UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

April 18, 2017

EPA-CASAC-17-002

The Honorable E. Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Consultation on the EPA's *Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides: Risk and Exposure Assessment Planning Document (External Review Draft – February 2017)*

Dear Administrator Pruitt:

EPA's Clean Air Scientific Advisory Committee (CASAC) Sulfur Oxides Panel held a public meeting on March 21, 2017, to conduct a consultation with EPA staff on the EPA's *Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides: Risk and Exposure Assessment Planning Document (External Review Draft – February 2017).* The Panel generally found the Draft Risk and Exposure Assessment Planning Document to be a useful roadmap for the development of the Risk and Exposure Assessment.

The Science Advisory Board Staff Office has developed the consultation as a mechanism to provide individual expert comments for the EPA's consideration early in the implementation of a project or action. A consultation is conducted under the normal requirements of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C., App.), which include advance notice of the public meeting in the Federal Register.

No consensus report is provided to the EPA because no consensus advice is given. The individual CASAC Sulfur Oxides Panel members' written comments are provided in Enclosure A.

We thank the EPA for the opportunity to provide advice early in the development of the Risk and Exposure Assessment and look forward to peer reviewing the completed Risk and Exposure Assessment.

Sincerely,

/s/

Dr. Ana V. Diez Roux, Chair
Clean Air Scientific Advisory Committee

Enclosure

NOTICE

This report has been written as part of the activities of the EPA's Clean Air Scientific Advisory Committee (CASAC), a federal advisory committee independently chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC provides balanced, expert assessment of scientific matters related to issues and problems facing the agency. This report has not been reviewed for approval by the agency and, hence, the contents of this report do not represent the views and policies of the EPA, nor of other agencies within the Executive Branch of the federal government. In addition, any mention of trade names or commercial products does not constitute a recommendation for use. The CASAC reports are posted on the EPA website at: http://www.epa.gov/casac.

U.S. Environmental Protection Agency
Clean Air Scientific Advisory Committee
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* Did not participate in review

Enclosure A

Individual Comments by CASAC Sulfur Oxides Panel Members
on the EPA's *Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides: Risk and Exposure Assessment Planning Document (External Review Draft – February 2017)*

Mr. George A. Allen

Analytical Approach and Study Area Selection

1. The overall analytical approach for the Risk and Exposure Assessment (REA) and its appropriateness for developing spatially and temporally varying 5-minute ambient SO2 concentrations, simulating population-based 5-minute peak exposures, and estimating study area health risk based on controlled human exposure study data. [Chapter 4]

The overall analytical approach in Figure 4-1 (page 4-2) for this REA is sound. Using a simple linear (proportional) adjustment to just meet existing [and alternative?] standards is appropriate for SO2, since concentrations of concern are relatively near the sources and on that spatial/temporal scale, SO2 is reasonably conserved, and expected adjustments are small. The choice to use modeled ambient SO2 concentrations instead of observed (measured) concentrations provides more detailed local scale spatial patterns. Modeled hourly SO2 concentrations with AERMOD combined with 5-minute variability information from observations should provide appropriate input for 5-minute exposure modeling (APEX). Comments on the approach to risk assessment are not my area of expertise.

2. The criteria identified and approach used to select potential study areas to evaluate for this REA. [Section 4.1.2, Exposure Domain]

The process of identifying a "short list" of potential study areas is well described and reasonable, based on monitor[s] in the area having a design value within 10 ppb of the current standard, 5-minute data from at least one monitor in the study area, and a population of at least 100,000 within 10 km of relevant monitors. These selection criteria result in the nine areas shown in Figure 4-1 (page 4-7). Some of these sites have more available data (sites, DV years), resulting in four "very short list" candidates. Modeling domains would be constrained to within 10 km of relevant emission sources to limit uncertainty in modeled concentrations. Overall, this approach should result in optimal exposure domains for this REA.

<u>Other Comments</u>

During the meeting it was noted by EPA staff that the REA would use the 2014 National Emissions Inventory (NEI) instead of 2011 NEI as used in this planning document. This is important given the large reductions in SO2 emissions from EGUs and other sources (such as ultra-low S diesel and heating oil) over the last several years.

A useful analysis of reported 5-minute SO2 concentrations in the context of design values and various health-relevant 5-minute concentrations is presented in Appendix B of this planning document (Occurrences of 5-Minute SO2 Concentrations of Interest in the Recent Ambient Air Monitoring Data (2013-2015)). The text of the document only mentions this appendix very briefly (one sentence on page 3-6); it may be useful to bring a summary of the information in Appendix B into chapter 3.

Table 4-1 lists lead smelting as a source in Marion County IN (Indianapolis); is this correct? It's my understanding that the last of the domestic lead smelters closed down several years ago. It would be useful to include a column listing the total 2014 NEI TPY emissions for each of the study areas in this table.

There is no mention in the planning document of performing exposure risk analysis using potential alternative standards (concentrations, forms). During the meeting it was noted by EPA staff that this could be done based on the results of the risk analysis at the current standard. It would be helpful if there was a brief discussion of this in the planning document.

AERMOD, the EPA regulatory SO2 model, will be used in the risk assessment to estimate exposures to both 1-hour and 5-minute SO2. However, AERMOD's performance is evaluated only at 1-hour, and its performance in estimating distributions of 5-minute peak SO2 concentrations is not well characterized. If this is a potential issue in estimating exposures of concern for the REA, some discussion of this in the planning document would be useful.

Dr. John R. Balmes

Analytical Approach and Study Area Selection

1. The overall analytical approach for the Risk and Exposure Assessment (REA) and its appropriateness for developing spatially and temporally varying 5-minute ambient SO2 concentrations, simulating population-based 5-minute peak exposures, and estimating study area health risk based on controlled human exposure study data. [Chapter 4].

The plan to follow the same conceptual model as used for the 2009 REA seems appropriate.

2. The criteria identified and approach used to select potential study areas to evaluate for this REA. [Section 4.1.2]

The planned approach seems reasonable.

Exposure Analysis

1. The overall approach to be used for the exposure analysis, including the use of the APEX model, given objectives of the analyses, which include development of 5-minute exposures for input to the risk assessment, assessment of factors that contribute to the upper percentile population-based 5-minute exposures. [Section 4.1]

The planned approach to the exposure analysis seems reasonable.

2. The selected study population groups of interest (adults with asthma, school-aged children with asthma) for which SO2 exposure estimates are to be developed. [Sections 3.2.1, 4.1.3]

The target study population groups are appropriate based on the review of the literature contained in the ISA.

Health Risk Assessment

1. The general structure and overall approach that staff plans to use for the risk assessment. [Section 4.2]

The overall approach for the health risk assessment is appropriate given the review of the literature contained in the ISA.

2. The approaches for using findings from the controlled human exposure studies.

a. The health benchmarks identified for this REA. [Sections 3.2.2, 4.2.3]

b. Plans for developing updated exposure-response functions, including the methodology, and specific studies to be relied on, for estimating exposure-response relationships for lung function decrements. [Sections 3.2.2, 4.2.4]

> *i. The focus on specific airway responsiveness (sRaw) for this quantitative risk assessment of short-term exposure-related endpoints.*
>
> *ii. The range of exposure concentrations appropriate to include in the dataset for deriving the exposure-response function.*

Given that there are no new controlled human exposure study data, I think that it is reasonable to include the Linn et al. (1983) and Horstman et al. (1986) data to improve the usefulness of the E-R curves for lower level exposures. I also like the plan to explore the effects of different forms of the E-R curve, such as using a curve with the 1000 ppb data removed. Finally, the plan to focus only on SRaw response data is wise given the paucity of FEV1 data.

Dr. James Boylan

Ambient Air Concentrations

1. The use of an AERMOD model-based approach to predict hourly concentrations at all receptor locations within selected study areas. [Sections 3.3.2, 4.1.3.3]

The model-based approach to predict hourly concentrations at all receptor locations within the selected study areas is appropriate and will better quantify the spatial variation in concentrations compared to using observations alone. AERMOD is an appropriate model for predicting SO_2 concentrations in ambient air. The approach that is described in the REA includes running AERMOD to obtain 1-hour SO_2 concentrations at all receptors and all hours, then uses the 5-minute SO_2 observations to convert the 1-hour AERMOD results into continuous 5-minute results. If AERMOD is performing well, this is a valid approach.

For the past 2 years, I have been running AERMOD to model SO_2 in the state of Georgia to meet the requirements of EPA's SO_2 Data Requirement Rule to inform our SO_2 designation recommendations for the 2010 standard. In my experience, AERMOD does not always perform well and can have significant over and under predictions depending on site-specific characteristics. At one monitor location in Georgia, AERMOD over predicted the SO_2 concentrations by a factor of 10 (the monitor was half the standard and the model was 5x the standard).

Page 4-18 of the REA states that "Model performance (e.g., comparison with available monitor data) can be evaluated using procedures outlined in the EPA Protocol for Determining Best Performing Model (U.S. EPA, 1992)." A summary of the specific model performance approach that will be implemented and the model performance "acceptance" criteria needs to be included. The ISA states, "For models intended for application to compliance assessments (e.g., related to the 1-h daily max SO_2 standard), the model's ability to capture the high end of the concentration distribution is important. Measures such as robust highest concentration (RHC) (Cox and Tikvart, 1990), and exploratory examinations of quantile-quantile plots (Chambers et al., 1983) are useful. The RHC represents a smoothed estimate of the top values in the distribution of hourly concentrations. In contrast, for dispersion modeling in support of health studies where the model must capture concentrations at specified locations and time periods, additional measures of bias and scatter are important."

Most published AERMOD model performance evaluations are associated with using the model for compliance assessments. In these cases, the model's ability to capture the high end of the concentration distribution is evaluated with Q-Q plots where the highest data point from the model is compared to the highest data point from the observations even if they occur at different locations, time of day, and season of the year). In the REA, the model is being used to support health studies where spatial and temporal accuracy is much more important compared with compliance assessments. The model results need to be evaluated against observations paired in time and space. The REA needs to discuss "acceptable" model performance criteria and options for correcting the model results if there are significant biases in the modeling results. For example, would it be acceptable to over predict the SO_2 concentrations by a factor of 2? How about 5? How about 10? If not, what will be done with these modeling results?

Also, the overall model performance may look good for the entire year due to compensating errors, but the daily temporal profiles and/or seasonal profiles might be way off. EPA should consider adjusting the REA model results up/down to match the SO_2 observations. This approach would keep the relative spatial distributions identified by the model in place, but would adjust the concentration levels to match the observations. This would minimize the impacts from poor model performance on the ambient SO_2 concentrations used in the exposure estimates.

2. The use of SO_2 measurements at ambient air monitors within and near the study areas to estimate continuous 5-minute concentrations, where appropriate (e.g., filling missing values, for AERMOD hourly predictions). [Sections 3.3.1, 4.1.3.1, 4.1.3.2]

The comprehensive 2011-2015 1-hour average and 5-minute SO_2 data sets will help estimate continuous 5-minute concentrations. On page 4-13, proposed step #3 states "Substitute any hours not having measurements for any year with a value of zero (0)." However, it might be more appropriate to substitute missing values with the lower detection limit (2 ppb) or half the LDL (1 ppb), or interpolate between the values before and after the missing value(s).

Equation 4-1 and Equation 4-3 are simple ways to fill the missing data. The REA proposes "to use a linear ramp" for Equation 4-2, but this equation is only truly linear for the case where the 5-min max is equal to 2 x 1-hour average. Equation 4-2 should be updated since the cases where the 5-min max is $\geq$2 x 1-hour average produces 5-min values for $C_6 – C_1$ that are lower than the cases where the 5-min max is <2 x 1-hour average. Also, an exponential ramp may be more appropriate than a linear ramp for cases where the 5-min max is $\geq$2 x 1-hour average. In addition, a minimum value should be assigned. Options for setting an appropriate minimum value could include using 50% or 25% of the 1-hour average SO_2 concentrations for the current hour or using the 1-hour average concentration for the hours before and after the current hour (assuming they are significantly lower than the current hour).

3. The proportional approach selected for adjusting ambient concentrations to simulate air quality that just meets the existing standard. [Section 4.1.3.4]

In general, the proportional approach selected for adjusting ambient concentrations to simulate air quality that just meets the existing standard seems to be appropriate. On page 4-20, it is stated "For the planned REA for the current review, in each study area, F will be calculated by dividing 75 ppb by the DV and will be used to adjust all SO_2 concentrations in a study area by this factor to simulate just meeting the existing standard." In order to just meet the standard, it would seem appropriate to only adjust the SO_2 concentrations for those receptors with a design value above 75 ppb and leave the receptors with a design value already below 75 ppb unchanged.

Study Areas and Time Periods (Section 4.1.2.1)

It seems appropriate to model three consecutive years to evaluate variability in exposures across a 3-year period since this is consistent with the form of the existing standard. Also, modeling domains with receptors within a 10-km radius of all nearby SO_2 emission sources greater than 100 tons/year is appropriate.

Four of the nine candidate study areas listed in Table 4-1 were selected for detailed analysis. It would be helpful to state the specific reasons why each of the other five areas were not selected. Finally, the maps in Figures 4-2, 4-3, 4-4, and 4-5 are difficult to read and interpret. I suggest showing DVs 0-75 (blue), 76-100 (yellow), and >100 (red). For the large SO_2 emission sources, it would be better to represent the emission sources with different size bubbles that are representative of the size of the SO_2 emissions (small bubble for low emissions, larger bubbles for higher emissions). Also, I would suggest break points of 100-500, 500-1000, 1000-2000, 2000-5000, >5000 tons.

Also, it is not clear how the four study areas (less than 1.5M people) will be used to calculate the number and percent of the total population across the country (> 325M people) experiencing 5-minute SO_2 exposures at or above benchmark levels of concern, the number of occurrences of lung function decrements in the at-risk populations across the country, and the number and percent of the at-risk populations across the country estimated to experience single or multiple occurrences of those lung function decrements. This needs to be done since this is a national standard. How will populations exposed to much higher or much lower ambient SO_2 concentrations in other areas of the country be factored into the analysis?

Other Potential Standard Levels

With so many improvements being implemented to better characterize the 5-minute SO_2 concentrations in ambient air (new 2011-2015 SO_2 measurements and enhancements to AERMOD) and the improvements to the exposure assessment (APEX and CHAD), it would seem appropriate to re-evaluate other potential standard levels (50 ppb and 100 ppb) besides the current level (75 ppb). If significant impacts are indicated by the current level of the standard, then a level of 50 ppb should be evaluated. If minimal impacts are indicated by the current level of the standard, then a level of 100 ppb should be evaluated.

Dr. Judith Chow

Analytical Approach and Study Area Selection

2. The criteria identified and approach used to select potential study areas to evaluate for this REA. [Section 4.1.2]

The four candidate study areas are reasonable as they meet the criteria for air quality data, design values, and population size. The four areas include different SO_2 sources (e.g., steel mill in Cuyahoga County, OH, lead smelting in Marion County, IN, pulp and paper in Brown County, WI, and a fertilizer plant in Hillsborough County, FL) in addition to electric generating units (EGUs). However, three of these areas are close to water bodies (with the exception of inland Marion County, IN). The selection does not cover all relevant geographical regions (i.e., Midwest, Northeast, South, and West) defined by the National Health Interview Survey (NHIS, Page 4-26). Complex terrain features (e.g., plume impact on elevated terrain) are ignored. Sites near the ocean or a lake may experience additional moisture resulting in enhanced SO_2 to sulfate transformation and therefore may not represent typical SO_2 exposure.

Although large SO_2 sources (>100 tons per year) are shown in Figures 4-2 to 4-5 (Pages 4-8 to 4-11), the range of emissions from 4,821 to 142,920 tons per year spans more than an order of magnitude; more refined divisions of large sources would be desirable. It would be helpful to provide the most recent (e.g., 2013 to 2015) statistical summary of 5-minute hourly and daily 1-hour maximum values, as well as hourly and daily average values, for the selected areas. With a design value of 65 to 85 ppb in these four areas, the number of days that 5-minute maximum values exceeded 100, 200, 300, and 400 ppb benchmark concentrations should be given. Figure B-1 of Appendix B shows that nationwide, there are 30 to 90 days with SO_2 concentrations exceeding 125 ppb. Perspective should be given with respect to the exposure-response of these elevated SO_2 concentrations.

Detailed national statistics are given in the second draft SO_x ISA (U.S. EPA, 2016a) for six focus areas during the 2013 to 2015 period. Other than four sites in Ohio included in both the Cleveland-Elyria-Mentor and Cuyahuga County study areas, none of the focus areas (i.e., Gila County, AZ, St. Louis, MO-IL, Houston-Sugar Land-Baytown, TX, Pittsburgh, PA, and New York-Northern New Jersey-Long Island, NY-NJ-PA) correspond to the selected REA modeling areas. The EPA may want to consider including some of the ISA focus areas (especially those like Gila County, AZ) in the West with high copper smelting emissions (>21,747 tons/year) and elevated (282 ppb) 5-minute hourly maximum SO_2 concentrations (see Figure 2-18, Page 2-43 of the second draft SO_x ISA).

Ambient Air Concentrations

1. The use of an AERMOD model-based approach to predict hourly concentrations at all receptor locations within selected study areas. [Sections 3.3.2, 4.1.3.3]

It is encouraging that the EPA has made several updates to the AERMOD modeling system and its data processors such as AERMET, AIRMINUTE, and AERMAP (U.S. EPA, 2016b). With the improvement in terrain and meteorological processors, better agreement should be found in hourly SO_2 concentrations between AERMOD model predictions and ambient SO_2 measurements. Sensitivity tests need to be conducted with the new options for adjustment of surface friction velocity under 1-minute low wind speeds and building downwash to demonstrate the improvements in AERMOD model simulation and exposure assessment. Performing preliminary model runs for surrounding sources to determine the spatial scale that best captures concentration gradients seems reasonable. As the current AERMOD model only predicts hourly SO_2 concentrations and does not account for plume looping and short-term touchdowns, the EPA is encouraged to further update the AERMOD model to estimate shorter averaging time (e.g., subhourly).

2. The use of SO_2 measurements at ambient air monitors within and near the study areas to estimate continuous 5-minute concentrations, where appropriate (e.g., filling missing values, for AERMOD hourly predictions). [Sections 3.3.1, 4.1.3.1, 4.1.3.2]

Although the number of monitors reporting 5-minute concentrations has increased since 2011 (Figure 3-1, Page 3-6), it is unfortunate that only ~40% of monitors in the compliance network report 12 consecutive 5-minute measurements for each hour (Page 3-5). A great deal of effort has been made (Section 4.1.3.2) to estimate the unreported 5-minute concentrations where only the hourly maximum 5-minute concentrations are reported.

The approach to estimate the other eleven 5-minute measurements seems reasonable. However, the progressive decrease in SO_2 concentrations in Tables 4-3 and 4-4 (Page 4-16 and 4-17) does not necessarily reflect the frequency and duration of plume touchdown and downwash mixing, adding uncertainties to the modeling results.

Federal Reference Method (FRM) instruments for SO_2 are capable of producing short-duration averages; consistent reporting of each 5-minute average by the states is preferred. This would allow for the examination of consecutive elevated 5-minute SO_2 concentrations and a clearer understanding of the exposure durations and diurnal variations. The EPA is encouraged to acquire past 5-minute measurements from states (even if it is not fully quality assured) to verify the adequacies of predicting the other eleven 5-minute SO_2 measurements. In the future, the EPA should mandate that states report each 5-minute average SO_2 measurement, as it will provide a database to evaluate a future 5-minute SO_2 NAAQS indicator.

3. The proportional approach selected for adjusting ambient concentrations to simulate air quality that just meets the existing standard.
[Section 4.1.3.4]

As the highest design value (DV) is used to derive a single multiplicative factor (F) to adjust the monitored concentrations across the study area, the selection of an appropriate DV is important. The REA asserts that the adjustment for ambient concentrations used in the exposure assessment is likely to be small (<10%, Page 4-20), inconsistent with the large variations in DV values (from 78 to 92 ppb in Marion County, IN and 66 to 93 ppb in Tampa, Hillsborough County, FL over the 2011 to 2013, 2012 to 2014, and 2013 to 2015 periods) shown in Table 4-1 (Page 4-7). The representativeness of DVs needs to be clarified.

References

U.S. EPA (2016a). Integrated Science Assessment for Sulfur Oxides—Health Criteria, Second External Review Draft. EPA/600/R-16/351. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

U.S. EPA (2016b). User's Guide for the AERMOD Terrain Preprocessor (AERMAP). EPA-454/B-16-012. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

Dr. Aaron Cohen

General Structure [Section 4.2]

The overall plan for the REA Health Risk Assessment is, for the most part, clearly described. It appears methodologically sound and consistent with the health evidence as reviewed in the draft ISA.

Approaches for using findings from controlled human exposure studies

The choice of health endpoints appears well-justified (page 4-31, Section 4.2.1).

Page 4-32, para.1: I assume that the scaling of ventilation by BSA is the appropriate way to handle adult-child differences, this approach having been used in other REA, but this is not my area of expertise.

Health benchmarks [Sections 3.2.2, 4.2.3]

The benchmark levels seem appropriate given the design of the controlled exposure studies.

Plans for E-R functions [Sections 3.2.2, 4.2.4]

The rationale for not including FEV_1 deserves further discussion. I am not sure I agree, given the ISA review and though estimates may be less precise than for sRaw FEV_1 decrements in exposed asthmatics are adverse. In any case, excluding FEV_1 seems to contradict what was said in Section 4.2.1.

Section 4.2.4, page 4-34, line 4: there seems to be a word (missing: "…people estimated to [have experienced?] at least one…"

Variability, covariability and uncertainty [Section 4.4]

The approaches to addressing variability in the underlying exposure and health evidence and characterizing uncertainty seem conceptually sound but it is not entirely clear to me what the sources of variability are that will actually be addressed. Perhaps a small table would help.

I understand that uncertainty will be characterized using sensitivity analysis, but I assume that the risk estimates will be also presented with uncertainty intervals. This is not discussed but should be, including which sources of uncertainty such intervals will include, e.g., uncertainty in exposure assignment as well as in the fitted E-R functions.

Dr. Alison C. Cullen

The focus of these comments is *Chapter 4 - Plan for the Current Health Risk and Exposure Assessment* (Section 4.1 Population Based Exposure Assessment pages 4-1 to 4-30).

This section of Chapter 4 is very informative and lays out the approach EPA proposes for assessing exposure in a systematic way. Below I outline questions/comments intended to sharpen details and answer remaining questions.

- For the assessment of human exposure to SO_2, EPA has selected study areas to represent the US. Over 100 potential areas fit the selection criteria related to air quality data availability and design values however only nine satisfied the population size criteria, so clearly population size is a pivotal criterion. Please say something about the choice of 100,000 as the cut point for population size. What impact would a different cut point be expected to have on the study area selection and ultimately the analysis? Also, please expand on the extent to which the final four study areas are representative of exposure locations of concern regarding SO_2 sources and how these areas reflect on the broader characteristics related to exposure, given the application of the set of selection criteria.
- Further, regarding the selection criteria, either refer to another section of the REA or explain here why 75% is considered to be complete enough to be the cut point for completeness. Also, clarify the impact that a different value would have. Finally, a separate point to address/clarify - why are areas with more complete data prioritized given that a model approach is ultimately used? Some acknowledgement of the most "relevant" data or the most "valuable" data may be as important as raw "completeness".
- The equations used to estimate missing 5-minute concentrations of SO_2 introduce an important role for the maximum 5-minute concentration and its position relative to the average. Please say more about the impact of this choice.
- In Figure 4-6 given that the one or two data points at the top of the percentile distribution for daily maximum one hour SO_2 are very influential on the fit of the slope of the regression line for each of the four locations – say more about the applicability of these derived relationships.
- Although the exclusion of children under the age of 5 in the at-risk population assessment is consistent with other REAs for other pollutants as stated in the REA for SO_2, and its justification is outlined, please say something further about the impact of this exclusion on the NAAQS.
- Asthma status is obviously important when considering SO_2 exposure and risk. Given that the 2014 REA for O_3 is referenced for its improved treatment of asthma and geographic level differences please say a bit more about the approach so that this REA can stand alone (while not repeating all previous content). Are the four study areas representative of the US national range in asthma prevalence? Is it possible to add gender breakdowns to Table 4-5?
- Clarify on page 4-28 or earlier how interactions between asthma status and exertion level will be handled, given the limitations of CHAD.
- Refer readers to a fuller discussion in this REA (outside of the US EPA 2012b reference which is a full treatment) of how the population diversity statistic D and the within-person autocorrelation statistic A are applied (page 4-29).

- Interdependencies are very important as noted in section 4.1.6.5. Personal Attributes, but the language is vague. How and when will these interdependencies be taken into account (beyond just “where possible”)?
- Is asthma status a physical attribute which could be referenced in section 4.1.6.5.2 Physical Attributes or does it belong elsewhere in the overall section 4.1.6?

Dr. Delbert J. Eatough

I was specifically asked to focus on Ambient Air Concentrations. However, as I read the document my areas of concern centered on both the material on Analytic Approach and Study Area Selection (Section 4.1.2) and Ambient Air Concentrations (Section 4.1.3). My comments will address both of those areas. I will focus on how decisions in the structure of these two sections effect the development of the “Exposure Modeling (Apex)” purple box and subsequent development of the “Lung Function Exposure-Response Function Relationship” red box in the Figure 4-1 (page 4-2) Overview of the analysis approach for the REA. In particular, I will comment how decisions made on the Study Area Selection (Section 4.1.2) may well lead to the underprediction of response.

Background on Areas of the ISA and REA which contribute to my concerns.

In my written comments on the ISA I pointed out that CASAC had requested the following of EPA in the development of the Second Draft ISA:

In the April 15, 2016 letter to Administrator McCarthy we stated,

> “The CASAC finds that the source categories and definitions of major sources are inconsistent throughout Chapter 2 as well as the entire ISA and recommends that these be consistent. The chapter should include locations and emissions for point sources (energy-generating units, integrated steel and iron mills and smelters) near urban centers.”

In the 03/10/16 Draft Report we further stated,

> “The importance of pollution sources and formation of non-sulfate compounds such as inorganic particulate S(IV) species, organic S(IV) species (e.g., bis-hydroxy dimethyl sulfone) and organic S(VI) species (e.g., alkyl sulfates) requires additional discussion. Studies such as Alarie et al. (1973) and Amdur (1971) demonstrated the relationship between exposure to inorganic S(IV) compounds and exacerbation of SO_2 inhalation responses in animals. These compounds are potential confounders or moderators of SO_2 health effects in epidemiological studies where copper smelter or integrated steel mill emissions are abundant and the possible influence of these compounds should be discussed.”

And in my Final Comments on Draft IRP I outlined in detail what was known about the above outlined chemistry and recommended,

> “Probably a more fruitful set of data to evaluate the relative importance of aerosol S(IV) species associated with smelter emissions would involve past epidemiological studies from about two to three decades ago when smelter emission were much more significant, for example from the TX smelters in El Paseo (ASARCO Cu smelter, closed in 1999), and Corpus Christi (ASARCO Pb smelter, closed in 1985), AZ smelters (ASARCO Cu smelter in Hayden, currently operating and Phelps Dodge Cu smelter in Douglas, closed in 1987), from the Kennecott Cu smelter in Magna, UT prior to construction of the tall stack, from the Tacoma WA smelter (American Smelting and

Refining, a Cu smelter specializing in high As ore refining, closed in 1985), or the smelters in Montana (ASARCO Pb smelter in East Helena, closed in 2001, Anaconda Cu smelter in Anaconda, closed in 1981) and Idaho (Bunker Hill Pb smelter in Kellogg, closed in 1982). I know that several epidemiological studies were conducted at these locations, but I am not familiar with the results of these studies with respect to asthma exacerbation. I recommend that EPA look at this older data to see if an estimate of the relative potency of SO2 and smelter associated aerosol S(IV) species can be determined. There will not be data on the concentrations of S(IV) in the aerosols emitted from these sources, so total particulate exposure would need to be used as a surrogate. The importance of elucidating the effect of these exposures is correctly alluded to in the ISA on Page 4-12, Line 11."

My comments on the Second Draft ISA point out that these requests were not responded to in the second draft ISA with the following two consequences:

1. It would appear from data in the ISA that the highest anthropogenic associated concentrations to which a population is exposed under current SO_2 emissions is dominated by emissions from smelters and integrated iron and steel mills. Further, with respect to current conditions, high exposure concentrations resulting from emissions from EGUs is rare. I have asked in my comments on the ISA for additional information from EPA in the ISA to make this point clearer.
2. The request to explore the hypothesis that the presence of particulate inorganic S(IV) species in emissions from smelters and integrated iron and steel mills will result in a greater exacerbation of asthma in exposed populations will lead to a higher risk than exposure to SO_2 alone, such as you might see in emissions from an EGU was not considered by EPA.

Consequence 1. means that the development of a Risk and Exposure Assessment document which focuses on EGU emissions will underestimate the highest exposures which will lead to the highest risk.

Consequence 2. Means that if the hypothesis is correct, the risk will be further underestimated by not focusing on the higher emissions to which populations are exposed from living near a smelter or an integrated iron or steel mill and which emissions are associated with a higher risk from sulfur oxides than that due to only SO_2.

Section 4.1.2 Exposure Domain

There are two statements in the material in Section 4 which precede 4.1.2 which appear to me to be contradictory and which directly affect the choice of Exposure Domains. On page 4-1 first paragraph the REA states "The objective for the REA for this review is to characterize exposure and health risk associated with SO2 from ambient air under conditions just meeting the current primary standard." In Section 4.1, page 4-3 last paragraph the REA states "Additionally, as part of this analysis, the population-based statistical distribution of exposures will also be evaluated to identify important exposure environments and/or influential activities that lead to those estimated as having greatest potential health risk." I would think the second point is more important than the first if the objective is to identify the risks which should guide decisions on whether the SO_2 standard needs to be revised.

With these points in mind, let me comment on the four identified potential study areas in Section 4.1.2. and on the associated figure for that study area.

Fist a general comment on the four figures: Figures, 4-2 through 4-5 are a little confusing. The various sources shown are given in the Key as squares, but show in the figure as circles.
It would also be very helpful if the sources were specifically identified and not only listed in Table 4-1 as to type and not as to size.

Brown County WI contains Green Bay. It is not one of the sites identified in Figure 2-11 of the second draft ISA as a site with the 99th percentile of 1-h daily max sulfur dioxide concentrations reported to be above 75 ppb. The data in Table 4-1 indicate the DV is just at 75 ppb. Impact appears to be from pulp and paper facilities, mostly near the single monitor in the Study area. It would help if the specific sources and emissions were given. I assume the EGU is the large source in the central circle. I further assume that it has a tall stack and will not significantly impact the single monitor in the study area. I would consider this study area (with only one monitor) to be less valuable than the FL study area.

Cuyahoga County OH contains Cleveland. It is one of the sites identified in Figure 2-11 of the draft ISA as a site with the 99th percentile of 1-h daily max sulfur dioxide concentrations reported to be above 75 ppb. The DV in Table 4-1 of the REA for this study area is 62. There are four monitors shown in the study area. The highest concentration for the four is for MONID 390350060. According to Figure 2-13 of the second draft ISA the 99th percentile of 5-minute hourly max sulfur dioxide concentration at that monitor during 2013-2015 was 61 ppb. Based on the data in Figure 2-13 of the second draft ISA I believe the emissions source to the right of the four monitors shown in Figure 4-3 is the 2133 tpy ArcelorMittal integrated iron and steel mill. The smaller emissions source in the middle of the four sampling stations in Figure 4-3 of the REA is not shown in the ISA. It would be useful to know what that source is. The advantage of this study area is the presence of four monitors to aid in the APEX analysis. It is possible that these four monitors are influenced by emissions from an integrated iron and steel mill. The highest monitoring site in this area given in Figure 2-13 of the ISA is E, which averages 85.7 ppb. Both the monitor and the nearby emissions source are within the domain shown in Figure 4-3, but they are not shown. The nearby 2745 tpy emission source is not identified, but I have asked for that to be added to the draft ISA. The large red source in the middle of the upper circle for Figure 4-3 is not identified, but I am sure it is an EGU (with an adjacent Monitor with a 20 ppb average values not shown in Figure 4-3) given in Figure 2-13 of the ISA. Distance from Cleveland to ISA E is 30 mi. The monitor by the power plant is about midway between the two. Why are these two additional monitors (and site) near Cleveland not included in the study area? It does not seem wisdom to not include the monitor with the highest SO_2 readings and a clear impact from a nearby source in the analysis. If all potential data were used, this could be a very viable study area. It further has the advantage that it would look at the probable impact from an integrated steel mill. I would surly also like to know that the emission source near Painesville is. If it is the Painesville Electric Plant (which does not appear to have a tall stack) it would be a unique opportunity to include the impact of an EGU in the study area analysis.

Hillsborough County, FL contains Tampa. It is not one of the sites identified in Figure 2-11 of the draft ISA as a site with the 99th percentile of 1-h daily max sulfur dioxide concentrations reported to be above 75 ppb. The DV in Table 4-1 of the REA for this study area has dropped over the years and is currently 66. Table 4-1 indicates there is only 1 monitor to be included in the analysis for the study area and sources are Fertilizer Plants and an EGU. However, there are five monitoring sites shown in Figure 4-4.

Why are the other monitoring sites not being included in the APEX analysis? This would surely increase the power of the analysis. I assume the red circle (the key looks like it should be a square) centered on the bottom blue circle is the EGU. I also assume it has a tall stack and will not have a major impact in the study area. What, specifically is the source vert near to the MONID 120570109 monitoring site. How probable is it that, even if it has emissions less than 1136 tpy, it will impact the site. Do the data from the nearby monitor suggest this will be the case? I consider this a reasonable study area if all monitoring site data are included in the analysis.

Marion County IN contains Indianapolis. It is not one of the sites identified in Figure 2-11 of the draft ISA as a site with the 99th percentile of 1-h daily max sulfur dioxide concentrations reported to be above 75 ppb. The "lead smelter" listed in Table 4-1 for Marion County IN is actually the RSR-Quemetco Battery Recycling Facility on the west side of Indianapolis (identified as yellow and directly west of the monitoring site MONID 180970057) and is not a smelter. There is only one monitor in the study area and it has a DV 79. There are two other monitoring stations identified but the key indicates they have no valid data. I would consider this site (with only one monitor) to be less valuable than the FL site.

Your choice of sites is skewed towards lower concentrations and generally avoids emissions from smelters and integrated steel mills. Because of the general use of tall stacks, EGU emissions will be low at all sites, with the possible exception of Cuyahoga County if the study area were enlarged as suggested in my comments. I suggest you at consider dropping both the proposed WI and IN study areas to give additional areas with multiple monitors and, ideally, increased attention to emissions from integrated iron and steel mills and smelters.

I suggest you consider including the Detroit, Wayne Co, MI study area. It would be useful to have a map of that study area like Figures 4-2 through 4-5 to further evaluate that possibility. If the data from the multiple monitors (6) in this potential study area could all be used in the APEX analysis this would be a strong point for including Detroit as a study area. In addition, if the possibility of looking at the impact of emissions from the Zug island steel mill or the Trenton Channel Power Plant located near the steel mill or the closely located together DTE Belle River Power Plant and St. Clair Power Plant in the northeast part of Detroit existed this would further indicate it would be an excellent study area. The three mentioned EGUs do not have tall stacks and they may contribute to more local impacts. The last point could be determined by examination of the data from the six monitors in Detroit.

I suggest you also consider adding Gila County (Figure 2-18 of the second ISA draft) as a study area. I recognize that it does not include the population minimum of 100,000 you listed in your criteria for a study area (current county population, 53,000). However, it does contain four monitoring site, each of which have 99th percentile 5-minute max concentration above 100 ppb during 2012 – 2015 (Figure 2-18, second ISA draft). It is the only place where exposure of a population to emissions from smelters can be modeled. As summarized in my comments on the ISA and my discussion at the start of these comments, EPA has been charged by CASAC to consider the effect of exposure to particulate inorganic S(IV) compounds in emissions from smelters as “These compounds are potential confounders or moderators of SO_2 health effects in epidemiological studies where copper smelter or integrated steel mill emissions are abundant and the possible influence of these compounds should be discussed.”

If EPA responds to the request to explore the hypothesis that these compounds are confounders of exposure to SO_2 alone and that the effect of the exposure to both is to increase the exacerbation of asthma, then failing to consider smelter emission in the REA analysis will lead to an underestimation of the Lung Function Exposure – Response Relationship and the Lung Function Risk (Figure 4-1). Of course, if EPA does not explore the hypotheses and the hypothesis is correct, the health effects of exposure of asthmatics to SO_2 will still be underestimated by EPA as decisions on the future form of the standard are made.

This will be true no matter how well the modeling exercise described in Section 4.1.3 is conducted.

Section 4.1.3 SO_2 Concentrations in Ambient Air

Section 4.1.3.2, page 4-13. Second paragraph. It is not clear to me that the assumption that “where ambient air measurements are missing likely occur at times where concentrations are relatively low, thereby yielding slightly lower means and standard deviations when comparing substituted data relative to the unsubstituted data” is valid. It seems to me that missing data are due to a monitor problem and not an ambient air concentration condition. What will be the effect if this assumption is not valid and the missing data are high?

I feel uncomfortable with Equations (4-1), (4-2) and (4-3). It seems to me that an important feature of the analysis should be the use of multiple monitors and a study area to predict exposure using AERMOD and APEX. How can 5-minute data from multiple monitors have any comparison value if estimated as outlined. Are we limited to hourly average modeling for sensible results? I will let modelers in the group comment on this.

Dr. H. Christopher Frey

This review focuses on Chapter 4: Plan for the Current Health Risk and Exposure Assessment, on pages 4-1 to 4-30, with a focus on exposure assessment.

The key points from this review are:

- Please explain why there are no plans for exposure assessment scenarios at levels of air quality below the current standard.
- How will the dispersion modeling approach be "supplemented and informed" by air quality monitoring measurements?
- Why use a linear ramp (Equation 4-2)?
- Will (and if so, how) will transport time be accounted for with regard to modeled concentration?
- Page 4-19 – there seems to be some ambiguity between the concept of a design value versus a decision to look at annual data. The rationale here is not stated.
- Figure 4-6: the R2 values do not imply that hourly data are correlated from one year to the next – this needs to be clearly communicated. The meaning of R2 here, as an indicator of similarity in the frequency distributions from one year to another, should be communicated carefully.
- There are some detailed comments on Equations 4-1 to 4-4 and regarding the hour-day-month specific factors. The latter are not clear.

Page 3-9: the new algorithm for resting metabolic rate should be documented, perhaps in an appendix, in the 1st draft HREA unless it is documented elsewhere in a report that can be provided to CASAC (e.g., the documentation of the expected Spring 2017 release of the APEX update). Similarly, updates to the algorithm using V_E (if different) should also be documented.

Page 4-3, the decision to evaluate potential risk associated with air quality adjusted to just meeting the existing SO2 standard (and recent unadjusted air quality) seems appropriate if the question is whether the current standard protects public health with an adequate margin of safety. What about other levels less than the current standard?

Page 4-6: "we are proposing to use the model-based approach to estimate ambient air concentrations in each study area, supplemented and informed by available local ambient monitor measurements." Please explain more clearly how the model-based approach will be "supplemented and informed by" measurements.

Page 4-6 – it would help to say what cities are included in these counties. More broadly, the choice of only four study areas needs discussion, as noted by other panelists.

Page 4-13: "Calculate an average distribution of hour-day-month specific factors using measured values" not clear what is meant by "hour-day-month specific factors." Does this mean factors that are specific to each hour for a given day for a given month? If so, the sample size would be very small. Or does this mean one factor for hour of day, another factor for day of month, and another factor for month of year? Or other?

Page 4-13: "Instances of where ambient air measurements are missing likely occur at times where concentrations are relatively low…" Explain why this is.

Equation 4-1. I finally figured this out, but the nomenclature is confusing. Nomenclature such as this would be more clear:

$C_{i,h,d,m}$	=	estimated concentration for the i^{th} 5 minute interval (I =1,12) in the h^{th} hour for the d^{th} day in the m^{th} month. [or could just be $C_{i,h}$]
$C_{max,h,d,m}$	=	maximum 5 minute average concentration in the h^{th} hour for the d^{th} day in the m^{th} month. [or could just be $C_{max,h}$]
$C_{ave,h,d,m}$	=	hourly average concentration in the h^{th} hour for the d^{th} day in the m^{th} month. [or could just be $C_{max,h}$]
i	=	index for 5 consecutive non-overlapping 5 minute periods in an hour, from 1 to 12.

Thus, Equation (4-1) would become:

$$C_{i,h,d,m} = \frac{\left(12 \times C_{ave,h,d,m}\right) - C_{max,h,d,m}}{11}$$

Or possibly:

$$C_{i,h} = \frac{\left(12 \times C_{ave,h}\right) - C_{max,h}}{11}$$

And so on for the other equations.

Page 4-15: Is there some underlying reason to use a linear ramp? This text just describes the linear ramp but does not offer a reason/rationale for it.

Page 4-16: "Because there is improved representation of 5-minute concentration variability based on the number of measurements in this data set." This is not clear – improved compared to what and in what way?

Equation (4-3) is unclear. For example, n is not defined. Could be more clear, perhaps something such as this:

$$C_{est,h} = \frac{\left(12 \times C_{ave,h}\right) - \sum_{i=1}^{n-m} C_{i,h}}{12 - (n - m)}$$

Where

$C_{i,h}$	=	concentration for the i^{th} *measured* 5 minute interval (I =1,m) in the h^{th} hour
$C_{est,h}$	=	estimated 5 minute average concentration in the h^{th} hour, applicable to each of the n-m 5-minute periods that were not measured.

$C_{ave,h}$	=	hourly average concentration in the h^{th} hour for the d^{th} day in the m^{th} month. [or could just be $C_{max,h}$]
m	=	number of measured 5 minute periods in hour h (must be 11 or fewer).
n	=	number of 5 minute periods in hour h (12).

Page 4-17:
"would" → "will"
"perspective" is vague and unclear → "quantification of"?
Text could address how factors such as complex terrain, built environment, and chemical reactivity and deposition of SO_2 will be addressed. What is known about validation of AERMOD for application to SO_2?

Page 4-18:
"can be" → will be?
"we would need to" → we will?

Equation 4-4: define the units as applicable.

Page 4-19: mention that the temporal pattern from one 5-min period to another at a monitor will be delayed compared to the pattern at the emission source because of transport time. For example, for a wind speed of 2 m/s, an air parcel would be transported 600 meters. Thus, a change in emission rate would manifest as a change in concentration 5 minutes later at a distance of 600 meters, 10 minutes later at a distance of 1,200 meters, and so on. At one hour, the air parcel would be 7.2 km from the source, which would likely still be within the study region. Thus, at a wind speed of 2 m/s, it is likely that the maximum 5-hour concentration would be misclassified by one hour compared to the timing of the emissions that lead to such a peak. Or, to put this another way, simulated emissions at hour h would lead to downwind air concentration at hour h+1 at a distance of 7.2 km to 14.4 km. Does this matter to the exposure assessment? If so, how much? For sources that emit approximately continuously, exposure concentration errors would have less error than for sources with more pronounced short-term temporal variation. Perhaps it can be argued that industrial sources that are the main sources of SO2 would be operating approximately continuously. More information about the load or emissions profile over time would be helpful.

Section 4.1.3.4 – page 4-19: as noted earlier, please explain the purpose of "air quality adjusted to just meet the existing primary SO2 standard, as well as for recent (unadjusted) air quality." Why not also look at air quality below the existing standard?

Same paragraph – design values are based on three years of averaging, but it is not clear that this text is using the term design value correctly. In a five-year period, there would be three design values, assuming that the three-year average rolls from one year to the next. Thus, there would not be a low concentration "year" but a low concentration 3-year average. Or explain why annual averages are used instead of three year averages, and be careful to clarify the choice of design value as a basis for assessing high or low concentrations in a given year. Please clarify. An example would help.

Page 4-20: Table 4-1 does not show adjustment factors. Need to explain more specifically how an adjustment factor can be inferred from data given in Table 4-1.

Figure 4-6: I think this makes sense from the perspective of evaluating whether two data sets are similarly distributed. However, it should be acknowledged in the text that the data are not actually paired this way. The data in both years have been sorted and the sorted values have been paired to assess whether the distributions are similar from one year to another. This does not imply that the data are correlated. The linear fit and R2 are indications of similarity of the hourly distributions but do not imply that data in one year are correlated with data in another year. Some readers are likely to misinterpret the very high R2 values to mean that hourly data in one year are highly correlated to data in the same hour of a different year, which is of course not valid.

Page 4-23: It would help to either state values of a, P, and k or, if these values (and distributions) have been developed and reported elsewhere, cite references for the values (and distributions) to be used. Or otherwise give more insight as the basis of these.

Page 4-28: a comparison of APEX model results (for PM2.5) based on using the Markov-chain clustering (MCC) algorithm, diversity and autocorrelation approach, and random resample is given by Che et al. (2014) (Risk Analysis, 34(12):2066-2079).

Dr. Steven Hanna

Note that my expertise is primarily in atmospheric transport and dispersion modeling and analysis of observed concentrations, and my comments focus on those areas. I was asked to comment on the areas related to “Ambient Air Concentrations”, and focus on three specific topic areas copied below in bold italics.

First I have a general request: Please explain why my suggestions on the SOx ISA were not followed here. These comments regarded better use of the literature and existing methods for estimating peak to mean concentrations and space and time variability of concentrations (the EPA work on 5 min vs 60 min peak concentrations appears to have been done without a general review of the topic).

Ambient Air Concentrations

1. The use of an AERMOD model-based approach to predict hourly concentrations at all receptor locations within selected study areas [Sections 3.3.2, 4.1.3.3]

I agree that, of the existing recommended suite of EPA air quality models, AERMOD is best and that AERMOD has a basic averaging time of one hour. CMAQ is certainly not applicable. However, line 4 of p 3-7 suggests that a comprehensive review has been done. If that had happened, the EPA authors would have discovered that most dispersion models used by other agencies can easily model smaller averaging times such as 5 minutes. SCIPUFF is a good example, and I thought that SCIPUFF/SCICHEM was on EPA’s list. From a basic science viewpoint (see dispersion texts by Pasquill, Stull, Arya, etc.) the models for industrial sources can apply to any averaging time. What is needed is parameterization of how turbulence and turbulence scales vary with averaging time, and this is known and parameterized in models such as SCIPUFF. AERMOD includes these parameterizations in order to provide required turbulence inputs. These formulations are “hidden” within the AERMOD software and operational users are not able to change them.

On 16 March, I confirmed the above facts during phone calls with Jeff Weil, former leader of the AERMIC group that developed AERMOD, and Akula Venkatram, former member of AERMIC who developed many of the AERMOD algorithms. I suggest that a subcommittee be formed to advise EPA on these key scientific facts.

I also asked David Carruthers, ADMS developer (in the UK), and he replied that ADMS has adjustments to plume width to account for varying averaging times (less than 1 hr). ADMS is the equivalent of AERMOD and is widely used as a regulatory model in Europe and Asia.

All plume dispersion experts agree that the ratio of 5 min to 1 hr peak concentration is dependent on stability (i.e., time of day and wind speed and cloudiness) and on nearness to major point sources or industrial complexes. The largest peak to mean ratios occur near large point sources during meandering conditions, which are known to have periods of about 5 to 10 minutes.

The estimation of 5 min values described in section 4.3.3 should also incorporate scientific knowledge

By the way, we feel that the EPA allegation (e.g., line 6 of section 4.1.3.3) that AERMOD is fine for showing spatial variability but does not show time variability is not a correct generalization and is at odds with our basic science concepts. Network observations and model simulations verify a large diurnal variability in SO_2 concentrations.

As described on p 4-18, it is a good idea the evaluate the model predictions with the 1 hr and 5 min observations. However, the 1992 EPA model performance measures have been revised as described in the 2005 AERMOD evaluation report and journal article.

p 4-18, first sentence of second paragraph – As described above, the EPA should at a minimum acknowledge that this purely-statistical and arbitrary approach could be enhanced by revising AERMOD to calculate 5 minute concentrations, following existing methods in SCIPUFF, ADMS, and most other dispersion models used across the globe. AERMOD already has the basic turbulence parameterization formulas and they can be easily modified to allow for averaging times other than 1 hr. Also, the preprocessor AERMINUTE can provide one-minute averaged wind inputs.

p 4-19 top half of page – Here too there is a need to use existing basic science concepts. Maybe the basic science approach does not give significantly different improvements over the arbitrary statistical approach. But the comparison exercise should be used to demonstrate this.

2. The use of SO_2 measurements at ambient air monitors within and near the study areas to estimate 5-minute concentrations, where appropriate (e.g., filling missing values for AERMOD hourly predictions) [Sections 3.3.1, 4.1.3.1, 4.1.3.2]

My main comment on this has already been stated in my general request at the beginning. In scientific studies, it is required that the existing literature first be reviewed. Gifford (1960), Slade (1968) and Turner (1970) all discuss observations of peak concentration variation with averaging time and propose some simple formulas. Ralph Larsen (career employee of EPA) spent decades studying this topic and published many papers. (e.g., see his paper on the log-normal distribution in the 1974 symposium proceedings referenced below). The literature from 40 to 50 years ago suggests that, on average, peak concentration is inversely proportional to averaging time (T_a) to the 1/5 power. Thus peak C (5 min)/peak C (1 hr) would be about 1.6. More recent papers suggest a power of ½ could also be used for certain types of sources, which gives a ratio of 3.46. In the current report, the EPA should have first reviewed the literature (inside and outside EPA), then describe where the existing methods are not appropriate, then justify why an alternate method is being used. Finally, the estimates of the new method should be compared with those of the old methods.

Section 4.1.3.2 addresses estimating missing values in the air monitoring data. This problem often comes up in all fields of environmental study. However, in the atmosphere, there is a need to preserve known correlations in space and time, and these are followed in several EPA analyses that I have reviewed. But I do not see those principles being followed here. For example, persistence or linear interpolation are usually assumed if there are only a few missing data. If available observations are indicating a high-pollution afternoon, then any missing data are likely to be high too. The current EPA report's method seems to go back to climatological values.

Similarly, the method on p 4-15 for "filling in" the missing 11 5 minute values, when only the max 5 minute value in an hour is reported, is non-scientific. At the minimum, use the known probability distribution function (pdf) of concentration variability (e.g., log-normal is often used). Known correlations (in time) among 5-minute values could be incorporated too.

3. The proportional approach selected for adjusting ambient concentrations to simulate air quality that just meets the existing standard [Section 4.1.3.4]

I have no comments since I am not sure of the rationale behind what is being done in this section.

Additional comments on the first part of the document (not covered under topic areas discussions)

p 1-2, lines 9-10 – "Advances in modeling tools and techniques and air quality data that have become available since the last review are also considered" – This statement implies that there has been a comprehensive review of the field in general; however, the current report suggests that, in my topic area, only internal EPA documents and work have been considered.

p 1-4, lines 13 – 15 – I disagree with this statement that "concentrations of SO_2 in ambient air do not exhibit consistently strong temporal variability over daily or seasonal time scales…" Maybe this is true for samplers in rural areas with no industrial sources nearby, but it does not apply in urban or industrial areas or within 20 km of large point sources. And I notice later that the regions being considered for further study are all urban metropolitan areas and include large point sources.

p 1-7 References – All references are to EPA reports instead of to general (possibly outside of EPA) relevant reports and papers.

p 2-24 References for EPA 2009 REA review section – There are no basic references on atmospheric processes, dispersion models, or statistical analysis of air quality data provided.

Chapter 3 introduction paragraph (p 3-1) and Conclusions Section 3.5 (p 3-10 and 3-11) – These sections emphasize that "newly-available information" is being assessed with respect to its potential effects on risk assessments. The EPA apparently is defining "new information" as that developed within their group (e.g., more 5-minute concentration data and revisions to AERMOD and its processors). I would hope that EPA would also consider relevant information from groups outside of their agency (and outside OAQPS). For example, the dispersion models of most European countries can model concentrations at a variety of averaging times, including less than 1 hour. Within the U.S., the DOD's SCIPUFF dispersion model can also handle any averaging time (following the theoretical derivations in basic turbulence and dispersion textbooks such as Pasquill, as well as fundamental dispersion formulas by Taylor, Batchelor, and Richardson). Note that a version of SCIPUFF called SCICHEM is an alternate model available from EPA.

Chapter 3 References include no "non-EPA" studies of statistical analysis of air quality data, and do not include the various recent updates to the AERMOD dispersion model itself.

References

EPA, (1974). Proceedings of Symposium on Statistical Aspects of Air Quality data. Chapel Hill NC Nov 1972, EPA-650/4-74-038 Environmental Monitoring Series, 270 pp. https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=2000X6RH.txt.

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Slade, D.H. (1968). Meteorology and Atomic Energy, U.S. Atomic Energy Commission (No. TID-24190). *U.S. Atomic Energy Commission*, pp 109-111, 154-156.

Turner, D.B. (1970). Workbook of Atmospheric Dispersion Estimates (No. 999-AP-26). *U.S. Environmental Protection Agency*, pp 37-38.

Dr. Jack Harkema

Analytical Approach and Study Area Selection

1. *The overall analytical approach for the Risk and Exposure Assessment (REA) and its appropriateness for developing spatially and temporally varying 5-minute ambient SO_2 concentrations, simulating population-based 5-minute peak exposures, and estimating study areas health risk based on controlled human exposure study data [Chapter 4].*

2. *The criteria identified and approach used to select potential study areas to evaluate for this REA [Section 4.1.2].*

Comments and Questions to be considered:

In Chapter 4, the authors should provide more rationale and justification for limiting the main objective to characterize exposure and health risk associated with SO2 from ambient air under conditions just meeting the current primary standard. Why not include conditions below the primary standard?

On page 4-22, the microenvironments appear to be selected primary for adult asthmatics rather than asthmatic children (e.g., day schools, preschools, elementary schools). Does the analytical approach have a built in bias for adult rather than childhood asthma?

Since obesity is more prevalent in children and adults (including those with asthma) then when the controlled human exposure studies were conducted, how will the proposed risk models take this into account?

Dr. Farla Kaufman

Health Risk Assessment

1. The general structure and overall approach that staff plans to use for the risk assessment. [Section 4.2]

The general structure and overall approach as outlined in section 4.2 of the planning document seem appropriate and clearly laid out.

2. The approaches for using findings from the controlled human exposure studies.
a. The health benchmarks identified for this REA. [Sections 3.2.2, 4.2.3]

Generally, the approaches for using findings from the controlled human exposure studies with regard to identifying health benchmarks seem appropriate. However, I would add the following caveat.

The REA states there is no evidence to indicate that individuals with severe asthma "would experience moderate or greater lung function decrements at lower SO2 exposure concentrations than individuals with moderate asthma". However, based on the available data there is not sufficient evidence to the contrary. As noted in the REA individuals with severe asthma are not generally represented in the controlled human exposure studies (second draft ISA, p 5-21). The effects of exercise and SO2 exposure in this population are not sufficiently understood, thus have the potential to influence these benchmarks.

Also, noted in the REA (section 4.2.3.2. footnote 55), "that studies utilizing a mouthpiece to deliver pollutant concentrations cannot be directly compared to studies involving freely breathing subjects, as nasal absorption of SO2 is bypassed during oral breathing…" Although the comparison may not be directly made, the ratio of nasal to oral breathing shifts during exercise where there is more oral breathing if not all oral breathing. This would seem to be informative to conditions of breathing through a mouthpiece.

b. Plans for developing updated exposure-response functions, including the methodology, and specific studies to be relied on, for estimating exposure-response relationships for lung function decrements. [Sections 3.2.2, 4.2.4]
i. The focus on specific airway responsiveness (sRaw) for this quantitative risk assessment of short-term exposure-related endpoints,
ii. The range of exposure concentrations appropriate to include in the dataset for deriving the exposure-response function.

The data seem to support the proposed focus on sRAW for this quantitative risk assessment in terms of short-term endpoints.

The approach for selecting the range of exposure concentrations to include in the dataset seems appropriate and well-reasoned.

The additional analyses, deriving the E-R functions with and without higher exposure concentrations, seems important to investigate based on the 2009 REA and from the results presented in Figure 4-7 and Table 4-7.

3. The approach for assessing variability/co-variability and characterizing uncertainty in each part of the risk assessment and the approach for model sensitivity evaluations. [Section 4.4]

In some instances, more recent survey data is available for factors such as physical attributes. Use of more recent data could reduce variability and should be used whenever it is available.

> Body weight and surface area: Each simulated individual's body mass was assigned using body mass distributions from the 1994-2004 NHANES data. More recent data is available and show a change in the body mass distributions. Presumably using more recent data could change the age- and sex-specific estimated BSA.
>
> Recent data from the National Health Interview Survey show a higher prevalence of asthma in Blacks especially in Black children (15.4%).

Uncertainties exist in many areas of risk assessment for children when using adjustments factors applied to data from adults. Many differences between adults and children may influence children's responses such as lung development throughout childhood, and breathing patterns in children during exercise (which also may be influenced by other factors, e.g. gender, race, overweight/obese status). These factors should be considered either quantitatively, where feasible, or qualitatively, where not.

Factors influencing asthma prevalence should also include race and obesity (4.1.6.2.).

This draft REA is based solely on exposure to sulfur dioxide. As known, exposure to mixtures of air pollutants, is the real world experience and may have greater health impacts than exposure to single pollutants. Thus, co-pollutants should not only be considered as confounders, but recognized as potentially modifying factors of the response to SO2 exposure, e.g. potentiating or acting synergistically.

<u>Other Comment</u>

Many sections of the document are well written. However, there are sections that could be written in a clearer manner, as they require much deciphering to determine the information being conveyed (e.g. 3.2.2.).

Dr. Donna Kenski

Analytical Approach and Study Area Selection

The overall approach seems sound and Chapter 4 starts out with a fairly clear description of the process, but loses some of that clarity in the sections on adjustments to ambient data, as noted below. I liked the choices of study areas, although it may be my Midwest bias. The criteria for selecting them were clear and rational. Terrain wasn't mentioned as a possible complicating factor; should it be?

Ambient Air Concentrations

1. Use of AERMOD: Based on what was presented in the REA and ISA, AERMOD seems like the only reasonable choice, and the ISA did a good job documenting its strengths and some remaining weaknesses. However, the panel discussed the possibility of modifying AERMOD to model 5-minute data, instead of using the convoluted data adjustment procedures outlined in the REA. If feasible, that would be a better approach; if not, the data adjustment processes need much better documentation and explanation.

2. Use of SO2 measurements from ambient monitors: The processes described in Section 4.1.3 on adjustments to the ambient data, then to the modeled data, were quite confusing. A diagram might help readers keep the various steps straight. I understand how the 5-minute ambient data estimation process works but not why it is being done this way. Some additional explanation is needed. For example, why are two different methods being used to fill in the missing data? Despite the stated goal of maintaining the features and bounds of the existing monitoring data, neither of the 2 equations used to estimate 5-minute averages yield realistic-looking data. The use of two different equations needs to be justified. If the goal is just to fill in with values that add up to the 1-hour average, then one method of expanding the data should be sufficient. Explain what advantages are conferred by using multiple methods, and why there is no effort to generate a realistic distribution of the expanded data.

3. Proportional approach to adjusting data to just meet the standard: This method is straightforward and worked well for the last review. I see no reason to change unless issues arise once the actual analyses are underway.

p.4-13, line 9: transpose is the wrong word. Perhaps you meant transfer or translate?

p. 4-16, last line: delete either

Dr. Elizabeth A. (Lianne) Sheppard

Exposure Analysis

Charge Question 1:

Overall the approach seems reasonable. We want to think about areas that are representative as a distinct consideration from those that have data. While without data to do a quantitative assessment this can only be discussed qualitatively, such a qualitative assessment should be covered in the REA. (See comments on exposure representativeness below.) The population size cut-off is reasonable based on discussion at the meeting indicating that low population areas aren't very informative. Consider reporting proportions in addition to absolute numbers as a way of facilitating broader interpretation. I agree with simplification of microenvironments.

Charge Question 2:

The selected population groups seem reasonable. Some modifications to the approach, e.g. in sensitivity analyses, may help foster a generalizable interpretation. For instance, consider using prevalences from other areas in an effort to make the results more nationally representative. Also consider using different assumptions for population density and proximity to monitors to make the results more nationally representative, as well as other environmental justice considerations. I note that the population characteristics can be separately overlaid on the areas since these are simulation studies. While choosing areas is limited by monitoring data, since the population information could be overlaid in other ways, this will facilitate more nationally representative estimates.

<u>General comments in the following bullets:</u>

Comments goal: Think about what analyses (e.g. sensitivity analyses) should be considered to enable the REA to address the protectiveness of the standard for public health and to ensure analyses are nationally representative

- Calibrating and getting 5-minute averages:
    - Filling in 5-minute data from the 1-hour average and 5-minute max:
        - Is it worth doing a more extreme approach where the 2nd 5 minutes is close to the maximum, as long as the mean is not exceeded, then continue until the remaining 5-minute values are 0 or small?
        - Alternatively use an exponential ramp? Is this also more extreme than the current approach?
    - Calibrating: Consider using measurements to adjust AERMOD values, calibrating them to measurements at nearby monitors.
- Asthma prevalences: Consider prevalences for other areas (e.g. places with higher prevalences) to address national impacts? Also obesity distributions from more obese locations? We can also consider other environmental justice types of considerations.

- Approaches to using findings from controlled human exposure studies. (Notes from the meeting discussion)
  - Roughly 6 m children with asthma. Doubling airway resistance will make individual asthmatic children symptomatic. How we extrapolate to children from the (healthier) adults with asthma in the controlled exposure studies is an important consideration.
  - Is there a threshold? In the population, there will be someone at risk at every exposure, so on a population level probably no threshold exists.
- Representativeness of exposure
  - We'd like areas to be studied that will facilitate us to extrapolate to the entire US. However, it seems that the areas to be studied all have sources. Is it worth quantifying the proportion of the US population within 10 km of sources?
  - Monitors: Which are source-oriented, which are population oriented? How relevant is this to the REA?
  - DV areas: How many areas exceed the DV by more than the upper limit used to select areas? How should this understanding be incorporated in the REA? Or does it belong in the PA?
- Assessing variability, characterizing uncertainty, and approach for model sensitivity evaluations
  - I suggest adding a table of key sensitivity analyses, and assumptions, particularly those that are expected to be important drivers of the results.
  - Given the health effect evidence is from controlled human exposures, I believe impacts of co-exposures can only be addressed as a source of uncertainty.

<u>Comments on Chapter 4</u>

Overall I thought the chapter was straightforward, easy to read, and covered the important issues. I have a few suggestions for changes that I hope will improve the document and ultimately the REA.

- Table 4-1, pdf p 64: I missed clearly understanding the number of monitors in a group and its misalignment with the monitors shown in the sample maps. Consider whether updates to the text will help document readers. If helpful, I suggest adding the number of source-oriented monitors in parentheses to the number of monitors column.
- Pdf p 70: I suggest (if feasible) the approach to filling in missing monitor data consider using local data, e.g. from the nearest monitor of the same type. This will be less smooth than the approach described.
- Pdf p 70: The discussion of why the 95^{th} percentile is lower once the missing data have been filled in is reasonable. It would be worth having a bit more documentation of this assertion since the focus of this work is on modeling exceedances.
- Pdf p 74, 4-17: It will be interesting to learn what the preliminary model runs show about how to best capture concentration gradients.
- P 4-20, pdf p 77: I don't follow how Table 4-1 shows the ambient air concentration adjustments will be small.
- Figure 4-6: I suggest ensuring the axes are identical and adding 1:1 lines so the multiple plots on a page can be interpreted more easily visually.
- Pdf p 82: The balance of benefit with practical considerations seems appropriate.
- Pdf p 83: Something is wrong with the wording of the last sentence in the first paragraph.

- Pdf p 86: It would be helpful to provide the reader with some context for the scale or range and interpretation of typical values for A and D.
- P 87 2nd paragraph: Is there something missing before “several”?
- P 87: While I agree the person-occurrences statistic is less informative than the count, including it would provide complementary information and should be considered for inclusion.
- Pdf p 93: Given the sensitivity to the E-R function used, I agree with the plan to incorporate sensitivity analyses to better understand the result of different E-R estimates.
- P 98: While there is good experience with the models and results from previous REAs, would it be worthwhile to list our expectations for the most important sources of variability or uncertainty? Also, is it worth considering some sensitivity analyses to address important sources of variability and uncertainty, particularly for quantities that are modeled based on assumptions?

Dr. Frank Speizer

Chapter 2

This is an excellent summary of what was done for the REA 2009 and provides an excellent road map of how to proceed with this current REA assessment. Both details of analytical procedures as well as limitations are discussed. The main issue in redoing this will be the hopefully far increased data base on 5 minutes (and 1 hour) daily averages and max/day.

Chapter 3

I would concur with the staff summary that the issues of change as summarized in chapter justify a redoing of the risk estimates. The two main issues are the far greater data base on 5 minute so2 measurements and thus the ability to quantitatively reduce uncertainty in the estimates at or around the current standard (75ppb hourly). There will still be a range of values that will need to be studied. In addition, I would hope to see in Chapter 4 a discussion of relooking at the form of the standard (5-min vs. 1-hour) as well as the number of exceedances above 98%ile vs 99%ile.

Page 4-3, Use of APEX model seems justified

Page 4-5-6. The criteria for selection of potential sites seem reasonable down to 9 potential sites. Going from 9 to 4 seems more arbitrary and raises some concern, particularly as 3 or the 4 sites are contiguous with large bodies of water. The demography of the places selected also could influence results as the asthma rates may be particularly high and the proportion of African American will also be high. Need to discuss: why not use all 9 sites? It would seem to me that once the programs are written one need only turn the crank. –I think I now understand better why only 4 sites are planned. However, I am still concerned about the fact that 3 of 4 are near water and thought the suggestion at the meeting by Dr. Sheppard was a good one.

Page 4-14, Table 4-2: Are not the Maximum values the same by design? It would not appear that a max could be estimated from missing data. If so, slightly misleading to put in table.

Page 4.16, 4.17 Table 4.3-4.4: For those of us that are naive re the use of formula 4.3 please plan for someone to demonstrate the calculation that produces the constant values in 4.3 for <2x only vs. in 4.4 for all four columns for C 1…C x.

Page 4.33 1st full paragraph. This paragraph discusses range of calculations as 100-400 ppb. Justification for lower bound is that group analysis at 200ppb is not significant. However, it is known that there are a small but significant number of individuals that do respond below 200 and thus under best case scenario and with an adequate margin of safety should be protected. I suggest we need to quantify how large this group is to justify not protecting them; and therefore recommend that the analysis be run to 50 ppb.

Page 4.34 end of first paragraph Description of how individual data will be used to construct APEX score raises concern about what will be categorized as responsive. For example, in the Linn 1987 paper there are among the 40 asthmatics (mild=16, severe=24) several who responded to 0.2 with more than a 0.5l drop in FEV. (Although average drop was only about 150 cc.) See above comment as I think this relates.

Section 4.2: Despite the numerous criticisms and comment above I found this whole section well written and the logic appropriate. One concern is that as far as I can tell all of the human exposure data that will be utilized is in adults with and without asthma. However, in section 4.2.4.2 mention is made of calculations for children and it is not clear what data base is being used for that. I suspect it is extrapolation of data from adults and if so should be stated.

Section 4.3 Discussion of Variability and Uncertainty. It is not as clear as it might be the relation between these two concepts. That is, how does variability influence the characterization of uncertainty? When the calculation crosses the null it DOES NOT mean that the presence of an effect is null. Rather that, in most cases, there is insufficient data or too much variability for the amount of data there is to be confident of the central tendency and thus the magnitude of uncertainty will be higher. This will need to be expanded upon and discussed.

Dr. James Ultman

Health Risk Assessment

Exposure analysis:

Benchmark levels used in the exposure analysis are apparently based on bronchial constriction measurements made on adult asthmatics (pg 4-33, para 2). It is erroneous to think of children simply as small adults. For several reasons, children are probably more vulnerable to SO_x than adults. Very important are ontogenical factors such as maturity of the immune system and airway anatomy (e.g., Foos, et al., 2008, J. Tox. Environ. Health, 71;149-165). Perhaps an additional lower benchmark level should be added to the exposure analysis to deal with our uncertainty of a child's response to SO_2.

Exposure-Response Relationship:

In developing an exposure-response relationship, bronchial constriction rather than FEV_1 decrement will be used as the response variable (pg 4-35, para 2). To support this decision, it would be useful to provide regressions, such as those in figure 4-7, comparing the two types of measurements. Which of the two response measurement has lower variability? Which of the two tends to be a more conservative estimate of a modification in lung function?

The exposure-response relationship is based on laboratory data taken on adults. It would be desirable to include some discussion of how the relationship might deviate for children. There is a literature on dosimetry modeling that could indicate how factors such as differences in airway anatomy and route of breathing come into play (e.g., Ginsberg et. al., 2008, J. Tox. Environ. Health, Part A, 71:166-195).

To evaluate how uncertainties in the exposure-response relationship affect the health risk calculation, particularly at exposures below 200 ppm where no data is available, the response of a single exposure bin will be set to zero (pg 4-43, 2nd bullet item). Another approach would be to use the confidence limits of the regression to examine upper and lower bounds of the errors in the health risk associated with variability of the data.

Dr. Ronald Wyzga

Overall, I believe that the plan describes a reasonable approach. Its implementation will involve many specific decisions and details that will merit further examination and be reviewed by the Panel.

Specific comments:

SO_2 emissions and levels have changed dramatically over the recent past. It is important that the REA use the most recent estimates of SO_2 emissions and exposures. For the former, see the comments of Dr. Chow on the second draft of the ISA.

The combination of a model-based approach supplemented by ambient measurements appears to be the only way to estimate the needed exposures. I would hope that some effort is expended to evaluate the implemented approach by possibly applying the method without the use of data from one monitor in an area where more than one set of monitoring data are available to see how well the chosen method predicts monitored values.

p. 4-18: It is stated the "Model performance…can be evaluated." I believe it should be evaluated.

p. 4-22: I believe that exposures for the Indoor MEs will be much lower than the outdoor MEs. For that reason, I suggest that minimal effort be expended on the indoor MEs. I would support Staff efforts to take shortcuts in addressing potential exposures for these MEs.

p. 4-42: I believe that uncertainty analyses and sensitivity analyses should be undertaken to provide as quantitative as possible estimates of uncertainty associated with the risk assessment outputs. In some cases, a qualitative approach may be the only possible approach, but I urge that a quantitative approach be applied to the fullest extent possible.

With respect to the choice of study areas, I believe the suggested approach is clearly articulated and is reasonable. My only hesitation is that the study areas are is not geographically heterogeneous.