COMMENTS OF THE UTILITY AIR REGULATORY GROUP ON EPA'S PROPOSED RULE ON THE PRIMARY NATIONAL AMBIENT AIR QUALITY STANDARD FOR SULFUR DIOXIDE (74 FED. REG. 64810 (DECEMBER 8, 2009))

DOCKET ID NO. EPA-HQ-OAR-2007-0352

HUNTON & WILLIAMS LLP

LUCINDA MINTON LANGWORTHY
E. CARTER CHANDLER CLEMENTS
1900 K STREET, NW
WASHINGTON, DC 20006
(202) 955-1500

COUNSEL FOR THE UTILITY AIR REGULATORY GROUP

FEBRUARY 8, 2010

COMMENTS OF THE UTILITY AIR REGULATORY GROUP ON EPA'S PROPOSED RULE ON THE PRIMARY NATIONAL AMBIENT AIR QUALITY STANDARD FOR SULFUR DIOXIDE (74 FED. REG. 64810 (DECEMBER 8, 2009))

On December 8, 2009, the United States Environmental Protection Agency ("EPA" or the "Agency") proposed revisions to its primary National Ambient Air Quality Standards ("NAAQS") for sulfur dioxide ("SO_2"). 74 Fed. Reg. 64810 (Dec. 8, 2009) ("Proposed Rule"). Specifically, the Agency proposed to adopt a new SO_2 NAAQS to limit the annual 99th percentile daily maximum hourly SO_2 concentration, averaged over three years, to a level within the range of 50 to 100 parts per billion ("ppb") and to revoke the present annual arithmetic average standard of 0.03 parts per million ("ppm") (30 ppb) and 24-hour average standard of 0.14 ppm (140 ppb) that may not be exceeded more than once a year. *Id.* at 64810/1. EPA also sought comment on the alternative of a daily maximum 1-hour SO_2 standard as high as 150 ppb. *Id.* at 64845/1. Finally, the Agency addressed various provisions for implementing any new SO_2 NAAQS. *Id.* at 64846/1 - 64864/3.

These are the comments of the Utility Air Regulatory Group ("UARG") on the Proposed Rule.[1] UARG has participated actively throughout the current review of the SO_2 NAAQS, submitting comments to EPA and to its Clean Air Scientific Advisory Committee ("CASAC" of the "Committee") on drafts of the Integrated Science

[1] UARG is a voluntary, nonprofit group of individual electric generating utilities and industry trade associations. UARG's purpose is to participate on behalf of its members collectively in EPA's rulemaking and other Clean Air Act proceedings that affect the interests of electric generators, and in related litigation. Since 1977, UARG has participated in virtually all key rulemakings, related litigation, and other arenas of policy development under the Clean Air Act that affect electric utility companies.

Assessment ("ISA"),[2] and of the Risk and Exposure Assessment ("REA")[3] on which the Administrator relies in the Proposed Rule.[4] Those comments, which are hereby incorporated by reference in these comments on the Proposed Rule itself, address in

---

[2] EPA, Integrated Science Assessment for Sulfur Oxides -- Health Criteria (September 2008).

[3] EPA, Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standards: Final Report (July 2009).

[4] *See* Comments of the Utility Air Regulatory Group on the Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standards: Second Draft (March 2009) (Docket ID. No. EPA-HQ-OAR-2007-0352-0031.1) (June 11, 2009) ("Second Draft REA Comments"); Anne E. Smith, Ph.D., Comments to CASAC on Draft #2 of the SO_2 Risk And Exposure Assessment, Public Comments Session, CASAC Meeting (Apr. 16-17, 2009) (Comments prepared on behalf of UARG), *available at* http://yosemite.epa.gov/sab/SABPRODUCT.NSF/PeopleSearch/F99F04D90A9425BE852575450067337C?OpenDocument; Comments of the Utility Air Regulatory Group on the First External Review Draft of the Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standards: Second Draft (July 2008) (Docket ID No. EPA-HQ-OAR-2007-0352-0014.1) (Aug. 28, 2008, corrected Sept. 4, 2008) ("First Draft REA Comments"); Comments of the Utility Air Regulatory Group on the Second External Review Draft of the Integrated Science Assessment for Sulfur Oxides -- Health Criteria (May 2008) (Docket ID No. EPA-HQ-ORD-2006-0260-0020.1) (Aug. 11, 2008) ("Second Draft ISA Comments"); Timothy H. Savage, Ph.D., Comments on Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standards: First Draft (Presentation on behalf of UARG to CASAC meeting of Dec. 5-6, 2007); J. Turim, Ph.D., S. Moolgavkar, M.D., Ph.D., E. Anderson, Ph.D., A.T.S.F., Comments on EPA's Integrated Science Assessment for Sulfur Oxides -- Health Criteria: Summary (Dec. 3, 2007) (written presentation to CASAC meeting of Dec. 5-6, 2007); Comments of the Utility Air Regulatory Group on the First External Review Draft of the Integrated Science Assessment for Sulfur Oxides -- Health Criteria (Sept. 2007) (Docket ID No. EPA-HQ-ORD-2006-0260-0009.1) (Nov. 30, 2007) ("First Draft ISA Comments"). Statements to CASAC do not appear to have been added to the public docket, although EPA states that the Administrator considered them in developing her rationale for the Proposed Rule. 74 Fed. Reg. at 64814/2. Copies of the presentations to CASAC by Timothy H. Savage, Ph.D. and by J. Turim, Ph.D., et al. are attached hereto as Attachments A and B respectively.

detail EPA's assessment of the science concerning SO_2 health effects and the risk of such health effects in contemporary ambient American air.

For the reasons explained below and in those earlier comments, UARG does not support the proposed 1-hour NAAQS in the range of 50 to 100 ppb, or even one at the alternative 150 ppb level. The human clinical evidence concerning health effects potentially associated with SO_2 is not indicative of adverse effects in the most sensitive population, exercising asthmatics, from exposure to short-term SO_2 peaks of less than 600 ppb. The epidemiological evidence cannot determine that SO_2 is a cause of or a contributor to hospital admissions ("HA"), emergency department ("ED") visits or respiratory symptoms, the effects cited in the Proposed Rule. *See* 74 Fed. Reg. at 64818/1-2. Moreover, as demonstrated in the REA, a 1-hour NAAQS in the range of 50 to 150 ppb would not reduce the risk of such effects in current ambient air. Thus, no such standard is requisite (or necessary) to protect the public health with an adequate margin of safety. Even if EPA rejects UARG's advice on the lack of justification for a new standard, however, the Agency should modify some aspects of its plans for implementing any new NAAQS.

I. Scientific Information Does Not Demonstrate that Short-term SO_2 Concentrations Below 600 ppb Cause Potentially Adverse Effects on Public Health.

Section 109 of the Clean Air Act ("CAA" or the "Act") requires the EPA Administrator ("Administrator") to set primary NAAQS for certain criteria pollutants, including SO_2, at levels that in her judgment are "requisite to protect the public health" while "allowing an adequate margin of safety." 42 U.S.C. § 7409(b)(1), CAA § 109(b)(1) (hereinafter, citations are given only to the Act). In determining what level is requisite to protect public health, she must consider the health of sensitive groups (or

subpopulations), such as those with particular medical conditions and those in particular age groups, but not the most sensitive individuals within those groups. *See* S. Rep. 1196 at 10 (1970), reprinted in 1 A LEGISLATIVE HISTORY OF THE CLEAN AIR ACT AMENDMENTS OF 1970 410 (1974) ("1970 Legis. Hist.").

Interpreting this congressional instruction not long after it was given, EPA established the initial NAAQS for lead at a level that it estimated would protect 99.5% of children under five years of age (which it identified as a the group most sensitive to lead exposure) against "potentially adverse" health effects. 43 Fed. Reg. 46246 (Oct. 5, 1978). At that time, EPA recognized that certain children might be at "enhanced risk" due to factors such as genetics, diet or residence, but did not treat them as an even more susceptible subgroup. *See id.* at 46252. The U.S. Court of Appeals for the District of Columbia upheld the lead NAAQS. *See Lead Indus. Ass'n v. EPA*, 647 F.2d 1130 (D.C. Cir. 1980). Indeed, EPA has consistently acknowledged that NAAQS are not intended to protect each member of a sensitive group or subpopulation.[5]

Further, Congress intended the NAAQS to protect the public against the risk of "adverse" health effects, 1970 Legis. Hist. at 410, not *all* health effects. EPA has therefore always set primary NAAQS at the level the Administrator judges adequate to protect public health from only such adverse effects. *See, e.g.* 36 Fed. Reg. 8186, 8186/2 (Apr. 30, 1971) (noting that the Administrator "has in each case promulgated a national primary standard which includes a margin of safety adequate to protect the public health from adverse effects suggested by the available data."). The level for such

a standard need not protect against all risks, only "significant" ones. *See Ethyl Corp. v. EPA*, 541 F.2d 1, 12-32 (D.C. Cir. 1976). EPA has acknowledged that NAAQS are not to be "zero risk" standards.[6] In determining the significance of the risk posed by the pollutant (in this case SO_2) in the ambient air, the Administrator must consider that risk in the context of the real world. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 494-95 (2001) (Breyer, J., concurring in part and concurring in judgment).

The Administrator must base her judgment concerning the adversity of effects and the significance of risks posed by a pollutant like SO_2 on air quality criteria that "adequately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on human health . . . which may be expected from the presence of such pollutant in the ambient air in varying quantities." CAA § 108(a)(2). She may not set a NAAQS at a level that is more stringent than necessary to protect public health with an adequate margin of safety. *Whitman*, 531 U.S. at 473, 476. In reaching her judgment, she must consider advice received from CASAC but is not bound to follow that advice or draw the same conclusions as drawn by that Committee. *See* CAA § 307(d)(3) (stating that if the Administrator's proposal in a proposed rulemaking "differs in any important respect" from CASAC's advice, the Administrator must include an explanation for such differences in the proposed rule); *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 522 (D.C. Cir. 2009) (remanding but not vacating a rule on the PM

---

[5] *See, e.g.*, 74 Fed. Reg. 34404, 34405 n.1 (July 15, 2009); 73 Fed. Reg. 16436, 16437 n.1 (Mar. 27, 2008); 71 Fed. Reg. 61144, 61145 n.1 (Oct. 17, 2006); 44 Fed. Reg. 8202, 8210/1 (Feb. 8, 1979).

[6] *See e.g.*, 62 Fed. Reg. 38856, 38857/2 (July 18, 1997); 62 Fed. Reg. 38652, 38653/2 (July 18, 1997).

NAAQS, holding that the Administrator had failed to provide a sufficient explanation for not following CASAC's advice, but stating that if the Agency could explain its decision adequately, it was free not to follow CASAC's advice).

Indeed, the Administrator may not delegate judgment regarding the requisite levels for the NAAQS to any person. CAA § 301. It is the Administrator who must "make a judgment as to the level of physiological response that should be considered adverse." 50 Fed. Reg. 37484, 37496/1 (Sept. 13, 1985). Additionally, when reviewing an existing NAAQS (which previously was determined to be at the level requisite to protect human health according to the CAA), the Administrator must provide a reasoned explanation for any conclusion that the existing NAAQS is no longer at the level requisite to protect public health with an adequate margin of safety.[7]

In the last review of the primary NAAQS for SO_2, the Administrator concluded that no revision of the existing NAAQS was necessary at that time to protect public health. 61 Fed. Reg. 25566 (May 22, 1996) ("1996 NAAQS Rule"). Focusing on the same types of lung function changes and respiratory symptoms in exercising asthmatics that are at issue in the current proceeding (i.e., increased specific airway resistance ("sRaw"), decreased forced expiratory volume ("FEV"), and respiratory symptoms such as chest tightness, wheezing and shortness of breath),[8] the Administrator noted that

---

[7] *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) ("an agency changing course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance"); *Atchison, Topeka and Santa Fe Ry. Co. v. Wichita Bd. of Trade*, 412 U.S. 800, 808 (1973) (an agency must "explain its departure from prior norms"); *AT&T Corp. v. FCC*, 263 F.3d 729, 736 (D.C. Cir. 2001) (reasoned decision making standard requires explanation of departure from prior decision).

[8] *Id.* at 25570/3.

variability in lung function is a typical feature of asthma.[9] She recognized that lung function in asthmatics tends to be better at certain times of the day than at others and may be affected by a variety of common stimuli, such as cold air, pollen and other allergens, which asthmatics encounter on a daily basis.[10] Exercise alone triggers bronchoconstriction in many asthmatics, a condition that is exacerbated if the exercise takes place in cold, dry (albeit clean) air.[11] Additionally, the Administrator noted that asthmatic responses to peak SO_2 exposure are transient -- unlike health effects associated with other stimuli, such as pollen, there are no "late phase" responses -- lung function typically returns to normal within an hour after exercise or exposure to SO_2 ends.[12] She also noted that the responses in asthmatics to SO_2 during exercise are "transient," generally returning to normal within an hour. *Id.* at 25570/3. Lung function started to improve if the exercise stopped, even if the SO_2 exposure continued. *Id.* at 25572/2. The Administrator concluded that "repeated occurrences" -- as opposed to a single incident -- of the responses of the more sensitive asthmatic subjects to SO_2 concentrations in the range of 0.6 to 1.0 ppm "should be regarded as significant from a public health standpoint." *Id.* at 25573/3.[13] Taking into account the infrequent, localized

---

[9] *Id.* at 25570/3.

[10] *Id.* at 25570/2-3.

[11] *Id.* at 25570/3.

[12] *Id.* at 25570/3. The responses often diminished even as the SO_2 exposure and exercise continued. *See* Linn WS, Avol EL, Peng RC, Shamoo DA, Hackney JD. (1987) Replicated Dose-Response Study of Sulfur Dioxide Effects in Normal, Atopic, and Asthmatic Volunteers. Am. Rev. Respir. Dis. 136:1127-34, at 1129.

[13] The Administrator noted that the effects in asthmatics exercising in 0.6 ppm were more pronounced than those in asthmatics exercising in lower SO_2

(continued on next page)

and site-specific nature of the responses, the Administrator concluded that revision of the NAAQS was not warranted. *Id.* at 25575/3.

In response to a challenge of the 1996 NAAQS Rule by the American Lung Association and the Environmental Defense Fund, the U.S. Court of Appeals for the District of Columbia Circuit held that the Administrator is required to provide an explanation of her use of the discretion delegated to her under the CAA. *See Am. Lung Ass'n v. EPA*, 134 F.3d 388, 392 (1998) ("Where . . . Congress has delegated to an administrative agency the critical task of assessing the public health and the power to make decisions of national import . . . that agency has the heaviest of obligations to explain and expose every step of its reasoning."). The court remanded the 1996 NAAQS Rule to the Agency, not because it disagreed with the Administrator's interpretation of the scientific evidence, but because the Administrator had not explained adequately her judgment that the existing NAAQS were requisite to protect public health, and therefore did not require revision. *See id.* at 392-93 ("[T]he Administrator may well be within her authority to decide that [the existing NAAQS is requisite to protect public health]. But unless she describes the standard under which she has arrived at this conclusion . . . we have no basis for exercising [judicial review] . . . . Given the gaps in the Final Decision's reasoning, we must remand this case to permit the Administrator to explain her conclusions more fully.").

In the Proposed Rule, the Administrator fails to provide a reasoned explanation for changing course by now concluding that the existing NAAQS do not to protect public

---

concentrations. *Id.* at 25571/2. In addition to pointing to group mean decreases in FEV of 15% or greater at 0.6 ppm SO_2, she pointed to sRaw increases of 200% or greater

(continued on next page)

health with an adequate margin of safety and require revision. *See Motor Vehicle Mfrs Ass'n,* 463 U.S. at 42. She has not explained why the "latest scientific knowledge" now indicates an adverse effect on human health "which may be expected from the presence of [SO_2] in the ambient air." CAA § 108(a)(2). She has failed to justify her conclusion that effects that were not considered adverse in 1996 should be deemed adverse now.

A. New clinical evidence does not justify a change in conclusions from the prior review.

The Proposed Rule states that EPA's conclusion that there is a causal relationship between respiratory morbidity and short term SO_2 exposure is based primarily on human clinical studies. 74 Fed. Reg. at 64816/2. The new clinical evidence presented in the ISA, however, does not represent a change in the character of the scientific evidence regarding effects of SO_2 exposure since the last review.[14] Rather, the changed conclusions are the result of changes in EPA's interpretation of the evidence. Only if she can supply a "reasoned analysis" for these changes can the Administrator rely on them for a change to the 1996 conclusion that effects of public health significance begin at 600 ppb, or for a reversal of the 1996 decision that no new short-term NAAQS was needed to protect public health with an adequate margin of safety. She has failed to present such an analysis. *See* 61 Fed. Reg. at 25573/3.

EPA's definition in the Proposed Rule of what constitutes an adverse health effect is inconsistent with the definition of effects considered to be of public health

---

and FEV decreases of 20% or greater in some individuals. *Id.* at 25571/2.

[14] *See id.* at 64816/3 (describing the newer human clinical studies as "supportive" of the evidence considered in the last review).

significance in 1996, and with the definition's purported basis. The Administrator acknowledges that her definition of adversity is different from that in the 1996 review. Specifically:

> [W]hereas the conclusions in the prior review of the SO_2 NAAQS were based on SO_2 exposure concentrations which resulted in large decrements in lung function and moderate to severe respiratory symptoms, the ISA's current review of data from controlled human exposure studies focused on moderate to large SO_2-induced decrements in lung function and/or respiratory symptoms ranging from mild . . . to severe.

74 Fed. Reg. at 64816/2.

The genesis of this change is obscure. First, the Proposed Rule seems to postulate that the health risk to asthmatics who experience lung function effects without symptoms might be greater than the health risk to those who experience both symptoms and lung function decrements. *See id.* at 64816/2. It is simply implausible that a failure to experience symptoms is worse than having them. Second, the Proposed Rule points to advice from CASAC as justification for the focus on moderate as well as large lung function decrements. *Id.* at 64817/3. But the Administrator culls this advice from comments of individual CASAC members in the transcript of a CASAC meeting; it is not reflected in the letter from the complete CASAC that followed that meeting. Finally, the Administrator simply provides no explanation of why she now considers mild symptoms to be adverse health effects. Clearly, this does not constitute a reasoned analysis in support of the change to the definition of adversity.

The Administrator also states that the Agency's definition of "adversity" is derived from a statement of the American Thoracic Society ("ATS"). *See id.* at 64816/3. In the Proposed Rule, however, EPA mischaracterizes and deviates substantially from the

ATS adversity definition. According to ATS, "a small, transient loss in lung function, by itself, should not automatically be designated as adverse," but should only be considered adverse when accompanied by symptoms. American Thoracic Society, *What Constitutes an Adverse Health Effect of Air Pollution?*, 161 Am. J. Respir. Crit. Care Med. 665, 670 (2000) (hereinafter "ATS Statement"). Additionally, ATS considers symptoms to be adverse at the individual level when they decrease quality of life or cause a change in clinical status. *Id.* at 671. As quoted above, though, in the Proposed Rule and contrary to the ATS Statement, EPA states that it is treating lung function decrements accompanied by even mild symptoms to be adverse effects. 74 Fed. Reg. at 64816/3.

With respect to adversity at the population level, based on the ATS Statement, the Proposed Rule argues that "an air pollution-induced shift in a population distribution of a given health-related endpoint (e.g. lung function) should be considered adverse, even if this shift does not result in the immediate occurrence of illness in any one individual in the population." *Id.* at 64816/3. The Proposed Rule attributes this definition of an adverse effect to the ATS Statement. However, EPA is not applying the ATS Statement appropriately in this context.

ATS gives the following illustration of its population level standard:

> A population of children with asthma could have a distribution of lung function such that no individual child has a level associated with impairment. Exposure to air pollution could shift the distribution toward lower levels without bringing any individual child to a level that is associated with clinically relevant consequences. Individuals within the population would, however, have diminished reserve function and are at potentially increased risk if affected by another agent, e.g. a viral infection.

ATS Statement at 668.

The scenario that ATS sets forth does not apply to the risks associated with SO_2 exposure primarily for two reasons. First, when they occur, the effects of SO_2 exposure on exercising asthmatics (the sensitive subpopulation here, analogous to the asthmatic children in the ATS illustration) are transient. *See* discussion *supra* at p. 7. As EPA has acknowledged, lung function returns to baseline levels within an hour, when either exercise or SO_2 exposure ceases. Therefore, a detectable shift in the lung function of the asthmatic population would never occur such that the population would become more susceptible to other agents as a result of diminished reserve capacity. Moreover, variation in lung function is a characteristic of asthma. *See supra* at 6-7. Second, in evaluating the effects of SO_2 exposure on public health in this review, the Administrator has focused on the responses of a small group of individuals that has responded to lower levels of SO_2 than the rest of the exercising asthmatic subjects. *See, e.g.,* 74 Fed. at 64842/2. As described *infra* at p. 14-15, there is no indication that these individuals are a distinct subpopulation that may be affected in the manner described in the ATS Statement.

It is unclear why the Administrator diverges from the guidance of the ATS Statement in determining adversity at the individual level or why she applies ATS's definition of adversity at the population level, without explanation, to a scenario to which the definition is not applicable. It appears that she may be interpreting the ATS Statement in a manner that supports her own speculation about the scientific research.

Indeed, the Administrator's conclusions in the Proposed Rule are based in large part on speculation. The range of possible levels for the proposed 1-hour NAAQS in the

Proposed Rule is justified in part on the basis that the participants in the clinical studies are most likely not the most severe asthmatics, *see id.* at 64844/2, and that more severe asthmatics may respond to lower levels of SO_2. There is a significant legal problem with the Agency's reasoning -- the Administrator's judgment must reflect the "latest scientific knowledge" regarding the relevant health effects from SO_2 in the ambient air, CAA § 108(a)(2), and she may not base her judgment on speculation. *Am. Petroleum Inst. v. Costle*, 665 F.2d 1176, 1186-87 (D.C. Cir. 1981) ("[T]he Administrator's conclusions must be supported by the record, and [s]he may not engage in sheer guesswork."). It is clearly speculative for the Administrator to base the level of the proposed NAAQS on the idea that individuals with asthma more severe than those that participated in clinical studies may experience health effects at lower levels -- there is nothing to support the idea that more severe asthmatics are likely to respond to lower levels of SO_2 -- in fact, there is evidence to the contrary.

There is published, peer-reviewed clinical evidence that, among asthmatics, responses to SO_2 exposure are *not* dependant on the clinical severity of asthma. Linn, et al. (1987) tested the effect of SO_2 exposure on lung function in exercising asthmatics, including a group of "minimal/mild" asthmatics and a group of "moderate/severe" asthmatics, and found that responses to SO_2 were not predictable based on either the severity of the disease or the subjects' tolerance for exercise.[15] In fact, the Linn study concluded that "the subjects at highest risk [of temporary respiratory disturbances from

[15] Linn WS, Avol EL, Peng RC, Shamoo DA, Hackney JD. (1987) Replicated Dose-Response Study of Sulfur Dioxide Effects in Normal, Atopic, and Asthmatic Volunteers. Am Rev Respir Dis 136:1127-34.

ambient SO_2] can be identified only by actually measuring their responses to SO_2."[16] EPA is aware of the Linn study -- it is cited in the Proposed Rule to support the proposition that SO_2-induced responses for individuals are reproducible. 74 Fed. Reg. at 64824/2. Thus, the Administrator acknowledges the portion of Linn's findings that seems consistent with her speculation -- that an asthmatic participant's sensitivity to SO_2 exposure was predictable on an individual basis (the same participants were shown to exhibit the same level of sensitivity to SO_2 in repeated trials) -- but ignores Linn's main finding -- that an asthmatic participant's sensitivity to SO_2 exposure was *not* predictable based on the severity of the participant's asthma. The inappropriateness of the Administrator's speculation, therefore, is exacerbated by the fact that she ignores scientific evidence that contradicts her assumption.

The Proposed Rule also states that EPA believes that 200 ppb does not represent a threshold below which adverse effects do not occur, based only on the fact that a relatively small percentage (5-30%) of exercising asthmatics experienced lung function decrements at 200-300 ppb, the lowest level tested in chamber studies. *Id.* at 64822/1. The Administrator's reliance on her assumption that some asthmatics will respond to SO_2 exposure at levels lower than other asthmatics is also contrary to congressional intent. As mentioned above, in setting the NAAQS, the Administrator must consider the health of sensitive subpopulations, but not the most sensitive individuals within those subpopulations. *See* discussion *supra* at p. 3-4. Asthmatics are a distinct subpopulation definable by biological criteria, and it is appropriate for the Administrator to consider the unusual susceptibility of asthmatics to SO_2 exposure in

[16] *Id.* at 1132.

setting the standard. However, it is beyond her authority to base her judgment on a consideration that certain *individuals* respond to lower levels of SO_2. These "responders" are not a sensitive subpopulation; they are merely individuals with no identifiable common characteristics. Even ATS recognizes that "[r]esearch now shows that some highly susceptible individuals may respond to common exposures that are often unavoidable . . . [and that] by definition, susceptible individuals cannot have the same margin of safety as the nonsusceptible groups within the population." ATS Statement at 669. It is inappropriate for the Administrator to consider these responders and to extrapolate from individual results to assume without evidence that these responders are part of some unidentified subpopulation.

In short, the Administrator has not provided a reasoned explanation for her definition of what constitutes an adverse health effect for purposes of interpreting the evidence from human clinical studies. Responses of exercising asthmatics to SO_2 exposure in recent studies merely support the findings of studies considered in promulgating the 1996 NAAQS Rule. Indeed, the lowest SO_2 concentration that arguably represents a public health concern among exercising asthmatics continues to be 600 ppb, as it was in 1996. The Administrator's speculation in the Proposed Rule that there may be a population of severe asthmatics or subset of asthmatics that is more sensitive to exposure at lower SO_2 concentrations is unavailing. The clinical studies do not support a conclusion that even exercising asthmatics require protection from brief SO_2 exposures below 600 ppb.

B. New epidemiological evidence does not justify change in conclusions from prior review

The Proposed Rule states that in addition to clinical studies, "the ISA based its causal finding of an association between short-term . . . exposure to SO_2 and respiratory morbidity on results from epidemiologic studies of respiratory symptoms, as well as [emergency department] visits and hospitalizations for all respiratory causes and asthma." 74 Fed. Reg. at 64818/2-3. Although the Proposed Rule acknowledges uncertainties with respect to the epidemiologic studies, it fails to account fully for the nature and magnitude of uncertainty that surrounds the epidemiologic research. This failure has persisted throughout the current review of the SO_2 NAAQS. As a result, although the epidemiologic research cites health effects, such as HA and ED visits, that are unquestionably adverse, there is no clear indication that these effects are the result of SO_2 exposure. In fact, there is evidence to suggest that they are not.

The epidemiologic studies cited in the Proposed Rule are inconsistent with the results of clinical studies. The Proposed Rule states that "[e]pidemiologic studies provide evidence of associations between SO_2 concentrations and more serious health endpoints (e.g., [HAs] and [ED visits]) that cannot be assessed in controlled human exposure studies." *Id.* at 64815/3. This statement is curious. Although no one would suggest that clinical studies could or should be conducted with the intent of sending people to the hospital, there is also no indication from the clinical studies of any population that would be susceptible to SO_2 such that a brief exposure to a low concentration could lead to hospital visits. As discussed above, research indicates that responsiveness to SO_2 in asthmatics is not dependant on the severity of the asthma. *See* discussion of Linn et al. (1987) *supra* at p. 13-14. Additionally, clinical studies

conducted at SO_2 concentrations far above ambient levels[17] report only effects in asthmatics that are transient and reversible and that dissipate rapidly. *See supra* at p. 7. EPA recognizes that human clinical studies "provide directly applicable information for determining causality" while for epidemiological studies "the degree of uncertainty introduced by confounding variables (e.g., other pollutants) affects the level of confidence that the health effects being investigated are attributable to SO_2 exposures." 74 Fed. Reg. at 64815/3 - 64816/1. Thus, the discrepancy between the nature of effects attributed to SO_2 in epidemiologic studies at ambient levels and those in clinical studies at much higher SO_2 concentrations must call into question the reliability of the epidemiological studies as evidence of effects from SO_2 exposure.

Although EPA acknowledges that confounding is an issue in epidemiologic research, the Agency fails to account for it appropriately. As epidemiologic studies are observational in nature, confounding by co-pollutants and other environmental factors can never be ruled out, but researchers can evaluate the possibility of confounding through the use of co-pollutant models. However, many of the epidemiologic studies that EPA relied on for the conclusions drawn in the ISA and that the Administrator cites as "key studies" in the Proposed Rule fail to account for confounding. For example, of the five epidemiologic studies cited in the Proposed Rule that studied respiratory symptoms, none appropriately accounted for confounding. The Proposed Rule states that the results of Mortimer et al. (2002) and Schildcrout et al. (2006) "remained robust and statistically significant" in co-pollutant models. *Id.* at 64818/2, 3. However, both of

---

[17] Clinical studies show pronounced, though transient, effects following exposure to SO_2 concentrations beginning at 0.6 - 1.0 ppm (600 - 1000 ppb). 61 Fed. Reg. at

(continued on next page)

these studies used regional monitoring as a surrogate for exposure, which leads to measurement errors in the estimate of SO_2 exposure, but also in exposure estimates for all of the other potentially confounding co-pollutants.[18] When all of the co-pollutants are measured with error, robustness of the association of one pollutant in multi-pollutant models is not sufficient to infer an absence of confounding. Schwartz et al. (1994) found that there was a possibility of confounding by PM_{10}. *See id.* at 8; 74 Fed. Reg. at 64818/3. Neither of the other two studies included multi-pollutant models. 74 Fed. Reg. at 64818/3. Likewise, only three of the ten "key studies" on HAs and ED visits included multi-pollutant models, and multi-pollutant models in those three studies reported mixed results. *See id.* at 64819/2-3. It is particularly inappropriate to rely on such studies when, as here, EPA has previously concluded that the very effects investigated in the studies are caused by co-pollutants.[19]

Another issue with the treatment of epidemiologic research in the Proposed Rule is the lack of statistical significance in many of the studies cited. Although the Administrator notes the importance of the strength of statistical associations in

---

25571/3.

[18] *See* J. Turim, Ph.D., C. Frankenfeld, Ph.D., S. Moolgavkar, M.D., Ph.D., Comments on EPA's Integrated Science Assessment for Sulfur Oxides-Health Criteria (Second External Review Draft) (July 25, 2008) at 7-8, attached as Enclosure 1 to Second Draft ISA Comments ("Turim 2007").

[19] Each of the Agency's 2006 $PM_{2.5}$ NAAQS, 2008 ozone NAAQS, and 2010 NO_2 NAAQS are based, at least in part, on epidemiologic evidence associating each of those pollutants with HAs and ED visits for respiratory causes. *See* National Ambient Air Quality Standards for Particulate Matter; Final Rule, 71 Fed. Reg. 61143, 61145/1 (Oct. 17, 2006); National Ambient Air Quality Standards for Ozone; Final Rule, 73 Fed. Reg. 16436, 16436/3 (Mar. 27, 2008); Primary National Ambient Air Quality Standards for Nitrogen Dioxide: Final Rule (Jan. 22, 2010), at 24.

epidemiologic studies, 74 Fed. Reg. 64816/1, she relies heavily on studies where there is no statistically significant association. *See, e.g., id.* at 64819/1 ("Taken together, [the ten "key" epidemiologic studies on HAs and ED visits] generally reported positive, but *frequently not statistically significant associations* between ambient SO_2 and ED visits and [HAs] for all respiratory causes and for asthma." (emphasis added)). This lack of statistical significance indicates a likelihood that the positive results of these studies are inaccurate, and they may well be indicating no effect at all.

Finally, EPA has failed to address recent studies relevant to the health effects of SO_2 exposure, even after UARG called them to the Agency's attention over two years ago in its comments on the first draft of the ISA.[20] These studies, which EPA has failed to account for in this NAAQS review, reported results that counter the Agency's conclusions regarding the health effects of SO_2 exposure. For example, Donoghue and Thomas reported "no evidence of any positive relation between peak SO_2 concentrations [ranging from 0 to 8700 $\mu g/m^3$] and hospital presentations or admissions for asthma, wheeze or shortness of breath." Donoghue et al. (1999) at 232. Erbas and Hyndman examined the sensitivity of associations between air pollution and HAs and reported that "the effects of . . . sulfur dioxide were highly sensitive to model specification for both COPD and asthma [HAs]." *See* Turim 2007 at 10.

---

[20] *See* First Draft ISA Comments at 10 n.28 (noting that neither Erbas, B & Hyndman, RJ (2005) Sensitivity of the estimated air pollution-respiratory admissions relationship to statistical model choice. Int. J. Environ. Health Res. 15:437-48 nor Donoghue, AM & Thomas M (1999) Point source sulphur dioxide peaks and hospital presentations for asthma. 56 Occup. Environ. Med. 56:232-36 is discussed in the ISA). Neither study was mentioned in subsequent drafts of the ISA or the REA, and neither is mentioned in the Proposed Rule.

EPA is required to consider all of the "latest scientific knowledge" relevant to the effects of SO_2 exposure on human health. CAA § 108(a)(2). It is just as important that EPA consider scientific research such as this, that indicates that there is no effect, as it is that the Agency consider research that indicates an effect -- the Agency must examine the entire range of outcomes in order to formulate a judgment that reflects the latest scientific knowledge. The fact that EPA has failed to examine, or even acknowledge the existence of these studies after they were pointed out in public comments, is a striking indication that EPA has not fulfilled its duty under the CAA.

II. Information on Both Exposure and Risk Demonstrates No Need for the Proposed 1-hour SO_2 NAAQS.

As discussed above, the Administrator is required to set primary SO_2 NAAQS at a level that in her judgment is "requisite to protect the public health" while "allowing an adequate margin of safety." CAA § 109(b)(1). In determining what level is requisite, she must base her judgment on air quality criteria that "adequately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on human health . . . *which may be expected from the presence of such pollutant in the ambient air* in varying quantities." CAA § 108(a)(2) (emphasis added). In other words, the Administrator must set the NAAQS at a level that is necessary to protect public health from risks presented by exposure to SO_2 in the ambient air, at levels that exist at the time of the review or that are expected to exist in the future. In doing so, she may not set the NAAQS at a level that is more stringent than necessary to protect public health with an adequate margin of safety. *See Whitman*, 531 U.S. at 473, 476 (2001).

According to information provided by EPA, there is no unacceptable risk to public health posed by current ambient levels of SO_2 and none is expected in the future. In

effect, the Proposed Rule seeks to fix a problem that does not exist. EPA has acknowledged repeatedly that SO_2 concentrations in the United States have been decreasing over the past several decades and that it expects this trend to continue. EPA reported in December 2009 that, as of 2008, annual SO_2 emissions had decreased by 56% compared with 1980 levels and 52% compared with 1990 levels. EPA, Acid Rain and Related Programs: 2008 Highlights, 2 (Dec. 2009). Additionally, the national composite average of the annual mean ambient concentration of SO_2 decreased by 71% between 1980 and 2008.[21] *Id.* at 5. In EPA's most recent National Air Quality Status and Trends Report, the Agency cited a downward trend in ambient SO_2 concentrations. EPA, National Air Quality Status and Trends Through 2007, 27 (Nov. 2008). The Agency attributed this trend to various national emissions control programs, including the NAAQS, and stated that it expects air quality to continue to improve in the coming years. *Id.* at 3, 27. Accordingly, any existing health risks from SO_2 exposure will be expected to decline in the future.

Significantly, however, EPA has not identified any health risks from exposure to current ambient concentrations of SO_2. Although the REA and the Proposed Rule include some information on risks at current ambient levels of SO_2, both the REA and the Proposed Rule focus on risks that would exist if air quality were adjusted to just meet the current NAAQS (either the 24-hour standard or the annual standard, whichever is controlling for a particular area) and to just meet potential alternative one-hour daily maximum standards of 50, 100, 150, 200 and 250 ppb respectively.

---

[21] EPA specifically noted that the decline in SO_2 emissions from the power industry has improved air quality. *Id.*

Throughout this NAAQS review process, UARG has commented repeatedly that EPA should base its analyses on the effects of current air quality and not air quality modeled to just meet the current standard or alternative standards.[22] There are a number of serious issues with EPA's use of modeled air quality. First, as described above, the Administrator, in reviewing and revising the NAAQS, is required to consider risks to public health associated with air quality under current conditions or conditions that are expected to exist in the future. EPA has been quite clear that current air quality has improved dramatically over the past several decades and that it is expected to continue to improve in the future. *See* discussion *supra* at p. 20-21. It is far better than needed to meet the current NAAQS in all but three areas in the continental United States.[23] Thus, ambient SO_2 concentrations are not expected to increase to just meet the current standard in the future, and setting aside the fact that EPA has stated that it expects SO_2 concentrations to continue decreasing, EPA has not identified any event or condition that could lead to a deterioration of air quality that would cause ambient SO_2 concentrations to reach the current NAAQS.

Although they are not reported in the Proposed Rule and apparently were not considered in the preparation thereof, the REA contains some data that address risk at current air quality. EPA has stated that the purpose of the proposed 1-hour standard is to protect against 5-minute SO_2 concentrations above 200 to 400 ppb. 74 Fed. Reg. at

---

[22] *See* First Draft REA Comments at 3-9; Second Draft REA Comments at 4-9.

[23] *See*, EPA's Green Book nonattainment areas for sulfur dioxide (primary standard), *available at* http://www.epa.gov/oar/oaqps/greenbk/snc.html (listing Armstrong County, PA, Hayden (Pinal County), AZ and Laurel Area (Yellowstone County), MT as nonattainment area for the primary SO_2 NAAQS.

64842/3; REA at 392. Thus, this is the level of risk that the Administrator has determined to be acceptable.[24] However, EPA's evaluation of data from 809 ambient SO_2 monitors, given the annual average SO_2 concentration between 1997-2006, reported that only approximately 1% of days included a 5-minute SO_2 concentration of 200 ppb, and less than 1% of days included a 5-minute SO_2 concentration of 300 or 400 ppb. REA at 127-28. Thus, 5-minute SO_2 concentrations in the range of interest are very rare, and health effects can only be related to such infrequent SO_2 levels if susceptible people (in this case, sensitive exercising asthmatics) are exposed to such levels. Additionally, as air quality is improving, 5-minute SO_2 concentrations in this range are likely to be even lower today.

EPA's REA included risk and exposure analysis case studies of asthmatics -- the subpopulation that EPA has identified as susceptible -- in St. Louis and in Greene County, Missouri. The Agency examined specifically the number of asthmatics living within 20 kilometers of a major SO_2 source experiencing 5-minute SO_2 exposures to 100, 200, 300 and 400 ppb while at elevated breathing rates, and modeled air quality to represent attainment of each of the targeted levels. *Id.* at 10. EPA reported that the exposure results for Greene County using "as is" air quality were similar to those for air quality adjusted to meet the proposed 99th percentile 1-hour daily maximum standards of 50 and 100 ppb, with few people being exposed, and that the results for St. Louis indicated that exposure results for "as is" air quality were within the range of exposures using the proposed 50 and 100 ppb standards. *Id.* at 312.

---

[24] The NAAQS is not intended to eliminate all risk. *See* discussion *supra* at p. 4-5.

EPA's risk modeling indicates that the risks associated with current ambient air quality are consistently comparable to or lower than the risks that are estimated to exist upon attainment of any of the 1-hour SO_2 standards under consideration. For example, Table 9-8 of the REA presents EPA's data on the percentages of asthmatic children engaged in moderate or greater exertion that are estimated to experience at least one lung function response per year associated with exposure to SO_2 concentrations at various levels in each of St. Louis and Greene County, Missouri. *See id.* at 338. Table 9-8 of the REA is reproduced below:

Table 9-8. Percent of asthmatic children engaged in moderate or greater exertion estimated to experience at least one lung function response associated with exposure to SO_2 concentrations under alternative air quality scenarios in a year.*

Exposure-Response Model	"As is" SO_2 Concentrations**	SO_2 Concentrations that Just Meet the Current Standards***	SO_2 Concentrations that Just Meet Alternative nth Percentile 1-Hr Daily Maximum Standards, with Levels (in ppb) of m (Standard Denoted n/m):					
			99/50	99/100	99/150	99/200	99/250	98/200
Response = Increase in sRaw >= 100%								
Greene County, MO								
2-Parameter Logistic	0.4% (0.1% - 1.8%)	1.4% (0.6% - 3.7%)	0.4% (0.1% - 1.6%)	0.4% (0.1% - 1.9%)	0.5% (0.1% - 2.1%)	0.7% (0.2% - 2.4%)	1% (0.3% - 2.9%)	0.9% (0.3% - 2.7%)
Probit	0.1% (0% - 0.9%)	0.9% (0.3% - 2.7%)	0.1% (0% - 0.8%)	0.1% (0% - 0.9%)	0.2% (0% - 1.1%)	0.3% (0.1% - 1.4%)	0.5% (0.2% - 1.9%)	0.4% (0.1% - 1.7%)
St. Louis, MO								
2-Parameter Logistic	1.4% (0.5% - 3.8%)	19.2% (14.8% - 24.9%)	0.9% (0.3% - 2.9%)	2.9% (1.3% - 6.3%)	5.4% (3% - 9.6%)	8.1% (5% - 12.8%)	10.9% (7.3% - 16%)	10.3% (6.8% - 15.3%)
Probit	0.8% (0.2% - 2.8%)	19.1% (14.4% - 24.7%)	0.4% (0.1% - 1.9%)	2.1% (0.9% - 5.3%)	4.6% (2.4% - 8.8%)	7.4% (4.5% - 12.3%)	10.4% (6.9% - 15.6%)	9.7% (6.3% - 14.9%)
Response = Increase in sRaw >= 200%								
Greene County, MO								
2-Parameter Logistic	0.1% (0% - 1%)	0.5% (0.1% - 1.9%)	0.1% (0% - 1%)	0.1% (0% - 1%)	0.2% (0% - 1.1%)	0.2% (0% - 1.3%)	0.3% (0.1% - 1.5%)	0.3% (0.1% - 1.4%)
Probit	0% (0% - 0.4%)	0.2% (0.1% - 1.2%)	0% (0% - 0.4%)	0% (0% - 0.4%)	0% (0% - 0.5%)	0.1% (0% - 0.6%)	0.1% (0% - 0.8%)	0.1% (0% - 0.8%)
St. Louis, MO								
2-Parameter Logistic	0.5% (0.1% - 1.9%)	8.1% (5.3% - 12.2%)	0.3% (0.1% - 1.5%)	1% (0.3% - 3%)	1.9% (0.8% - 4.5%)	3% (1.5% - 6%)	4.2% (2.3% - 7.5%)	3.9% (2.1% - 7.2%)
Probit	0.2% (0% - 1.2%)	7.9% (5% - 12%)	0.1% (0% - 0.8%)	0.5% (0.2% - 2.3%)	1.4% (0.5% - 3.8%)	2.5% (1.2% - 5.4%)	3.7% (2% - 7%)	3.4% (1.8% - 6.7%)

*Percents are median (50th percentile) percents of asthmatic children. Percents in parentheses below the median are 95% credible intervals based on statistical uncertainty surrounding the SO_2 coefficient in the logistic and probit exposure-response functions. Percents are rounded to the nearest tenth.

**The "as is" exposure scenario was based on monitoring and modeling using 2002 air quality information.

***The current primary SO_2 standards include a 24-hour standard set at 0.14 parts per million (ppm), not to be exceeded more than once per year, and an annual standard set at 0.03 ppm, calculated as the arithmetic mean of hourly averages.

As indicated in Table 9-8, EPA's St. Louis analysis reported that, using the 2-parameter logistic model, the percentage of asthmatic children engaged in moderate or greater exercise who are estimated to experience an increase in specific airway resistance (sRAW) of 100% or greater at least once in a year from exposure to current ambient air is 1.4%, which is lower than the percentage of children estimated to

experience such a response upon exposure to air that meets a 99th percentile daily maximum 1-hour standard of either 100 ppb (2.9%) or 150 ppb (5.4%). Although the percentage estimated to experience such a response upon exposure to air that meets the 50 ppb standard appears slightly lower (0.9%), it is indistinguishable from the percentage responding to current air quality, as it falls within the 95% credible interval (0.5% - 3.8%). The same is true using the probit model, with 0.8% estimated to respond following exposure to current air quality, compared to 2.1% and 4.6% estimated to respond following exposure to air meeting either of the proposed 100 or 150 ppb standards respectively, and 0.4% estimated to respond following exposure at the proposed 50 ppb level (which is within the 95% credible interval of 0.2% - 2.8%). Similarly, the Greene County analysis reported that, using either the 2-parameter logistic model[25] or the probit model,[26] the percentage of asthmatic children predicted to experience an increase in sRAW of 100% or greater at least once in a year is identical for current air quality, and for air quality that attains a 99th percentile daily maximum 1-hour standard of 50 ppb, and lower with current air quality than with a 99th percentile daily maximum standard of 100 ppb, or 150 ppb. Indeed, EPA's modeling indicates that the comparability among the levels of residual risk permitted by current air quality and

---

[25] According to EPA, in Greene County, 0.4% of exercising asthmatic children would be expected to experience at least one lung function response associated with SO_2 per year following exposure to current air quality and following exposure to air meeting the 50 or the 100 ppb standard, and 0.5% would be expected to experience such a reaction upon exposure to air meeting the 150 ppb standard.

[26] According to EPA, in Greene County, 0.1% of exercising asthmatic children would be expected to experience at least one lung function response associated with SO_2 per year following exposure to current air quality or air meeting the proposed 99th percentile daily maximum 1-hour standard of either 50 or 100 ppb, and 0.2% would be expected to respond to air meeting the 150 ppb standard.

by the proposed 1-hour standards of 50, 100 and 150 ppb holds true for EPA's estimates of the number[27] and percent[28] of asthmatics engaged in moderate or greater exertion estimated to experience an increase in sRAW of 100% or greater at least once in a year; the number of occurrences of such an increase in sRAW among asthmatics;[29] the number of asthmatic children estimated to experience such an increase in sRAW;[30] and the number of occurrences of such an increase in sRAW among asthmatic children.[31] The same is also true of EPA's estimates of decreases in FEV_1 of 15% and 20% following exposure to current air quality and air adjusted to meet the proposed 1-hour standards of 50, 100 and 150 ppb, which appear in Appendix C.[32]

---

[27] *See id.* at 334, Table 9-4.

[28] *See id.* at 335, Table 9-5.

[29] *See id.* at 336, Table 9-6.

[30] *See id.* at 337, Table 9-7.

[31] *See id.* at 339, Table 9-9.

[32] *See* REA Appendix C at 4-18, Table 4-3 (number of occurrences in a year among asthmatics engaged in moderate or greater exertion); 4-19, Table 4-4 number of occurrences in a year among asthmatic children engaged in moderate or greater exertion); 4-22, Table 4-7 (number of asthmatics engaged in moderate or greater exertion estimated to experience one such response in year); 4-23, Table 4-8 (number of asthmatic children engaged in moderate or greater exertion estimated to experience one such response in year); 4-26, Table 4-11 (percent of asthmatics engaged in moderate or greater exertion estimated to experience one such response in year); and 4-27, Table 4-12 (percent of asthmatics engaged in moderate or greater exertion estimated to experience one such response in year). In each case, the number or percentage estimated for current air quality is indistinguishable from or lower than the number or percentage estimated for air quality adjusted to meet the proposed 1-hour standards of 50, 100 and 150 ppb (or the number or percentage for the proposed standard is within the 95% credible interval for the estimate at current air quality).

Moreover, EPA overestimates the risk to the health of asthmatics and asthmatic children associated with current air quality and attainment of any of the alternative standards as a result of the techniques used in the analysis.[33] In addition, the Agency's analysis fails to reflect that only repeated exposures or lung function changes should be deemed to be of public health significance.

It is important to note that, although the REA is not a comprehensive examination of risk nationally, it examined risks in areas where SO_2 emissions were among the highest currently found in the U.S. REA at 189 ("In a ranking of estimated SO_2 emissions reported in the National Emissions Inventory . . . Missouri ranked 7th out of all U.S. states for the number of stacks with annual emissions greater than 1,000 tons."). Additionally, the estimates of current air quality are actually based on air quality information from 2002. *Id.* at 332. Thus, these numbers are not representative of the United States now that SO_2 levels have fallen and likely overstate current risks. Even within this limited Missouri data set, EPA consistently emphasizes the results of the St. Louis analysis and disregards the results of the analysis in rural Greene County.[34] This

---

[33] *See* Memorandum from Edmund Crouch, Ph.D., to Utility Air Regulatory Group, Response to EPA-HQ-ORD-2006-0260-0036 3-4 (Feb. 5, 2010) (Attached hereto as Attachment C) (explaining that EPA has failed to respond in any meaningful way to his technical comments on the draft REA on behalf of UARG, detailing substantial technical errors that led to significant overprediction of risk, and that EPA has failed to account properly for such overprediction of risk).

[34] *See, e.g.*, 74 Fed. Reg. at 64827/2 ("when considering the risk and exposure results as they relate to the adequacy of the current standards, the REA concluded that the St. Louis results were more informative [than the Greene County results] in terms of ascertaining the extent to which the current standards protect against effects linked to various benchmarks"); *Id.* at 64842/3 to 43/1 (basing determination of the level of the proposed 1-hour standard on the St. Louis risk and exposure analyses but not mentioning the Greene County analyses).

is inappropriate. As indicated in the REA,[35] Greene County is a reasonable model for exposures in rural areas.

In summary, as described above, in the REA and the Proposed Rule, EPA has vastly overestimated the public health risk presented by SO_2 concentrations. In fact, risks are below those identified by EPA as dangerous, or unacceptable, and will continue to decrease as air quality continues to improve. Therefore, there is no justification for the proposed 1-hour NAAQS.[36]

III. The Agency Must Base Nonattainment Decisions on Monitors Qualifying as Federal Reference Method Monitors Under The Agency's New Specifications.

In the Proposed Rule, the Administrator proposes to establish a new Federal Reference Method ("FRM") for measuring ambient levels of SO_2, 74 Fed. Reg. 64846/1, and to update the performance based requirements for Federal Equivalent Method ("FEM") analyzers. *Id.* at 64847/1. She proposes further to retain the current FRM for a period of time after the final rule (including the new FRM) is promulgated in order to

---

[35] *See, e.g.*, REA at 311 (noting that the St. Louis and Greene County exposure analyses "[t]aken together . . . provide useful insights about urban and rural counties with SO2 emission sources").

[36] The health evidence at most suggests that exercising asthmatics should be protected from brief exposures to 600 ppb. Assuming that the ratio between a 5-minute peak and a 1-hour average is in the range of 2 or 3 to 1, an hourly standard in the range of 200 to 300 ppb would appear protective. Any such standard should use the 98th percentile form given that only multiple responses by an asthmatic to SO_2 might legitimately be considered of public health significance. Moreover, the 98th percentile form would be consistent with the form used for the Agency's recently promulgated 1-hour primary NAAQS for NO_2 and the Agency's 24-hour primary NAAQS for $PM_{2.5}$. No such standard is requisite to protect public health, however, because SO_2 levels currently found in ambient air are already protective against such effects.

avoid disruption of the SO_2 monitoring network. *Id.* at 64848/1-2. While UARG agrees that a new FRM for judging compliance with a new 1-hour SO_2 NAAQS is appropriate, the proposed approach for implementing it is contrary to the terms of the CAA, and therefore must be abandoned.

The Proposed Rule acknowledges that any data to be used in determining compliance with the SO_2 NAAQS must be collected using either an FRM or an FEM. *Id.* at 64846/1. One primary purpose of FRMs is "to provide a specified, definitive methodology for routinely measuring concentrations of various ambient air pollutants for comparison to the NAAQS. *Id.* at 64846/2. An FRM is designated is to ensure consistency and fairness when judging compliance with a NAAQS. Thus, EPA designates a single FRM for judging compliance with each NAAQS.[37] Therefore, if the Administrator promulgates a new 1-hour NAAQS for SO_2, she must specify a single FRM for that standard, and only data collected using that FRM (or monitors designated as an FEM with regard to the FRM) can be used to assess compliance with that NAAQS.[38]

---

[37] *See* 40 C.F.R. App. A (specifying a single FRM for the SO_2 NAAQS codified in 40 C.F.R. 50.4 & 50.5), App. C (describing a single measurement principle and calibration procedure defining an FRM for the carbon monoxide NAAQS codified in 40 C.F.R. 50.8), App. D (describing a single measurement principle and calibration procedure defining an FRM for the ozone NAAQS codified at 40 C.F.R. 50.9, 50.10 & 50.15), App. G (specifying a single FRM for the lead NAAQS codified at 40 C.F.R. 50.12 & 50.16) and App. L (specifying a single FRM for the $PM_{2.5}$ NAAQS codified at 40 C.F.R. 50.7 & 50.13).

[38] EPA would have the option of retaining the existing FRM for judging compliance with the 3-hour, 24, hour and annual NAAQS to the extent that any or all of those standards are retained. Certainly, EPA has designated different FRMs for measuring different regulated forms of particulate matter. It might be less burdensome for the States, however, for EPA to designate a single FRM for all of the SO_2 NAAQS.

With regard to EPA's decision to use a different FRM to judge compliance with any new SO_2 NAAQS, UARG agrees that that is appropriate. The ability of this monitor to accurately measure low hourly concentrations of SO_2 has not, to UARG's knowledge, ever been demonstrated. In fact, as the Proposed Rule explains:

> The existing FRM is primarily a 24-hour integrated method, whereas a 1-hour SO_2 FRM measurement capability would be needed to implement the proposed 1-hour SO_2 NAAQS. . . . While the existing manual reference method can produce 1-hour averages, it is clearly impractical for routine use in making 1-hour SO_2 measurements. Also, the 1-hour mode of the manual methods is not a good standard for approving new FEMs with 1-hour measurement capability, because scores of 1-hour measurements would be needed during equivalency testing.

74 Fed. Reg. at 64846/3.

The proposal to specify a different FRM to judge compliance is therefore entirely reasonable. UARG is generally supportive of the proposed specifications for a new FRM. We question, however, the Agency's proposed total interferent limit. EPA proposed to reduce the allowable interference equivalent limits for the total of all interferents from 60 ppb to 20 ppb. *Id.* at 64848/3. Although this is a substantial reduction, even 20 ppb is a significant percentage of any of the 1-hour NAAQS that EPA proposes.[39] UARG therefore recommends that the Agency further limit the total of all interferents.[40]

---

[39] The Administrator's proposed total interferent limit of 20 ppb amounts to 20-40% of the proposed NAAQS (50-150 ppb). Eric S. Edgerton, Comments on Proposed SO_2 Rule 1 (Feb. 3, 2010) (Attached hereto as Attachment D).

[40] *See id.* (demonstrating that the Administrator's proposed total interferent limit is likely to lead to false positive exceedances of the proposed NAAQS).

As EPA recognizes, specification of a new FRM has implications for existing SO_2 monitoring networks. *See* 74 Fed. Reg. at 64848/3. For the reasons discussed above, however, EPA's proposal to retain the existing FRM for several years -- thus having two FRMs specified for a given NAAQS -- is not viable. *See id.* at 64848/2. Although EPA states that the existing FEMs that constitute the bulk of the SO_2 monitoring network "are adequate for the current and the proposed SO_2 NAAQS," *Id.* at 64848/1, the Agency has provided no support for this statement. Although they may be adequate "for many other purposes," *Id.* at 64848/1-2, they may only to used to judge compliance with the 1-hour NAAQS if they are shown to qualify as FRMs or FEMS under the new FRM definition.

EPA therefore would have two options for making initial designations with regard to any 1-hour NAAQS that it adopts. First, it could designate all areas as unclassifiable until adequate data have been collected using the new FRM. Second, if the Agency believes that many of the monitors in the existing networks might qualify as new FRMs or FEMs, the Agency could take advantage of its authority to extend the deadline for designations by a year, *see* CAA § 107(d)(1)(B),[41] and use that year to determine which monitors would qualify under the new FRM and FEM definitions. For those monitors that qualify, EPA could then appropriately rely on existing data to make designations.

[41] EPA recently used this provision to defer designations for the 2008 ozone NAAQS by a year while it reconsiders that rule. 75 Fed. Reg. 2936 (Jan. 19, 2010). Extending the date for designations in light of the lack of data from monitors then qualified as FRMs or FEMs would be at least as appropriate as that use of the provision.

IV. Other Implementation Concerns

A. Monitoring Network Design

EPA proposes to revise the design of the monitoring network for SO_2 to reflect two components: (1) a requirement for monitoring tied to an EPA-developed population-weighted emissions index based on populations and the emissions inventory of a CBSA, and (2) monitoring tied to total state-level SO_2 emissions. *See* 74 Fed. Reg. at 64851/2 to 53/3. UARG's primary concern with this network design is its reliance on old emissions data. For electric utilities which report their SO_2 emissions to EPA annually, the use of more recent data would be appropriate.

UARG believes that it is appropriate to tie the monitoring network for a standard intended to protect public health to the size of the population in an area, as opposed to the alternative approach to network design on which EPA is soliciting comments. That approach would appear to focus solely on monitoring near SO_2 sources. *See id.* at 64854/3. Moreover, that approach would be laborious. It would rely on highly conservative screening models for selecting which sources might require a monitor, and would then require further modeling with AERMOD to site monitors. EPA recognizes that AERMOD will likely require adjustments before it would be suitable for use with a new 1-hour SO_2 standard. *Id.* at 64862/1. More basically, however, AERMOD would simply not be appropriate for siting a monitor at the likely site of the expected maximum 1-hour concentration -- the model has been validated by comparing it with observed high ambient concentrations, but its performance for matching concentrations at a specific time or location has not been evaluated.

B. Data Interpretation

The Proposed Rule also contains provisions to ensure data completeness. *See Id.* 64856/2-3. These provisions suggest that at least 75% of the monitoring data that should have resulted from monitoring in accordance with the schedule during a calendar quarter must be available. *Id.* 64856/2. If it is not, but 50% percent of the expected data is available, the Administrator's plan "would substitute a high hypothetical concentration for as much of the missing data as needed to meet the 100% requirement." *Id.* at 64856/3. The concentrations that would be substituted would be the highest daily maximum 1-hour concentration observed during the same calendar quarter. *Id.* 64856/3. Finally, the Proposed Rule would give the Administrator "general discretion to use incomplete data," either at the request of a state or on her own. *Id.* at 64856/3.

UARG agrees that there should be completeness criteria for compliance data. However, there are several flaws with the Administrator's approach. First, giving the Administrator authority to use incomplete data despite the rule on data completeness renders the rule meaningless and opens the possibility of arbitrary decisions, or decisions that appear arbitrary. The rule should include a system for determining the circumstances under which incomplete data should be used, rather than giving unfettered discretion to the Administrator. Second, substituting the highest reported concentrations for missing data will lead to data sets that are not representative of actual conditions. If the rule provides for substitution of hypothetical data, those data should be set at values that would have been likely to be recorded and not at extreme values. Third, given that only 75% of the expected data are required for completeness, if hypothetical data are substituted, only enough to make up 75% of the expected data

should be substituted, as opposed to 100%. The goal of the monitoring program should be to obtain an accurate measurement of ambient SO_2 levels and the measurement will be more accurate, not only the higher the percentage of expected data points are used, but also the higher the percentage of such data points that represent actual monitored data.

C. Exceptional Events

The Proposed Rule provides further that, with respect to exceptional events, to the extent 2011 data is considered for SO_2 designations, "2011 data must be flagged and detailed event documentation submitted 60 days after the end of a calendar quarter in which the event occurred or by March 31, 2011." *Id.* 64858/1-2. This proposal seems so odd that UARG suspects that it may be an error. According to Table 6 of the Proposed Rule, the detailed documentation submission deadline for 2011 occurs after the deadline for 2010 documentation. *See* Table 6, 74 Fed. Reg. at 64858 (listing the deadline for 2010 as June 1, 2011 and the deadline for 2011 as the earlier of (i) 60 days after the end of the calendar quarter in which the event occurred and (ii) March 31, 2011). March 31, 2011 is the end of the first calendar quarter of 2011 and will always occur before 60 days after any calendar quarter for 2011. Therefore, the Administrator's framework for determining the 2011 deadline is at best arbitrary and at worst nonsensical. Finally, this deadline will not allow for consideration of a full year of data for 2011, something that would be required if any 2011 data were to be considered. *See* 74 Fed. Reg. at 64873/1 (defining a year as a calendar year).

UARG suggests that the deadline for detailed 2011 documentation submission should be March 31, 2012, or in the alternative, 60 days after the end of each calendar

quarter. The deadline should be March 31, 2013 if necessary to qualify FRMs and FEMs under new specifications.

D. Issues Requiring Further Rulemaking

The Proposed Rule suggests development of new screening tools, such as significant impact levels ("SILs"), significant emissions rates ("SERs") and significant monitoring concentrations ("SMCs"), to accompany the proposed 1-hour standard. *Id.* 64862/2-3. It also suggests that it may consider new PSD increments. *Id.* at 64861/1.[42] Furthermore, it suggests the need for anti-backsliding provisions if either the annual or 24-hour NAAQS is repealed. *Id.* at 64863/3. The Proposed Rule does not provide sufficient details to provide for meaningful public comment on these issues. As a result, the Proposed Rule does not provide adequate notice of the Administrator's plans for these regulations. Thus, if the Administrator intends to specify new requirements in these areas, she must conduct separate notice-and-comment rulemaking before doing so, allowing adequate opportunity for interested parties to develop and provide thoughtful comments.

V. Conclusion

In summary, the scientific record and EPA's own modeling of the risks associated with ambient SO_2 do not justify the Agency's proposed 1-hour primary SO_2 NAAQS.

---

[42] Ideally, EPA would provide the regulatory framework for a PSD program at the time that it promulgates a new NAAQS. Clearly, that is not possible in this case. Promulgating a NAAQS without the framework to implement it -- whether that framework is a PSD program or models that can be used to provide realistic estimates of ambient air quality for purposes of SIP development -- imposes a significant burden on States and source owners. The problems associated with an inadequately developed implementation program are exacerbated in this case, where States have only 18 months after a nonattainment designation to submit an approved SIP to EPA. *See* CAA § 191(a).

Nor do they establish a basis for a 1-hour NAAQS of 150 ppb. Indeed, given the low risk of short-term health effects posed by SO_2 in current ambient air, the record simply does not show that revision of the primary SO_2 NAAQS through promulgation of any 1-hour NAAQS is appropriate. If, contrary to UARG's recommendations, EPA nevertheless promulgates a 1-hour SO_2 NAAQS, the Agency should revise its implementation program for that standard as explained in these comments.

Attachment A

Timothy H. Savage, Ph.D., Comments on Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standards: First Draft (Presentation on behalf of UARG to CASAC meeting of Dec. 5-6, 2007)

Comments on Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standards: First Draft

CRA INTERNATIONAL

Dr. Timothy H. Savage
Prepared on behalf of UARG

Three Issues in Five Minutes

- Decline in the Number of Monitors
- Prediction of 5-Minute Max Exceedances
- Roll-Up to "Just-Meet" Standards

CRA INTERNATIONAL

Decline in Number of Monitors

- **Draft REA documents large decline in the number of 5-minute max and 1-hour average SO_2 monitors.**

CRA INTERNATIONAL

Figure 6-11: Decline in 5-Min Max Monitors

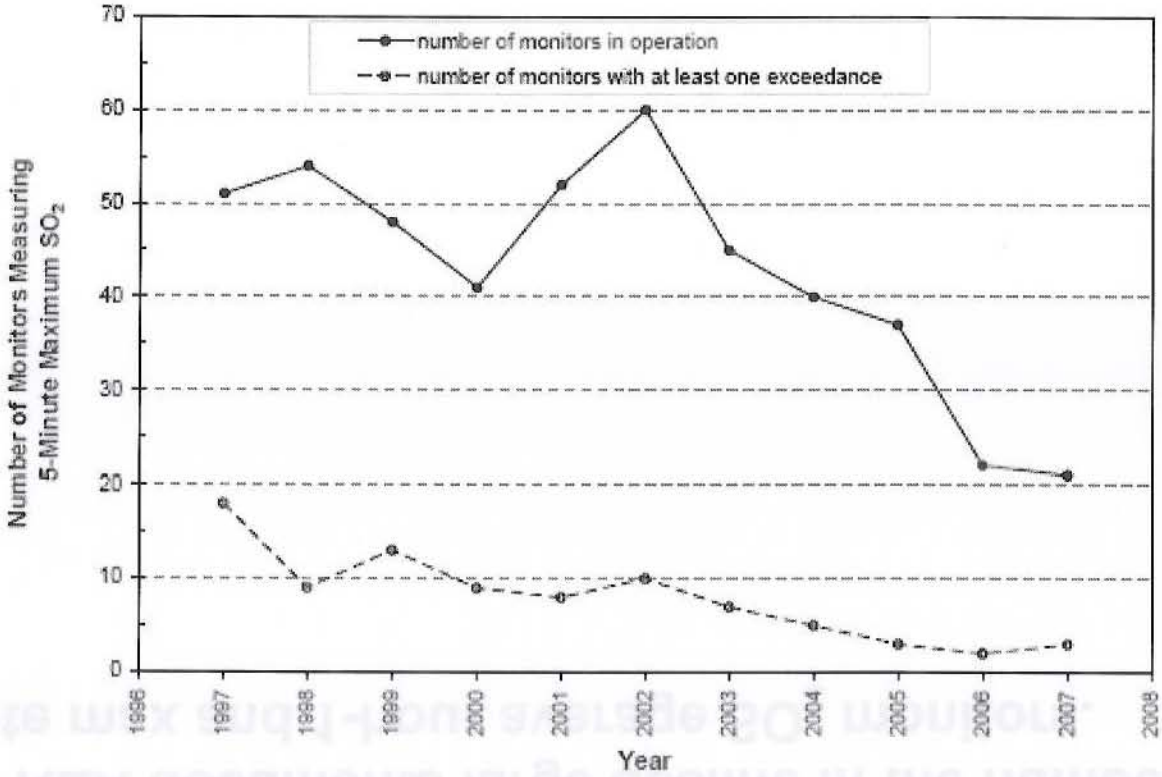

Figure 6-11. Number of ambient monitors measuring 5-minute maximum SO_2 concentrations and number of monitors with at least one benchmark exceedance by year, Years 1997 through 2007.

CRA INTERNATIONAL

Figure 6-17: Decline in 1-Hour Average Monitors

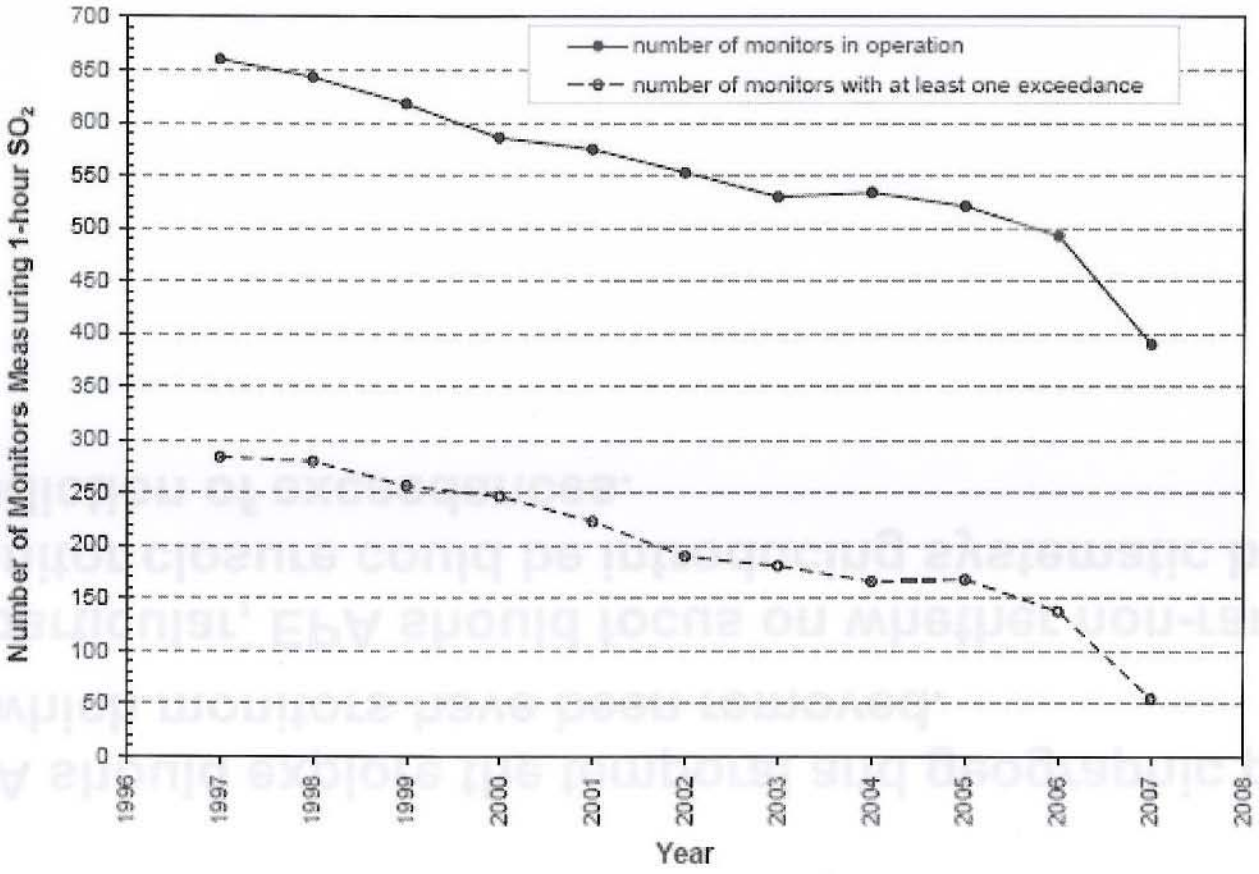

Figure 6-17. Number of ambient monitors measuring 1-hour average SO_2 concentration concentrations and number of monitors with at least one benchmark exceedance by year, Years 1997 through 2007.

CRA INTERNATIONAL

Assessing the Effect

- EPA should explore the temporal and geographic patterns in which monitors have been removed.
- In particular, EPA should focus on whether non-random monitor closure could be introducing systematic bias in the prediction of exceedances.

Prediction Using Peak-to-Mean Ratio (PMR)

- **EPA employs a PMR to predict 5-minute max concentrations from 1-hour average concentrations.**
- **EPA's current PMR is based on COV.**
- **COV is useful for summarizing dispersion of data.**
- **It is less appropriate as a predictive method in this setting.**
  - Traditional standard deviation of normally distributed data.

Evidence of Over-Prediction for 400 PPB Level

Table 6-3. Comparison of measured and modeled number of 5-minute maximum concentrations above 400 ppb located near a petroleum refinery.

Monitor ID	Number of 5-minute Maximum SO_2 > 400 ppb	
	Measured	Mean Modeled
291831002	0	3
301110066	5	13
301110079	0	0
301110080	3	3
301110082	0	0
301110083	1	1
301110084	0	0
301112008	0	0

Predicting Exceedances

- **EPA should recognize that it is predicting exceedances, which is a "rare" event.**
- **EPA should consider using more standard parametric models for prediction.**
  - Logistic, exponential, and/or log-normal.
- **EPA should document the quality of any prediction method using actual 5-minute max concentrations as a benchmark.**
- **EPA should develop confidence intervals for any prediction method to assess the relevance of sampling variability.**

Roll-Up Approach Stretches the Bounds of Realism

- **Following the NO_2 REA, EPA conducts a roll-up of the "as-is" standard to a "just-meets" standard.**
- **EPA's roll-up factors used in the draft SO_2 REA are even larger than those used in the NO_2 REA.**
  - Median factor is 3.75.
  - Top 25% of factors range from 4.47 to 15.85.
- **Process lacks scientific credibility as it requires an unwarranted degree of extrapolation from observed data.**
- **Statistically, it is unclear whether an entire distribution can be credibly "rolled up" in such a manner.**

Timothy H. Savage
CRA International
1155 Avenue of the Americas
New York, NY 10036
(212) 520-7227
tsavage@crai.com

Attachment B

J. Turim, Ph.D., S. Moolgavkar, M.D., Ph.D., E. Anderson, Ph.D., A.T.S.F., Comments on EPA's Integrated Science Assessment for Sulfur Oxides -- Health Criteria: Summary (Dec. 3, 2007) (written presentation to CASAC meeting of Dec. 5-6, 2007)

COMMENTS ON EPA'S INTEGRATED SCIENCE ASSESSMENT FOR SULFUR OXIDES-HEALTH CRITERIA

SUMMARY

J. Turim, PhD
S. Moolgavkar, MD, PhD
E.L. Anderson, PhD, ATSF

Exponent, Inc.

December 3, 2007

COMMENTS ON EPA'S INTEGRATED SCIENCE ASSESSMENT FOR SULFUR OXIDES-HEALTH CRITERIA

SUMMARY

This is the summary of a report prepared by Exponent, Inc. commenting on EPA's Integrated Science Assessment for Sulfur Oxides – Health Criteria (First External Review Draft) September 2007 (ISA). The full text was filed with comments of the Utility Air Regulatory Group to EPA on November 30, 2007. The report focused on Chapters 3 and 4 of the ISA that summarized the clinical (chamber) and epidemiological studies of sulfur oxides and the ISA interpretation of the totality of the literature. The emphasis of the report was on new human studies that may have significant impact on the EPA Administrator's decision on whether to revise the primary SO_2 NAAQS.

The ISA states "there is a *causal* relationship between *peak* (1 h or less, typically 5 to 15 min) exposure to SO_2 and effects on the respiratory system, based on evidence from human clinical studies. Human clinical studies provide clear and consistent evidence of a causal relationship between peak exposures to SO_2 at levels of 0.5 to 1.0 ppm and effects on the respiratory system, namely decrements in lung function in exercising asthmatic adults."

Five papers published in 1990 or later reporting on four clinical studies are included in ISA Table 5A-2 that provides results on key human health effects of peak exposure to SO_2 (Magnussen et al (1990), Gong et al (1995), Tunnicliffe et al (2001, 2003), and Routledge et al (2007)). Of the five publications, only two consider exposures in the range of 0.5 to 1.0 ppm, and their results provide little additional support for the ISA's conclusion of a causal relationship between peak exposure and respiratory system effects in exercising asthmatics. Magnussen et al. (1990) simply confirmed previous findings that asthmatics are more sensitive than non-asthmatics to SO_2 concentrations of 500 ppb.

Gong et al. (1995) found a decrease in FEV1 and an increase in SRaw with increasing SO_2 exposure. Contrary to what would be expected, these trends did not increase with an increasing level of exercise. Of the remaining three papers, the Tunnicliffe et al. (2001) and Routledge et al. (2007) studies offer, as described in the ISA, 'weak and inconsistent evidence' of changes in heart rate variability at SO_2 exposures to 200 ppb for one-hour duration. Tunnicliffe et al. (2003) did not show any change in lung function in a group of asthmatic and non-asthmatic subjects exposed to SO_2 at 200 ppb. Although taken together, these five clinical studies may somewhat contribute to the weight of evidence concerning effects on the respiratory system and peak exposure to SO_2, they do not contribute substantively to the information that was available to EPA previously and lend only marginal support to the ISA's conclusion that a causal relationship exists between peak exposure to SO_2 and effects on the respiratory system of exercising adult asthmatics.

The ISA also concluded that "there is a *likely causal relationship* between *short-term* (generally 24-h average) SO_2 exposure at ambient levels and respiratory health effects, mostly based on the epidemiological studies." Fifteen epidemiological studies, published since 1990 and conducted in the U.S. or Canada, are cited along with older studies in ISA Tables 5A-3 and 5A-4 as providing results on respiratory symptoms among children and on emergency department visits and hospital admissions in support of this finding. While the ISA acknowledges the numerous methodological issues in the interpretation of the human studies of air pollution, it does not discuss the implications of these issues specifically for SO_2. A discussion of these issues is particularly important for SO_2 because most of the studies on which the ISA relies, even those appearing after 1990, were published before the methodological difficulties were recognized.

The ISA fails to discuss recent literature that has direct bearing on these issues, its review of individual studies is not sufficiently critical, and it does not recognize significant limitations. Specific issues that are not addressed adequately in the ISA include: treatment of exposure measurement error, the S-plus convergence problem, publication

bias, effects of model choice, and interpretation of results in light of confounding by other pollutants, notably ozone and particulates. While the ISA acknowledges that exposure measurement error could seriously bias the results of epidemiological studies of air pollution, it should recognize that the correlation between ambient concentration measurements and personal exposures is poorly understood. The reanalyses of particulate time-series studies prompted by the S-plus convergence problem indicate that reanalyses of sulfur dioxide studies could be generally expected to result in effect estimates that become smaller and confidence intervals that become wider. A consequence of SO_2 not having been the primary exposure of interest in recent studies is that the studies did not pay particular attention to optimizing analytic approaches and sensitivity analyses to the SO_2 associations with health effects. Another consequence is the very real possibility of publication bias in the SO_2 literature appearing in the last decade. With the generally small risks estimated in air pollution epidemiology, and the lack of biological information to guide the choice of models for control of weather, temporal trends and co-pollutants, the strategy for model selection for the analyses of time-series data is of critical importance. Although this problem of "model choice" is increasingly recognized in the epidemiological literature, most of the important papers on this issue have been ignored in the ISA.

Although the ISA admits to the uncertainties surrounding the interpretation of the health evidence from the epidemiological studies associated with ambient short-term SO_2 exposure, it has neither discussed nor treated them appropriately. Because of the profound unresolved issues, the fifteen epidemiological studies published since 1990 with U.S. or Canadian cohorts cannot be taken to support the existence of a likely causal relationship between short-term SO_2 exposure and respiratory effects.

Attachment C

Memorandum from Edmund Crouch, Ph.D., to Utility Air Regulatory Group, Response to EPA-HQ-ORD-2006-0260-0036 (Feb. 5, 2010).

MEMORANDUM

To: Utility Air Regulatory Group

From: Edmund Crouch, Ph.D.

Subject: Response to EPA-HQ-ORD-2006-0260-0036

Date: February 5, 2010

Purpose of this memo

As you requested, I have examined docket entry EPA-HQ-ORD-2006-0260-0036 consisting of a memorandum entitled "Quality assurance review of individual subject data presented in Table 3-1 of the 2008 Integrated Science Assessment (ISA) for Sulfur Oxides" from Douglas Johns and Kirsten Simmons, EPA, NCEA-RTP to the Sulfur Oxides NAAQS Review Docket and dated October 2, 2009 ("Johns & Simmons Memo"). I have also examined the material in that docket associated with that memorandum (EPA-HQ-ORD-2006-0260-0036.1 through 0036.5, "Johns & Simmons Material"), and the final REA document EPA-HQ-OAR-2007-0352-0033 ("Final REA"). This memorandum presents my evaluation of the cited memorandum considered as a response to our previous technical comments.

The Johns & Simmons Memo is clearly a response to the discussion of data entry errors in our technical comments (EPA-HQ-OAR-2007-0352-0031.1, Attachment 1, "Our Comments"), and represents a welcome quality control step by the EPA, albeit one that should have been undertaken at the beginning of the process of utilizing these data. It appears that EPA has now done a relatively good job of entering the individual data for the Linn *et al.* studies, for those studies for which individual data are available in the previous air docket (previously A-84-25, now EPA-HQ-OAR-2004-0112, "Previous Data").

EPA data entry quality control

I have examined the quality of the new EPA data entry by comparison with my own entries for sRaw only (not FEV_1) for Linn *et al.* 1983 and 1987 (the sRaw data for the1983 study were not previously available; these data were provided by Ron Wyzga at EPA-HQ-OAR-2007-0352-0038 and 0038.1 through 0038.8, "Wyzga Data") and find that EPA now has only minor data entry errors for sRaw for these two studies.

Specifically, for Linn *et al.* 1983 the following discrepancies still exist:

Cambridge Environmental Inc

58 Charles Street Cambridge, Massachusetts 02141
617-225-0810 FAX: 617-225-0813 www.CambridgeEnvironmental.com

Subject	Condition	When	Column	Presented	EPA
582	2	Pre	Mean	5.76	5.75
592	3	Pre	Minute 7	2.67	2.69
584	3	Post	Minute 4	7.56	7.59
416	2	Post	Minute 7	5.62	5.66
416	2	Post	Mean	6.05	6.03

Subject: subject ID used by Linn *et al.* 1983.
Condition: the exposure group, as recorded in Wyzga Material.
When: indicates pre or post exposure and exercise.
Column: column in Wyzga Material, with "Mean" being the entry handwritten above the regular entry in Minute 7 (corresponding to "Presented average" in the Johns & Simmons Material).
Presented: value given on the handwritten sheet in the Wyzga Material (at 0038.2).
EPA: value entered in the Johns & Simmons Material (at 0036.1).

For Linn *et al.* 1987 the following discrepancies still exist:

Subject	Day	Conc.	When	Column	Presented	EPA
879	2	0.6 ppm	Post	Measurement 4	35.78	35.75
1051	2	0.2 ppm	Pre	Measurement 4	22.07	22.09
611	2	0.2 ppm	Post	Measurement 2	14.51	14.54
1028	1	0.4 ppm	Pre	Measurement 4	4.56	4.54
892	2	0.4 ppm	Post	Measurement 4	29.46	29.76

Subject: subject ID used by Linn *et al.* 1987.
Day: day number of experiment as recorded in the Wyzga Material and Previous Data.
Conc: exposure concentration.
When: indicates pre or post exposure and exercise.
Column: name of the column in the Johns & Simmons material.
Presented: column is the value given on the relevant handwritten sheets in the Wyzga Material (at 0038.3 through 0038.8), or equivalently in the Previous Data (at item IV-B-5).
EPA: value entered in the Johns & Simmons Material (at 0036.2).

The effect of the remaining data entry errors should be negligible on any correct analysis of the data (such as that I performed in Our Comments), although it might affect the EPA's treatment (I have not checked) because EPA categorizes results as being above or below thresholds (so even minor differences in values can throw the entry into the wrong category).

The data entries in the Johns & Simmons Material at 0036.3 check out against the Previous Data, but these are mean sRaw values only. EPA has apparently not located the individual raw data values for sRaw for this experiment (Linn *et al.* 1988). Presumably EPA originally had such data to produce these mean values, but copied only the mean values to the Previous Data.

I have not checked the data entry in the Johns & Simmons Material at 0036.4, for Linn *et al.* 1990 for sRaw (this file also contains individual raw FEV_1 entries for Linn *et al.* 1988). The

Attachment D

Eric S. Edgerton, Comments on Proposed SO_2 Rule (Feb. 3, 2010).

Comments on Proposed SO_2 Rule

Prepared by
Eric S. Edgerton
Atmospheric Research & Analysis, Inc.
Cary, NC 27513

EPA is proposing new performance requirements for the continuous FRM that are generally reasonable and likely to be achievable with current UV fluorescent (UVF) analyzers. It is not clear to me, however, that EPA has actually demonstrated compliance with all of the proposed new performance requirements. In addition, one major concern is the proposal to lower the allowable interference equivalent from +/- 20 ppb to +/- 5 ppb for each interferent and from 60 ppb to 20 ppb for the total of all interferents. The latter amounts to 20-40% of the proposed NAAQS (50-100 ppb) and provides much too much room for false positives. Not only that, but it is unclear whether or not present day analyzers are capable of limiting "total interference" to 20 ppb.

The SEARCH network has amassed a record of "total interference" because of the unique approach it uses to zero SO_2 analyzers. SEARCH uses a "native" zeroing approach, which involves scrubbing SO_2 immediately upstream of the analyzer with a sodium carbonate impregnated annular denuder. The denuder removes SO_2 and acidic gases, but allows basic and neutral gases to pass more or less quantitatively into the UVF detection cell. Ambient air is diverted through the annular denuder for 10 minutes every 2 hours and the resulting zeroes are used to continuously adjust the SO_2 baseline by linear interpolation between successive zeros. The SO_2 baseline is then subtracted from the total SO_2 measurement to arrive at the "true" SO_2 concentration.

Figure 1 contains time series of maximum daily SO_2 zeros for two urban SEARCH sites (Jefferson Street (JST), Atlanta, GA and Birmingham (BHM), AL) for CY 2008 and CY2009. Values shown are 5-minute averages and reflect the last 5 minutes of data when the zeroing scrubber is engaged. It should be noted that instrument baselines are initially set to 0.5-1.0 ppb with scrubbed zero air and therefore the "total interference" is roughly equal to the maximum daily SO_2 zero minus 1 ppb. Inspection of Figure 1 shows several relevant features. First, the lowest zeros are on the order of 0.5-1 ppb, the scrubbed zero air setpoint. This indicates there are times with little or no interference, but also strongly suggests that the preponderance of interferences in these two cities are positive (i.e., increase apparent concentrations). Second, "total interferences" for both sites exceed 10 ppb, but maximum values at JST are more than twice those at BHM (i.e., 27 ppb vs. 12.5 ppb). This is significant because Birmingham, AL has many industrial sources, including metallurgy and steelmaking that are absent or much more limited in Atlanta, GA. If daily maximum zeros were higher at BHM than JST, we might ascribe such to unique industrial sources. Since this is not the case, we infer this level of interference to be widespread among urban sites. Third,

there is a strong seasonality in the zeros and this is much more apparent at JST than BHM. Highest zeros occur in the coldest months and lowest zeros in the warmest months. Maximum daily zeroes above 5 ppb are rare at JST from April through September, but much more common at BHM during the same time period. Given that these are intermittent estimates of interference (i.e., every two hours) it is almost certain that that actual interferences were even higher than those shown in Figure 1.

The above results show that "total interference" in SO_2 measurements, using late model continuous analyzers, can be a serious issue and can potentially lead to false positive exceedances of the proposed NAAQS. It then becomes incumbent upon EPA to demonstrate that FRM and FEM SO_2 analyzers have the capability to minimize interferences, not only in a laboratory setting, but on a continuing basis in the field.

Figure 1. Maximum daily SO_2 zeros (5-minute average) for JST (upper) and BHM (lower), 2008-9.