased [level of] protection," 73 Fed. Reg. 16436/3, 16444/2, JA__, __, does not undermine EPA's prior conclusion that a 0.08 ppm standard is "sufficient, but not more than necessary" to protect public health with an adequate margin of safety. *Whitman*, 531 U.S. at 473.

In this regard, because EPA assumes "a continuum of the potential for health effects of concern," with no discernible threshold, 73 Fed. Reg. 16466/1, JA_, *see also id.* at 16442/3, JA__, a lower NAAQS will *always* provide increased protection. "Increased protection" from "the potential for health effects," however, is *not* the criterion for standard revision set forth in the plain language of the CAA. The Supreme Court has explained that "requisite" means "not lower or higher than is necessary … to protect the public health with an adequate margin of safety." *Whitman*, 531 U.S. at 475-76. Thus, "requisite" does not mean lower is better. Accordingly, EPA must justify why the existing standard (0.08 ppm) is now less protective "than necessary" to address unacceptable public health risk. *Id.* at 476; *cf. NRDC*, 824 F.2d at 1152 (EPA's task under § 109 is to provide a "*reasonable* degree of protection" against known or suspected hazards.) (emphasis in original); *cf. Am. Farm Bureau*, 559 F.3d at 530 (rejecting secondary NAAQS for fine

particulate matter because EPA's "analysis of the relative protection" of different alternative NAAQS did not satisfy the "requisite" standard).

Here, the centerpiece of EPA's decision to revise the existing NAAQS is that a lower NAAQS will provide an "increased level of protection" with respect to various uncertainties. Because EPA substituted an "increased level of protection" criterion under which EPA need not address why any specific level is "requisite" – i.e., "not higher or lower than necessary" to address unacceptable health risk – the Court should set aside the 0.075 ppm NAAQS, leaving in place the 1997 standard of 0.08 ppm.

II. The "New" Health Evidence in 2008 Does Not Materially Differ From the Evidence Cited in 1997 and Does Not Support Standard Revision Under the "Requisite" Standard.

The 1997 NAAQS review "focused primarily on evidence from short-term (e.g., 1 to 3 hours) and prolonged (6 to 8 hours) controlled-exposure studies reporting lung function decrements, respiratory symptoms, and respiratory inflammation in humans, as well as epidemiology studies reporting excess hospital admissions and emergency department visits for respiratory causes." 73 Fed. Reg. 16440/1, JA__. In support of the decision at issue here to revise the 1997 ozone NAAQS, EPA explained that "the current primary [ozone] standard is not sufficient and thus not requisite to protect public health with an adequate margin of safety, and that revision is needed to provide increased public health protection,"

id. at 16472/2-3, JA__, because "much new evidence … has become available since the last [1997] review," *id.* at 16470/3, JA__. In reaching this decision, however, EPA fails to compare what was known or assumed in 1997, when it determined the 1997 primary NAAQS was set at the requisite level to protect public health, 62 Fed. Reg. 38859/1, JA __, __, with the so-called "new evidence" purportedly showing that "increased public health protection" is needed. For the reasons discussed below, such a comparison would have confirmed the 1997 conclusion, upheld by this Court, *ATA III*, 283 F.3d at 379-80, that the 0.08 ppm standard is "requisite."

Clinical studies – In 1997, EPA explained that the human clinical studies provided the clearest evidence of potential associations between ozone exposures and lung function decrements, respiratory symptoms, nonspecific bronchial responsiveness, and biochemical indicators of pulmonary inflammation. 62 Fed. Reg. 38863/3 to 38864/1, JA__-__. In 2008, according to EPA, human clinical studies continue to "provide the clearest and most compelling evidence for an array of human health effects that are directly attributable to acute exposures to [ozone] *per se*," 73 Fed. Reg. 16444/3, JA__, including "clear evidence of causal associations" between short-term ozone exposures and lung function decrements, respiratory symptoms, pulmonary inflammation, and increased airway responsiveness, *id.* at 16445/1, JA__. Moreover, as in 1997, "the large bulk of this

evidence derives from studies of exposures at levels of 0.080 [ppm] and above." *Id.* at 16476/1, JA__; *see also* 62 Fed. Reg. 38872/1, JA__.

If the "large bulk of the evidence" derives from the same type of studies used in 1997 and documents the same associations, what has changed to support a revision of the 1997 ozone NAAQS? EPA cites two new controlled human exposure studies (Adams 2002 and Adams 2006) that examined respiratory effects at exposure levels below 0.08 ppm. According to EPA, these two studies – the only clinical studies that examined exposures to ozone levels between 0.08 ppm and 0.0 ppm – "provide *very limited* evidence of [ozone]-related lung function decrements and respiratory symptoms at this lower exposure level." 73 Fed. Reg. 16445/1 (emphasis added), JA__.

EPA's conclusion contradicts that of Dr. Adams, the author of these studies, who concluded that these studies provided *no evidence* of health effects below 0.08 ppm. Adams 2006, 18 INHALATION TOXICOLOGY at 130 (noting "[p]ostexposure percent change in [forced expiratory volume ("FEV")] for the [filtered air] protocol … was not significantly different from those for the two 0.06 ppm exposures"), JA__; Adams 2002, 14 INHALATION TOXICOLOGY at 747 ("no statistically significant differences in pulmonary function or symptoms responses from those observed for the [filtered air] exposure were observed" at 0.06 ppm), JA__; Adams Comments at 4 (studies "do[] not demonstrate a significant mean effect by

ordinarily acceptable statistical analysis" from exposure to ozone levels below 0.08 ppm), JA__. EPA nevertheless asserted that a then-unpublished Agency reanalysis of a small subset of these data using a different statistical test reported "small group mean decrements in lung function" to be "statistically significant at the 0.060 ppm exposure level."[6] 73 Fed. Reg. 16445/1, JA__. Although Dr. Adams and others have questioned the validity of the approach EPA used in this reanalysis, *see, e.g.,* Adams Comments at 3-4, JA_, Smith, Richard L., Dep't of Statistics & Operations Research, University of North Carolina, Public Comment on EPA Draft Ozone Standard, at 1-5 (Oct. 9, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4143 ("Smith Comments"), JA__-__, according to EPA, the reanalysis can be read to mean that "a small percentage of subjects" experienced lung function decrements of at least 10% and provides "very limited evidence" of respiratory symptoms at levels as low as 0.06 ppm, 73 Fed. Reg. 16445/1, JA__.

EPA's reanalysis of a portion of the Adams studies to suggest "very limited evidence" of respiratory symptoms below 0.08 ppm provides no basis for revising the ozone NAAQS. First, whatever the merits of EPA's unpublished reanalysis, EPA's finding in 1997 that the 0.08 ppm standard was "requisite" recognized that

[6] EPA's long-standing practice is to base NAAQS decisions on studies and related information that has been assessed in a criteria document. 73 Fed. Reg. 16438/3, JA__. EPA's reanalysis of some of the Adams data is *not* addressed in the CD.

sensitive individuals had experienced FEV decrements as large as 50% when exposed to ozone concentrations as low as 0.08 ppm. 62 Fed. Reg. 38860/2, JA__. Furthermore, EPA assumed at that time that lung function decrements and symptoms could occur below the 0.08 ppm level,[7] for both typical and more sensitive individuals.[8] Thus, even accepting EPA's reanalysis, it merely recognizes and confirms what EPA assumed as the basis for the 1997 NAAQS.

Second, that reanalysis does not provide a valid basis for concluding the 0.08 ppm standard is no longer "requisite," given Dr. Adams' disagreement with the approach EPA took. Moreover, EPA's reliance on the reanalysis, which was unpublished at that time, violated EPA's IQA Guidelines, as discussed in more detail *infra.*

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[7] 62 Fed. Reg. 38873/1 (noting "the continuum of risk likely posed by exposures to ambient [ozone] potentially down to background level"), JA__; *id.* at 38867/1-2 (concluding the risk assessment approach was "appropriate" despite comments questioning extrapolation of risks to "background levels"), JA__.

[8] *Id.* at 38864/1 ("While group mean responses in clinical studies at the lowest exposure level tested of 0.08 ppm are typically small or mild in nature, responses of some sensitive individuals are sufficiently severe and extended in duration to be considered adverse."), JA__; *see also* 73 Fed. Reg. 16463/2 (acknowledging EPA focused in the last review "on the fact that some individuals experience more severe effects that may be clinically significant"), JA__; 2007 Staff Paper at 5-20 (explaining that in the previous review, EPA assumed a linear relationship between ozone concentration and lung function responses below the levels at which data were available), JA__.

In short, the clinical studies on which EPA relies for the 2008 decision do not contradict, but are consistent with and confirm the basis for the 1997 "requisite" findings. They provide no justification for EPA to revise the 1997 NAAQS.

Epidemiological Studies – In 1997, EPA explained that "[n]umerous epidemiological studies have reported excess hospital admissions and emergency department visits for respiratory causes (for asthmatic individuals and the general population) attributed primarily to ambient [ozone] exposures…." 62 Fed. Reg. 38864/1, JA__. EPA relied on this epidemiological evidence to conclude that respiratory effects leading to hospital visits could occur down to background levels as a result of ozone exposures. *Id*. at 38863 ("[I]t is likely that [ozone] may elicit a continuum of biological responses down to background concentrations.") (quotation omitted), JA__. Nevertheless, EPA concluded in 1997 that standard levels below 0.08 ppm were more stringent than necessary to protect public health. *Id*. at 38868/2-3, JA__.

EPA now cites "new[er]" epidemiological studies that "increased the Administrator's confidence" that these effects "are causally related to [ozone] exposures," 73 Fed. Reg. 16450/1, JA__, and "offer added evidence of associations between acute ambient [ozone] exposures and lung function decrements and respiratory symptoms…," *id*. at 16440/2, JA__; *see also id*. at 16444/2 (asserting

that "newly available information reinforces the judgments … from the last review about the likelihood of causal relationships between [ozone] exposures and respiratory effects"), JA__. That EPA now has "added evidence" that has "increased confidence" it was correct in 1997 merely confirms the 1997 NAAQS was "requisite." It does not suggest any difference in EPA's view of evidence concerning the relationship between ozone and respiratory effects, and it does not support a decision that the 1997 NAAQS is no longer requisite.

EPA also asserts some newer epidemiological studies examine "relationships between ambient [ozone] concentrations and school absenteeism." *Id.* at 16440/2, JA__. The 2006 Criteria Document, however, explains that "[f]urther replication is needed before firm conclusions can be reached regarding the effect of [ozone] on school absences." 2006 CD at 7-60, JA__. Similarly, although EPA alludes to new epidemiological evidence of a relationship between ambient ozone and cardiac-related physiological endpoints, 73 Fed. Reg. 16440/2, JA__, the 2006 Criteria Document acknowledges that the evidence is "limited" and that "much remains to be done to more fully substantiate links between ambient [ozone] exposure and adverse cardiovascular outcomes," 2006 CD at E-17, JA__.

Finally, during the 1997 review, although EPA considered epidemiological evidence suggestive of an association between daily mortality and ozone concentrations in areas with high ambient ozone levels, 1996 Staff Paper at 41-42,

JA__-__, EPA concluded that the evidence was "insufficient" to conclude that the association was "likely causal" and therefore was not relied upon for the 1997 NAAQS, 73 Fed. Reg. 16446/2, JA__; 1996 CD at 7-143, JA__. Although EPA asserts that the evidence related to mortality is now "relatively strong" compared to the evidence at hand in 1997, it still does not conclude that this evidence currently supports a finding of a "likely causal" association and characterizes it only as "highly suggestive."[9] 73 Fed. at 16446/3, JA__; 2006 CD at E-18, 8-78, JA__, __.

In short, any association between ambient ozone and these effects remains uncertain. In 1997, EPA set the ozone NAAQS at the level of 0.08 ppm "to address uncertainties associated with inconclusive science and technical information" and "hazards that research has not yet identified." 62 Fed. Reg. 38857/1, JA__. To now rely on "uncertainty" that EPA fully accounted for in determining that the 1997 NAAQS was "requisite" as justification that a revision of that NAAQS is now needed, suggests "sheer guesswork" on the part of EPA. *Am. Petroleum Inst.*, 665 F.2d at 1187. For all of these reasons, the

[9] As CASAC pointed out in discussing evidence from epidemiology studies of an association between short-term ozone exposure and mortality: "Because results of time-series studies implicate all of the criteria pollutants, findings of mortality time-series studies do not seem to allow us to confidently attribute observed effects specifically to individual pollutants. This raises concern about the utility of these types of studies in the current NAAQS-setting process." Letter from Dr. Rogene Henderson, Chair, CASAC, to Stephen L. Johnson, Adm'r, EPA, at 3 (June 5, 2006), EPA-CASAC-06-007 ("Henderson 6/2006"), JA__.

epidemiological evidence has changed little since 1997 and does not justify a conclusion that the 1997 NAAQS is no longer "requisite" to protect public health.

Toxicology Studies – In 1997, even without full knowledge of the biological mechanisms for respiratory effects purportedly produced by low level ozone exposures, EPA assumed the biological plausibility of acute health effects. For example, in 1997 EPA cited animal toxicological studies (including studies of decreased effectiveness of defenses to bacterial respiratory infections) in support of the biological plausibility of hospital admissions and emergency department visits for respiratory causes, 62 Fed. Reg. 38864/1, JA__, and based the NAAQS in part on assuming such effects, *id.* at 38864/3, 38868/1, JA__, __.

In support of its 2008 decision to revise the 1997 NAAQS, EPA suggests that animal toxicology studies "provide new information regarding potential mechanisms of action, increased susceptibility to respiratory infection, and biological plausibility of acute effects…." 73 Fed. Reg. 16440/2, JA__. Assuming *arguendo* that more recent toxicology studies provide new information and that the understanding of "potential mechanisms" has "advanc[ed]," *id*. at 16444/2, JA__, this merely provides further support for the assumptions made by EPA in 1997. Indeed, EPA still recognizes that "biological plausibility becomes increasingly uncertain" with decreasing ozone exposure levels. *Id*. at 16456/1, JA__; *see also id*. at 16483/2 (pointing to "uncertainties that remain" in interpreting the human

exposure and epidemiological studies), JA__. It does not establish that the 1997 NAAQS is no longer "requisite."

Sensitive populations – In 1997, EPA identified "active children and outdoor workers who regularly engage in outdoor activities and individuals with preexisting respiratory disease (e.g., asthma, chronic obstructive lung disease)," as well as "some individuals [who] are unusually responsive to [ozone]" as sensitive groups at increased risk from ozone exposure. 62 Fed. Reg. 38859/3, JA__. In 2008, EPA asserts that its findings concerning asthmatics "differ from the [Agency's] presumption" in the last review about asthmatics' sensitivity to ozone. 73 Fed. Reg. 16440/2, JA__. That EPA now finds that asthmatics are sensitive to ozone does not undermine the 1997 NAAQS. Rather, EPA's 2008 finding that asthmatics are indeed a sensitive population merely confirms that EPA properly considered asthmatics a sensitive population in the 1997 review and that the 1997 NAAQS is "requisite."

* * *

In sum, the more recent health studies that EPA considered during the 2008 proceeding merely confirm the health evidence EPA considered in 1997 in concluding that a standard of 0.08 ppm was at the level requisite to protect public health with an adequate margin of safety. They do not demonstrate that the 0.08

ppm standard is now higher than necessary. Accordingly, the Court should vacate the new 0.075 ppm standard.

III. The Risks EPA Estimates To Remain Upon Attainment of the 1997 Ozone NAAQS Are No Greater Than Those Found "Requisite" in 1997.

EPA has long used risk assessment to inform decisions regarding whether to revise NAAQS. In the 1979 ozone NAAQS revision, for example, EPA relied upon risk assessment as a "[f]urther aid to the Administrator in establishing the ozone standards." *Am. Petroleum Inst.*, 665 F.2d at 1182. When EPA next revised the ozone NAAQS in 1997, it used risk assessment to "aid in comparing the public health protection associated with [alternative ozone levels]." 62 Fed. Reg. 38865/2, JA__; *see also ATA III*, 283 F.3d at 376-77. EPA's consideration of risk assessment in deciding whether to revise the 1997 NAAQS, 73 Fed. Reg. 16472/1, JA__, was therefore unsurprising and appropriate.

In the 1997 ozone NAAQS rulemaking, EPA considered a range of standard levels from 0.07 ppm to 0.09 ppm, with an 8-hour averaging time, 62 Fed. Reg. 38858/3, JA__, and recognized that none of these standard levels was risk free, *id.* at 38873/1, JA__. After discussing its estimates of risk and exposure for this range of standards, EPA concluded that risks associated with ozone exposures at 0.08 ppm were "important and sufficiently large as to warrant a standard set at … [this] level," *id*. at 38868/2, JA__, but that a standard of 0.07 ppm was "not requisite to protect public health with an adequate margin of safety," *id.* at 38868/3, JA__.

Given the similarities in the scientific records underlying the 1997 and 2008 ozone NAAQS decisions, commenters suggested it was important for EPA to use risk assessment "to help inform [the] evaluation of the adequacy of the current standard," 73 Fed. Reg. 16471/2, and "explain the risk it consider[s] tolerable in meeting the requirements" of the CAA, *NRDC v. EPA*, 902 F.2d 962, 974 (D.C. Cir. 1990).

Indeed, based on the scientific record and the small difference between the 1997 NAAQS (0.08 ppm) and the 2008 NAAQS (0.075 ppm), Industry Petitioners explained in their comments that risks associated with a 0.075 ppm standard differed little from the risk levels associated with the 0.08 ppm standard that EPA found in 1997, and this Court affirmed in 2002, to be "requisite." *See* American Chemistry Council, Comments on National Ambient Air Quality Standards for Ozone, at 31 (Oct. 9, 2007), Doc ID No. EPA-HQ-OAR-2005-0172-4159 ("ACC Comments"), JA__; API Comments at 30-31, JA__; ExxonMobil Comments at 82, JA__; UARG Comments at 28, JA__. In fact, some commenters explained the new scientific evidence would result in *lower* risk estimates for specific ozone exposure levels, with the result that risks associated with exposure at a 0.08 ppm level under an updated risk analysis to reflect the latest scientific data were even lower than those found "requisite" to protect public health in 1997. *See, e.g.*, ExxonMobil Comments at 82, JA __.

In response, EPA contends "it is *factually* inappropriate to compare the quantitative risks estimated in 1997 with those estimated in the current rulemaking." 73 Fed. Reg. 16466/3 (emphasis added), JA__. EPA then points to facts that complicate – but do not render impossible – its ability to make risk comparisons. For example, EPA notes it chose to examine larger geographic areas in the present review than in 1997, *id.* at 16466/3-16467/1, JA__, __, different time periods, *id*. at 16467/1, JA__, and different subsets of sensitive populations, *id*.

Furthermore, EPA chose to use a different method of calculating background air quality (i.e., a level below which risks would not be calculated because they could not be controlled by a NAAQS) for the 2008 NAAQS decision, *see id.* at 16468/2-3, JA__; 2007 Staff Paper at 5-92, JA__,[10] which demonstrably produced higher risk estimates, *see* API Comments at 24-26, JA__-__; *see also* ExxonMobil

[10] During the rulemaking that led to the 1997 NAAQS, EPA estimated a background ozone level of 0.04 ppm for its risk assessment based on monitored data, whereas in 2007, EPA relied upon an air quality model (the global GEOS-CHEM model) to predict background ozone concentrations between 0.015 ppm and 0.035 ppm. 2007 Staff Paper at 2-54, 5-92, JA__, __. Contrary to EPA's new model estimates, monitoring data from remote sites show background ozone concentrations when air flow includes sources outside of continental North America of repeatedly greater than 0.05 ppm and as high as hourly average levels of 0.066 ppm (66 ppb). *See* Lefohn, Allen S., Underestimated Policy-Relevant Background and Its Effect on EPA's Human Health Risk Estimates 20-24 & Table 1 (Oct. 8, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4187, JA__-__ & __. Thus, the 0.075 ppm standard is as close to peak background levels documented in 2008 as a standard of 0.07 ppm would have been in 1997. *See* 62 Fed. Reg. 38868/3, JA __.

Comments at 79 (noting "if EPA had used a higher summer estimate of average ozone background levels of 0.04 ppm (which was used in EPA's 1997 review rather than the lower value that EPA is using in the 2007 review), the estimated number of potential deaths and other health effects … would fall by over 95%"), JA__; UARG Comments at 27 (noting that using the background air quality used during the 1997 review would have resulted in 90% to 100% lower estimates of mortality risk), JA__. Indeed, EPA acknowledges that "[m]uch" of the estimated mortality risk in its 2008 assessment is due to ozone concentrations between the levels considered background in 2007 and those considered background in 1997. 2007 Staff Paper at 5-97, JA__.

Regardless of these changes in approach, however, if EPA had undertaken to compare its 2008 evaluation to the risks deemed acceptable in 1997, it would have found the risks currently associated with attaining the 1997 ozone NAAQS are no greater than those risks EPA concluded in 1997 were "requisite" to protect public health. For example, EPA estimated hospital admissions of asthmatics in New York City both for the review completed in 1997 and for the 2008 review. *See* 62 Fed. Reg. 38860/3, JA__; 2007 Staff Paper at 5-92, JA__. In both cases, the estimated number of hospital admissions is based on the same study by Thurston. *Compare* 1996 Staff Paper at 113, Table V-16 (New York City respiratory hospital admissions estimated based on Thurston, 1992), JA_ , *with*

EPA, EPA 452/R-07-009, OZONE HEALTH RISK ASSESSMENT FOR SELECTED URBAN AREAS at 4-56, Table 4-12 (July 2007) (New York City unscheduled respiratory hospital admissions estimated based on Thurston, 1992) ("Health Risk Assessment"), JA_. Because EPA based the risk estimates on the same study, the underlying risk rate for calculating population risks cannot have changed as between the two risk assessments. As EPA recognizes, the greater number of estimated ozone-related hospital admissions in 2007 results solely from the change in EPA's treatment of background air quality, not from new data showing greater health effects. 2007 Staff Paper at 5-92, JA__.

Similarly, EPA considered the risk of lung function decrements in children in both 1997 and 2008. Although changes in the populations modeled (outdoor children versus all children and asthmatic children)[11] make direct comparisons difficult, one can nevertheless draw conclusions about relative risk based on the data that provide the basis for the two assessments. Data on response rates for the 2008 review came from (i) the same three studies used previously, and (ii) the newer studies by Adams (Adams 2002 and Adams 2006), which generally found a smaller percentage of subjects responding to a given level of ozone than in the earlier studies. 2007 Staff Paper at 5-18, 5-22, JA__, __. Thus, the response rate

[11] 73 Fed. Reg. 16442/3, JA__; 62 Fed. Reg. 38865/2, JA__.

for a given ozone exposure was *lower* in the 2008 review than in the 1997 review. For example, in 2008, approximately 10% to 12% of individuals are estimated to have a 10% or greater decrement in lung function at exposures of 0.06 ppm, *id.* at 5-26, Figure 5-4a, JA__, whereas in 1997, between 20% and 40% of individuals were estimated to have such a response at that level, 1996 Staff Paper at 115, Figure V-12, JA__. This means there is *less* risk from ambient ozone exposure today than EPA believed to exist in 1997.

In addition, in the 1997 review, EPA estimated the risk of respiratory symptoms in children based on the human exposure studies. EPA provided no risk estimates for such responses in the 2008 review because of a "lack of symptoms found in field studies."[12] Clearly, if the data now show a "lack of symptoms," the risk of this effect is less than was estimated in 1997.[13]

Similarly, in 1997, EPA assessed exposures and risks in "outdoor workers." 62 Fed. Reg. 38860/2. In 2008, however, EPA did not develop quantitative exposure estimates for this population "due to the lack of information about the number of individuals who regularly work or exercise outdoors." 73 Fed. Reg.

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[12] Health Risk Assessment at 3-3, JA__.

[13] EPA nevertheless estimated respiratory symptoms of asthmatic children in one city (Boston) based on a single panel study, 2007 Staff Paper at 5-93, JA__, a study that is much like the field studies that led EPA to reject assessing risks of

16442/1. EPA's discovery in 2008 that it is not possible to perform a reliable risk assessment on outdoor workers does not mean that it is factually inappropriate to compare risk estimates. Nor does it mean the risks are greater. It merely calls into question the reliability of the 1997 estimates for this population.

Other elements of the 2008 risk assessment also fail to establish that risks are any greater upon attainment of the 1997 NAAQS than those EPA found "requisite" to protect public health in 1997. For example, in both 1997 and 2008, EPA notes the substantial uncertainty in its risk estimates. *Compare* 73 Fed. Reg. 16466/3, JA__, *with* 62 Fed. Reg. 38860/2, JA__; *see also* 73 Fed. Reg. 16483/1 (explaining the uncertainties of the risk assessment led EPA not to follow CASAC's advice for a standard at or below 0.070 ppm), JA__; 73 Fed. Reg. 16482/3, JA__ (The current risk assessment "does not provide a clear enough basis for choosing a specific level within the range of 0.075 to 0.070 ppm."). In short, despite the newer science, EPA's estimates of risks remain uncertain and do not support a conclusion that the 0.08 standard is no longer "requisite."

EPA may not reverse prior policy decisions without providing a reasoned explanation for the change. *Dillmon v. NTSB*, 588 F.3d 1085, 1089-90 (D.C. Cir. 2009) (citing *FCC v. Fox Television Stations, Inc*., 129 S. Ct. 1800, 1811 (2009))

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symptoms in children generally and that shares many of their flaws. *See* ExxonMobil Comments at 21-23, JA __-__.

("Reasoned decision making … necessarily requires the agency to acknowledge and provide an adequate explanation for its departure from established precedent."); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983); *AT&T Corp. v. FCC*, 236 F.3d 729, 736-37 (D.C. Cir. 2001) (reasoned decision making standard requires explanation for departure from prior decision).

In all events, EPA's failure to perform a comparison between the risks it deemed acceptable from exposure to ambient ozone in 1997 and the estimated risk from comparable ozone exposure now renders the ozone NAAQS arbitrary and capricious. *See State Farm*, 463 U.S. at 43 ("Normally, an agency rule would be arbitrary and capricious if the agency has … entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency…."); *see also Earth Island Inst. v. Forest Serv.*, 442 F.3d 1147, 1157 (9th Cir. 2006) ("We reverse under the arbitrary and capricious standard … if the agency has … entirely failed to consider an important aspect of the problem."). This Court has set aside rules because an agency failed to consider a particular piece of evidence, empirical data, or "an argument inconsistent with its conclusion." *Comcast Corp. v. FCC*, 579 F.3d 1, 8 (D.C. Cir. 2009) (citations omitted); *see also Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1217 (D.C. Cir. 2004) (setting aside agency rule for

failure to consider and explain certain factors); *D&F Afonso Realty Trust v. Garvey*, 216 F.3d 1191, 1196-97 (D.C. Cir. 2000) (remanding agency determination as arbitrary and capricious because agency failed to consider key aspects in its hazard determination analysis and otherwise failed to provide substantial evidence to support determination); *Orion Commc'ns Ltd. v. FCC*, 131 F.3d 176, 180, 181 (D.C. Cir. 1997) (overturning licensing decision in part because of the agency's "abbreviated discussions" and "woefully partial consideration" of certain factors). Because EPA neglected to compare risks in 1997 to those available at the time of this rulemaking, it "entirely failed to consider an important aspect of the problem," and, for this reason alone, this Court should vacate the ozone NAAQS.

IV. EPA's Revised Ozone NAAQS Fail To Reflect Accurately the Latest Scientific Knowledge.

As noted above, NAAQS decisions must be based on air quality criteria that "*accurately reflect the latest scientific knowledge useful in indicating …* identifiable effects on public health or welfare" from the pollutant. CAA § 108(a)(2) (emphasis added). Moreover, Congress provided that any decision to revise a NAAQS must be made "in accordance with section 108," *id.* § 109(d)(1), including that section's insistence on "accurate[ ]" and "useful" scientific data and analysis. Thus, as explained below, a NAAQS can be revised in a way that satisfies § 108 only if EPA: (1) accurately represents the results of any new

studies; and (2) evaluates in a transparent manner both the strengths and weaknesses of these new studies against any older studies.

Because the CAA does not define the terms "accurate[ ]" and "useful," this Court must presume that Congress meant to give those terms their ordinary meaning. *See, e.g.*, *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187 (1995) ("When terms used in a statute are undefined, we give them their ordinary meaning."). "Accurate" means "free from error …[;] exact[]," *see* MERRIAM WEBSTER DICTIONARY, *available at* http://www.merriam-webster.com, and "useful" means "capable of being put to use" or "serviceable for an end or purpose," *id.* As a result, when Congress insisted EPA rely on accurate information useful in identifying the effect that a given pollutant has on public health and welfare, Congress required EPA to consider and rely upon all scientific information that is capable of being put to use and serviceable for that end (useful) and that is free from error (accurate).

Furthermore, in giving meaning to the terms "accurate[ ]" and "useful," this Court should look to relevant congressional enactments using those terms. To be sure, later enactments that do not bear directly on earlier-enacted terms are not authoritative, *see, e.g., Gutierrez v. Ada*, 528 U.S. 250, 257-58 (2000), but that does not mean a later enactment cannot serve as persuasive authority in determining a term's ordinary meaning in an earlier enactment, *see Branch v.*

Smith, 538 U.S. 254, 280-81 (2003) (the meaning of a later-enacted statute can "shed[ ] light" on the meaning of an earlier-enacted statute). In addition, this Court has held that it will "read a body of statutes addressing the same subject matter *in pari materia*," including "later-enacted statutes as well." *Griffith v. Lanier*, 521 F.3d 398, 402 (D.C. Cir. 2008).

Notably, in the IQA, Congress set forth what agencies must do to ensure the accuracy and usefulness of the data and analyses used for regulatory decisionmaking. Pub. L. No. 106-554, § 515(a), 114 Stat. 2763, 2763A-153 to -154 (2000). In particular, the IQA requires federal agencies to maximize and ensure the quality, objectivity, utility, and integrity of information they use – requirements that apply to EPA and must be read *in pari materia* with the requirements embodied in §§ 108 and 109 of the CAA.

Based on guidelines issued pursuant to the IQA, OMB and EPA have determined the IQA requires information used by EPA for decisionmaking to be: (1) objective (both from a substantive and presentation point of view); and (2) useful for the purpose in which it was intended. 67 Fed. Reg. 8452, JA__; EPA IQA Guidelines at 10, 15, 22, 26, JA__, __, __, __. Objectivity requires ensuring accurate, reliable, and unbiased information. 67 Fed. Reg. 8459/3, JA__; EPA IQA Guidelines at 15, JA__. To ensure information is useful, EPA must present the information within a proper context and in a manner that ensures the public can

assess whether there is a reason to question the objectivity of the sources. 67 Fed. Reg. 8459/3, JA__. Finally, EPA's review should also be transparent to allow the public to determine whether the relevant information is being presented in an accurate, clear, complete, and unbiased manner. *Id.* at 8459/3, JA__; EPA IQA Guidelines at 13, JA__; *see also Home Box Office, Inc. v. FCC*, 567 F.2d 9, 36 (D.C. Cir. 1977) (noting that, under *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, (1971), a reviewing court must "assure itself that all relevant factors have been considered by the agency").[14]

As discussed below, EPA has inaccurately characterized the results of some studies and relied heavily on other studies without acknowledging their weaknesses (including clinical studies, panel studies, and time-series studies). Furthermore, EPA has refused to correct these deficiencies in response to comments that the data relied upon run afoul of IQA requirements for quality, objectivity, utility, and integrity. *See* ACC Comments at 34, JA__; Engler, John, President and CEO, National Association of Manufacturers, Letter to Stephen L. Johnson, Adm'r, EPA, Request for Correction, at 9-64 (Oct. 9, 2007), Doc. ID No.

[14] In the context of the ozone NAAQS rulemaking at issue, the IQA covers the criteria documents, staff paper, exposure and risk documents, the proposed rule, and EPA memoranda submitted to the record that bear directly on the assessment of risk, as well as the underlying studies that EPA endorses in each of those documents. All of these documents constitute influential, scientific, and technical documents subject to the IQA.

EPA-HQ-OAR-2005-0172-4861, JA____. EPA's decision to revise the ozone NAAQS therefore is unlawful and must be vacated for these reasons, as well.

A. EPA's Conclusions Regarding New Clinical Studies Misrepresent Those Studies' Results and Therefore Do Not Accurately Reflect the Latest Scientific Knowledge of Identifiable Effects.

Contrary to the requirement that NAAQS decisions "accurately reflect" the science, EPA claims Adams 2002 and Adams 2006 support a finding of identifiable effects at 0.06 ppm. This claim is belied, however, by the author of the studies, who found statistically significant respiratory effects at 0.08 ppm exposures (consistent with EPA's 1997 "requisite" finding) but *no statistically significant differences at levels below 0.08 ppm*. *See* 2006 CD at 6-6, 8-17 to 8-18, 8-42, 8A-2, JA__, __-__, __, __.[15]

Despite the findings of Dr. Adams, EPA asserts that the "effects described by Adams (2002), along with the cursory evaluation of the Adams (2006) data as described above, *strongly suggest* that exposure to 0.06 ppm [ozone] causes small group mean FEV_1 decrements in healthy adults with some individuals having notable effects." 2007 Staff Paper at 3-8 (emphasis added), JA__. In making this

[15] Although not included in the two "external" drafts on which the public was given an opportunity to comment, the *final* ozone criteria document discussed Adams 2006 – a soon to be published paper at the time, 2006 CD at 6-10, JA__ – at the request of CASAC. Letter from Dr. Rogene Henderson, Chair, CASAC, to Stephen L. Johnson, Adm'r, EPA, at 5 (Feb. 10, 2006), EPA-CASAC-6-003 ("Henderson 2/2006"), JA__.

assertion, EPA provides no explanation as to how these observations and "cursory evaluation" (which did not undergo any independent peer review) accurately reflect the "latest scientific knowledge" over the findings of the author himself, which were subject to peer review. Adams, among others, questioned the scientific basis for EPA's conclusions.[16] *See* Adams Email at 1 ("I believe that EPA has misinterpreted the statistics contained in my published, peer-reviewed paper."), JA__; *see also* Lefohn, Ph.D., Allen S., A.S.L. & Associates, Testimony, at 3-4 (Sept. 5, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-4649 ("It is highly questionable if the data points [of individual subjects in the Adams studies] should be used for setting a public health standard."), JA__-__.

In support of its conclusions that the Adams studies mean something different from what the author concluded, EPA asserts that CASAC did not object to the 2007 Staff Paper. CASAC, however, is an advisory board and does not relieve EPA from its duties to engage in reasoned decisionmaking. Moreover, CASAC itself "is subject to following information quality guidelines." EPA, Response to Significant Comments on the 2007 Proposed Rule on the National Ambient Air Quality Standards for Ozone, at 150 (Mar. 2008), Doc. ID No. EPA-

[16] The statistical method used by EPA for its reanalysis of exposures was also questioned by Dr. Adams, with no response by EPA. Adams Comments at 3, JA__.

HQ-OAR-2005-0172-13079 ("RTC"), JA__. These guidelines require that agencies ensure "accurate, reliable and unbiased information" and that analytic results "be developed, using sound statistical and research methods." 67 Fed. Reg. 8459/3, JA__; *cf.* EPA IQA Guidelines 21 (holding analytic results for influential information to higher standards of reproducibility and transparency concerning sources of information, assumptions used, analytical methods, and statistical procedures), JA__. These criteria have not been met here concerning the reinterpretation and reanalysis of Dr. Adams' work.

Moreover, CASAC appears to have supported Dr. Adams' own findings and conclusions by requesting that EPA include the Adams 2006 study in the 2006 Criteria Document. Henderson 2/2006 at 5, JA__. Indeed, at least one panel member questioned EPA's reliance on one or two data points to support a finding of statistical significance:

> [T]his approach amounts to attempting to find effects in a very few individuals when the statistical tests are not significant, which is a dangerous precedent – especially in this case where we are looking at small effects in 3 of 30 vs. 1 of 30, a pitiful number on which to attempt to base policy.

Letter from Dr. Rogene Henderson, Chair, CASAC, to Stephen L. Johnson, Adm'r, EPA, at C-31 (Mar. 26, 2007), EPA-CASAC-07-002 (statement of Dr. Vedal), JA__.

Apparently recognizing the lack of accurate and useful "science" supporting its claims with respect to the Adams studies, EPA attempted to rehabilitate the "science" through a memorandum to the docket, which is dated June 14, 2007 – six days before the proposed rule was signed. Memorandum from James S. Brown, EPA, to the Ozone NAAQS Review Docket (June 14, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-0175, JA__-__; 72 Fed. Reg. 37818, 37828/2 & n.15 (July 11, 2007), JA__. This memorandum, which was not referenced in either the 2006 Criteria Document or the 2007 Staff Paper and was not peer-reviewed when disseminated, was widely criticized in public comments as not being scientifically valid. Smith Comments at 1, JA__; Adams Comments at 1-4, JA__-__; ExxonMobil Comments at 6-9, JA__-__. EPA nevertheless cited this memorandum in support of it revision of the NAAQS. 73 Fed. Reg. 16445/1, JA__.

In disregarding the conclusions of the author of a published peer-reviewed study and instead relying on an unpublished, non-peer reviewed reanalysis of a selective subset of data from that study that reached different conclusions, EPA violated § 108(b) of the CAA and the IQA standards for accuracy and objectivity, as expressed in both the OMB IQA Guidelines and EPA's IQA Guidelines.

B. EPA's Selective Reliance on Time-Series Epidemiological Studies that Use Ambient Air Quality Measurements Instead of Personal Exposure Monitors Fails To Meet Standards of Accuracy and Objectivity.

Numerous studies and CASAC itself have rejected reliance on ambient monitors instead of personal monitors to measure and to estimate ozone exposures. Nevertheless, in deciding to revise the ozone NAAQS, EPA selectively relied on ambient monitoring data to the exclusion of personal monitoring data.

The overwhelming view in the scientific community is that ambient ozone measurements do not provide reliable estimates of personal exposure for use in time-series studies. This conclusion is supported by numerous studies including Brauer *et al*. (1989, 2002),[17] Linaker *et al*. (2000),[18] Liu *et al*. (1997),[19] Patterson *et al.* (2000),[20] J. Sarnat et al. (2001, 2005), [21] and S. Sarnat (2006).[22] ExxonMobil

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[17] Brauer, M., *et al.*, *Personal Exposures to Acidic Aerosols and Gases*, 23 ENVT'L SCI. TECH. 1408-12 (1989), JA__-__; Brauer, M., *et al.*, *Exposure Misclassification and Threshold Concentrations in Time-Series Analyses of Air Pollution Health Effects*, 22 RISK ANALYSIS 1183-93 (2002), JA__-__.

[18] Linaker, C.H., *et al.*, *Personal exposures of children to nitrogen dioxide relative to concentrations in outdoor air*, 57 OCCUP. ENVTL. MED. 472-76 (2000), JA__-__.

[19] Liu, L.S., *et al.*, *Ozone Exposure Assessment in a Southern California Community*, 105 ENVTL. HEALTH PERSP. 58-65 (Jan. 1997), JA__-__.

[20] Patterson, E. & D.J. Eatough, *Indoor/Outdoor Relationships for Ambient $PM_{2.5}$ and Associated Pollutants: Epidemiological Implications in Lindon, Utah*, 50 J. AIR & WASTE MGMT. ASS'N 103-10 (Jan. 2000), JA__-__.

Comments at 15-20, JA__-__. As CASAC explained in its June 5, 2006 letter to EPA: "[O]f particular importance for the ozone time-series studies, there can be *no correlation* between personal concentrations of ozone measured over time and concentrations measured at central outdoor sites." Henderson 6/2006, at 3 (emphasis added), JA__. This is important because ambient measurements at central outdoor sites cannot represent all of the conditions affecting a person's exposure (e.g., indoor versus outdoor exposures, home versus office exposures), making it unlikely that observed effects can be attributed to ozone exposures. *Id.* at 3-4, JA__-__.

Given these findings, EPA's reliance on studies using ambient monitors, especially for large geographical areas and populations that do not spend a high proportion of the study period outdoors, introduces a significant bias in the science that EPA asserts supports a finding of identifiable effects from ozone exposure.

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[21] Sarnat, J., *et al.*, *Gaseous Pollutants in Particulate Matter Epidemiology: Confounders or Surrogates?*, 109 ENVTL. HEALTH PERSP. 1053-61 (Oct. 2001) ("Sarnat 2001"), JA__-__; Sarnat, J., *et al*., *Ambient Gas Concentrations and Personal Particulate Matter Exposures: Implications for Studying the Health Effects of Particles*, 16 EPIDEMIOLOGY 385-95 (2005) ("Sarnat 2005"), JA__-__.

[22] Sarnat, S.E., *et al.*, *Factors Affecting the Association between Ambient Concentrations and Personal Exposure to Particles and Gases*, 114 ENVTL. HEALTH PERSP. 649-54 (May 2006) ("Sarnat 2006"), JA__-__.

This problem is particularly acute in studies by Mortimer *et al*. (2002)[23] and Gent *et al*. (2003)[24] that EPA cites repeatedly as supporting its decision to revise the standard to make it more stringent. 73 Fed. Reg. 16445/2-3, JA__; 72 Fed. Reg. 37829/1-2, 37865/1-2, 37876/1, JA__, __, __. For example, in the case of Mortimer, all ambient monitors in the county were averaged for each of the eight urban study locations while Gent used the average of all available ambient monitoring data in a large (6691 square mile) study area to assess exposures. ExxonMobil Comments at 17, JA__.

Instead of accounting for this known bias, EPA dismisses its significance by first focusing on only a limited number of studies evaluating the ability of ambient monitors to represent an individual's ozone exposure (Sarnat 2001, Sarnat 2005) and then, second, by mischaracterizing their results by claiming they support using ambient ozone concentrations from central monitors as valid surrogate measures for personal exposure levels. This finding is not supported by the data or the authors' conclusions. For example, Sarnat 2001 concluded that "[a]mbient concentrations of gaseous air pollutants *cannot be considered as surrogates* for

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[23] Mortimer, K.M., *et al.*, *The effect of air pollution on inner-city children with asthma*, 19 EUR. RESPIR. J. 699-705 (2002) ("Mortimer"), JA__-__.

[24] Gent, J.**,** *et al.*, *Association of Low-Level Ozone and Fine Particles With Respiratory Symptoms in Children With Asthma*, 290 J. AM. MED. ASS'N 1859-67 (2003) ("Gent"), JA__-__.

their respective personal exposures without site-specific evidence to support that assumption." Sarnat 2001, 109 ENVTL. HEALTH PERSP. at 1060 (emphasis added), JA__; *see also* ExxonMobil Comments at 17-18, JA__-__.

Moreover, EPA inaccurately characterized the results of Sarnat 2006, stating the study found strong associations between ambient ozone exposure and personal exposure. RTC at 39, JA__. In that study, however, the authors explained that "[t]he results suggest that time-series health studies based on 24-hr ambient concentrations may not be able to identify the effects of gases on health, and better exposure surrogates are needed." Sarnat 2006, 114 ENVTL. HEALTH PERSP. at 654, JA__, *see also* ExxonMobil Comments at 18, JA__.

EPA's failure to report accurately the results of these studies and to account for their effect on the validity of ozone time-series studies violates the requirements of § 108(b) of the CAA and the IQA standards for accuracy and objectivity, as expressed in both the OMB IQA Guidelines and EPA IQA Guidelines.

C. EPA Fails To Meet CAA and IQA Standards for Accuracy and Utility by Ignoring Studies that Find No Association and Relying Instead on Studies that Fail To Account for Other Possible Causes of Observed Health Effects.

In support of its decision that the 1997 NAAQS is no longer "requisite," EPA dismisses the results of peer-reviewed epidemiology studies of ozone at exposure levels higher than 0.08 ppm that found *no association with observed*

health effects, and focuses instead on a subset of studies that found an association without adequate controls for possible confounders.[25] The need to account for the effects of other air pollutants in epidemiological studies is particularly important in assessing potential effects from ozone exposure.

First, recent epidemiological studies have focused almost entirely on particulate matter ("PM"), with ozone being treated, if at all, as a potential confounder. Moolgavkar, Suresh, M.D., Ph.D., Exponent, Inc., A Critical Review of the Staff Paper on Ozone, at 2 (June 25, 2007), Doc. ID No. EPA-HQ-OAR-2005-0172-0493 ("For this reason, many of the studies cited in the Staff Paper do not pay sufficient attention to optimizing analytic approaches and sensitivity analyses to the association of ozone with health effects."), JA__; *see also* ExxonMobil Comments at 10, JA__. This creates a bias in the published studies, which may not accurately reflect the effects of ozone.

Second, EPA has found that PM is causally related to the same effects it attributes to ozone. 71 Fed. Reg. 61144, 61145/1-2 (Oct. 17, 2006), JA__-__. For

[25] A confounder is a factor that can confuse the results, such that EPA would be unable to discern whether the observed effect is caused by ozone or some other factor(s). A common confounder in NAAQS review is the presence of other pollutants besides the pollutant at issue.

example, Huang *et al.* (2005)[26] observed significant confounding of the ozone-mortality relationship by coarse particulate matter ("PM_{10}"). *See* ExxonMobil Comments at 21, JA__. When PM_{10} was included in the statistical model, Huang showed that the ozone mortality coefficients in many cities were reduced to *non-statistically significant levels*. Huang, 16 ENVIRONOMETRICS at 557, Fig. 5 (illustrating diminution of association with ozone in several cities with PM_{10} in the model), JA__. In other words, the ozone exposure was *not* shown to be a significant cause of the effect. Similarly, in another key study cited by EPA, Korrick *et al.* (1998),[27] when adjustment for $PM_{2.5}$ and aerosol acidity were included, the pulmonary function changes attributed to ozone were *not* statistically significant. Korrick, 106 ENVTL. HEALTH PERSP. at 96-97, JA__-__; ExxonMobil Comments at 27-28, JA__-__.

Thus, it is not surprising CASAC referenced the problems with time-series epidemiology studies and cautioned against using them to identify effects from ozone: "The [CAA] requires that NAAQS be set for individual criteria air

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[26] Huang, Y., *et al.*, *Bayesian hierarchical distributed-lag models for summer ozone exposure and cardio-respiratory mortality*, 16 ENVIRONOMETRICS 547-62 (2005) ("Huang"), JA__-__.

[27] Korrick, S.A., *et al.*, *Effects of Ozone and Other Pollutants on the Pulmonary Function of Adult Hikers*, 106 ENVTL. HEALTH PERSP. 93-99 (Feb. 1998). ("Korrick"), JA__-__.

pollutants using the best available science. Because results of time-series studies implicate all of the criteria pollutants, findings of mortality time-series studies do not seem to allow us to confidently attribute observed effects specifically to individual pollutants." Henderson 6/2006 at 3, JA__. EPA's reliance on such studies and refusal to account for peer-reviewed studies that found no observable effects at levels derived from the confounded studies is inconsistent with the statutory mandates for accuracy and objectivity.

For all of these reasons, EPA's decision to revise the 1997 NAAQS does not comport with the accuracy and usefulness requirement of the CAA or similar standards under the IQA, as set forth in the OMB IQA Guidelines and EPA IQA Guidelines. Nor does it reflect reasoned decisionmaking. As a result, the 2008 ozone NAAQS should be vacated.

V. The Revised Secondary Standard Should Be Set Aside.

Although EPA determined the secondary standard should be revised, it also concluded based on "significant uncertainties" that any standard more stringent than the revised primary NAAQS "may be more than necessary to provide the requisite degree of protection" for public welfare. 73 Fed. Reg. 16500/1-2, JA__. Given the "remain[ing] significant uncertainties in determining or quantifying the degree of risk attributable to varying levels of [ozone] exposure," *id.* at 16500/1, JA__, EPA set the "revise[d] … secondary standard to be *identical in every way* to

the revised primary standard," *id.* at 16500/2 (emphasis added), JA__. "Because the secondary standards are at least in part based on" the primary standards, *ATA I*, 175 F.3d at 1040, those standards should be set aside and remanded to EPA if the primary standards are declared unlawful.

CONCLUSION

For the foregoing reasons, EPA should vacate the revised ozone NAAQS. Because EPA has not established that revision of the 1997 NAAQS is requisite to protect public health or welfare, the deficiencies of the revised ozone NAAQS are serious and may not be curable. *See Allied-Signal, Inc. v. NRC*, 988 F.2d 146, 150-51 (D.C. Cir. 1993). In the event of vacatur, the 1997 NAAQS, which this Court endorsed and which are nearly as stringent as the revised ozone NAAQS, will continue to protect health and welfare while EPA completes the ongoing five-year NAAQS review required by the CAA.

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Dated: April 17, 2012

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure and Circuit Rules 32(a)(1) and 32(a)(2)(C), I hereby certify that the foregoing Joint Opening Brief of Petitioner State of Mississippi and Industry Petitioners contains 13,974 words, as counted by a word processing system that includes headings, footnotes, quotations, and citations in the count, and therefore is within the word limit set by the Court.

__/s/ Allison D. Wood_____

Dated: April 17, 2012

CERTIFICATE OF SERVICE

Pursuant to Rule 25 of the Federal Rules of Appellate Procedure and Circuit Rule 25(c), I hereby certify that I have this 17th day of April, 2012, served a copy of the foregoing Joint Opening Brief of Petitioner State of Mississippi and Industry Petitioners electronically through the Court's CM/ECF system.

/s/ Allison D. Wood

Statutory and Regulatory Addendum

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1. Clean Air Act § 107, 42 U.S.C. § 7407

1. §7407. Air quality control regions

(a) Responsibility of each State for air quality; submission of implementation plan

Each State shall have the primary responsibility for assuring air quality within the entire geographic area comprising such State by submitting an implementation plan for such State which will specify the manner in which national primary and secondary ambient air quality standards will be achieved and maintained within each air quality control region in such State.

(b) Designated regions

For purposes of developing and carrying out implementation plans under section 7410 of this title—

(1) an air quality control region designated under this section before December 31, 1970, or a region designated after such date under subsection (c) of this section, shall be an air quality control region; and

(2) the portion of such State which is not part of any such designated region shall be an air quality control region, but such portion may be subdivided by the State into two or more air quality control regions with the approval of the Administrator.

(c) Authority of Administrator to designate regions; notification of Governors of affected States

The Administrator shall, within 90 days after December 31, 1970, after consultation with appropriate State and local authorities, designate as an air quality control region any interstate area or major intrastate area which he deems necessary or appropriate for the attainment and maintenance of ambient air quality standards. The Administrator shall immediately notify the Governors of the affected States of any designation made under this subsection.

(d) Designations

(1) Designations generally

(A) Submission by Governors of initial designations following promulgation of new or revised standards

By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 7409 of this title, the Governor of each State shall (and at any other time the Governor of a State deems appropriate the Governor may) submit to the Administrator a list of all areas (or portions thereof) in the State, designating as—

(i) nonattainment, any area that does not meet (or that contributes to ambient air quality in a nearby area that does not meet) the national primary or secondary ambient air quality standard for the pollutant,

(ii) attainment, any area (other than an area identified in clause (i)) that meets the national primary or secondary ambient air quality standard for the pollutant, or

(iii) unclassifiable, any area that cannot be classified on the basis of available information as meeting or not meeting the national primary or secondary ambient air quality standard for the pollutant.

The Administrator may not require the Governor to submit the required list sooner than 120 days after promulgating a new or revised national ambient air quality standard.

(B) Promulgation by EPA of designations

(i) Upon promulgation or revision of a national ambient air quality standard, the Administrator shall promulgate the designations of all areas (or portions thereof) submitted under subparagraph (A) as expeditiously as practicable, but in no case later than 2 years from the date of promulgation of the new or revised national ambient air quality standard. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations.

(ii) In making the promulgations required under clause (i), the Administrator may make such modifications as the Administrator deems necessary to the designations of the areas (or portions thereof) submitted under subparagraph (A) (including to the boundaries of such areas or portions thereof). Whenever the Administrator intends to make a modification, the Administrator shall notify the State and provide such State with an opportunity to demonstrate why any proposed modification is inappropriate. The Administrator shall give such notification no later than 120 days before the date the Administrator promulgates the designation, including any modification thereto. If the Governor fails to submit the list in whole or in part, as required under subparagraph (A), the Administrator shall promulgate the designation that the

Administrator deems appropriate for any area (or portion thereof) not designated by the State.

(iii) If the Governor of any State, on the Governor's own motion, under subparagraph (A), submits a list of areas (or portions thereof) in the State designated as nonattainment, attainment, or unclassifiable, the Administrator shall act on such designations in accordance with the procedures under paragraph (3) (relating to redesignation).

(iv) A designation for an area (or portion thereof) made pursuant to this subsection shall remain in effect until the area (or portion thereof) is redesignated pursuant to paragraph (3) or (4).

(C) Designations by operation of law

(i) Any area designated with respect to any air pollutant under the provisions of paragraph (1)(A), (B), or (C) of this subsection (as in effect immediately before November 15, 1990) is designated, by operation of law, as a nonattainment area for such pollutant within the meaning of subparagraph (A)(i).

(ii) Any area designated with respect to any air pollutant under the provisions of paragraph (1)(E) (as in effect immediately before November 15, 1990) is designated by operation of law, as an attainment area for such pollutant within the meaning of subparagraph (A)(ii).

(iii) Any area designated with respect to any air pollutant under the provisions of paragraph (1)(D) (as in effect immediately before November 15, 1990) is designated, by operation of law, as an unclassifiable area for such pollutant within the meaning of subparagraph (A)(iii).

(2) Publication of designations and redesignations

(A) The Administrator shall publish a notice in the Federal Register promulgating any designation under paragraph (1) or (5), or announcing any designation under paragraph (4), or promulgating any redesignation under paragraph (3).

(B) Promulgation or announcement of a designation under paragraph (1), (4) or (5) shall not be subject to the provisions of sections 553 through 557 of title 5 (relating to notice and comment), except nothing herein shall be construed as precluding such public notice and comment whenever possible.

(3) Redesignation

(A) Subject to the requirements of subparagraph (E), and on the basis of air quality data, planning and control considerations, or any other air quality-related considerations the Administrator deems appropriate, the Administrator may at

any time notify the Governor of any State that available information indicates that the designation of any area or portion of an area within the State or interstate area should be revised. In issuing such notification, which shall be public, to the Governor, the Administrator shall provide such information as the Administrator may have available explaining the basis for the notice.

(B) No later than 120 days after receiving a notification under subparagraph (A), the Governor shall submit to the Administrator such redesignation, if any, of the appropriate area (or areas) or portion thereof within the State or interstate area, as the Governor considers appropriate.

(C) No later than 120 days after the date described in subparagraph (B) (or paragraph (1)(B)(iii)), the Administrator shall promulgate the redesignation, if any, of the area or portion thereof, submitted by the Governor in accordance with subparagraph (B), making such modifications as the Administrator may deem necessary, in the same manner and under the same procedure as is applicable under clause (ii) of paragraph (1)(B), except that the phrase "60 days" shall be substituted for the phrase "120 days" in that clause. If the Governor does not submit, in accordance with subparagraph (B), a redesignation for an area (or portion thereof) identified by the Administrator under subparagraph (A), the Administrator shall promulgate such redesignation, if any, that the Administrator deems appropriate.

(D) The Governor of any State may, on the Governor's own motion, submit to the Administrator a revised designation of any area or portion thereof within the State. Within 18 months of receipt of a complete State redesignation submittal, the Administrator shall approve or deny such redesignation. The submission of a redesignation by a Governor shall not affect the effectiveness or enforceability of the applicable implementation plan for the State.

(E) The Administrator may not promulgate a redesignation of a nonattainment area (or portion thereof) to attainment unless—

(i) the Administrator determines that the area has attained the national ambient air quality standard;

(ii) the Administrator has fully approved the applicable implementation plan for the area under section 7410(k) of this title;

(iii) the Administrator determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable implementation plan and applicable Federal air pollutant control regulations and other permanent and enforceable reductions;

(iv) the Administrator has fully approved a maintenance plan for the area as meeting the requirements of section 7505a of this title; and

(v) the State containing such area has met all requirements applicable to the area under section 7410 of this title and part D of this subchapter.

(F) The Administrator shall not promulgate any redesignation of any area (or portion thereof) from nonattainment to unclassifiable.

(4) Nonattainment designations for ozone, carbon monoxide and particulate matter (PM–10)

(A) Ozone and carbon monoxide

(i) Within 120 days after November 15, 1990, each Governor of each State shall submit to the Administrator a list that designates, affirms or reaffirms the designation of, or redesignates (as the case may be), all areas (or portions thereof) of the Governor's State as attainment, nonattainment, or unclassifiable with respect to the national ambient air quality standards for ozone and carbon monoxide.

(ii) No later than 120 days after the date the Governor is required to submit the list of areas (or portions thereof) required under clause (i) of this subparagraph, the Administrator shall promulgate such designations, making such modifications as the Administrator may deem necessary, in the same manner, and under the same procedure, as is applicable under clause (ii) of paragraph (1)(B), except that the phrase “60 days” shall be substituted for the phrase “120 days” in that clause. If the Governor does not submit, in accordance with clause (i) of this subparagraph, a designation for an area (or portion thereof), the Administrator shall promulgate the designation that the Administrator deems appropriate.

(iii) No nonattainment area may be redesignated as an attainment area under this subparagraph.

(iv) Notwithstanding paragraph (1)(C)(ii) of this subsection, if an ozone or carbon monoxide nonattainment area located within a metropolitan statistical area or consolidated metropolitan statistical area (as established by the Bureau of the Census) is classified under part D of this subchapter as a Serious, Severe, or Extreme Area, the boundaries of such area are hereby revised (on the date 45 days after such classification) by operation of law to include the entire metropolitan statistical area or consolidated metropolitan statistical area, as the case may be, unless within such 45-day period the Governor (in consultation with State and local air pollution control agencies) notifies the Administrator that additional time is necessary to evaluate the application of clause (v). Whenever a Governor has submitted such a notice to the Administrator, such boundary revision shall occur on the later of the date 8 months after such classification or 14 months after November 15, 1990, unless

the Governor makes the finding referred to in clause (v), and the Administrator concurs in such finding, within such period. Except as otherwise provided in this paragraph, a boundary revision under this clause or clause (v) shall apply for purposes of any State implementation plan revision required to be submitted after November 15, 1990.

(v) Whenever the Governor of a State has submitted a notice under clause (iv), the Governor, in consultation with State and local air pollution control agencies, shall undertake a study to evaluate whether the entire metropolitan statistical area or consolidated metropolitan statistical area should be included within the nonattainment area. Whenever a Governor finds and demonstrates to the satisfaction of the Administrator, and the Administrator concurs in such finding, that with respect to a portion of a metropolitan statistical area or consolidated metropolitan statistical area, sources in the portion do not contribute significantly to violation of the national ambient air quality standard, the Administrator shall approve the Governor's request to exclude such portion from the nonattainment area. In making such finding, the Governor and the Administrator shall consider factors such as population density, traffic congestion, commercial development, industrial development, meteorological conditions, and pollution transport.

(B) PM–10 designations

By operation of law, until redesignation by the Administrator pursuant to paragraph (3)—

(i) each area identified in 52 Federal Register 29383 (Aug. 7, 1987) as a Group I area (except to the extent that such identification was modified by the Administrator before November 15, 1990) is designated nonattainment for PM–10;

(ii) any area containing a site for which air quality monitoring data show a violation of the national ambient air quality standard for PM–10 before January 1, 1989 (as determined under part 50, appendix K of title 40 of the Code of Federal Regulations) is hereby designated nonattainment for PM–10; and

(iii) each area not described in clause (i) or (ii) is hereby designated unclassifiable for PM–10.

Any designation for particulate matter (measured in terms of total suspended particulates) that the Administrator promulgated pursuant to this subsection (as in effect immediately before November 15, 1990) shall remain in effect for purposes of implementing the maximum allowable increases in concentrations of particulate matter (measured in terms of total suspended particulates) pursuant to section

7473(b) of this title, until the Administrator determines that such designation is no longer necessary for that purpose.

(5) Designations for lead

The Administrator may, in the Administrator's discretion at any time the Administrator deems appropriate, require a State to designate areas (or portions thereof) with respect to the national ambient air quality standard for lead in effect as of November 15, 1990, in accordance with the procedures under subparagraphs (A) and (B) of paragraph (1), except that in applying subparagraph (B)(i) of paragraph (1) the phrase "2 years from the date of promulgation of the new or revised national ambient air quality standard" shall be replaced by the phrase "1 year from the date the Administrator notifies the State of the requirement to designate areas with respect to the standard for lead".

(6) Designations

(A) Submission

Notwithstanding any other provision of law, not later than February 15, 2004, the Governor of each State shall submit designations referred to in paragraph (1) for the July 1997 $PM_{2.5}$ national ambient air quality standards for each area within the State, based on air quality monitoring data collected in accordance with any applicable Federal reference methods for the relevant areas.

(B) Promulgation

Notwithstanding any other provision of law, not later than December 31, 2004, the Administrator shall, consistent with paragraph (1), promulgate the designations referred to in subparagraph (A) for each area of each State for the July 1997 $PM_{2.5}$ national ambient air quality standards.

(7) Implementation plan for regional haze

(A) In general

Notwithstanding any other provision of law, not later than 3 years after the date on which the Administrator promulgates the designations referred to in paragraph (6)(B) for a State, the State shall submit, for the entire State, the State implementation plan revisions to meet the requirements promulgated by the Administrator under section 7492(e)(1) of this title (referred to in this paragraph as "regional haze requirements").

(B) No preclusion of other provisions

Nothing in this paragraph precludes the implementation of the agreements and recommendations stemming from the Grand Canyon Visibility Transport Commission Report dated June 1996, including the submission of State implementation plan revisions by the States of Arizona, California, Colorado, Idaho, Nevada, New Mexico, Oregon, Utah, or Wyoming by December 31, 2003, for implementation of regional haze requirements applicable to those States.

(e) Redesignation of air quality control regions

(1) Except as otherwise provided in paragraph (2), the Governor of each State is authorized, with the approval of the Administrator, to redesignate from time to time the air quality control regions within such State for purposes of efficient and effective air quality management. Upon such redesignation, the list under subsection (d) of this section shall be modified accordingly.

(2) In the case of an air quality control region in a State, or part of such region, which the Administrator finds may significantly affect air pollution concentrations in another State, the Governor of the State in which such region, or part of a region, is located may redesignate from time to time the boundaries of so much of such air quality control region as is located within such State only with the approval of the Administrator and with the consent of all Governors of all States which the Administrator determines may be significantly affected.

(3) No compliance date extension granted under section 7413(d)(5) [1] of this title (relating to coal conversion) shall cease to be effective by reason of the regional limitation provided in section 7413(d)(5) [1] of this title if the violation of such limitation is due solely to a redesignation of a region under this subsection.

2. Clean Air Act § 108, 42 U.S.C. § 7408

2. §7408. Air quality criteria and control techniques

(a) Air pollutant list; publication and revision by Administrator; issuance of air quality criteria for air pollutants

(1) For the purpose of establishing national primary and secondary ambient air quality standards, the Administrator shall within 30 days after December 31, 1970, publish, and shall from time to time thereafter revise, a list which includes each air pollutant—

(A) emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;

(B) the presence of which in the ambient air results from numerous or diverse mobile or stationary sources; and

(C) for which air quality criteria had not been issued before December 31, 1970 but for which he plans to issue air quality criteria under this section.

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

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

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

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

(b) Issuance by Administrator of information on air pollution control techniques; standing consulting committees for air pollutants; establishment; membership

(1) Simultaneously with the issuance of criteria under subsection (a) of this section, the Administrator shall, after consultation with appropriate advisory committees and Federal departments and agencies, issue to the States and

appropriate air pollution control agencies information on air pollution control techniques, which information shall include data relating to the cost of installation and operation, energy requirements, emission reduction benefits, and environmental impact of the emission control technology. Such information shall include such data as are available on available technology and alternative methods of prevention and control of air pollution. Such information shall also include data on alternative fuels, processes, and operating methods which will result in elimination or significant reduction of emissions.

(2) In order to assist in the development of information on pollution control techniques, the Administrator may establish a standing consulting committee for each air pollutant included in a list published pursuant to subsection (a)(1) of this section, which shall be comprised of technically qualified individuals representative of State and local governments, industry, and the academic community. Each such committee shall submit, as appropriate, to the Administrator information related to that required by paragraph (1).

(c) Review, modification, and reissuance of criteria or information

The Administrator shall from time to time review, and, as appropriate, modify, and reissue any criteria or information on control techniques issued pursuant to this section. Not later than six months after August 7, 1977, the Administrator shall revise and reissue criteria relating to concentrations of NO**2** over such period (not more than three hours) as he deems appropriate. Such criteria shall include a discussion of nitric and nitrous acids, nitrites, nitrates, nitrosamines, and other carcinogenic and potentially carcinogenic derivatives of oxides of nitrogen.

(d) Publication in Federal Register; availability of copies for general public

The issuance of air quality criteria and information on air pollution control techniques shall be announced in the Federal Register and copies shall be made available to the general public.

(e) Transportation planning and guidelines

The Administrator shall, after consultation with the Secretary of Transportation, and after providing public notice and opportunity for comment, and with State and local officials, within nine months after November 15, 1990, and periodically thereafter as necessary to maintain a continuous transportation-air quality planning process, update the June 1978 Transportation-Air Quality Planning Guidelines and publish guidance on the development and implementation of transportation and other measures necessary to demonstrate and maintain attainment of national ambient air quality standards. Such guidelines shall include information on—

(1) methods to identify and evaluate alternative planning and control activities;

(2) methods of reviewing plans on a regular basis as conditions change or new information is presented;

(3) identification of funds and other resources necessary to implement the plan, including interagency agreements on providing such funds and resources;

(4) methods to assure participation by the public in all phases of the planning process; and

(5) such other methods as the Administrator determines necessary to carry out a continuous planning process.

(f) Information regarding processes, procedures, and methods to reduce or control pollutants in transportation; reduction of mobile source related pollutants; reduction of impact on public health

(1) The Administrator shall publish and make available to appropriate Federal, State, and local environmental and transportation agencies not later than one year after November 15, 1990, and from time to time thereafter—

(A) information prepared, as appropriate, in consultation with the Secretary of Transportation, and after providing public notice and opportunity for comment, regarding the formulation and emission reduction potential of transportation control measures related to criteria pollutants and their precursors, including, but not limited to—

(i) programs for improved public transit;

(ii) restriction of certain roads or lanes to, or construction of such roads or lanes for use by, passenger buses or high occupancy vehicles;

(iii) employer-based transportation management plans, including incentives;

(iv) trip-reduction ordinances;

(v) traffic flow improvement programs that achieve emission reductions;

(vi) fringe and transportation corridor parking facilities serving multiple occupancy vehicle programs or transit service;

(vii) programs to limit or restrict vehicle use in downtown areas or other areas of emission concentration particularly during periods of peak use;

(viii) programs for the provision of all forms of high-occupancy, shared-ride services;

(ix) programs to limit portions of road surfaces or certain sections of the metropolitan area to the use of non-motorized vehicles or pedestrian use, both as to time and place;

(x) programs for secure bicycle storage facilities and other facilities, including bicycle lanes, for the convenience and protection of bicyclists, in both public and private areas;

(xi) programs to control extended idling of vehicles;

(xii) programs to reduce motor vehicle emissions, consistent with subchapter II of this chapter, which are caused by extreme cold start conditions;

(xiii) employer-sponsored programs to permit flexible work schedules;

(xiv) programs and ordinances to facilitate non-automobile travel, provision and utilization of mass transit, and to generally reduce the need for single-occupant vehicle travel, as part of transportation planning and development efforts of a locality, including programs and ordinances applicable to new shopping centers, special events, and other centers of vehicle activity;

(xv) programs for new construction and major reconstructions of paths, tracks or areas solely for the use by pedestrian or other non-motorized means of transportation when economically feasible and in the public interest. For purposes of this clause, the Administrator shall also consult with the Secretary of the Interior; and

(xvi) program to encourage the voluntary removal from use and the marketplace of pre-1980 model year light duty vehicles and pre-1980 model light duty trucks.

(B) information on additional methods or strategies that will contribute to the reduction of mobile source related pollutants during periods in which any primary ambient air quality standard will be exceeded and during episodes for which an air pollution alert, warning, or emergency has been declared;

(C) information on other measures which may be employed to reduce the impact on public health or protect the health of sensitive or susceptible individuals or groups; and

(D) information on the extent to which any process, procedure, or method to reduce or control such air pollutant may cause an increase in the emissions or formation of any other pollutant.

(2) In publishing such information the Administrator shall also include an assessment of—

(A) the relative effectiveness of such processes, procedures, and methods;

(B) the potential effect of such processes, procedures, and methods on transportation systems and the provision of transportation services; and

(C) the environmental, energy, and economic impact of such processes, procedures, and methods.

(g) Assessment of risks to ecosystems

The Administrator may assess the risks to ecosystems from exposure to criteria air pollutants (as identified by the Administrator in the Administrator's sole discretion).

(h) RACT/BACT/LAER clearinghouse

The Administrator shall make information regarding emission control technology available to the States and to the general public through a central database. Such information shall include all control technology information received pursuant to State plan provisions requiring permits for sources, including operating permits for existing sources.

3. Clean Air Act § 109, 42 U.S.C. § 7409

3. §7409. National primary and secondary ambient air quality standards

(a) Promulgation

(1) The Administrator—

(A) within 30 days after December 31, 1970, shall publish proposed regulations prescribing a national primary ambient air quality standard and a national secondary ambient air quality standard for each air pollutant for which air quality criteria have been issued prior to such date; and

(B) after a reasonable time for interested persons to submit written comments thereon (but no later than 90 days after the initial publication of such proposed standards) shall by regulation promulgate such proposed national primary and secondary ambient air quality standards with such modifications as he deems appropriate.

(2) With respect to any air pollutant for which air quality criteria are issued after December 31, 1970, the Administrator shall publish, simultaneously with the issuance of such criteria and information, proposed national primary and secondary ambient air quality standards for any such pollutant. The procedure provided for in paragraph (1)(B) of this subsection shall apply to the promulgation of such standards.

(b) Protection of public health and welfare

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

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

(c) National primary ambient air quality standard for nitrogen dioxide

The Administrator shall, not later than one year after August 7, 1977, promulgate a national primary ambient air quality standard for NO**2** concentrations over a period of not more than 3 hours unless, based on the criteria issued under section 7408(c) of this title, he finds that there is no significant evidence that such a standard for such a period is requisite to protect public health.

(d) Review and revision of criteria and standards; independent scientific review committee; appointment; advisory functions

(1) Not later than December 31, 1980, and at five-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 7408 of this title and the national ambient air quality standards promulgated under this section and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 7408 of this title and subsection (b) of this section. The Administrator may review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph.

(2)(A) The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.

(B) Not later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 7408 of this title and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 7408 of this title and subsection (b) of this section.

(C) Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

4. Clean Air Act § 110(a), 42 U.S.C. § 7410(a)

4. §7410. State implementation plans for national primary and secondary ambient air quality standards

(a) Adoption of plan by State; submission to Administrator; content of plan; revision; new sources; indirect source review program; supplemental or intermittent control systems

(1) Each State shall, after reasonable notice and public hearings, adopt and submit to the Administrator, within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof) under section 7409 of this title for any air pollutant, a plan which provides for implementation, maintenance, and enforcement of such primary standard in each air quality control region (or portion thereof) within such State. In addition, such State shall adopt and submit to the Administrator (either as a part of a plan submitted under the preceding sentence or separately) within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national ambient air quality secondary standard (or revision thereof), a plan which provides for implementation, maintenance, and enforcement of such secondary standard in each air quality control region (or portion thereof) within such State. Unless a separate public hearing is provided, each State shall consider its plan implementing such secondary standard at the hearing required by the first sentence of this paragraph.

(2) Each implementation plan submitted by a State under this chapter shall be adopted by the State after reasonable notice and public hearing. Each such plan shall—

(A) include enforceable emission limitations and other control measures, means, or techniques (including economic incentives such as fees, marketable permits, and auctions of emissions rights), as well as schedules and timetables for compliance, as may be necessary or appropriate to meet the applicable requirements of this chapter;

(B) provide for establishment and operation of appropriate devices, methods, systems, and procedures necessary to—

(i) monitor, compile, and analyze data on ambient air quality, and

(ii) upon request, make such data available to the Administrator;

(C) include a program to provide for the enforcement of the measures described in subparagraph (A), and regulation of the modification and

construction of any stationary source within the areas covered by the plan as necessary to assure that national ambient air quality standards are achieved, including a permit program as required in parts C and D of this subchapter;

(D) contain adequate provisions—

(i) prohibiting, consistent with the provisions of this subchapter, any source or other type of emissions activity within the State from emitting any air pollutant in amounts which will—

(I) contribute significantly to nonattainment in, or interfere with maintenance by, any other State with respect to any such national primary or secondary ambient air quality standard, or

(II) interfere with measures required to be included in the applicable implementation plan for any other State under part C of this subchapter to prevent significant deterioration of air quality or to protect visibility,

(ii) insuring compliance with the applicable requirements of sections 7426 and 7415 of this title (relating to interstate and international pollution abatement);

(E) provide (i) necessary assurances that the State (or, except where the Administrator deems inappropriate, the general purpose local government or governments, or a regional agency designated by the State or general purpose local governments for such purpose) will have adequate personnel, funding, and authority under State (and, as appropriate, local) law to carry out such implementation plan (and is not prohibited by any provision of Federal or State law from carrying out such implementation plan or portion thereof), (ii) requirements that the State comply with the requirements respecting State boards under section 7428 of this title, and (iii) necessary assurances that, where the State has relied on a local or regional government, agency, or instrumentality for the implementation of any plan provision, the State has responsibility for ensuring adequate implementation of such plan provision;

(F) require, as may be prescribed by the Administrator—

(i) the installation, maintenance, and replacement of equipment, and the implementation of other necessary steps, by owners or operators of stationary sources to monitor emissions from such sources,

(ii) periodic reports on the nature and amounts of emissions and emissions-related data from such sources, and

(iii) correlation of such reports by the State agency with any emission limitations or standards established pursuant to this chapter, which reports shall be available at reasonable times for public inspection;

(G) provide for authority comparable to that in section 7603 of this title and adequate contingency plans to implement such authority;

(H) provide for revision of such plan—

(i) from time to time as may be necessary to take account of revisions of such national primary or secondary ambient air quality standard or the availability of improved or more expeditious methods of attaining such standard, and

(ii) except as provided in paragraph (3)(C), whenever the Administrator finds on the basis of information available to the Administrator that the plan is substantially inadequate to attain the national ambient air quality standard which it implements or to otherwise comply with any additional requirements established under this chapter;

(I) in the case of a plan or plan revision for an area designated as a nonattainment area, meet the applicable requirements of part D of this subchapter (relating to nonattainment areas);

(J) meet the applicable requirements of section 7421 of this title (relating to consultation), section 7427 of this title (relating to public notification), and part C of this subchapter (relating to prevention of significant deterioration of air quality and visibility protection);

(K) provide for—

(i) the performance of such air quality modeling as the Administrator may prescribe for the purpose of predicting the effect on ambient air quality of any emissions of any air pollutant for which the Administrator has established a national ambient air quality standard, and

(ii) the submission, upon request, of data related to such air quality modeling to the Administrator;

(L) require the owner or operator of each major stationary source to pay to the permitting authority, as a condition of any permit required under this chapter, a fee sufficient to cover—

(i) the reasonable costs of reviewing and acting upon any application for such a permit, and

(ii) if the owner or operator receives a permit for such source, the reasonable costs of implementing and enforcing the terms and conditions of any such permit (not including any court costs or other costs associated with any enforcement action),

until such fee requirement is superseded with respect to such sources by the Administrator's approval of a fee program under subchapter V of this chapter; and

(M) provide for consultation and participation by local political subdivisions affected by the plan.

(3)(A) Repealed. Pub. L. 101–549, title I, §101(d)(1), Nov. 15, 1990, 104 Stat. 2409.

(B) As soon as practicable, the Administrator shall, consistent with the purposes of this chapter and the Energy Supply and Environmental Coordination Act of 1974 [15 U.S.C. 791 et seq.], review each State's applicable implementation plans and report to the State on whether such plans can be revised in relation to fuel burning stationary sources (or persons supplying fuel to such sources) without interfering with the attainment and maintenance of any national ambient air quality standard within the period permitted in this section. If the Administrator determines that any such plan can be revised, he shall notify the State that a plan revision may be submitted by the State. Any plan revision which is submitted by the State shall, after public notice and opportunity for public hearing, be approved by the Administrator if the revision relates only to fuel burning stationary sources (or persons supplying fuel to such sources), and the plan as revised complies with paragraph (2) of this subsection. The Administrator shall approve or disapprove any revision no later than three months after its submission.

(C) Neither the State, in the case of a plan (or portion thereof) approved under this subsection, nor the Administrator, in the case of a plan (or portion thereof) promulgated under subsection (c) of this section, shall be required to revise an applicable implementation plan because one or more exemptions under section 7418 of this title (relating to Federal facilities), enforcement orders under section 7413(d) of this title, suspensions under subsection (f) or (g) of this section (relating to temporary energy or economic authority), orders under section 7419 of this title (relating to primary nonferrous smelters), or extensions of compliance in decrees entered under section 7413(e) of this title (relating to iron- and steel-producing operations) have been granted, if such plan would have met the requirements of this section if no such exemptions, orders, or extensions had been granted.

(4) Repealed. Pub. L. 101–549, title I, §101(d)(2), Nov. 15, 1990, 104 Stat. 2409.

(5)(A)(i) Any State may include in a State implementation plan, but the Administrator may not require as a condition of approval of such plan under this section, any indirect source review program. The Administrator may approve and enforce, as part of an applicable implementation plan, an indirect source review program which the State chooses to adopt and submit as part of its plan.

(ii) Except as provided in subparagraph (B), no plan promulgated by the Administrator shall include any indirect source review program for any air quality control region, or portion thereof.

(iii) Any State may revise an applicable implementation plan approved under this subsection to suspend or revoke any such program included in such plan, provided that such plan meets the requirements of this section.

(B) The Administrator shall have the authority to promulgate, implement and enforce regulations under subsection (c) of this section respecting indirect source review programs which apply only to federally assisted highways, airports, and other major federally assisted indirect sources and federally owned or operated indirect sources.

(C) For purposes of this paragraph, the term "indirect source" means a facility, building, structure, installation, real property, road, or highway which attracts, or may attract, mobile sources of pollution. Such term includes parking lots, parking garages, and other facilities subject to any measure for management of parking supply (within the meaning of subsection (c)(2)(D)(ii) of this section), including regulation of existing off-street parking but such term does not include new or existing on-street parking. Direct emissions sources or facilities at, within, or associated with, any indirect source shall not be deemed indirect sources for the purpose of this paragraph.

(D) For purposes of this paragraph the term "indirect source review program" means the facility-by-facility review of indirect sources of air pollution, including such measures as are necessary to assure, or assist in assuring, that a new or modified indirect source will not attract mobile sources of air pollution, the emissions from which would cause or contribute to air pollution concentrations—

(i) exceeding any national primary ambient air quality standard for a mobile source-related air pollutant after the primary standard attainment date, or

(ii) preventing maintenance of any such standard after such date.

(E) For purposes of this paragraph and paragraph (2)(B), the term "transportation control measure" does not include any measure which is an "indirect source review program".

(6) No State plan shall be treated as meeting the requirements of this section unless such plan provides that in the case of any source which uses a supplemental, or intermittent control system for purposes of meeting the requirements of an order under section 7413(d) of this title or section 7419 of this title (relating to primary nonferrous smelter orders), the owner or operator of such source may not temporarily reduce the pay of any employee by reason of the use of such supplemental or intermittent or other dispersion dependent control system.

5. Clean Air Act §§ 181-185, 42 U.S.C. §§ 7511-7511d

5. §7511. Classifications and attainment dates

(a) Classification and attainment dates for 1989 nonattainment areas

(1) Each area designated nonattainment for ozone pursuant to section 7407(d) of this title shall be classified at the time of such designation, under table 1, by operation of law, as a Marginal Area, a Moderate Area, a Serious Area, a Severe Area, or an Extreme Area based on the design value for the area. The design value shall be calculated according to the interpretation methodology issued by the Administrator most recently before November 15, 1990. For each area classified under this subsection, the primary standard attainment date for ozone shall be as expeditiously as practicable but not later than the date provided in table 1.

TABLE 1

Area class	Design value*	Primary standard attainment date**
Marginal	0.121 up to 0.138	3 years after November 15, 1990
Moderate	0.138 up to 0.160	6 years after November 15, 1990
Serious	0.160 up to 0.180	9 years after November 15, 1990
Severe	0.180 up to 0.280	15 years after November 15, 1990
Extreme	0.280 and above	20 years after November 15, 1990

*The design value is measured in parts per million (ppm).

**The primary standard attainment date is measured from November 15, 1990.

(2) Notwithstanding table 1, in the case of a severe area with a 1988 ozone design value between 0.190 and 0.280 ppm, the attainment date shall be 17 years (in lieu of 15 years) after November 15, 1990.

(3) At the time of publication of the notice under section 7407(d)(4) of this title (relating to area designations) for each ozone nonattainment area, the Administrator shall publish a notice announcing the classification of such ozone nonattainment area. The provisions of section 7502(a)(1)(B) of this title (relating to lack of notice and comment and judicial review) shall apply to such classification.

(4) If an area classified under paragraph (1) (Table 1) would have been classified in another category if the design value in the area were 5 percent greater or 5 percent less than the level on which such classification was based, the Administrator may, in the Administrator's discretion, within 90 days after the

initial classification, by the procedure required under paragraph (3), adjust the classification to place the area in such other category. In making such adjustment, the Administrator may consider the number of exceedances of the national primary ambient air quality standard for ozone in the area, the level of pollution transport between the area and other affected areas, including both intrastate and interstate transport, and the mix of sources and air pollutants in the area.

(5) Upon application by any State, the Administrator may extend for 1 additional year (hereinafter referred to as the "Extension Year") the date specified in table 1 of paragraph (1) of this subsection if—

(A) the State has complied with all requirements and commitments pertaining to the area in the applicable implementation plan, and

(B) no more than 1 exceedance of the national ambient air quality standard level for ozone has occurred in the area in the year preceding the Extension Year.

No more than 2 one-year extensions may be issued under this paragraph for a single nonattainment area.

(b) New designations and reclassifications

(1) New designations to nonattainment

Any area that is designated attainment or unclassifiable for ozone under section 7407(d)(4) of this title, and that is subsequently redesignated to nonattainment for ozone under section 7407(d)(3) of this title, shall, at the time of the redesignation, be classified by operation of law in accordance with table 1 under subsection (a) of this section. Upon its classification, the area shall be subject to the same requirements under section 7410 of this title, subpart 1 of this part, and this subpart that would have applied had the area been so classified at the time of the notice under subsection (a)(3) of this section, except that any absolute, fixed date applicable in connection with any such requirement is extended by operation of law by a period equal to the length of time between November 15, 1990, and the date the area is classified under this paragraph.

(2) Reclassification upon failure to attain

(A) Within 6 months following the applicable attainment date (including any extension thereof) for an ozone nonattainment area, the Administrator shall determine, based on the area's design value (as of the attainment date), whether the area attained the standard by that date. Except for any Severe or Extreme area, any area that the Administrator finds has not attained the standard by that date shall be reclassified by operation of law in accordance with table 1 of subsection (a) of this section to the higher of—

(i) the next higher classification for the area, or
(ii) the classification applicable to the area's design value as determined at the time of the notice required under subparagraph (B).

No area shall be reclassified as Extreme under clause (ii).

(B) The Administrator shall publish a notice in the Federal Register, no later than 6 months following the attainment date, identifying each area that the Administrator has determined under subparagraph (A) as having failed to attain and identifying the reclassification, if any, described under subparagraph (A).

(3) Voluntary reclassification

The Administrator shall grant the request of any State to reclassify a nonattainment area in that State in accordance with table 1 of subsection (a) of this section to a higher classification. The Administrator shall publish a notice in the Federal Register of any such request and of action by the Administrator granting the request.

(4) Failure of Severe Areas to attain standard

(A) If any Severe Area fails to achieve the national primary ambient air quality standard for ozone by the applicable attainment date (including any extension thereof), the fee provisions under section 7511d of this title shall apply within the area, the percent reduction requirements of section 7511a(c)(2)(B) and (C) of this title (relating to reasonable further progress demonstration and NO_x control) shall continue to apply to the area, and the State shall demonstrate that such percent reduction has been achieved in each 3-year interval after such failure until the standard is attained. Any failure to make such a demonstration shall be subject to the sanctions provided under this part.

(B) In addition to the requirements of subparagraph (A), if the ozone design value for a Severe Area referred to in subparagraph (A) is above 0.140 ppm for the year of the applicable attainment date, or if the area has failed to achieve its most recent milestone under section 7511a(g) of this title, the new source review requirements applicable under this subpart in Extreme Areas shall apply in the area and the term “major source” and “major stationary source” shall have the same meaning as in Extreme Areas.

(C) In addition to the requirements of subparagraph (A) for those areas referred to in subparagraph (A) and not covered by subparagraph (B), the provisions referred to in subparagraph (B) shall apply after 3 years from the applicable attainment date unless the area has attained the standard by the end of such 3-year period.

(D) If, after November 15, 1990, the Administrator modifies the method of determining compliance with the national primary ambient air quality standard, a design value or other indicator comparable to 0.140 in terms of its relationship to the standard shall be used in lieu of 0.140 for purposes of applying the provisions of subparagraphs (B) and (C).

(c) References to terms

(1) Any reference in this subpart to a "Marginal Area", a "Moderate Area", a "Serious Area", a "Severe Area", or an "Extreme Area" shall be considered a reference to a Marginal Area, a Moderate Area, a Serious Area, a Severe Area, or an Extreme Area as respectively classified under this section.

(2) Any reference in this subpart to "next higher classification" or comparable terms shall be considered a reference to the classification related to the next higher set of design values in table 1.

6. §7511a. Plan submissions and requirements

(a) Marginal Areas

Each State in which all or part of a Marginal Area is located shall, with respect to the Marginal Area (or portion thereof, to the extent specified in this subsection), submit to the Administrator the State implementation plan revisions (including the plan items) described under this subsection except to the extent the State has made such submissions as of November 15, 1990.

(1) Inventory

Within 2 years after November 15, 1990, the State shall submit a comprehensive, accurate, current inventory of actual emissions from all sources, as described in section 7502(c)(3) of this title, in accordance with guidance provided by the Administrator.

(2) Corrections to the State implementation plan

Within the periods prescribed in this paragraph, the State shall submit a revision to the State implementation plan that meets the following requirements—

(A) Reasonably available control technology corrections

For any Marginal Area (or, within the Administrator's discretion, portion thereof) the State shall submit, within 6 months of the date of classification

under section 7511(a) of this title, a revision that includes such provisions to correct requirements in (or add requirements to) the plan concerning reasonably available control technology as were required under section 7502(b) of this title (as in effect immediately before November 15, 1990), as interpreted in guidance issued by the Administrator under section 7408 of this title before November 15, 1990.

(B) Savings clause for vehicle inspection and maintenance

(i) For any Marginal Area (or, within the Administrator's discretion, portion thereof), the plan for which already includes, or was required by section 7502(b)(11)(B) of this title (as in effect immediately before November 15, 1990) to have included, a specific schedule for implementation of a vehicle emission control inspection and maintenance program, the State shall submit, immediately after November 15, 1990, a revision that includes any provisions necessary to provide for a vehicle inspection and maintenance program of no less stringency than that of either the program defined in House Report Numbered 95–294, 95th Congress, 1st Session, 281–291 (1977) as interpreted in guidance of the Administrator issued pursuant to section 7502(b)(11)(B) of this title (as in effect immediately before November 15, 1990) or the program already included in the plan, whichever is more stringent.

(ii) Within 12 months after November 15, 1990, the Administrator shall review, revise, update, and republish in the Federal Register the guidance for the States for motor vehicle inspection and maintenance programs required by this chapter, taking into consideration the Administrator's investigations and audits of such program. The guidance shall, at a minimum, cover the frequency of inspections, the types of vehicles to be inspected (which shall include leased vehicles that are registered in the nonattainment area), vehicle maintenance by owners and operators, audits by the State, the test method and measures, including whether centralized or decentralized, inspection methods and procedures, quality of inspection, components covered, assurance that a vehicle subject to a recall notice from a manufacturer has complied with that notice, and effective implementation and enforcement, including ensuring that any retesting of a vehicle after a failure shall include proof of corrective action and providing for denial of vehicle registration in the case of tampering or misfueling. The guidance which shall be incorporated in the applicable State implementation plans by the States shall provide the States with continued reasonable flexibility to fashion effective, reasonable, and fair programs for the affected consumer. No later than 2 years after the Administrator promulgates regulations under section 7521(m)(3) of this title (relating to emission control

diagnostics), the State shall submit a revision to such program to meet any requirements that the Administrator may prescribe under that section.

(C) Permit programs

Within 2 years after November 15, 1990, the State shall submit a revision that includes each of the following:

(i) Provisions to require permits, in accordance with sections 7502(c)(5) and 7503 of this title, for the construction and operation of each new or modified major stationary source (with respect to ozone) to be located in the area.

(ii) Provisions to correct requirements in (or add requirements to) the plan concerning permit programs as were required under section 7502(b)(6) of this title (as in effect immediately before November 15, 1990), as interpreted in regulations of the Administrator promulgated as of November 15, 1990.

(3) Periodic inventory

(A) General requirement

No later than the end of each 3-year period after submission of the inventory under paragraph (1) until the area is redesignated to attainment, the State shall submit a revised inventory meeting the requirements of subsection (a)(1) of this section.

(B) Emissions statements

(i) Within 2 years after November 15, 1990, the State shall submit a revision to the State implementation plan to require that the owner or operator of each stationary source of oxides of nitrogen or volatile organic compounds provide the State with a statement, in such form as the Administrator may prescribe (or accept an equivalent alternative developed by the State), for classes or categories of sources, showing the actual emissions of oxides of nitrogen and volatile organic compounds from that source. The first such statement shall be submitted within 3 years after November 15, 1990. Subsequent statements shall be submitted at least every year thereafter. The statement shall contain a certification that the information contained in the statement is accurate to the best knowledge of the individual certifying the statement.

(ii) The State may waive the application of clause (i) to any class or category of stationary sources which emit less than 25 tons per year of volatile organic compounds or oxides of nitrogen if the State, in its submissions under subparagraphs (1) or (3)(A), provides an inventory of emissions from such

class or category of sources, based on the use of the emission factors established by the Administrator or other methods acceptable to the Administrator.

(4) General offset requirement

For purposes of satisfying the emission offset requirements of this part, the ratio of total emission reductions of volatile organic compounds to total increased emissions of such air pollutant shall be at least 1.1 to 1.

The Administrator may, in the Administrator's discretion, require States to submit a schedule for submitting any of the revisions or other items required under this subsection. The requirements of this subsection shall apply in lieu of any requirement that the State submit a demonstration that the applicable implementation plan provides for attainment of the ozone standard by the applicable attainment date in any Marginal Area. Section 7502(c)(9) of this title (relating to contingency measures) shall not apply to Marginal Areas.

(b) Moderate Areas

Each State in which all or part of a Moderate Area is located shall, with respect to the Moderate Area, make the submissions described under subsection (a) of this section (relating to Marginal Areas), and shall also submit the revisions to the applicable implementation plan described under this subsection.

(1) Plan provisions for reasonable further progress

(A) General rule

(i) By no later than 3 years after November 15, 1990, the State shall submit a revision to the applicable implementation plan to provide for volatile organic compound emission reductions, within 6 years after November 15, 1990, of at least 15 percent from baseline emissions, accounting for any growth in emissions after 1990. Such plan shall provide for such specific annual reductions in emissions of volatile organic compounds and oxides of nitrogen as necessary to attain the national primary ambient air quality standard for ozone by the attainment date applicable under this chapter. This subparagraph shall not apply in the case of oxides of nitrogen for those areas for which the Administrator determines (when the Administrator approves the plan or plan revision) that additional reductions of oxides of nitrogen would not contribute to attainment.

(ii) A percentage less than 15 percent may be used for purposes of clause (i) in the case of any State which demonstrates to the satisfaction of the Administrator that—

(I) new source review provisions are applicable in the nonattainment areas in the same manner and to the same extent as required under subsection (e) of this section in the case of Extreme Areas (with the exception that, in applying such provisions, the terms "major source" and "major stationary source" shall include (in addition to the sources described in section 7602 of this title) any stationary source or group of sources located within a contiguous area and under common control that emits, or has the potential to emit, at least 5 tons per year of volatile organic compounds);

(II) reasonably available control technology is required for all existing major sources (as defined in subclause (I)); and

(III) the plan reflecting a lesser percentage than 15 percent includes all measures that can feasibly be implemented in the area, in light of technological achievability.

To qualify for a lesser percentage under this clause, a State must demonstrate to the satisfaction of the Administrator that the plan for the area includes the measures that are achieved in practice by sources in the same source category in nonattainment areas of the next higher category.

(B) Baseline emissions

For purposes of subparagraph (A), the term "baseline emissions" means the total amount of actual VOC or NO_x emissions from all anthropogenic sources in the area during the calendar year 1990, excluding emissions that would be eliminated under the regulations described in clauses (i) and (ii) of subparagraph (D).

(C) General rule for creditability of reductions

Except as provided under subparagraph (D), emissions reductions are creditable toward the 15 percent required under subparagraph (A) to the extent they have actually occurred, as of 6 years after November 15, 1990, from the implementation of measures required under the applicable implementation plan, rules promulgated by the Administrator, or a permit under subchapter V of this chapter.

(D) Limits on creditability of reductions

Emission reductions from the following measures are not creditable toward the 15 percent reductions required under subparagraph (A):

(i) Any measure relating to motor vehicle exhaust or evaporative emissions promulgated by the Administrator by January 1, 1990.

(ii) Regulations concerning Reid Vapor Pressure promulgated by the Administrator by November 15, 1990, or required to be promulgated under section 7545(h) of this title.

(iii) Measures required under subsection (a)(2)(A) of this section (concerning corrections to implementation plans prescribed under guidance by the Administrator).

(iv) Measures required under subsection (a)(2)(B) of this section to be submitted immediately after November 15, 1990 (concerning corrections to motor vehicle inspection and maintenance programs).

(2) Reasonably available control technology

The State shall submit a revision to the applicable implementation plan to include provisions to require the implementation of reasonably available control technology under section 7502(c)(1) of this title with respect to each of the following:

(A) Each category of VOC sources in the area covered by a CTG document issued by the Administrator between November 15, 1990, and the date of attainment.

(B) All VOC sources in the area covered by any CTG issued before November 15, 1990.

(C) All other major stationary sources of VOCs that are located in the area.

Each revision described in subparagraph (A) shall be submitted within the period set forth by the Administrator in issuing the relevant CTG document. The revisions with respect to sources described in subparagraphs (B) and (C) shall be submitted by 2 years after November 15, 1990, and shall provide for the implementation of the required measures as expeditiously as practicable but no later than May 31, 1995.

(3) Gasoline vapor recovery

(A) General rule

Not later than 2 years after November 15, 1990, the State shall submit a revision to the applicable implementation plan to require all owners or operators of gasoline dispensing systems to install and operate, by the date prescribed under subparagraph (B), a system for gasoline vapor recovery of emissions from the fueling of motor vehicles. The Administrator shall issue guidance as appropriate as to the effectiveness of such system. This

subparagraph shall apply only to facilities which sell more than 10,000 gallons of gasoline per month (50,000 gallons per month in the case of an independent small business marketer of gasoline as defined in section 7625–1 of this title).

(B) Effective date

The date required under subparagraph (A) shall be—

(i) 6 months after the adoption date, in the case of gasoline dispensing facilities for which construction commenced after November 15, 1990;

(ii) one year after the adoption date, in the case of gasoline dispensing facilities which dispense at least 100,000 gallons of gasoline per month, based on average monthly sales for the 2-year period before the adoption date; or

(iii) 2 years after the adoption date, in the case of all other gasoline dispensing facilities.

Any gasoline dispensing facility described under both clause (i) and clause (ii) shall meet the requirements of clause (i).

(C) Reference to terms

For purposes of this paragraph, any reference to the term "adoption date" shall be considered a reference to the date of adoption by the State of requirements for the installation and operation of a system for gasoline vapor recovery of emissions from the fueling of motor vehicles.

(4) Motor vehicle inspection and maintenance

For all Moderate Areas, the State shall submit, immediately after November 15, 1990, a revision to the applicable implementation plan that includes provisions necessary to provide for a vehicle inspection and maintenance program as described in subsection (a)(2)(B) of this section (without regard to whether or not the area was required by section 7502(b)(11)(B) of this title (as in effect immediately before November 15, 1990) to have included a specific schedule for implementation of such a program).

(5) General offset requirement

For purposes of satisfying the emission offset requirements of this part, the ratio of total emission reductions of volatile organic compounds to total increase emissions of such air pollutant shall be at least 1.15 to 1.

(c) Serious Areas

Except as otherwise specified in paragraph (4), each State in which all or part of a Serious Area is located shall, with respect to the Serious Area (or portion thereof, to the extent specified in this subsection), make the submissions described under subsection (b) of this section (relating to Moderate Areas), and shall also submit the revisions to the applicable implementation plan (including the plan items) described under this subsection. For any Serious Area, the terms "major source" and "major stationary source" include (in addition to the sources described in section 7602 of this title) any stationary source or group of sources located within a contiguous area and under common control that emits, or has the potential to emit, at least 50 tons per year of volatile organic compounds.

(1) Enhanced monitoring

In order to obtain more comprehensive and representative data on ozone air pollution, not later than 18 months after November 15, 1990, the Administrator shall promulgate rules, after notice and public comment, for enhanced monitoring of ozone, oxides of nitrogen, and volatile organic compounds. The rules shall, among other things, cover the location and maintenance of monitors. Immediately following the promulgation of rules by the Administrator relating to enhanced monitoring, the State shall commence such actions as may be necessary to adopt and implement a program based on such rules, to improve monitoring for ambient concentrations of ozone, oxides of nitrogen and volatile organic compounds and to improve monitoring of emissions of oxides of nitrogen and volatile organic compounds. Each State implementation plan for the area shall contain measures to improve the ambient monitoring of such air pollutants.

(2) Attainment and reasonable further progress demonstrations

Within 4 years after November 15, 1990, the State shall submit a revision to the applicable implementation plan that includes each of the following:

(A) Attainment demonstration

A demonstration that the plan, as revised, will provide for attainment of the ozone national ambient air quality standard by the applicable attainment date. This attainment demonstration must be based on photochemical grid modeling or any other analytical method determined by the Administrator, in the Administrator's discretion, to be at least as effective.

(B) Reasonable further progress demonstration

A demonstration that the plan, as revised, will result in VOC emissions reductions from the baseline emissions described in subsection (b)(1)(B) of this section equal to the following amount averaged over each consecutive 3-year period beginning 6 years after November 15, 1990, until the attainment date:

(i) at least 3 percent of baseline emissions each year; or

(ii) an amount less than 3 percent of such baseline emissions each year, if the State demonstrates to the satisfaction of the Administrator that the plan reflecting such lesser amount includes all measures that can feasibly be implemented in the area, in light of technological achievability.

To lessen the 3 percent requirement under clause (ii), a State must demonstrate to the satisfaction of the Administrator that the plan for the area includes the measures that are achieved in practice by sources in the same source category in nonattainment areas of the next higher classification. Any determination to lessen the 3 percent requirement shall be reviewed at each milestone under subsection (g) of this section and revised to reflect such new measures (if any) achieved in practice by sources in the same category in any State, allowing a reasonable time to implement such measures. The emission reductions described in this subparagraph shall be calculated in accordance with subsection (b)(1)(C) and (D) of this section (concerning creditability of reductions). The reductions creditable for the period beginning 6 years after November 15, 1990, shall include reductions that occurred before such period, computed in accordance with subsection (b)(1) of this section, that exceed the 15-percent amount of reductions required under subsection (b)(1)(A) of this section.

(C) NO_x control

The revision may contain, in lieu of the demonstration required under subparagraph (B), a demonstration to the satisfaction of the Administrator that the applicable implementation plan, as revised, provides for reductions of emissions of VOC's and oxides of nitrogen (calculated according to the creditability provisions of subsection (b)(1)(C) and (D) of this section), that would result in a reduction in ozone concentrations at least equivalent to that which would result from the amount of VOC emission reductions required under subparagraph (B). Within 1 year after November 15, 1990, the Administrator shall issue guidance concerning the conditions under which NO_x control may be substituted for VOC control or may be combined with VOC control in order to maximize the reduction in ozone air pollution. In accord with such guidance, a lesser percentage of VOCs may be accepted as an adequate demonstration for purposes of this subsection.

(3) Enhanced vehicle inspection and maintenance program

(A) Requirement for submission

Within 2 years after November 15, 1990, the State shall submit a revision to the applicable implementation plan to provide for an enhanced program to reduce hydrocarbon emissions and NO_x emissions from in-use motor vehicles registered in each urbanized area (in the nonattainment area), as defined by the Bureau of the Census, with a 1980 population of 200,000 or more.

(B) Effective date of State programs; guidance

The State program required under subparagraph (A) shall take effect no later than 2 years from November 15, 1990, and shall comply in all respects with guidance published in the Federal Register (and from time to time revised) by the Administrator for enhanced vehicle inspection and maintenance programs. Such guidance shall include—

(i) a performance standard achievable by a program combining emission testing, including on-road emission testing, with inspection to detect tampering with emission control devices and misfueling for all light-duty vehicles and all light-duty trucks subject to standards under section 7521 of this title; and

(ii) program administration features necessary to reasonably assure that adequate management resources, tools, and practices are in place to attain and maintain the performance standard.

Compliance with the performance standard under clause (i) shall be determined using a method to be established by the Administrator.

(C) State program

The State program required under subparagraph (A) shall include, at a minimum, each of the following elements—

(i) Computerized emission analyzers, including on-road testing devices.

(ii) No waivers for vehicles and parts covered by the emission control performance warranty as provided for in section 7541(b) of this title unless a warranty remedy has been denied in writing, or for tampering-related repairs.

(iii) In view of the air quality purpose of the program, if, for any vehicle, waivers are permitted for emissions-related repairs not covered by warranty, an expenditure to qualify for the waiver of an amount of $450 or more for such repairs (adjusted annually as determined by the Administrator on the

basis of the Consumer Price Index in the same manner as provided in subchapter V of this chapter).

(iv) Enforcement through denial of vehicle registration (except for any program in operation before November 15, 1990, whose enforcement mechanism is demonstrated to the Administrator to be more effective than the applicable vehicle registration program in assuring that noncomplying vehicles are not operated on public roads).

(v) Annual emission testing and necessary adjustment, repair, and maintenance, unless the State demonstrates to the satisfaction of the Administrator that a biennial inspection, in combination with other features of the program which exceed the requirements of this chapter, will result in emission reductions which equal or exceed the reductions which can be obtained through such annual inspections.

(vi) Operation of the program on a centralized basis, unless the State demonstrates to the satisfaction of the Administrator that a decentralized program will be equally effective. An electronically connected testing system, a licensing system, or other measures (or any combination thereof) may be considered, in accordance with criteria established by the Administrator, as equally effective for such purposes.

(vii) Inspection of emission control diagnostic systems and the maintenance or repair of malfunctions or system deterioration identified by or affecting such diagnostics systems.

Each State shall biennially prepare a report to the Administrator which assesses the emission reductions achieved by the program required under this paragraph based on data collected during inspection and repair of vehicles. The methods used to assess the emission reductions shall be those established by the Administrator.

(4) Clean-fuel vehicle programs

(A) Except to the extent that substitute provisions have been approved by the Administrator under subparagraph (B), the State shall submit to the Administrator, within 42 months of November 15, 1990, a revision to the applicable implementation plan for each area described under part C of subchapter II of this chapter to include such measures as may be necessary to ensure the effectiveness of the applicable provisions of the clean-fuel vehicle program prescribed under part C of subchapter II of this chapter, including all measures necessary to make the use of clean alternative fuels in clean-fuel vehicles (as defined in part C of subchapter II of this chapter) economic from the standpoint of vehicle owners. Such a revision shall also be submitted for each

area that opts into the clean fuel-vehicle program as provided in part C of subchapter II of this chapter.

(B) The Administrator shall approve, as a substitute for all or a portion of the clean-fuel vehicle program prescribed under part C of subchapter II of this chapter, any revision to the relevant applicable implementation plan that in the Administrator's judgment will achieve long-term reductions in ozone-producing and toxic air emissions equal to those achieved under part C of subchapter II of this chapter, or the percentage thereof attributable to the portion of the clean-fuel vehicle program for which the revision is to substitute. The Administrator may approve such revision only if it consists exclusively of provisions other than those required under this chapter for the area. Any State seeking approval of such revision must submit the revision to the Administrator within 24 months of November 15, 1990. The Administrator shall approve or disapprove any such revision within 30 months of November 15, 1990. The Administrator shall publish the revision submitted by a State in the Federal Register upon receipt. Such notice shall constitute a notice of proposed rulemaking on whether or not to approve such revision and shall be deemed to comply with the requirements concerning notices of proposed rulemaking contained in sections 553 through 557 of title 5 (related to notice and comment). Where the Administrator approves such revision for any area, the State need not submit the revision required by subparagraph (A) for the area with respect to the portions of the Federal clean-fuel vehicle program for which the Administrator has approved the revision as a substitute.

(C) If the Administrator determines, under section 7509 of this title, that the State has failed to submit any portion of the program required under subparagraph (A), then, in addition to any sanctions available under section 7509 of this title, the State may not receive credit, in any demonstration of attainment or reasonable further progress for the area, for any emission reductions from implementation of the corresponding aspects of the Federal clean-fuel vehicle requirements established in part C of subchapter II of this chapter.

(5) Transportation control

(A) Beginning 6 years after November 15, 1990, and each third year thereafter, the State shall submit a demonstration as to whether current aggregate vehicle mileage, aggregate vehicle emissions, congestion levels, and other relevant parameters are consistent with those used for the area's demonstration of attainment. Where such parameters and emissions levels exceed the levels projected for purposes of the area's attainment demonstration, the State shall within 18 months develop and submit a revision of the applicable implementation plan that includes a transportation control measures program

consisting of measures from, but not limited to, section 7408(f) of this title that will reduce emissions to levels that are consistent with emission levels projected in such demonstration. In considering such measures, the State should ensure adequate access to downtown, other commercial, and residential areas and should avoid measures that increase or relocate emissions and congestion rather than reduce them. Such revision shall be developed in accordance with guidance issued by the Administrator pursuant to section 7408(e) of this title and with the requirements of section 7504(b) of this title and shall include implementation and funding schedules that achieve expeditious emissions reductions in accordance with implementation plan projections.

(6) De minimis rule

The new source review provisions under this part shall ensure that increased emissions of volatile organic compounds resulting from any physical change in, or change in the method of operation of, a stationary source located in the area shall not be considered de minimis for purposes of determining the applicability of the permit requirements established by this chapter unless the increase in net emissions of such air pollutant from such source does not exceed 25 tons when aggregated with all other net increases in emissions from the source over any period of 5 consecutive calendar years which includes the calendar year in which such increase occurred.

(7) Special rule for modifications of sources emitting less than 100 tons

In the case of any major stationary source of volatile organic compounds located in the area (other than a source which emits or has the potential to emit 100 tons or more of volatile organic compounds per year), whenever any change (as described in section 7411(a)(4) of this title) at that source results in any increase (other than a de minimis increase) in emissions of volatile organic compounds from any discrete operation, unit, or other pollutant emitting activity at the source, such increase shall be considered a modification for purposes of section 7502(c)(5) of this title and section 7503(a) of this title, except that such increase shall not be considered a modification for such purposes if the owner or operator of the source elects to offset the increase by a greater reduction in emissions of volatile organic compounds concerned from other operations, units, or activities within the source at an internal offset ratio of at least 1.3 to 1. If the owner or operator does not make such election, such change shall be considered a modification for such purposes, but in applying section 7503(a)(2) of this title in the case of any such modification, the best available control technology (BACT), as defined in section 7479 of this title, shall be substituted for the lowest achievable emission rate (LAER). The Administrator shall establish and

publish policies and procedures for implementing the provisions of this paragraph.

(8) Special rule for modifications of sources emitting 100 tons or more

In the case of any major stationary source of volatile organic compounds located in the area which emits or has the potential to emit 100 tons or more of volatile organic compounds per year, whenever any change (as described in section 7411(a)(4) of this title) at that source results in any increase (other than a de minimis increase) in emissions of volatile organic compounds from any discrete operation, unit, or other pollutant emitting activity at the source, such increase shall be considered a modification for purposes of section 7502(c)(5) of this title and section 7503(a) of this title, except that if the owner or operator of the source elects to offset the increase by a greater reduction in emissions of volatile organic compounds from other operations, units, or activities within the source at an internal offset ratio of at least 1.3 to 1, the requirements of section 7503(a)(2) of this title (concerning the lowest achievable emission rate (LAER)) shall not apply.

(9) Contingency provisions

In addition to the contingency provisions required under section 7502(c)(9) of this title, the plan revision shall provide for the implementation of specific measures to be undertaken if the area fails to meet any applicable milestone. Such measures shall be included in the plan revision as contingency measures to take effect without further action by the State or the Administrator upon a failure by the State to meet the applicable milestone.

(10) General offset requirement

For purposes of satisfying the emission offset requirements of this part, the ratio of total emission reductions of volatile organic compounds to total increase emissions of such air pollutant shall be at least 1.2 to 1.

Any reference to "attainment date" in subsection (b) of this section, which is incorporated by reference into this subsection, shall refer to the attainment date for serious areas.

(d) Severe Areas

Each State in which all or part of a Severe Area is located shall, with respect to the Severe Area, make the submissions described under subsection (c) of this section (relating to Serious Areas), and shall also submit the revisions to the

applicable implementation plan (including the plan items) described under this subsection. For any Severe Area, the terms "major source" and "major stationary source" include (in addition to the sources described in section 7602 of this title) any stationary source or group of sources located within a contiguous area and under common control that emits, or has the potential to emit, at least 25 tons per year of volatile organic compounds.

(1) Vehicle miles traveled

(A) Within 2 years after November 15, 1990, the State shall submit a revision that identifies and adopts specific enforceable transportation control strategies and transportation control measures to offset any growth in emissions from growth in vehicle miles traveled or numbers of vehicle trips in such area and to attain reduction in motor vehicle emissions as necessary, in combination with other emission reduction requirements of this subpart, to comply with the requirements of subsection (b)(2)(B) and (c)(2)(B) of this section (pertaining to periodic emissions reduction requirements). The State shall consider measures specified in section 7408(f) of this title, and choose from among and implement such measures as necessary to demonstrate attainment with the national ambient air quality standards; in considering such measures, the State should ensure adequate access to downtown, other commercial, and residential areas and should avoid measures that increase or relocate emissions and congestion rather than reduce them.

(B) The State may also, in its discretion, submit a revision at any time requiring employers in such area to implement programs to reduce work-related vehicle trips and miles travelled by employees. Such revision shall be developed in accordance with guidance issued by the Administrator pursuant to section 7408(f) of this title and may require that employers in such area increase average passenger occupancy per vehicle in commuting trips between home and the workplace during peak travel periods. The guidance of the Administrator may specify average vehicle occupancy rates which vary for locations within a nonattainment area (suburban, center city, business district) or among nonattainment areas reflecting existing occupancy rates and the availability of high occupancy modes. Any State required to submit a revision under this subparagraph (as in effect before December 23, 1995) containing provisions requiring employers to reduce work-related vehicle trips and miles travelled by employees may, in accordance with State law, remove such provisions from the implementation plan, or withdraw its submission, if the State notifies the Administrator, in writing, that the State has undertaken, or will undertake, one or more alternative methods that will achieve emission reductions equivalent to those to be achieved by the removed or withdrawn provisions.

(2) Offset requirement

For purposes of satisfying the offset requirements pursuant to this part, the ratio of total emission reductions of VOCs to total increased emissions of such air pollutant shall be at least 1.3 to 1, except that if the State plan requires all existing major sources in the nonattainment area to use best available control technology (as defined in section 7479(3) of this title) for the control of volatile organic compounds, the ratio shall be at least 1.2 to 1.

(3) Enforcement under section 7511d

By December 31, 2000, the State shall submit a plan revision which includes the provisions required under section 7511d of this title.

Any reference to the term "attainment date" in subsection (b) or (c) of this section, which is incorporated by reference into this subsection (d), shall refer to the attainment date for Severe Areas.

(e) Extreme Areas

Each State in which all or part of an Extreme Area is located shall, with respect to the Extreme Area, make the submissions described under subsection (d) of this section (relating to Severe Areas), and shall also submit the revisions to the applicable implementation plan (including the plan items) described under this subsection. The provisions of clause (ii) of subsection (c)(2)(B) of this section (relating to reductions of less than 3 percent), the provisions of paragraphs (6), (7) and (8) of subsection (c) of this section (relating to de minimus rule and modification of sources), and the provisions of clause (ii) of subsection (b)(1)(A) of this section (relating to reductions of less than 15 percent) shall not apply in the case of an Extreme Area. For any Extreme Area, the terms "major source" and "major stationary source" includes (in addition to the sources described in section 7602 of this title) any stationary source or group of sources located within a contiguous area and under common control that emits, or has the potential to emit, at least 10 tons per year of volatile organic compounds.

(1) Offset requirement

For purposes of satisfying the offset requirements pursuant to this part, the ratio of total emission reductions of VOCs to total increased emissions of such air pollutant shall be at least 1.5 to 1, except that if the State plan requires all existing major sources in the nonattainment area to use best available control technology (as defined in section 7479(3) of this title) for the control of volatile organic compounds, the ratio shall be at least 1.2 to 1.

(2) Modifications

Any change (as described in section 7411(a)(4) of this title) at a major stationary source which results in any increase in emissions from any discrete operation, unit, or other pollutant emitting activity at the source shall be considered a modification for purposes of section 7502(c)(5) of this title and section 7503(a) of this title, except that for purposes of complying with the offset requirement pursuant to section 7503(a)(1) of this title, any such increase shall not be considered a modification if the owner or operator of the source elects to offset the increase by a greater reduction in emissions of the air pollutant concerned from other discrete operations, units, or activities within the source at an internal offset ratio of at least 1.3 to 1. The offset requirements of this part shall not be applicable in Extreme Areas to a modification of an existing source if such modification consists of installation of equipment required to comply with the applicable implementation plan, permit, or this chapter.

(3) Use of clean fuels or advanced control technology

For Extreme Areas, a plan revision shall be submitted within 3 years after November 15, 1990, to require, effective 8 years after November 15, 1990, that each new, modified, and existing electric utility and industrial and commercial boiler which emits more than 25 tons per year of oxides of nitrogen—

(A) burn as its primary fuel natural gas, methanol, or ethanol (or a comparably low polluting fuel), or

(B) use advanced control technology (such as catalytic control technology or other comparably effective control methods) for reduction of emissions of oxides of nitrogen.

For purposes of this subsection, the term "primary fuel" means the fuel which is used 90 percent or more of the operating time. This paragraph shall not apply during any natural gas supply emergency (as defined in title III of the Natural Gas Policy Act of 1978 [15 U.S.C. 3361 et seq.]).

(4) Traffic control measures during heavy traffic hours

For Extreme Areas, each implementation plan revision under this subsection may contain provisions establishing traffic control measures applicable during heavy traffic hours to reduce the use of high polluting vehicles or heavy-duty vehicles, notwithstanding any other provision of law.

(5) New technologies

The Administrator may, in accordance with section 7410 of this title, approve provisions of an implementation plan for an Extreme Area which anticipate development of new control techniques or improvement of existing control technologies, and an attainment demonstration based on such provisions, if the State demonstrates to the satisfaction of the Administrator that—

(A) such provisions are not necessary to achieve the incremental emission reductions required during the first 10 years after November 15, 1990; and

(B) the State has submitted enforceable commitments to develop and adopt contingency measures to be implemented as set forth herein if the anticipated technologies do not achieve planned reductions.

Such contingency measures shall be submitted to the Administrator no later than 3 years before proposed implementation of the plan provisions and approved or disapproved by the Administrator in accordance with section 7410 of this title. The contingency measures shall be adequate to produce emission reductions sufficient, in conjunction with other approved plan provisions, to achieve the periodic emission reductions required by subsection (b)(1) or (c)(2) of this section and attainment by the applicable dates. If the Administrator determines that an Extreme Area has failed to achieve an emission reduction requirement set forth in subsection (b)(1) or (c)(2) of this section, and that such failure is due in whole or part to an inability to fully implement provisions approved pursuant to this subsection, the Administrator shall require the State to implement the contingency measures to the extent necessary to assure compliance with subsections (b)(1) and (c)(2) of this section.

Any reference to the term "attainment date" in subsection (b), (c), or (d) of this section which is incorporated by reference into this subsection, shall refer to the attainment date for Extreme Areas.

(f) NO_x requirements

(1) The plan provisions required under this subpart for major stationary sources of volatile organic compounds shall also apply to major stationary sources (as defined in section 7602 of this title and subsections (c), (d), and (e) of this section) of oxides of nitrogen. This subsection shall not apply in the case of oxides of nitrogen for those sources for which the Administrator determines (when the Administrator approves a plan or plan revision) that net air quality benefits are greater in the absence of reductions of oxides of nitrogen from the sources concerned. This subsection shall also not apply in the case of oxides of nitrogen for—

(A) nonattainment areas not within an ozone transport region under section 7511c of this title, if the Administrator determines (when the Administrator approves a plan or plan revision) that additional reductions of oxides of nitrogen would not contribute to attainment of the national ambient air quality standard for ozone in the area, or

(B) nonattainment areas within such an ozone transport region if the Administrator determines (when the Administrator approves a plan or plan revision) that additional reductions of oxides of nitrogen would not produce net ozone air quality benefits in such region.

The Administrator shall, in the Administrator's determinations, consider the study required under section 7511f of this title.

(2)(A) If the Administrator determines that excess reductions in emissions of NO_x would be achieved under paragraph (1), the Administrator may limit the application of paragraph (1) to the extent necessary to avoid achieving such excess reductions.

(B) For purposes of this paragraph, excess reductions in emissions of NO_x are emission reductions for which the Administrator determines that net air quality benefits are greater in the absence of such reductions. Alternatively, for purposes of this paragraph, excess reductions in emissions of NO_x are, for—

(i) nonattainment areas not within an ozone transport region under section 7511c of this title, emission reductions that the Administrator determines would not contribute to attainment of the national ambient air quality standard for ozone in the area, or

(ii) nonattainment areas within such ozone transport region, emission reductions that the Administrator determines would not produce net ozone air quality benefits in such region.

(3) At any time after the final report under section 7511f of this title is submitted to Congress, a person may petition the Administrator for a determination under paragraph (1) or (2) with respect to any nonattainment area or any ozone transport region under section 7511c of this title. The Administrator shall grant or deny such petition within 6 months after its filing with the Administrator.

(g) Milestones

(1) Reductions in emissions

6 years after November 15, 1990, and at intervals of every 3 years thereafter, the State shall determine whether each nonattainment area (other than an area

classified as Marginal or Moderate) has achieved a reduction in emissions during the preceding intervals equivalent to the total emission reductions required to be achieved by the end of such interval pursuant to subsection (b)(1) of this section and the corresponding requirements of subsections (c)(2)(B) and (C), (d), and (e) of this section. Such reduction shall be referred to in this section as an applicable milestone.

(2) Compliance demonstration

For each nonattainment area referred to in paragraph (1), not later than 90 days after the date on which an applicable milestone occurs (not including an attainment date on which a milestone occurs in cases where the standard has been attained), each State in which all or part of such area is located shall submit to the Administrator a demonstration that the milestone has been met. A demonstration under this paragraph shall be submitted in such form and manner, and shall contain such information and analysis, as the Administrator shall require, by rule. The Administrator shall determine whether or not a State's demonstration is adequate within 90 days after the Administrator's receipt of a demonstration which contains the information and analysis required by the Administrator.

(3) Serious and Severe Areas; State election

If a State fails to submit a demonstration under paragraph (2) for any Serious or Severe Area within the required period or if the Administrator determines that the area has not met any applicable milestone, the State shall elect, within 90 days after such failure or determination—

(A) to have the area reclassified to the next higher classification,

(B) to implement specific additional measures adequate, as determined by the Administrator, to meet the next milestone as provided in the applicable contingency plan, or

(C) to adopt an economic incentive program as described in paragraph (4).

If the State makes an election under subparagraph (B), the Administrator shall, within 90 days after the election, review such plan and shall, if the Administrator finds the contingency plan inadequate, require further measures necessary to meet such milestone. Once the State makes an election, it shall be deemed accepted by the Administrator as meeting the election requirement. If the State fails to make an election required under this paragraph within the required 90-day period or within 6 months thereafter, the area shall be reclassified to the next higher classification by operation of law at the expiration of such 6-month period. Within 12 months after the date required for the State to make an election, the State shall submit a

revision of the applicable implementation plan for the area that meets the requirements of this paragraph. The Administrator shall review such plan revision and approve or disapprove the revision within 9 months after the date of its submission.

(4) Economic incentive program

(A) An economic incentive program under this paragraph shall be consistent with rules published by the Administrator and sufficient, in combination with other elements of the State plan, to achieve the next milestone. The State program may include a nondiscriminatory system, consistent with applicable law regarding interstate commerce, of State established emissions fees or a system of marketable permits, or a system of State fees on sale or manufacture of products the use of which contributes to ozone formation, or any combination of the foregoing or other similar measures. The program may also include incentives and requirements to reduce vehicle emissions and vehicle miles traveled in the area, including any of the transportation control measures identified in section 7408(f) of this title.

(B) Within 2 years after November 15, 1990, the Administrator shall publish rules for the programs to be adopted pursuant to subparagraph (A). Such rules shall include model plan provisions which may be adopted for reducing emissions from permitted stationary sources, area sources, and mobile sources. The guidelines shall require that any revenues generated by the plan provisions adopted pursuant to subparagraph (A) shall be used by the State for any of the following:

(i) Providing incentives for achieving emission reductions.

(ii) Providing assistance for the development of innovative technologies for the control of ozone air pollution and for the development of lower-polluting solvents and surface coatings. Such assistance shall not provide for the payment of more than 75 percent of either the costs of any project to develop such a technology or the costs of development of a lower-polluting solvent or surface coating.

(iii) Funding the administrative costs of State programs under this chapter. Not more than 50 percent of such revenues may be used for purposes of this clause.

(5) Extreme Areas

If a State fails to submit a demonstration under paragraph (2) for any Extreme Area within the required period, or if the Administrator determines that the area has not met any applicable milestone, the State shall, within 9 months after such failure or determination, submit a plan revision to implement an economic

incentive program which meets the requirements of paragraph (4). The Administrator shall review such plan revision and approve or disapprove the revision within 9 months after the date of its submission.

(h) Rural transport areas

(1) Notwithstanding any other provision of section 7511 of this title or this section, a State containing an ozone nonattainment area that does not include, and is not adjacent to, any part of a Metropolitan Statistical Area or, where one exists, a Consolidated Metropolitan Statistical Area (as defined by the United States Bureau of the Census), which area is treated by the Administrator, in the Administrator's discretion, as a rural transport area within the meaning of paragraph (2), shall be treated by operation of law as satisfying the requirements of this section if it makes the submissions required under subsection (a) of this section (relating to marginal areas).

(2) The Administrator may treat an ozone nonattainment area as a rural transport area if the Administrator finds that sources of VOC (and, where the Administrator determines relevant, NO_x) emissions within the area do not make a significant contribution to the ozone concentrations measured in the area or in other areas.

(i) Reclassified areas

Each State containing an ozone nonattainment area reclassified under section 7511(b)(2) of this title shall meet such requirements of subsections (b) through (d) of this section as may be applicable to the area as reclassified, according to the schedules prescribed in connection with such requirements, except that the Administrator may adjust any applicable deadlines (other than attainment dates) to the extent such adjustment is necessary or appropriate to assure consistency among the required submissions.

(j) Multi-State ozone nonattainment areas

(1) Coordination among States

Each State in which there is located a portion of a single ozone nonattainment area which covers more than one State (hereinafter in this section referred to as a "multi-State ozone nonattainment area") shall—

(A) take all reasonable steps to coordinate, substantively and procedurally, the revisions and implementation of State implementation plans applicable to the nonattainment area concerned; and

(B) use photochemical grid modeling or any other analytical method determined by the Administrator, in his discretion, to be at least as effective.

The Administrator may not approve any revision of a State implementation plan submitted under this part for a State in which part of a multi-State ozone nonattainment area is located if the plan revision for that State fails to comply with the requirements of this subsection.

(2) Failure to demonstrate attainment

If any State in which there is located a portion of a multi-State ozone nonattainment area fails to provide a demonstration of attainment of the national ambient air quality standard for ozone in that portion within the required period, the State may petition the Administrator to make a finding that the State would have been able to make such demonstration but for the failure of one or more other States in which other portions of the area are located to commit to the implementation of all measures required under this section (relating to plan submissions and requirements for ozone nonattainment areas). If the Administrator makes such finding, the provisions of section 7509 of this title (relating to sanctions) shall not apply, by reason of the failure to make such demonstration, in the portion of the multi-State ozone nonattainment area within the State submitting such petition.

7. §7511b. Federal ozone measures

(a) Control techniques guidelines for VOC sources

Within 3 years after November 15, 1990, the Administrator shall issue control techniques guidelines, in accordance with section 7408 of this title, for 11 categories of stationary sources of VOC emissions for which such guidelines have not been issued as of November 15, 1990, not including the categories referred to in paragraphs (3) and (4) of subsection (b) of this section. The Administrator may issue such additional control techniques guidelines as the Administrator deems necessary.

(b) Existing and new CTGS

(1) Within 36 months after November 15, 1990, and periodically thereafter, the Administrator shall review and, if necessary, update control technique guidance issued under section 7408 of this title before November 15, 1990.

(2) In issuing the guidelines the Administrator shall give priority to those categories which the Administrator considers to make the most significant contribution to the formation of ozone air pollution in ozone nonattainment areas,

including hazardous waste treatment, storage, and disposal facilities which are permitted under subtitle C of the Solid Waste Disposal Act [42 U.S.C. 6921 et seq.]. Thereafter the Administrator shall periodically review and, if necessary, revise such guidelines.

(3) Within 3 years after November 15, 1990, the Administrator shall issue control techniques guidelines in accordance with section 7408 of this title to reduce the aggregate emissions of volatile organic compounds into the ambient air from aerospace coatings and solvents. Such control techniques guidelines shall, at a minimum, be adequate to reduce aggregate emissions of volatile organic compounds into the ambient air from the application of such coatings and solvents to such level as the Administrator determines may be achieved through the adoption of best available control measures. Such control technology guidance shall provide for such reductions in such increments and on such schedules as the Administrator determines to be reasonable, but in no event later than 10 years after the final issuance of such control technology guidance. In developing control technology guidance under this subsection, the Administrator shall consult with the Secretary of Defense, the Secretary of Transportation, and the Administrator of the National Aeronautics and Space Administration with regard to the establishment of specifications for such coatings. In evaluating VOC reduction strategies, the guidance shall take into account the applicable requirements of section 7412 of this title and the need to protect stratospheric ozone.

(4) Within 3 years after November 15, 1990, the Administrator shall issue control techniques guidelines in accordance with section 7408 of this title to reduce the aggregate emissions of volatile organic compounds and PM–10 into the ambient air from paints, coatings, and solvents used in shipbuilding operations and ship repair. Such control techniques guidelines shall, at a minimum, be adequate to reduce aggregate emissions of volatile organic compounds and PM–10 into the ambient air from the removal or application of such paints, coatings, and solvents to such level as the Administrator determines may be achieved through the adoption of the best available control measures. Such control techniques guidelines shall provide for such reductions in such increments and on such schedules as the Administrator determines to be reasonable, but in no event later than 10 years after the final issuance of such control technology guidance. In developing control techniques guidelines under this subsection, the Administrator shall consult with the appropriate Federal agencies.

(c) Alternative control techniques

Within 3 years after November 15, 1990, the Administrator shall issue technical documents which identify alternative controls for all categories of stationary sources of volatile organic compounds and oxides of nitrogen which emit, or have

the potential to emit 25 tons per year or more of such air pollutant. The Administrator shall revise and update such documents as the Administrator determines necessary.

(d) Guidance for evaluating cost-effectiveness

Within 1 year after November 15, 1990, the Administrator shall provide guidance to the States to be used in evaluating the relative cost-effectiveness of various options for the control of emissions from existing stationary sources of air pollutants which contribute to nonattainment of the national ambient air quality standards for ozone.

(e) Control of emissions from certain sources

(1) Definitions

For purposes of this subsection—

(A) Best available controls

The term "best available controls" means the degree of emissions reduction that the Administrator determines, on the basis of technological and economic feasibility, health, environmental, and energy impacts, is achievable through the application of the most effective equipment, measures, processes, methods, systems or techniques, including chemical reformulation, product or feedstock substitution, repackaging, and directions for use, consumption, storage, or disposal.

(B) Consumer or commercial product

The term "consumer or commercial product" means any substance, product (including paints, coatings, and solvents), or article (including any container or packaging) held by any person, the use, consumption, storage, disposal, destruction, or decomposition of which may result in the release of volatile organic compounds. The term does not include fuels or fuel additives regulated under section 7545 of this title, or motor vehicles, non-road vehicles, and non-road engines as defined under section 7550 of this title.

(C) Regulated entities

The term "regulated entities" means—

(i) manufacturers, processors, wholesale distributors, or importers of consumer or commercial products for sale or distribution in interstate commerce in the United States; or

(ii) manufacturers, processors, wholesale distributors, or importers that supply the entities listed under clause (i) with such products for sale or distribution in interstate commerce in the United States.

(2) Study and report

(A) Study

The Administrator shall conduct a study of the emissions of volatile organic compounds into the ambient air from consumer and commercial products (or any combination thereof) in order to—

(i) determine their potential to contribute to ozone levels which violate the national ambient air quality standard for ozone; and

(ii) establish criteria for regulating consumer and commercial products or classes or categories thereof which shall be subject to control under this subsection.

The study shall be completed and a report submitted to Congress not later than 3 years after November 15, 1990.

(B) Consideration of certain factors

In establishing the criteria under subparagraph (A)(ii), the Administrator shall take into consideration each of the following:

(i) The uses, benefits, and commercial demand of consumer and commercial products.

(ii) The health or safety functions (if any) served by such consumer and commercial products.

(iii) Those consumer and commercial products which emit highly reactive volatile organic compounds into the ambient air.

(iv) Those consumer and commercial products which are subject to the most cost-effective controls.

(v) The availability of alternatives (if any) to such consumer and commercial products which are of comparable costs, considering health, safety, and environmental impacts.

(3) Regulations to require emission reductions

(A) In general

Upon submission of the final report under paragraph (2), the Administrator shall list those categories of consumer or commercial products that the

Administrator determines, based on the study, account for at least 80 percent of the VOC emissions, on a reactivity-adjusted basis, from consumer or commercial products in areas that violate the NAAQS for ozone. Credit toward the 80 percent emissions calculation shall be given for emission reductions from consumer or commercial products made after November 15, 1990. At such time, the Administrator shall divide the list into 4 groups establishing priorities for regulation based on the criteria established in paragraph (2). Every 2 years after promulgating such list, the Administrator shall regulate one group of categories until all 4 groups are regulated. The regulations shall require best available controls as defined in this section. Such regulations may exempt health use products for which the Administrator determines there is no suitable substitute. In order to carry out this section, the Administrator may, by regulation, control or prohibit any activity, including the manufacture or introduction into commerce, offering for sale, or sale of any consumer or commercial product which results in emission of volatile organic compounds into the ambient air.

(B) Regulated entities

Regulations under this subsection may be imposed only with respect to regulated entities.

(C) Use of CTGS

For any consumer or commercial product the Administrator may issue control techniques guidelines under this chapter in lieu of regulations required under subparagraph (A) if the Administrator determines that such guidance will be substantially as effective as regulations in reducing emissions of volatile organic compounds which contribute to ozone levels in areas which violate the national ambient air quality standard for ozone.

(4) Systems of regulation

The regulations under this subsection may include any system or systems of regulation as the Administrator may deem appropriate, including requirements for registration and labeling, self-monitoring and reporting, prohibitions, limitations, or economic incentives (including marketable permits and auctions of emissions rights) concerning the manufacture, processing, distribution, use, consumption, or disposal of the product.

(5) Special fund

Any amounts collected by the Administrator under such regulations shall be deposited in a special fund in the United States Treasury for licensing and other services, which thereafter shall be available until expended, subject to annual appropriation Acts, solely to carry out the activities of the Administrator for which such fees, charges, or collections are established or made.

(6) Enforcement

Any regulation established under this subsection shall be treated, for purposes of enforcement of this chapter, as a standard under section 7411 of this title and any violation of such regulation shall be treated as a violation of a requirement of section 7411(e) of this title.

(7) State administration

Each State may develop and submit to the Administrator a procedure under State law for implementing and enforcing regulations promulgated under this subsection. If the Administrator finds the State procedure is adequate, the Administrator shall approve such procedure. Nothing in this paragraph shall prohibit the Administrator from enforcing any applicable regulations under this subsection.

(8) Size, etc.

No regulations regarding the size, shape, or labeling of a product may be promulgated, unless the Administrator determines such regulations to be useful in meeting any national ambient air quality standard.

(9) State consultation

Any State which proposes regulations other than those adopted under this subsection shall consult with the Administrator regarding whether any other State or local subdivision has promulgated or is promulgating regulations on any products covered under this part. The Administrator shall establish a clearinghouse of information, studies, and regulations proposed and promulgated regarding products covered under this subsection and disseminate such information collected as requested by State or local subdivisions.

(f) Tank vessel standards

(1) Schedule for standards

(A) Within 2 years after November 15, 1990, the Administrator, in consultation with the Secretary of the Department in which the Coast Guard is

operating, shall promulgate standards applicable to the emission of VOCs and any other air pollutant from loading and unloading of tank vessels (as that term is defined in section 2101 of title 46) which the Administrator finds causes, or contributes to, air pollution that may be reasonably anticipated to endanger public health or welfare. Such standards shall require the application of reasonably available control technology, considering costs, any nonair-quality benefits, environmental impacts, energy requirements and safety factors associated with alternative control techniques. To the extent practicable such standards shall apply to loading and unloading facilities and not to tank vessels.

(B) Any regulation prescribed under this subsection (and any revision thereof) shall take effect after such period as the Administrator finds (after consultation with the Secretary of the department in which the Coast Guard is operating) necessary to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance within such period, except that the effective date shall not be more than 2 years after promulgation of such regulations.

(2) Regulations on equipment safety

Within 6 months after November 15, 1990, the Secretary of the Department in which the Coast Guard is operating shall issue regulations to ensure the safety of the equipment and operations which are to control emissions from the loading and unloading of tank vessels, under section 3703 of title 46 and section 1225 of title 33. The standards promulgated by the Administrator under paragraph (1) and the regulations issued by a State or political subdivision regarding emissions from the loading and unloading of tank vessels shall be consistent with the regulations regarding safety of the Department in which the Coast Guard is operating.

(3) Agency authority

(A) The Administrator shall ensure compliance with the tank vessel emission standards prescribed under paragraph (1)(A). The Secretary of the Department in which the Coast Guard is operating shall also ensure compliance with the tank vessel standards prescribed under paragraph (1)(A).

(B) The Secretary of the Department in which the Coast Guard is operating shall ensure compliance with the regulations issued under paragraph (2).

(4) State or local standards

After the Administrator promulgates standards under this section, no State or political subdivision thereof may adopt or attempt to enforce any standard respecting emissions from tank vessels subject to regulation under paragraph (1)

unless such standard is no less stringent than the standards promulgated under paragraph (1).

(5) Enforcement

Any standard established under paragraph (1)(A) shall be treated, for purposes of enforcement of this chapter, as a standard under section 7411 of this title and any violation of such standard shall be treated as a violation of a requirement of section 7411(e) of this title.

(g) Ozone design value study

The Administrator shall conduct a study of whether the methodology in use by the Environmental Protection Agency as of November 15, 1990, for establishing a design value for ozone provides a reasonable indicator of the ozone air quality of ozone nonattainment areas. The Administrator shall obtain input from States, local subdivisions thereof, and others. The study shall be completed and a report submitted to Congress not later than 3 years after November 15, 1990. The results of the study shall be subject to peer and public review before submitting it to Congress.

(h) Vehicles entering ozone nonattainment areas

(1) Authority regarding ozone inspection and maintenance testing

(A) In general

No noncommercial motor vehicle registered in a foreign country and operated by a United States citizen or by an alien who is a permanent resident of the United States, or who holds a visa for the purposes of employment or educational study in the United States, may enter a covered ozone nonattainment area from a foreign country bordering the United States and contiguous to the nonattainment area more than twice in a single calendar-month period, if State law has requirements for the inspection and maintenance of such vehicles under the applicable implementation plan in the nonattainment area.

(B) Applicability

Subparagraph (A) shall not apply if the operator presents documentation at the United States border entry point establishing that the vehicle has complied with such inspection and maintenance requirements as are in effect and are applicable to motor vehicles of the same type and model year.

(2) Sanctions for violations

The President may impose and collect from the operator of any motor vehicle who violates, or attempts to violate, paragraph (1) a civil penalty of not more than $200 for the second violation or attempted violation and $400 for the third and each subsequent violation or attempted violation.

(3) State election

The prohibition set forth in paragraph (1) shall not apply in any State that elects to be exempt from the prohibition. Such an election shall take effect upon the President's receipt of written notice from the Governor of the State notifying the President of such election.

(4) Alternative approach

The prohibition set forth in paragraph (1) shall not apply in a State, and the President may implement an alternative approach, if—

(A) the Governor of the State submits to the President a written description of an alternative approach to facilitate the compliance, by some or all foreign-registered motor vehicles, with the motor vehicle inspection and maintenance requirements that are—

(i) related to emissions of air pollutants;

(ii) in effect under the applicable implementation plan in the covered ozone nonattainment area; and

(iii) applicable to motor vehicles of the same types and model years as the foreign-registered motor vehicles; and

(B) the President approves the alternative approach as facilitating compliance with the motor vehicle inspection and maintenance requirements referred to in subparagraph (A).

(5) Definition of covered ozone nonattainment area

In this section, the term “covered ozone nonattainment area” means a Serious Area, as classified under section 7511 of this title as of October 27, 1998.

8. §7511c. Control of interstate ozone air pollution

(a) Ozone transport regions

A single transport region for ozone (within the meaning of section 7506a(a) of this title), comprised of the States of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode

Island, Vermont, and the Consolidated Metropolitan Statistical Area that includes the District of Columbia, is hereby established by operation of law. The provisions of section 7506a(a)(1) and (2) of this title shall apply with respect to the transport region established under this section and any other transport region established for ozone, except to the extent inconsistent with the provisions of this section. The Administrator shall convene the commission required (under section 7506a(b) of this title) as a result of the establishment of such region within 6 months of November 15, 1990.

(b) Plan provisions for States in ozone transport regions

(1) In accordance with section 7410 of this title, not later than 2 years after November 15, 1990 (or 9 months after the subsequent inclusion of a State in a transport region established for ozone), each State included within a transport region established for ozone shall submit a State implementation plan or revision thereof to the Administrator which requires the following—

(A) that each area in such State that is in an ozone transport region, and that is a metropolitan statistical area or part thereof with a population of 100,000 or more comply with the provisions of section 7511a(c)(2)(A) of this title (pertaining to enhanced vehicle inspection and maintenance programs); and

(B) implementation of reasonably available control technology with respect to all sources of volatile organic compounds in the State covered by a control techniques guideline issued before or after November 15, 1990.

(2) Within 3 years after November 15, 1990, the Administrator shall complete a study identifying control measures capable of achieving emission reductions comparable to those achievable through vehicle refueling controls contained in section 7511a(b)(3) of this title, and such measures or such vehicle refueling controls shall be implemented in accordance with the provisions of this section. Notwithstanding other deadlines in this section, the applicable implementation plan shall be revised to reflect such measures within 1 year of completion of the study. For purposes of this section any stationary source that emits or has the potential to emit at least 50 tons per year of volatile organic compounds shall be considered a major stationary source and subject to the requirements which would be applicable to major stationary sources if the area were classified as a Moderate nonattainment area.

(c) Additional control measures

(1) Recommendations

Upon petition of any State within a transport region established for ozone, and based on a majority vote of the Governors on the Commission (or their designees), the Commission may, after notice and opportunity for public comment, develop recommendations for additional control measures to be applied within all or a part of such transport region if the commission determines such measures are necessary to bring any area in such region into attainment by the dates provided by this subpart. The commission shall transmit such recommendations to the Administrator.

(2) Notice and review

Whenever the Administrator receives recommendations prepared by a commission pursuant to paragraph (1) (the date of receipt of which shall hereinafter in this section be referred to as the "receipt date"), the Administrator shall—

(A) immediately publish in the Federal Register a notice stating that the recommendations are available and provide an opportunity for public hearing within 90 days beginning on the receipt date; and

(B) commence a review of the recommendations to determine whether the control measures in the recommendations are necessary to bring any area in such region into attainment by the dates provided by this subpart and are otherwise consistent with this chapter.

(3) Consultation

In undertaking the review required under paragraph (2)(B), the Administrator shall consult with members of the commission of the affected States and shall take into account the data, views, and comments received pursuant to paragraph (2)(A).

(4) Approval and disapproval

Within 9 months after the receipt date, the Administrator shall (A) determine whether to approve, disapprove, or partially disapprove and partially approve the recommendations; (B) notify the commission in writing of such approval, disapproval, or partial disapproval; and (C) publish such determination in the Federal Register. If the Administrator disapproves or partially disapproves the recommendations, the Administrator shall specify—

(i) why any disapproved additional control measures are not necessary to bring any area in such region into attainment by the dates provided by this subpart or are otherwise not consistent with the chapter; and

(ii) recommendations concerning equal or more effective actions that could be taken by the commission to conform the disapproved portion of the recommendations to the requirements of this section.

(5) Finding

Upon approval or partial approval of recommendations submitted by a commission, the Administrator shall issue to each State which is included in the transport region and to which a requirement of the approved plan applies, a finding under section 7410(k)(5) of this title that the implementation plan for such State is inadequate to meet the requirements of section 7410(a)(2)(D) of this title. Such finding shall require each such State to revise its implementation plan to include the approved additional control measures within one year after the finding is issued.

(d) Best available air quality monitoring and modeling

For purposes of this section, not later than 6 months after November 15, 1990, the Administrator shall promulgate criteria for purposes of determining the contribution of sources in one area to concentrations of ozone in another area which is a nonattainment area for ozone. Such criteria shall require that the best available air quality monitoring and modeling techniques be used for purposes of making such determinations.

9. §7511d. Enforcement for Severe and Extreme ozone nonattainment areas for failure to attain

(a) General rule

Each implementation plan revision required under section 7511a(d) and (e) of this title (relating to the attainment plan for Severe and Extreme ozone nonattainment areas) shall provide that, if the area to which such plan revision applies has failed to attain the national primary ambient air quality standard for ozone by the applicable attainment date, each major stationary source of VOCs located in the area shall, except as otherwise provided under subsection (c) of this section, pay a fee to the State as a penalty for such failure, computed in accordance with subsection (b) of this section, for each calendar year beginning after the attainment date, until the area is redesignated as an attainment area for ozone. Each such plan revision should include procedures for assessment and collection of such fees.

(b) Computation of fee

(1) Fee amount

The fee shall equal $5,000, adjusted in accordance with paragraph (3), per ton of VOC emitted by the source during the calendar year in excess of 80 percent of the baseline amount, computed under paragraph (2).

(2) Baseline amount

For purposes of this section, the baseline amount shall be computed, in accordance with such guidance as the Administrator may provide, as the lower of the amount of actual VOC emissions ("actuals") or VOC emissions allowed under the permit applicable to the source (or, if no such permit has been issued for the attainment year, the amount of VOC emissions allowed under the applicable implementation plan ("allowables")) during the attainment year. Notwithstanding the preceding sentence, the Administrator may issue guidance authorizing the baseline amount to be determined in accordance with the lower of average actuals or average allowables, determined over a period of more than one calendar year. Such guidance may provide that such average calculation for a specific source may be used if that source's emissions are irregular, cyclical, or otherwise vary significantly from year to year.

(3) Annual adjustment

The fee amount under paragraph (1) shall be adjusted annually, beginning in the year beginning after 1990, in accordance with section 7661a(b)(3)(B)(v) of this title (relating to inflation adjustment).

(c) Exception

Notwithstanding any provision of this section, no source shall be required to pay any fee under subsection (a) of this section with respect to emissions during any year that is treated as an Extension Year under section 7511(a)(5) of this title.

(d) Fee collection by Administrator

If the Administrator has found that the fee provisions of the implementation plan do not meet the requirements of this section, or if the Administrator makes a finding that the State is not administering and enforcing the fee required under this section, the Administrator shall, in addition to any other action authorized under this subchapter, collect, in accordance with procedures promulgated by the Administrator, the unpaid fees required under subsection (a) of this section. If the Administrator makes such a finding under section 7509(a)(4) of this title, the Administrator may collect fees for periods before the determination, plus interest computed in accordance with section 6621(a)(2) of title 26 (relating to computation

of interest on underpayment of Federal taxes), to the extent the Administrator finds such fees have not been paid to the State. The provisions of clauses (ii) through (iii) of section 7661a(b)(3)(C) of this title (relating to penalties and use of the funds, respectively) shall apply with respect to fees collected under this subsection.

(e) Exemptions for certain small areas

For areas with a total population under 200,000 which fail to attain the standard by the applicable attainment date, no sanction under this section or under any other provision of this chapter shall apply if the area can demonstrate, consistent with guidance issued by the Administrator, that attainment in the area is prevented because of ozone or ozone precursors transported from other areas. The prohibition applies only in cases in which the area has met all requirements and implemented all measures applicable to the area under this chapter.

6. Clean Air Act § 307(b)(1), (d)(1)(A), and (d)(9), 42 U.S.C. § 7607(b)(1), (d)(1)(A), and (d)(9)

10. §7607. Administrative proceedings and judicial review

(b) Judicial review

(1) A petition for review of action of the Administrator in promulgating any national primary or secondary ambient air quality standard, any emission standard or requirement under section 7412 of this title, any standard of performance or requirement under section 7411 of this title, any standard under section 7521 of this title (other than a standard required to be prescribed under section 7521(b)(1) of this title), any determination under section 7521(b)(5) of this title, any control or prohibition under section 7545 of this title, any standard under section 7571 of this title, any rule issued under section 7413, 7419, or under section 7420 of this title, or any other nationally applicable regulations promulgated, or final action taken, by the Administrator under this chapter may be filed only in the United States Court of Appeals for the District of Columbia. A petition for review of the Administrator's action in approving or promulgating any implementation plan under section 7410 of this title or section 7411(d) of this title, any order under section 7411(j) of this title, under section 7412 of this title, under section 7419 of this title, or under section 7420 of this title, or his action under section 1857c–10(c)(2)(A), (B), or (C) of this title (as in effect before August 7, 1977) or under regulations thereunder, or revising regulations for enhanced monitoring and compliance certification programs under section 7414(a)(3) of this title, or any other final action of the Administrator under this chapter (including any denial or disapproval by the Administrator under subchapter I of this chapter) which is locally or regionally applicable may be filed only in the United States Court of Appeals for the appropriate circuit. Notwithstanding the preceding sentence a petition for review of any action referred to in such sentence may be filed only in the United States Court of Appeals for the District of Columbia if such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination. Any petition for review under this subsection shall be filed within sixty days from the date notice of such promulgation, approval, or action appears in the Federal Register, except that if such petition is based solely on grounds arising after such sixtieth day, then any petition for review under this subsection shall be filed within sixty days after such grounds arise. The filing of a petition for reconsideration by the Administrator of any otherwise final rule or action shall not

affect the finality of such rule or action for purposes of judicial review nor extend the time within which a petition for judicial review of such rule or action under this section may be filed, and shall not postpone the effectiveness of such rule or action.

(2) Action of the Administrator with respect to which review could have been obtained under paragraph (1) shall not be subject to judicial review in civil or criminal proceedings for enforcement. Where a final decision by the Administrator defers performance of any nondiscretionary statutory action to a later time, any person may challenge the deferral pursuant to paragraph (1).

* * *

(d) Rulemaking

(1) This subsection applies to—

(A) the promulgation or revision of any national ambient air quality standard under section 7409 of this title,

* * *

(9) In the case of review of any action of the Administrator to which this subsection applies, the court may reverse any such action found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or

(D) without observance of procedure required by law, if (i) such failure to observe such procedure is arbitrary or capricious, (ii) the requirement of paragraph (7)(B) has been met, and (iii) the condition of the last sentence of paragraph (8) is met.

7. Information Quality Act, Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153 to -154 (2000)

Sec. 515. (a) In General.–The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency involvement, issue guidelines under sections 3504(d)(1) and 3516 of title 44, United States Code, that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.

(b) Content of Guidelines.–The guidelines under subsection (a) shall–

(1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and

(2) require that each Federal agency to which the guidelines apply–

(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and

(C) report periodically to the Director–

(i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency; and

(ii) how such complaints were handled by the agency.

8. 40 C.F.R. § 50.1(e)

Sec. 50.1 Definitions.

* * *

(e) *Ambient air* means that portion of the atmosphere, external to buildings, to which the general public has access.