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US ENVIRONMENTAL PROTECTION AGENCY
SCIENCE ADVISORY BOARD (SAB) STAFF OFFICE
CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE
(CASAC)

OXIDES OF NITROGEN PRIMARY NAAQS
REVIEW PANEL PUBLIC MEETING

MARRIOTT AT RESEARCH TRIANGLE PARK

4700 Guardian Drive

Durham, North Carolina 27703

OCTOBER 25, 2007

8:36 A.M.

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1 U.S. ENVIRONMENTAL PROTECTION AGENCY
 2 CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE
 3 PUBLIC MEETING
 4 OCTOBER 25, 2007
 5 DR. HENDERSON: I want to thank everyone
 6 for being so timely in submitted your paragraphs to
 7 Angela, and I thank Angela for bringing it all
 8 together. Now that what's being distributed - -
 9 SPEAKER: Hello?
 10 DR. HENDERSON: Hello.
 11 SPEAKER: Rogene, can you, you need to
 12 speak into the microphone.
 13 DR. HENDERSON: Okay.
 14 SPEAKER: Thank you.
 15 DR. HENDERSON: What's being passed out
 16 is a compilation of what was submitted, and these are
 17 all, everything, it's truly a compilation, but I've
 18 read it through it, and I compared it with the list,
 19 this small list is, these are the points we listed
 20 yesterday afternoon that we thought should be included.
 21 So, you might, quickly, compare this list with what's
 22 in, what you'd submitted to see if we left anything
 23 out.
 24 But the consideration that we're going to be
 25 making is, is this the substance, does this include

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1 everything you want to say to the Administrator in our
 2 letter. And, it's not the exact words, because Angela
 3 and I will have to go through and make it sound like it
 4 was written by one person instead of a committee.
 5 But, that is, it's not, it's going to be
 6 smoothed out, but does it contain the substance of what
 7 we want to say? Can we agree? Do you feel comfortable
 8 with what is written here as a compilation of
 9 everything that we want to say to the Administrator in
 10 terms of our peer review of the first draft of the ISA?
 11 And, while you're reading that, I think with, I'm going
 12 to, I have neglected to let Angela do a roll call of
 13 who's on the phone. So, I will turn it back to her
 14 while you're reading it.
 15 DR. NUGENT: Thank you, Rogene. As we
 16 start this second day, and we complete the discussion
 17 of the ISA, and then move ahead to the discussion of
 18 the methods document, I wanted to welcome the people
 19 on
 20 the phone, and make sure everyone in the room knows
 21 who's on the phone, and then talk a little bit about
 22 the public comment period, here. So, may I ask,
 23 please, what CASAC panel members are on the phone
 24 today? Are the CASAC panel members on the phone
 25 right
 26 now?

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1 DR. NUGENT: Good morning.
 2 DR. LARSON: Tim Larson.
 3 DR. NUGENT: Good morning.
 4 DR. ULTMAN: Jim Ultman is.
 5 DR. NUGENT: Jim?
 6 DR. HENDERSON: Jim Ultman.
 7 DR. NUGENT: Ultman. And, Lee Anne, are
 8 you on the phone? Okay, all right, and just a note
 9 about public comments. I'd mentioned yesterday that we
 10 were inviting public comments on yesterday's discussion
 11 relating to the ISA. No member of the public has asked
 12 me to speak this morning about the ISA. I'll ask one
 13 more time, because we want to be a little structured
 14 about how the discussion proceeds. Are there members
 15 of the public who'd like to present some comments?
 16 MR. HICE: Angela?
 17 DR. NUGENT: Yes?
 18 MR. HICE: This is John Hice on the
 19 phone.
 20 DR. NUGENT: Yes?
 21 MR. HICE: I'd like to make a very, very
 22 short comment, if I could.
 23 DR. NUGENT: Thank you, okay. I'll write
 24 that down, and we'll turn to you in a moment.
 25 MR. HICE: Thank you.

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1 DR. NUGENT: Let me also mention that we
 2 didn't explicitly list on the agenda public comments
 3 for the methods document. And, I would like to know
 4 whether, once we complete this ISA discussion, there
 5 are members of the public who'd like to present some
 6 brief comments on the methods document. Okay, hearing
 7 none, I think we should proceed. Rogene, John Hice has
 8 some remarks, and I propose that we take them now.
 9 DR. HENDERSON: Now would be a great
 10 time.
 11 DR. NUGENT: Thanks. I think your
 12 audio's working well for us here, so please, speak into
 13 your phone set, and we'd love, we'd like to hear your
 14 comments now, please.
 15 MR. HICE: Thank you very much. I just
 16 wanted to reiterate that we'll be providing written
 17 comments for the record to EPA by that deadline, it was
 18 October 31st. And I'm sure several other groups will
 19 also. And I would just ask that the CASAC folks take a
 20 look through those comments, at their convenience, and
 21 add those thoughts to their own as they think about the
 22 review of the next draft. That's all.
 23 DR. NUGENT: Thank you.
 24 DR. HENDERSON: And I thank you, too. I,
 25 now, can people hear me if I hold the mike up like



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1 this?
 2 SPEAKER ON PHONE: It's fine, Rogene, for
 3 me.
 4 DR. HENDERSON: Okay, that's good. This
 5 is probably easier than dragging that hand mike. Okay,
 6 have, Angela sent the list of substantive material that
 7 we want to have in the letter to the Administrator.
 8 Have people had a chance to look at it?
 9 SPEAKER: Rogene, you talking about the
 10 short list or you talking about the big one?
 11 SPEAKER: Big one.
 12 DR. HENDERSON: I kind of meant the big
 13 one. This list, this small list, that doesn't have a
 14 time on it, is just the notes I jotted down when we
 15 were talking at the end of the day yesterday, when I
 16 said, you know, what are the substantive issues we want
 17 to convey to the Administrator. And these are simply
 18 my notes. We were in agreement yesterday that this
 19 list included everything we wanted to say.
 20 Now, would, what I'm asking you, now, do you
 21 think these were captured in the more formal listing
 22 that Angela pulled together from the people who
 23 summarized each charge question? Well, that's a good
 24 idea. Though some of these overlap quite a bit. We
 25 have charge question one that, have you had a chance to

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1 look at it? Would you like to have ten minutes just to
 2 look at this one, okay. Gary's nodding his head.
 3 Okay, let's, we will just, we're not breaking. We're
 4 just giving you time to read it, because this is
 5 important enough. I'd like for you to have had a
 6 chance to look at it carefully.
 7 (WHEREUPON, the members read the document.)
 8 DR. HENDERSON: I gather from the
 9 conversation that is starting that people are
 10 approaching the end of their reading. Are you about
 11 ready to move on? Okay, what I'd like to hear from you
 12 first is, is there anything left out of this that
 13 should be added?
 14 SPEAKER: Are you asking just about
 15 question one, or about all of the questions?
 16 SPEAKER: Let's go question by question.
 17 DR. HENDERSON: You want to go question
 18 by question? Okay. We'll take charge question one.
 19 Is the response written her, does it include everything
 20 that you think should be included? Ron?
 21 DR. WYZGA: One of the things that I
 22 think could be useful could be, if they could have more
 23 quantitative discussion about the rates of
 24 transformation of, I guess, emissions into different
 25 species of NOx and what are the influences on these

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1 rates. I don't know if that information is available.
 2 It's not my area quantitatively, but I was looking for
 3 it, and I didn't see it in there.
 4 DR. HENDERSON: Okay.
 5 DR. CRAPO: Also, with respect to
 6 question one, I think that this is an appropriate place
 7 where we need to ask if there could be a better
 8 assessment of issues related to background, and peaks,
 9 and variations in exposure, more data about the
 10 variations in exposure across groups, so that we know
 11 what the, what percent of, or some idea about what
 12 fraction of the country are people, or indoors, or
 13 outdoors, is exceeding, or not exceeding the current
 14 standard, but substantially higher than the current
 15 annual average. So, that the, the focus on an average
 16 annual number makes it really hard for me to analyze
 17 what the exposures really are. So, I think we need
 18 more data on that side of the table.
 19 DR. HENDERSON: Okay.
 20 SPEAKER: Well, I think that actually
 21 falls directly under question two.
 22 DR. CRAPO: Two, that be great.
 23 SPEAKER: That's where ambient mon-,
 24 concentrations are. Some of it's there, but maybe just
 25 what more might need to be there.

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1 DR. HENDERSON: Okay, we're looking at it
 2 again. We come to two, does anybody else have things
 3 on one, yes, Terry?
 4 DR. GORDON: Just the general, when I
 5 read over this, I got the feeling that we were, I mean,
 6 it's, the ISA is supposed to help us assess things, and
 7 seems like some of the things asked to be added were
 8 just making it more criteria document like, just making
 9 it longer, and not, not helping us decide things.
 10 DR. HENDERSON: Well, that's the strug- -
 11 DR. GORDON: Just a caution.
 12 DR. HENDERSON: That's the struggle
 13 that's going on, and some of this might go in the
 14 annex. I mean, but, we ask that it be condensed, and
 15 that the only policy relevant information given. And
 16 what you're saying is, now, we're asking to expand it
 17 in - -
 18 DR. GORDON: In some areas.
 19 DR. HENDERSON: In some areas. Mary?
 20 DR. ROSS: Well, that was a point of
 21 clarification I was going to ask for in general. It
 22 says in the ISA's to include material. Maps, in
 23 particular, will make it longer. So, one of the
 24 questions is, can we balance between annexes and have,
 25 expand the ISA a little bit more, but add more of the



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1 annexes, too, and just a clarification if that's what
 2 CASAC means when they say in the ISA, or it really mean
 3 in the ISA.
 4 DR. HENDERSON: Okay. That's a very good
 5 point, and if we say ISA, do we really mean the annex,
 6 so.
 7 DR. WYZGA: And Mary, if these could be
 8 cross references to the annex, I think that would be
 9 helpful, too.
 10 DR. HENDERSON: We'll go on to question
 11 two, because that is what James asked for, you think,
 12 is that included in this answer to question two?
 13 DR. POSTLETHWAIT: Actually, as a present
 14 follow up to James' point, I'm wondering about this
 15 issue about getting a little better handle on, first of
 16 all, exposures. I don't know what data is available,
 17 but even if some relative analyses of speciation of NOx
 18 could be included, just to give us a feel. I mean if
 19 NO2 is 95 percent of it, then the rest of it's fairly
 20 trivial. If it's 25 percent of it, then, you know,
 21 there's certainly other issues to consider. And, I
 22 think those two things ought to be in the ISA, and not
 23 in the annex, so the reader has that, sort of that,
 24 visceral feel as he, as they continue on to the health
 25 effects portions, et cetera.

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1 DR. HENDERSON: Present those, the two
 2 points again, so I'll be sure and get them right.
 3 DR. POSTLETHWAIT: Well, again, to
 4 speciate NOx, whatever's available, and then the issue
 5 of what we know about personal exposure, temporal
 6 paradigms.
 7 DR. HENDERSON: Okay, some of that may
 8 not be available in any of the exploits, but we, and I
 9 agree with you, then, by healing what you want. Yes,
 10 Ted.
 11 DR. RUSSELL: If I might, and this, also,
 12 is captured in response to question three. There's the
 13 discussion about the importance of the height of the
 14 monitors that shows up both in the last, sort of,
 15 section on the response here, as well as in, there's a
 16 fairly large bullet in the next one.
 17 There's, currently, a pretty large section in
 18 the ISA on the impact of monitoring height, and I,
 19 actually, found that was much larger than it should be,
 20 and maybe even a red herring as such, in terms of how
 21 it might be addressed in the ISA. For one, there's a
 22 lot of information out there where you could compare
 23 the values between different height monitors, as
 24 opposed to just looking at one special study where they
 25 did it. Which, I think, would, gives you a biased

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1 view.
 2 So, my recommendation would be much the
 3 opposite as, maybe, minimize this, say that monitoring
 4 height could be important, but if they're going to
 5 address it in the ISA, they should do it in a more
 6 conclusive fashion, and look at more monitors where
 7 this, where they could pick up this impact.
 8 DR. HENDERSON: Okay, I know, Dale, you -
 9 -
 10 DR. HATTIS: Yeah, I want to slightly
 11 disagree with the fact that that's over-emphasized. I
 12 think that's a critical component of the analysis that,
 13 if anything, should be extended to an analysis of,
 14 actually, what the biases are in, as-, you know, would
 15 be, in assuming that the distribution of levels of the
 16 existing monitoring sites are representative of outside
 17 outdoor levels, because it does mean that you can't
 18 really directly com-, without an analysis of that
 19 problem, you cannot directly compare the levels
 20 inferred from monitors with the, it helps you
 21 reconcile, to a degree that it's possible, the, any
 22 concentration response relationships you infer from it,
 23 the epidemiological data, with concentration in your
 24 response you infer from things like the Australian
 25 study and the indoor, other indoor studies, which are

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1 based on - -
 2 DR. RUSSELL: But you now, tremendously
 3 larger impacts horizontally and spatially than
 4 vertically, so I think that that's being blown out of
 5 proportion, versus where you're placing a monitor close
 6 to a road, or you know, four or five hundred meters
 7 away from a road in a park, because that's where you're
 8 going to have the bigger differences.
 9 DR. HATTIS: Well, I think that's, also,
 10 an important area, but this is a systematic error, you
 11 know, and the other may well be much more - -
 12 DR. RUSSELL: No, it's, they're both
 13 systematic.
 14 DR. HATTIS: The health studies are based
 15 upon aggregate exposure, agg-, exposures within big
 16 cities, okay. And those includes both stuff near
 17 roadways and not near roadways. So, essentially, that
 18 tends to be biased by the verticality, although, there
 19 are, in fact, some sub-populations within cities that
 20 are even more exposed, okay, because of their, you
 21 know, proximity to roads. So, I think that the
 22 influences are different, even though there may be a
 23 bigger overall number, ratio in the near roadway, far
 24 roadway. This other effect, really, is a substantial,
 25 why, I say, now, I don't think that it's overemphasized



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1 in the existing document. I would like to see a fuller
 2 analysis of both kinds of effects.
 3 DR. HENDERSON: I want to be sure I
 4 understand what you're saying here. What is the
 5 difference, say, between, you know, vertically. Does
 6 Albuquerque have a different from San Diego, I mean,
 7 they, is that what you're talking about, I mean?
 8 DR. HATTIS: No, no, no. This is a
 9 matter of the fact that, the monitors for all the
 10 cities are high.
 11 DR. HENDERSON: Yeah, and people are
 12 breathing down low.
 13 DR. HATTIS: And people are breathing
 14 down low, so that means that, systematically, the epi
 15 studies are based upon concentrations that are
 16 measured, that are underestimated.
 17 DR. HENDERSON: And what is, what is the
 18 difference, the degree of difference, I mean, that
 19 you're taking?
 20 DR. HATTIS: Well, I think that, that
 21 from the, you know, the brief discussion that I
 22 remember from the ISA, that that difference is two-
 23 three-fold. But that's different heights of monitors.
 24 If you go down to the ground level, it looks like, you
 25 know, that could even be a larger factor. The fact

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1 level, it's fairly sparse.
 2 DR. HATTIS: Well, whatever the best
 3 sources of information are to estimate the effect, you
 4 know, they need to be used. The fact of the matter is
 5 that, the existing epidemiological studies are based
 6 upon, what appear to be, biased measurements of the
 7 concentrations people actually receive. And,
 8 therefore, they are not directly comparable with the
 9 indoor measured concentrations that led to the
 10 observations in the Australian study and in the, well,
 11 Australian study. So, that's a big problem that needs
 12 to be addressed.
 13 DR. LARSON: I'm unaware of any, or many
 14 NO2 EPA monitors that are actually sited on top of it,
 15 is that what we're talking about? I don't think that's
 16 true.
 17 DR. GORDON: Well, it just seems that,
 18 from this discussion, I'm agreeing with Ted, now,
 19 'cause I thought there was a big verticality problem.
 20 And if there is more data out there, this chapter
 21 doesn't get that across to me. It says there's a big
 22 vertical problem, but they might be variable by site,
 23 and that's not brought out. So, maybe Ted's right. It
 24 should be condensed but expanded in other areas. I
 25 mean they both should be discussed.

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1 that it's a systematic, you know, biases of several
 2 fold can have a big impact on what you might infer is a
 3 level that was, you know, protective of public health.
 4 DR. LARSON: This is Tim Larson. I think
 5 the EPA monitors are sited, in most cases, in such a
 6 way that the inlet height biases are not capturing what
 7 you're thinking about, which is the vertical
 8 distribution in urban areas, primarily, in confined
 9 urban areas. And that, I agree, is a significant
 10 gradient that can be threefold. But, you're not going
 11 to see that at most NO2 monitoring sites, because
 12 their, the way their sited, they're, they tend to be in
 13 open areas. And the differences in heights of the
 14 inlets in those are-, in those open areas just don't
 15 capture the kinds of gradients of exposure that are
 16 important.
 17 So, doing an analysis of all the inlet
 18 heights for all the NO2 monitors that EPA has isn't
 19 going to really capture that. And, unfortunately,
 20 there's just not a lot of data on the vertical
 21 distribution of the heights in the urban areas that are
 22 systematically done. We're doing a big study in New
 23 York City right now, trying to capture some of that,
 24 and there is some European data on this subject, but
 25 compared to the data that's measured at or near street

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1 DR. HENDERSON: Well, I hear-, what I
 2 hear people saying is that in urban areas, there may be
 3 a difference in, there may be a problem with the siting
 4 of the monitors, as far as the vertical differences in
 5 concentrations with NO2, but we don't have much
 6 information. I hear people saying, we don't need them,
 7 we don't know if that's true, so would you like, Dale,
 8 in the letter to say that this is a potential problem?
 9 That should be addressed.
 10 DR. LARSON: There is some literature on
 11 this. I mean, if you could cite that, I, there, it's
 12 just not a lot of it.
 13 DR. HATTIS: Well, whatever the
 14 literature is that's relevant to estimating the
 15 population exposures, that are true versus the
 16 population exposures that are estimated in the
 17 epidemiological studies, that's relevant to judging the
 18 levels at which you expect how many of X.
 19 DR. HENDERSON: Sure.
 20 DR. LARSON: But I think I'm on balance
 21 on Ted's, come down on, with Ted on this. I think
 22 relative, the NO2 EPA monitors in urban areas, the
 23 biggest gradients are horizontal. And they're not
 24 proximity to roadway per se. They're, actually,
 25 proximity to confined roadways, where you can get up



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1 factors of three to five times differences relative to
 2 the same traffic, of the same distance from a road in
 3 an unconfined location. So, you're not talking about
 4 twenty percent here. You're talking about three to
 5 five hundred percent differences. And similarly,
 6 factors two to three in the verticality at those
 7 confined locations with height of, those are big
 8 effects, none of which are being captured by any of
 9 this.

10 DR. HENDERSON: For any epi studies,
 11 there's always the problem of exposure. I mean, we're
 12 never happy with the exposure. Now, and, I think this
 13 is an example of some of the issues that come up. I
 14 think it should be mentioned in the letter. As I
 15 recall in reading through the document, it was
 16 discussed quite a bit, but - -

17 DR. LARSON: Well, the inlet height
 18 effect of the monitors is discussed, which I'm not sure
 19 is the important parameter.

20 DR. HENDERSON: I think in the letter, we
 21 do, we confirmed the fact that we are aware that the
 22 exposures, there's always a problem with measuring
 23 personal exposures in an epi study.

24 DR. HATTIS: Yeah, but this is not just
 25 the usual problem. This is not, the usual problem is a

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1 random error. And we know how to deal with that.

2 DR. HENDERSON: I understand. You're
 3 saying that this is - -

4 DR. HATTIS: This is a systematic error.

5 DR. HENDERSON: - - systematic because
 6 the, you think the inlets are consistently higher than
 7 the level of - -

8 DR. HATTIS: Look it, all I know is what
 9 I read in the ISA, and this seems to be, you know, what
 10 the ISA seems to say. And then I, sort of, believe
 11 that they will have located the monitors at elevated
 12 levels. You know, maybe, and if it's not true, then
 13 fine, you know, but.

14 DR. HENDERSON: Well, I, our charge is to
 15 advise them on how to improve the ISA, and are you
 16 saying you'd like the - -

17 DR. HATTIS: I'd like that, and I think
 18 that if it's, you know, if the analysis, if the
 19 statements in the ISA are correct, then, you know,
 20 maybe they need to be modified with, including the
 21 information from a larger literature base. But, you
 22 know, if they are, then it's worth an a-, worth some
 23 much more quantitative analysis, because it creates a
 24 serious difference between the types of measurements
 25 that are used as the basis of the epi studies, and the

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1 types of measurements that are used in some of the, you
 2 know, the better direct studies establishing the
 3 effects of the NO2.

4 DR. HENDERSON: To point out the
 5 uncertainties associated with the other, go ahead,
 6 George.

7 DR. THURSTON: Yeah, right, well, yeah, I
 8 agree with that last part that the problem is when you
 9 go to compare it to, like, indoor measurements and
 10 those measurements. But, it's not a problem with
 11 regard to interpreting and the epidemiology, I think we
 12 have to keep that clear, and applying it to for
 13 standard setting. Because, ultimately, you know,
 14 you're applying the standards at the central site
 15 monitors.

16 So, that's what you want to use in the
 17 epidemiology, and the fact that, let's say, those
 18 levels, let's say, they were fifty percent of what
 19 people were actually exposed to, it, then you would
 20 take all the numbers, double them, and then when you go
 21 to set the standards, divide them by two. I mean, it
 22 would be a waste of time.

23 So, I think that it's a fact, but it's not a
 24 problem that there are differences in the absolute
 25 levels between what's at the central site monitor, and

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1 what people experience on, at street level. But, only,
 2 the only place where I, you know, I think it is a
 3 problem that I can think of, you know, I agree.

4 When you go, if we're going to put some
 5 importance on these indoor studies, we ought to
 6 remember that those concentrations are not directly
 7 comparable to the central site concentrations. And
 8 that's, I think, the key that Dale brought out.

9 DR. WYZGA: And the clinical studies as
 10 well.

11 DR. THURSTON: Yeah, and the clinical
 12 studies as well, yeah, that's true. Because the actual
 13 concentrations associated with the NO2 exposures that
 14 we measure at the central site monitors are, actually,
 15 higher. And so, that might explain some of the
 16 differences that we see between the exposure studies,
 17 the indoor studies, and the ambient results. So, it,
 18 yeah, so that's going to have some importance later on
 19 in interpreting the results, so that is an important
 20 point to bring up in that respect.

21 DR. HENDERSON: Yeah, I can see that - -

22 DR. HATTIS: A condition of the central,
 23 there is always random error, addition, to effect, you
 24 know, and that's also a problem to be analyzed, but.

25 DR. HENDERSON: Well, okay, I see the



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1 point that, George, that, you know, you just made, and
 2 Dale, too, that there is, the, how something comparing
 3 the clinical and the indoor dose response first to what
 4 you may see in epidemiology. That can be, I think,
 5 clearly stated. Yes, George, do you have - -
 6 DR. THURSTON: I just have one separate
 7 comment. I guess it, I'm not sure if it goes on two or
 8 three, but I think two, that I brought up something
 9 that I, in my quick review, I don't see reflected with,
 10 yesterday, which was that we need to, more clearly,
 11 delineate the difference between personal exposures to
 12 all NOx versus personal exposures to ambient NOx, and
 13 their respective relationships to outdoor central site
 14 monitors. I didn't see that written in here anywhere,
 15 and I did bring that up. And I hope that that's
 16 included.
 17 DR. LARSON: Well, we had a bullet in
 18 section three on trying to look at the alpha, I guess
 19 I, the ratio of the outdoor to personal ambient.
 20 DR. THURSTON: Is that what that bullet
 21 means?
 22 DR. LARSON: Yeah, alpha.
 23 DR. THURSTON: I didn't get it.
 24 DR. LARSON: Okay, we'll fix it.
 25 DR. CRAPO: Could I ask a question for

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1 clarification as I listened to the conversation. When
 2 we get an average annual level expressed for us, is
 3 that what, is that the average over the whole 24-hour
 4 day, then averaged annually. Or is that the high for
 5 the day averaged annually. Are we talking about - -
 6 SPEAKER: Everything.
 7 DR. CRAPO: - - everything averaged
 8 together, so when NO2's have the peaks during the
 9 traffic periods of the day, and it goes down very low
 10 at night, you're taking these high levels that occur
 11 during the day and averaging it out with twelve to
 12 twenty hours with, of low levels and getting a fairly
 13 low level out of it. That's, so, we need a lot more
 14 information about the peak, 'cause, probably, the
 15 average annual is about the last thing we want to look
 16 at to assess this st-, this substance.
 17 DR. HENDERSON: You know, I think, that's
 18 what I have written down for your, what I wrote down
 19 for this. And we need to remember about the pattern.
 20 DR. HATTIS: I've made a series of plots,
 21 actually, of the distributions of, for different
 22 average-, of NO2 levels for different averaging times
 23 from the existing data in one of the annex tables.
 24 And, so, we can talk about that later. Yeah, that's
 25 the, yeah, that's the graph, so, essentially, so if you

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1 want to talk about that in the context of the ISA,
 2 fine, or context of the other is fine, too.
 3 DR. HENDERSON: Were you proposing that,
 4 well, this would be quite a few individual comments,
 5 but can you explain it to us what it's saying?
 6 DR. HATTIS: Yeah. What this, I need to
 7 get it in front of me. What this is, is, essentially,
 8 plotting the, it is, basically, a lo-, what these are
 9 called is log normal probability plots. And,
 10 essentially, what's being plotted is the Z score, which
 11 is, essentially, the number of standard deviations that
 12 each value represents in the distribution.
 13 So, that, for example, the first data point
 14 here is, generally, the first per-, is the one
 15 percentile level. The next is the, I think the five
 16 percentile level, et cetera.
 17 But, plotted on a probability scale, so that,
 18 if, in fact, the data corresponded to a log normal
 19 distribution, which is the usual expectation, then the
 20 points would fall on the straight line. The regression
 21 equation in each case is an estimate of the, the
 22 intercept is the log of the geometr-, it's an estimate
 23 of the log of the geometric mean, and the slope is the,
 24 an estimate of the log of the geometric standard
 25 deviation, okay.

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1 So, essentially, these, so these, if these
 2 log transformed values were normally distributed, they
 3 should fall more or less on the line, and they more or
 4 less do. They are not perfect log normal
 5 distributions. In fact, the actual data have, don't
 6 have as fat a, in the tails as they should for a
 7 perfect log normal. But, essentially, what this does
 8 is to show the change in the slope is, means,
 9 essentially, the longer averaging time or, you know,
 10 more tightly distributive than the shorter averaging
 11 time. So, the shorter the averaging time that you
 12 take, the data are further spread out, just because of
 13 regression of the mean effects. And this says how,
 14 how, what?
 15 DR. HENDERSON: I mean that's what you
 16 need said, isn't it?
 17 DR. HATTIS: Yes, and this, basically,
 18 quantifies how much less the dispersed the lo-, the
 19 yearly and three averages are relative to the one-hour
 20 averages.
 21 DR. HENDERSON: And that's what James is
 22 saying, that they didn't give us much information, I
 23 mean, yes.
 24 DR. CRAPO: So, let me just ask a real
 25 practical question from a real simple mind. How many,



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1 if I, and instead of doing the average annual and
 2 saying that was fifteen parts per billion, what would
 3 be, if I took the highest one hour from each day, would
 4 that be two hundred parts per billion?
 5 DR. HATTIS: Those data are in the table,
 6 and I didn't plot them.
 7 SPEAKER: Actually, they're in the ISA,
 8 too.
 9 SPEAKER: They're in the hot spot.
 10 DR. CRAPO: Right, so what's the answer?
 11 SPEAKER: 201.
 12 (WHEREUPON, there was a discussion off the record.)
 13 DR. CRAPO: Did I guess, I guessed it
 14 right on the money?
 15 SPEAKER: Yes.
 16 DR. HENDERSON: You get a gold star this
 17 morning.
 18 DR. CRAPO: And the excursion, the high
 19 end excursion is from that? Do we have a significant
 20 if the population is exposed 500 ppd?
 21 SPEAKER: No, that was an excursion.
 22 DR. CRAPO: That is an excursion, I was,
 23 that is the excursion, okay.
 24 DR. HENDERSON: Well, okay, Ed, go ahead.
 25 DR. POSTLETHWAIT: Well, if there are

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1 estimates made of personal exposures, won't that
 2 capture that issue, as opposed to, when we compare data
 3 back just to annual averages, which gets back to the
 4 central issue of how much stuff are people really
 5 inhaling, versus, you know, what's the average floating
 6 around.
 7 DR. HATTIS: Not exactly, because it
 8 depends upon, on the averaging time for the personal
 9 exposures, where you also will have a similar - -
 10 DR. POSTLETHWAIT: Well, that's where,
 11 that's where temporal plot, if it was possible, would
 12 be really useful, even from a qualitative standpoint.
 13 DR. HATTIS: Yeah. But essentially,
 14 you'd have to have comparable, you know, different
 15 lengths of time averages to be able to compare. And I,
 16 offhand, I don't know whether the internal, the indoor
 17 exposures are more variable with time than the outdoor.
 18 So, you can have a different, you could have different
 19 comparability depending upon the, you know, how, what
 20 that looks like.
 21 I mean, there's, also, a likely case that the
 22 indoor exposures will be correlated with differences in
 23 breathing rate. So, for example, it may well be that
 24 while I'm up and about, one of the things I'm doing is
 25 cooking on my gas stove, and exposing myself to

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1 proportionally more while I'm breathing more.
 2 DR. CRAPO: Ted has just pointed to me
 3 that the 200 ppb that we were talking about is probably
 4 at fifteen feet up and not at ground level, so that the
 5 ground level might twice that level. What?
 6 DR. LARSON: Ron, wait, no way, no way.
 7 DR. RUSSELL: More likely at four meters,
 8 aren't more of your monitors at four meters than - -
 9 (WHEREUPON, there was a discussion off the record.)
 10 DR. LARSON: Those kinds of gradients
 11 don't exist.
 12 SPEAKER: What?
 13 DR. CRAPO: You say gradients of that
 14 nature don't exist?
 15 DR. LARSON: Not that, I mean, not that
 16 strong a gradient over three meters.
 17 DR. PINTO: Yeah, no, I think you're
 18 right, I mean. I think what I was trying to say was,
 19 no, this particular data point, okay, where it was a
 20 change in Lakewood, California, downtown Los Angeles,
 21 in other words, and is one of the roadside monitors, so
 22 you would expect it a, first of all to be very hot; b,
 23 you would also expect the inlet to be at, you know, the
 24 standard there, at the standard height, which of the
 25 order of three meters or so.

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1 DR. CRAPO: The reason I'm bringing this
 2 up is that I think those of us that are really focusing
 3 on the health effects are not even in our heads not
 4 even correlated to the right thing. And we're sitting
 5 here looking at the ambient levels and thinking 15 ppb
 6 average annual, and we're seeing health effects in
 7 asthmatics and people living near roadsides. When, in
 8 fact, the people near the roadsides are getting 200
 9 ppb. And our correlation, all these correlation
 10 coefficients on the things that we're looking at are,
 11 at least, I'm not sure that because we've used a, such
 12 a bad metric to correlate what's going on, I don't
 13 think that we're thinking correctly on the health
 14 effects side.
 15 DR. HENDERSON: I think one thing we can
 16 emphasize in our letter is the importance of the
 17 temporal and spatial variability in the NOx exposures,
 18 and how that will vary.
 19 DR. CRAPO: Because this makes our
 20 biological plausibility, the discussion yesterday,
 21 change directions completely. It puts us, it, we were
 22 arguing that we weren't exposing enough to NO2 to get
 23 the level. If these things, if these exposure metrics
 24 change, then our whole argument yesterday, the
 25 biological plausibility is met, becomes much more



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1 likely.

2 DR. RUSSELL: No, maybe Jill wants to go
3 into this further. I mean, again, the high monitor is
4 Lakewood in downtown Los Angeles. It's a roadside
5 monitor, so it's going to be high. You know, actually,
6 some of these monitors are sitting really near
7 freeways.

8 DR. CRAPO: Well, so am I.

9 DR. RUSSELL: Right, but what I'm saying
10 is that, keep in mind, when you're talking about, these
11 monitors, many of these monitors are capturing very
12 much the highest levels that you're going to get,
13 except in a very confined street canyon.

14 DR. CRAPO: Okay, and that's what I'm
15 thinking, is that the high levels that are causing the
16 disease that we're seeing, and we're not understanding
17 who's got that high level, and where it is, and why.
18 As well as, at least, the medical side of us are,
19 because we're not dealing with the numbers in the form.
20 So, I'm just wondering if the, if this is, a large part
21 of our discussion yesterday wasn't confounded by some
22 of us not quite understanding the exposure levels that
23 our sub-populations were being exposed to. And, you
24 know, the fact that your, having those, no NO2 all
25 night long is irrelevant to the fact that you get up in

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1 the morning and get a big dose from 8:00 a.m. to 12:00
2 noon or whatever.

3 DR. BALMES: This is John Balmes. I have
4 to, I need a clarification. I thought I heard Tim
5 Larson say that most of the site, and I don't have any
6 map in front of me here on the phone. I heard Tim
7 Larson say that most of the regular monitoring sites
8 are not, they're in open areas and are not necessarily
9 near freeways. But I just heard that a lot of the
10 monitors are by freeways. That makes a big difference
11 to me.

12 DR. LARSON: Not a lot of them. Some of
13 them are, but not a lot of them.

14 DR. BALMES: Right, I think that's
15 important to know.

16 DR. LARSON: Most of them are not.

17 DR. BALMES: Yes. That was my
18 understanding, too.

19 DR. RUSSELL: Yeah, so I misspoke when I
20 said a lot, but you do have a representative population
21 of ones that are near freeways.

22 DR. BALMES: Right.

23 DR. RUSSELL: And those are the ones, or
24 very heavily traffic roads, and those are the ones that
25 you do see on the one extreme of our population. If

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1 you were, had actually got, a see-, cumulative
2 distribution function, that those are the ones you'd
3 see at the upper tail. So, I think we are capturing
4 those. And, actually, in response to your question
5 about the biologic plausibility is, I think it goes
6 both ways, is that in many cases, I think we might be
7 looking at overestimates of what the potential exposure
8 to NO2 is in a general population. Because a lot of
9 people live out in the suburbs, and you know, again,
10 I'm sort of parochial in knowing at Atlanta, is that,
11 we've got more monitors near busy areas, than we do
12 sort of in the general suburbs.

13 DR. HENDERSON: I, well, again, I think
14 maybe we can cover this by a paragraph discussing the
15 importance of the temporal and spatial variability of
16 the pollutants and this is not special to NOx. It's
17 always a problem, and that we, that this should be
18 emphasized to discuss in the ISA. And it is true that
19 we'll extend, but I don't hear anything that's, that
20 couldn't be covered under the importance of temporal
21 and spatial variability, and the, what we listed, as
22 far as monitoring and determining exposures that we, we
23 had discussed this yesterday afternoon, there's the,
24 you know, you have the indoor outdoor exposures, the
25 spatial and temporal variability, the siting of the

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1 monitors, all of that is something that we've already
2 said is very important. So, I would like to just
3 summarize that in a paragraph in the letter, and
4 emphasize how the differences between the more precise
5 measurement indoor in the clinical studies, and, as
6 opposed to outdoor ambient studies.

7 Does that, would that co-, I mean, we've,
8 you're absolutely ri-, and if you don't have the
9 correct exposure, the response then is, it can't be
10 related to the amount of, precisely towards lead and,
11 but that stands, that's always a problem with epi
12 studies. They don't have it for very long exposures.

13 DR. AVOL: Just one small point of
14 information, I think what Joe meant was Lynwood,
15 California not Lakewood. The Lynwood station is
16 alongside the Long Beach Freeway, and gets several
17 hundred thousand vehicles a day.

18 SPEAKER: Yeah, thanks, Ed.

19 DR. LARSON: Well, as my comments
20 yesterday, and you know, at each of those, you know,
21 two sites, there is a information in the database on
22 distance from major roads. And you could compile that
23 fairly easily, and probably, compare that with the
24 population, U.S. population at large.

25 DR. HATTIS: I think that'd be a good



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1 thing to do to try to see what biases one should expect
 2 and what, you know, how do we characterize the
 3 variability and the likely exposures in relation to the
 4 variability that we see in the monitors.
 5 DR. HENDERSON: Is that something, Mary,
 6 that could be done?
 7 DR. ROSS: We can look into it.
 8 DR. PINTO: I mean, perhaps, with help
 9 from the program offices, I mean, I tend to think that
 10 that sort of effort if, you know, if done well, I mean,
 11 could take a bit of time and maybe, even, longer. I'm
 12 thinking in terms of longer than the time scale for
 13 setting the next draft to come out. But we'd have to
 14 look into that, Rogene.
 15 DR. HENDERSON: Okay, well, let's, I
 16 think we've had a good discussion of this issue, which
 17 is a, certainly, an important one. Can we look now
 18 beyond the first three charge questions to going to the
 19 health, unless there's anybody else has something else
 20 on the first three charge questions. The next four
 21 charge questions relate to the health effects. And,
 22 was there, were there things that were left out or
 23 that, yes, Ed.
 24 DR. POSTLETHWAIT: As part of the charge
 25 four things, and this just may be simply an issue of

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1 verbiage. On that third line, where it says only the
 2 key studies that support an NAAQS should be included.
 3 I wasn't sure what that meant, in terms of, to support
 4 what we have now; to support a new one, I mean. And
 5 when you read that, it almost sounds like you, as we
 6 discussed yesterday, you could, inadvertently,
 7 introduce selection bias on what studies you were
 8 reporting, positive versus negative.
 9 DR. HENDERSON: Well, this still is from
 10 the, has a little history behind it. And that's what
 11 I, how I interpret it. If you looked at the CD, it
 12 includes everything from, you know, a 500 ppm exposure
 13 of a toad frog to, you know, something at ambient
 14 levels. And you're right. How do you choose the key
 15 studies. But I think the meaning of this statement is
 16 that, that chapter three could be condensed to even
 17 more to make it less like a CD, and more, just includes
 18 studies that are relevant for setting a standard. I
 19 think that's the meaning of it, but you're bringing up
 20 a problem which we have discussed, CASAC has
 21 discussed,
 22 and who chooses, you know. But we came down that it
 23 was more beneficial for us doing this review to have
 24 the Agency choose what they felt were the key relevant
 25 studies.
 DR. BALMES: But that, this is John

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1 Balmes, again. I think the last sentence in the bullet
 2 here, is, contains key information about that the ISA
 3 would be improved if a plan or process for integration
 4 and study selection is clearly laid out. So, that it
 5 would be clear to some, to a reader, such as Ed, why
 6 studies were included.
 7 DR. HENDERSON: That's a good point.
 8 Yeah. Are there other things?
 9 DR. WYZGA: Rogene, I had a couple of
 10 things on five, but.
 11 DR. HENDERSON: Okay, Ron, and then
 12 Joyce, go ahead.
 13 DR. WYZGA: Okay. I guess, first of all,
 14 I'm flattered that my name is mentioned, but I would
 15 also mention that John, in number five, John Balmes
 16 mentioned some toxicological studies that weren't
 17 included. And I would change the wording to say that,
 18 instead of several of the latest NOx human field
 19 studies is, basically, several recent epidemiological
 20 studies that examine the association between health
 21 outcomes and NO2, were, either, not included nor
 22 studied correctly, and say, especially, in describing
 23 the impacts of other pollutants on the NO2 health
 24 associations.
 25 DR. HENDERSON: Certainly, and nobody's

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1 saying it's going to be mentioned in here, I mean.
 2 DR. WYZGA: Okay.
 3 DR. HENDERSON: You know, I mean, as I
 4 said, I mean, this will not be covered - -
 5 DR. WYZGA: But, I guess, part of it is,
 6 it's broader than simply the epidemiological is because
 7 there's some toxicological studies as well.
 8 DR. HENDERSON: Okay, yeah, okay. And,
 9 is that ment-, it's a tox study, yeah, Balmes, oh,
 10 yeah. No, we, it's mentioned there. Sure, Ron, never
 11 in my wildest dreams would I mention names.
 12 DR. COTE: This is an opportunity,
 13 though, for me to ask people if you, if there are
 14 specific papers that you're aware of that we don't
 15 have, please give us the references. Because, you
 16 know, we've done this careful lit search, for whatever
 17 reason those papers have not popped up. So, you know,
 18 if it's a flaw in the keywords or whatever, so please
 19 help us by giving us the specific references rather
 20 than.
 21 DR. BALMES: So, I will include, this is
 22 John Balmes. I'll include the ones that I referred to
 23 yesterday in my written comments. But the nitrogen
 24 dioxide will get the one paper published in 2005. You
 25 don't have to get fancy with the keywords.



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1 DR. COTE: Thank you.
 2 DR. HENDERSON: Okay, so, Ron and John
 3 will provide, you will provide those in your written
 4 individual comments. Then that, then in the letter, we
 5 can refer to it. We can, see individual comments of,
 6 with them, okay. Anything about question six that
 7 people have problems with or would like to add.
 8 DR. THURSTON: Well, as to the question
 9 five.
 10 DR. HENDERSON: You back to five, okay.
 11 DR. THURSTON: Yeah, well, I mean,
 12 actually, the reason I put Ron's name in there was to,
 13 so that I knew he would respond to that and clarify
 14 that sentence with it. I figured that, otherwise, he
 15 might get ignored and he would make sure it was
 16 correct. So, we could just write members also pointed
 17 out, or something, instead of put, naming names here.
 18 The other thing is, in the iterations, I don't know,
 19 either I didn't have it in the beginning, or it got
 20 left out or something, but I would add at the, in the
 21 last sentence, just, well, I'm just going to get this,
 22 finally, examining the epidemiology results, and I
 23 would say, after results, add the words across outcomes
 24 as a function of. Because, the whole idea was to look,
 25 not just individually, but look across outcomes and

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1 you say that yesterday?
 2 DR. SHEPPARD: I don't think I was the
 3 one that brought that up.
 4 DR. WYZGA: Okay.
 5 DR. SHEPPARD: Probably is an important
 6 point.
 7 DR. HENDERSON: Okay, are there more
 8 comments on the substance of answers to question five?
 9 Go on to six, then.
 10 DR. AVOL: I have a question on six.
 11 This Ed Avol. My question is this. About seven lines
 12 in, there's a comment about sensitive populations.
 13 There's no comment about genetic susceptibility in
 14 that, and I just have a question for whoever wrote
 15 this, if that was a conscious exclusion because they
 16 don't believe it's sufficient - -
 17 DR. CRAPO: It wasn't conscious. It was
 18 late at night in the middle of a bad Rockies game.
 19 SPEAKER: That was a good game.
 20 DR. CRAPO: So, let's add that, let's
 21 just add that.
 22 DR. HENDERSON: So, what line, at what
 23 line, yeah, where is it, what line is it, that - -
 24 DR. AVOL: It's about seven lines down,
 25 the last just in, I'm sorry, there's evidence of

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1 look for coherence. That's it.
 2 DR. HENDERSON: Okay, and I will remind
 3 you, as far as wordsmithing, when we finish here this
 4 morning, Angela and I will be drafting the actual
 5 letter, based on the substance of these comments. And
 6 you will be receiving it for concurrence and review.
 7 So, small wordsmithing, you can take care of at that
 8 point if you want. Can we go on to charge question
 9 six, then?
 10 DR. WYZGA: One, on question five.
 11 DR. HENDERSON: Five, I'm still on five.
 12 DR. WYZGA: And, is Lianne on the phone?
 13 DR. HENDERSON: Lianne wasn't coming on
 14 till when, 9:00. What's Angela's time.
 15 DR. NUGENT: Rogene?
 16 DR. HENDERSON: Yes.
 17 DR. NUGENT: Is Lianne on the phone? She
 18 said she would be on the phone.
 19 DR. SHEPPARD: Yeah, I'm here.
 20 DR. WYZGA: Okay, Lianne, this is Ron
 21 Wyzga. You said something yesterday, number five,
 22 something about, and I wanted to see if I could capture
 23 it, about looking more systematically or in a better
 24 organized way at the, how one deals with co-pollutants
 25 and interpret studies using co-pollutants. Did I hear

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1 adverse health effects in sensitive populations such
 2 as.
 3 DR. CRAPO: And how would you say that,
 4 though. The only ones that have really been studied
 5 are the ones that are mentioned here, really. I mean,
 6 genetic is a theoretic thing, but there's no hard study
 7 that says this is a gene that creates susceptibility to
 8 NO2.
 9 DR. HENDERSON: You could add a sentence
 10 - -
 11 DR. CRAPO: I mean, I believe it's true.
 12 I just don't think, I can't think of a study that would
 13 prove it.
 14 DR. HENDERSON: You could add a sentence
 15 saying, genetic polymorphisms may also influence the
 16 response.
 17 DR. AVOL: I mean, there is some
 18 published information from our lab and others on GST,
 19 and the sensitive to oxidative stress mechanistic
 20 pathways.
 21 DR. HENDERSON: We can put into the,
 22 genetically perception.
 23 DR. POSTLETHWAIT: Will that fall under,
 24 stuff under question seven. I mean, does, six and
 25 seven are, essentially, addressing the same chapter in



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1 the ISA. And there is this issue of defining
 2 susceptible populations.
 3 DR. AVOL: Yeah, that's, I mean, I think
 4 that's fine. I'd be happy to put it into seven. I
 5 just pointed it out there, because it seemed like it
 6 was - -
 7 DR. POSTLETHWAIT: Right, yeah, I mean,
 8 this becomes redundant, just like, you know, I said
 9 it's redundant.
 10 DR. HENDERSON: Okay, I noted that that
 11 should be mentioned. Are there other things for six or
 12 seven?
 13 DR. RUSSELL: Rogene, before going on,
 14 I'm actually curious. On the last sentence, that, I
 15 mean, to me that's a rather important sentence.
 16 DR. HENDERSON: Which question are you -
 17 -
 18 DR. RUSSELL: Oh, six. That we concur on
 19 the findings and, et cetera, directly result in adverse
 20 impacts. And this comes, you know, I was sitting here
 21 a little uncomfortably yesterday about the use of the
 22 word likely causal when we, they say the strongest new
 23 evidence comes from epidemiologic studies of ED visits
 24 and hospitalization. And I'm an air quality person, so
 25 I, the medical end is somewhat beyond me, but,

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1 recognizing that the epi studies that we've talked
 2 about the problems with the monitoring and the spatial
 3 variability. There are some that find associations.
 4 There's others that don't. And, it almost struck me
 5 that, I was sitting here going, the strongest new
 6 evidence, and you have some studies that go the other
 7 direction, and I recognize EPA was, sort of, sitting on
 8 the fence on this one, too. Directly result may just
 9 overstate how I think I feel on this. And I'm
 10 wondering how others feel, too.
 11 DR. HENDERSON: I think that's a strong
 12 statement considering our discussion. I agree with
 13 you. I don't find, I think we're all trying to figure
 14 out is there something here or not, and - -
 15 DR. SHEPPARD: Yeah, I agree as well. I
 16 think that's pretty strong.
 17 DR. AVOL: I think, in fact, that
 18 yesterday in the discussion, John Samet challenged the
 19 consistent coherent issue.
 20 DR. POSTLETHWAIT: James, yesterday, you
 21 and I were talking, and you came up with a really great
 22 multi-word descriptor, you know, that might soften this
 23 a bit. And I'm trying to remember what you said. It
 24 was something about, you know, NO2 appears to be a key
 25 player, I mean, you said it better than that. And

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1 whether, in verbiage that, while it may not be the
 2 chemical species NO2, per se, certainly, there's a
 3 linkage between NO2 in the air and all the other
 4 goodies and these adverse health outcomes.
 5 DR. CRAPO: I don't remember exactly what
 6 I said. I can tell you that I, last night, I
 7 deliberately wrote this sentence very strong, 'cause I
 8 wanted to make us talk about it. I think we have to
 9 decide, I mean, this is, I think, the heart of the
 10 paper right here in that one sentence. It tell them
 11 whether we really agree or don't agree with the
 12 fundamental conclusion of the document. The, when I
 13 get, at the end of the day, I'm impressed that the,
 14 it's not, we have to cite the few studies that were
 15 negative; but in fact, this is a, it's a ten to one
 16 vote in favor of positive, but it's not an equal, half
 17 were positive and half were negative.
 18 These are, the most of the studies that come
 19 out are showing strong effects. And I do think that
 20 it's likely the effects are tracking primarily the
 21 products of combustion, which the paragraph says. The,
 22 but the, but there are, overwhelmingly, strong data
 23 showing an association that we haven't really dealt
 24 with. And I'm concerned that the biggest problem is in
 25 our exposure metric. I think that our correlation

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1 needs with, needs to be with the highest one-hour
 2 average.
 3 Not, like ozone was before it changed to an
 4 eight hour averaging time. And if we converted all of
 5 our data to one-hour averaging time, we might have a
 6 lot more confidence in this conclusion. But I don't,
 7 but I can't walk away from the strength of the data
 8 that's summarized in the ISA. It's a very strong
 9 document with studies from every dimension from every,
 10 from lots of different countries, consistently finding
 11 associations with products of combustion that metric
 12 was within all.
 13 DR. BALMES: So, the, this is John
 14 Balmes. I agree with you, Jim, James, that the
 15 epidemiologic data taken as a whole from a
 16 stratospheric level are pretty impressive. My problem
 17 is that I don't think the coherence is, necessarily,
 18 there with the toxicologic data. We talked about that
 19 yesterday. And I don't, actually, personally, have a
 20 problem with the Agency moving ahead with a new
 21 standard if that's the ultimate outcome, based on
 22 epidemiologic data. I do epidemiology.
 23 I appreciate its value. But I think it's, I
 24 don't think the toxicology is really there to support
 25 the epidemiologic findings. And it's often that



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1 toxicology is behind epi.
 2 So, I think we should recognize that, I mean,
 3 if we have to say that. Because, otherwise, people
 4 will criticize the document for not, sort of, fairly
 5 representing the literature. And I think, with regard
 6 to respiratory infection risk, I think the toxicology
 7 is there.
 8 But I don't think that we understand why NO₂
 9 causes, or is associated with a kind of lung function
 10 decrements that the children's health study found. I
 11 think that's a very important finding that should be
 12 very strongly emphasized in the document. But I don't,
 13 I, certainly, don't understand how that occurs.
 14 DR. CRAPO: Would you say the toxicology
 15 does support it if we're speaking about 200 ppb instead
 16 of 15 ppb?
 17 DR. BALMES: Uh - -
 18 DR. CRAPO: 'Cause I've changed my mind
 19 on that one.
 20 DR. BALMES: Well, I think that's a
 21 greyer area, but I'm not sure that 200 ppb, the
 22 toxicology supports 200 ppb.
 23 DR. LARSON: James, Tim Larson, again.
 24 15 ppb is your annual average. The 200 ppb is your
 25 one-hour max. So - -

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1 DR. CRAPO: Well, that's one-hour max in
 2 monitors on certain places. It's not the one-hour
 3 personal max.
 4 DR. LARSON: Right, but what's the, what
 5 is the annual average at that monitor. I mean, that,
 6 in terms of, if there isn't, I mean, there's two things
 7 going on here. One of them is spatial, you know,
 8 proximity to roads, et cetera. The other one is the
 9 annual average versus the one-hour average. Both cause
 10 differences in these numbers. But, when you say 200
 11 versus 15, one's a chronic exposure and one of them's
 12 acute exposure.
 13 DR. CRAPO: Well, I know that, but the
 14 toxicology's almost all acute. And the peaks are
 15 acute. And I, see, yesterday, I was sitting here
 16 thinking about the 15 ppb and saying, I've got an order
 17 of magnitude or two orders of magnitude difference in
 18 my toxicology and my epidemiology. But, in fact, I
 19 don't. It's, they're coming together. The lowest
 20 threshold effects for NO are, you know, are in some, a
 21 few hundred ppb. We saw that yesterday, where they
 22 looked at the lower limits of toxicology having
 23 effects. And now, we've got peak levels at fifteen
 24 feet up in the atmosphere, in certain locations,
 25 pushing the same levels.

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1 DR. LARSON: I'm not disagreeing with
 2 your general conclusion, but I'm just saying, to be
 3 more precise, those epidemiology studies are probably
 4 looking at 24 hour time series. And those 24 hour
 5 averages are certainly at a max greater than 15 ppb.
 6 DR. CRAPO: Yeah, and I'm, but I'm also
 7 saying that is a, I think that NO is not driven, NO's
 8 health effects are not driven by the daily average.
 9 That's probably driven by the peak, and - -
 10 DR. LARSON: Right, but - -
 11 DR. CRAPO: - - and the, and we never
 12 looked at the peak in terms of comparison of.
 13 DR. LARSON: Right, because a relevant
 14 comparison would be the 24 hour versus daily max hourly
 15 average. Because the type, and the epi are based,
 16 primarily, I believe, on the 24 hour, but I'm just
 17 saying, those are the two numbers to compare.
 18 DR. CRAPO: Well, it is except that we're
 19 looking at fairly profound health effects, and, I mean,
 20 in many of these studies, and - -
 21 DR. LARSON: Well, and I'm agreeing with
 22 you. I'm just saying that the change from one day to
 23 the next is greater than 15 ppb. And, you know, in
 24 some cases, the one-hour max could be several hundred,
 25 and the change from one hour to the next could be

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1 fairly large, too. So, I mean, the 15 ppb, it seems
 2 like, is, it's not even in the range of what we're
 3 talking about. I mean, that's an annual average, and
 4 it just gets washed out, as you say, by all the
 5 seasonally flow seasons and all the midnights and
 6 everything else, so.
 7 DR. AVOL: This is Ed Avol. Not to go
 8 back to discussion of the health effects, but since the
 9 lung function changes in the children health study we
 10 brought up, let me just point out one perspective. And
 11 that is that in, of course, in looking at lung function
 12 growths or decrements in lung function growth among
 13 children, we're looking at long-term changes of
 14 children that are moving around their communities, and
 15 we're looking at those annual averages from those
 16 central site monitors in those areas. And so, while it
 17 may be true that close to roadways or at traffic peaks,
 18 there are several hundred parts per billion
 19 concentrations, in fact, our relationships with those
 20 changes in lung function are with the annual average.
 21 DR. CRAPO: Well, I understand that
 22 factor. I'm just hypothesizing, I mean, I'm saying
 23 that the health effects appear to be real. And I,
 24 biologically, couldn't explain them with the annual
 25 average, but then it occurs to me that what's likely



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1 happening, maybe I only need to hit my kid with 200 ppb
 2 once a week in order to cause adverse changes in his
 3 growth of his lung. And I take him on my freeway for
 4 three or four hours a week while I'm driving various
 5 places. So, it could be that that's the problem, and
 6 we have-, but my point is, we haven't even analyzed it
 7 that way.

8 DR. LARSON: Right.

9 DR. HENDERSON: Well, there is no - -

10 DR. CRAPO: But the health effects are
 11 real. That's what this sentence says. The health
 12 effects are real. I don't know why yet, but I, there,
 13 and it might not, and it might be a surrogate, but
 14 they're, but they are so uniform across so many
 15 studies, that we have to take them serious.

16 DR. HENDERSON: Now, as far as - -

17 DR. BALMES: This is John Balmes. I
 18 agree with that. It's, but I, so the, the coherence in
 19 the epi, I have, I'm comfortable with. It's, if people
 20 are assuming from that statement that we mean coherence
 21 with the toxicology, I don't think we're really there
 22 yet. That's all I'm trying to say.

23 DR. THURSTON: Could I say?

24 DR. HENDERSON: George?

25 DR. THURSTON: Yeah, I don't really think

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1 we're at with, we may end up where this last sentence
 2 is, but I don't think we're there yet, in my opinion.
 3 So, I mean, I would just say, concur that the
 4 epidemiologic findings, you know, indicate, let me see.
 5 I had it written down here, too. Yeah, concurs that
 6 the epidemiologic findings indicate that current
 7 ambient NO2 exposures are associated with adverse
 8 effects on the public health. But the document needs
 9 to better document, or better, you know, lay out the
 10 plausibility, a consistency in coherence. I think that
 11 work, that needs to tightened up, and that's where we
 12 ought to be focusing this next iteration. I don't
 13 think we're done yet, and this gives the impression
 14 we're done.

15 DR. HENDERSON: That we're done. No, I
 16 would agree with that, and I'll let Mary talk on it.

17 Would you write down your modified sentence so that.

18 DR. ROSS: While you're on that subject,
 19 I just want to draw your attention to a sentence a few
 20 sentences earlier. CASAC recognizes that the primary
 21 associations are between products of combustion and
 22 adverse health effects. That's also a strong
 23 conclusion that will have policy implications. And
 24 just wanted to make sure if that's something you agreed
 25 with. It's helpful if you provide why, you know, what

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1 supports that, too.

2 DR. CRAPO: Well, I'll say it, 'cause,
 3 actually, I wrote it with, we said it several times
 4 yesterday, but when, every time you do the study, you
 5 find that there's an adverse health effect, which you
 6 can link it, like, to the roadway, or to the children's
 7 study with an open fuel on their furnace in the home,
 8 the powerful correlations that go with this, the fact
 9 the primary source of NOx is combustion. So, it seemed
 10 like an obvious to me.

11 DR. RUSSELL: Yeah, that one I have no
 12 problems with.

13 DR. HENDERSON: I have no problems with
 14 that, either. I think that's a solid statement, but
 15 George, would you repeat your modification of the last
 16 - -

17 DR. THURSTON: Yes, I may have it here.
 18 CASAC concurs that the epidemiologic findings indicate,
 19 we'll see, that current ambient, is directly, no, are
 20 associated with. That's what epidemiology tells us,
 21 associations. Are associated with adverse impacts on
 22 the public health, comma, but that the document needs
 23 to better - -

24 SPEAKER: Articulate?

25 DR. THURSTON: Well, you could say the

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1 ISA needs to, yeah, the ISA needs to better document
 2 that these findings are plausible, consistent and
 3 coherent with, now do we want to say with toxicology
 4 or something with other evidence?

5 DR. CRAPO: Well, to me, I would say, in
 6 looking at lots of different medical kinds of issues, I
 7 see more consistency of this data than anything,
 8 virtually, anything that I make medical decisions on.
 9 A lot of consistency across broad settings, where the
 10 issue has been plausibility or coherence with the
 11 toxicology. And that was a dose issue. It was not,
 12 there's plenty of toxicology at high dose. There's no
 13 question about if you're talking about 10 ppb, I mean,
 14 10 ppm, there's no question it correlates. So, the
 15 whole issue is, to me, the only issue is dose.

16 SPEAKER: Well, yeah, I mean, that is a
 17 big - -

18 DR. THURSTON: Well, I just think it
 19 needs to be better. I think you're probably right.
 20 There is, having read it, you know, there is a lot of
 21 that evidence, but it hasn't been laid out in a way
 22 that makes it obvious that where the coherencies are.

23 DR. BALMES: Well, one thing that might
 24 be useful is to look at the relationship between these
 25 one-hour peak exposures and the annual averages.



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1 DR. HENDERSON: I thought that was done
 2 in there, but I - -
 3 DR. HATTIS: We do have direct evidence
 4 in a table in the ISA on that point, that essentially,
 5 the 99th percentile of the one-hour maximum is like 72
 6 ppb. It's not the highest is like 200, but that's the
 7 highest of 288,000 measurements. So, I mean, you're a
 8 little bit far out on the scale there with the 200.
 9 But, certainly, the 99th percentile is about, is 72
 10 parts per billion whereas the 99th percentile, the one
 11 hour of the yearly averages is 33 parts per billion.
 12 So, you have a couple fold there, which gets a little
 13 closer to the toxicology, but.
 14 DR. HENDERSON: Mary?
 15 DR. ROSS: You know, when we talk about -
 16 -
 17 DR. HATTIS: But that's again, for the
 18 monitors that, some of them, which may be close to
 19 roadways, but they're still a little high up, so it
 20 may, may still be some additional distortions.
 21 DR. HENDERSON: Mary?
 22 DR. ROSS: We tried to evaluate the
 23 short-term exposure studies that looked at different
 24 indices, and there's a small discussion on page 5-5 of
 25 24 hour studies versus one-hour max studies. And they

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1 don't find, there's not a lot of difference in the
 2 epidemiologic. Now, that is one-hour max on a given
 3 day, but, you know, we did try to evaluate that, and
 4 we'll look at if there are any further studies.
 5 DR. HENDERSON: Okay, Ron?
 6 DR. WYZGA: Rogene, I would say, I guess
 7 in the spirit of what we said, if you look at the
 8 previous sentence, we, basically, say NOx is a
 9 significant factor, and I wonder, given what we said
 10 later, if we could change the is to can be.
 11 DR. HENDERSON: Yeah, I know, I see
 12 (WHEREUPON, Dr. Henderson reviewed the document.)
 13 DR. ROSS: And can I ask one more, I'm
 14 sorry to keep bothering you but, when you say NOx, do
 15 you mean NO2 or NOx, and it's one of the things we
 16 battle with all the time is selecting the term.
 17 DR. CRAPO: I use them interchangeably,
 18 because we did it yesterday. I don't think we know,
 19 exactly, what the species is, but NO2 seems to be a
 20 good surrogate for it, so you could use NO2, but, in
 21 fact, you're measuring the, you're measuring the, well,
 22 you're using it as a surrogate for NOx, so probably, I
 23 think NOx is your better term, because you don't really
 24 know it's NO2, do you?
 25 DR. WYZGA: Except the studies have

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1 tended to look at NO2.
 2 DR. CRAPO: Yeah, so I mean, you could
 3 say it either way, but since they interconvert, you're
 4 a little bit wondering what it really is you're. I
 5 mean, is the NO2 a surrogate for NO-, for all the other
 6 species. And so that's why I use them interchangeably,
 7 without being very discretionary. I knew, I need, you
 8 should use the same term.
 9 DR. HENDERSON: So, you're saying, I
 10 mean, what you're suggesting, Ron, is that NOx can be a
 11 significant factor?
 12 DR. WYZGA: Yes.
 13 DR. HENDERSON: Does anybody have an
 14 objection, I mean, can we agree on can be?
 15 DR. CRAWFORD-BROWN: Now, is that can be
 16 in the sentence of can be under some circumstances?
 17 DR. WYZGA: Well, we've avoided making
 18 definitive conclusion in the last sentence, and we're
 19 saying, you know, we're waiting for the document to,
 20 basically, organize and, you know, give us a redraft.
 21 And it seems to me to make that conclusion that it is,
 22 it can be, and I think that's one of the things we're
 23 waiting on, you know, the next round, to see whether or
 24 not the document supports, you know, it is a
 25 significant factor.

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1 DR. HENDERSON: Yes, that's the sense
 2 that I understood. Okay, did we, for the NOx issue, we
 3 decided to keep the same term. What did you decide on
 4 the - -
 5 DR. CRAPO: I like NOx better, because it
 6 - -
 7 DR. KENSKI: I actually would prefer NO2
 8 in the, you know, all of the epi stuff is based on NO2
 9 measurements, and the tox stuff is NO2 measurements,
 10 and you know, yes, they are, they do interconvert, but
 11 you know, the peak, peak, I mean, you know, what we
 12 measure as NOx is, what we measure as NO2 is, you
 13 know,
 14 the difference between NOx and NO-, so I, I don't know.
 15 I just think it's better to be consistent and keep
 16 that, you know, link with NO2.
 17 DR. HENDERSON: The toxicity data is
 18 based on NO2, I mean.
 19 DR. KENSKI: Right.
 20 DR. HENDERSON: Yeah, I mean, the
 21 clinical and the - -
 22 DR. KENSKI: And what's repor-, and
 23 what's reported, granted, it's not, you know,
 24 absolutely pure, you know, true NO2, but it's as close
 25 to it - -
 DR. CRAPO: Well, I wouldn't be, I'd be



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1 happy to accept either one, as long as that, someplace
 2 in it, you defined that three was interconversion and
 3 that NO2 is as, is a critical species in the sequence.
 4 So, you just make, as long as you define what you're
 5 using, that's fine to use the other term, as far as I'm
 6 concerned.
 7 DR. KENSKI: It just might be good to add
 8 a sentence, you know, up front saying that, you know,
 9 we acknowledge that, you know, the NO2 that we measure
 10 is not, you know, true a hundred percent - -
 11 DR. WYZGA: But I think the other thing
 12 is that, that we use NO2 with the relationship between
 13 NO2 and the other components of NOx may change
 14 temporally and spatially, and we don't really have
 15 enough evidence to say that it's consistent. And if
 16 that relationship were consistent, then, I think, we
 17 could jump to NOx, but it's not consistent.
 18 DR. KENSKI: Right, and we're asking for
 19 a better, you know, definition of some of those.
 20 DR. HENDERSON: Can we go on to seven and
 21 eight. I put in on seven about the genetics. I
 22 thought, I don't know who wrote eight, but I thought
 23 that was well written. It was very clearly written.
 24 Somebody wrote that. It's Doug. Oh, we, we'll get a
 25 my kudos to Doug. I thought that was well written.

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1 The, we've talked about the multi-pollutant aspects,
 2 and I'm, hope-, I think Ellis, probably, you
 3 contributed that. And, that will be, can be worked
 4 into the letter as a major point that, you know, after
 5 all our discussions, we still have this problem of the
 6 multi-pollutant aspects for, when we try to assess the
 7 risk of air pollutants, particularly the different
 8 oxidant pollutants. But, let's see if there's any big
 9 changes in seven and eight that we want to make.
 10 Particularly, anything we want to add.
 11 DR. BALMES: I thought I heard yesterday
 12 that some people were uncomfortable with the idea of
 13 defining a susceptible group relative based on their
 14 where they live. That's the first bullet in, uh - -
 15 DR. HENDERSON: Page seven.
 16 DR. AVOL: I think Tim's right. There
 17 was some discussion about moving the issues of high
 18 exposure locations and near roadway into exposure.
 19 DR. POSTLETHWAIT: Yes, and when I put
 20 this together during the Rockies game - -
 21 DR. CRAWFORD-BROWN: I don't think the
 22 Rockies actually had a game.
 23 DR. POSTLETHWAIT: That's what I was
 24 thinking. Yeah, I mean, that's, it can go wherever.
 25 The question is is whether it does, does increased,

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1 inherently increased exposure represent susceptibility.
 2 DR. HENDERSON: Oh, okay, or whether it
 3 goes in the exposure.
 4 DR. COTE: Just as a point of
 5 clarification on that. We tend to talk about
 6 susceptible and vulnerable populations, and susceptible
 7 is a more innate quality. And vulnerable being people
 8 at increased risk, or individuals at increased risk for
 9 some not intrinsic attribute. So, exposure would be
 10 increased vulnerability.
 11 DR. POSTLETHWAIT: Then the first bullet
 12 needs to be changed to incorporate, not only defining
 13 susceptible, but defining vulnerable. And then, depend
 14 upon what the panel feels, you can leave the high
 15 exposure in there, or not.
 16 DR. HENDERSON: Okay, I see, you, there
 17 is the, the people near the roadway are vulnerable
 18 because of the high exposure. That makes sense. I,
 19 and that's what the question asks, susceptible or
 20 vulnerable.
 21 DR. ROSS: And to expand on that, the
 22 vulnerable population includes the two sub-categories,
 23 other than the biological, the socio-economic and the
 24 geographic were, generally, extrinsically sensitive.
 25 So, we could split that vulnerability up into two

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1 components, and that would address, I think, Dr. Avol's
 2 questions.
 3 DR. AVOL: Yeah, but I think there is a
 4 interaction here in the sense that vulnerable
 5 populations, those are the high exposure alongside
 6 roadways, are likely, are disproportionately likely to
 7 be lower SES and get into issues of environmental
 8 justice. And then, they may have biological in that
 9 sense, be the former susceptible. They may also fall
 10 into the susceptible population as well. So, they get,
 11 sort of, a double whammy. But I think that it is true
 12 that there are susceptible and vulnerable sub-
 13 categories here.
 14 DR. HENDERSON: Okay. Any more for
 15 charge question seven?
 16 DR. COTE: If you have time, I had a
 17 quick question. The two on this, on the page five, the
 18 partial bullet at the top, the last sentence, the
 19 chapter did not address biologic plausibility with
 20 regard to specific populations, thus it's difficult to
 21 attribute health outcomes to direct causal. I think
 22 we're all in agreement when you have biologic
 23 plausibility, you're much better off. Or is this
 24 intended to mean, though, if you don't have mechanism
 25 of action information, then you can't say there's a



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1 causal outcome?
 2 DR. POSTLETHWAIT: Well, my intent was
 3 to, sort of, throw that open for discussion that, would
 4 it make the document more robust to have, why would an
 5 asthmatic be more susceptible to NO2 than a normal.
 6 For example, what is it about the biology of NO2 that
 7 induces susceptibility in a specific subset of the
 8 population. Yes?
 9 DR. COTE: Yeah, I think we can make that
 10 stronger. I'm not sure we can actually, and in each
 11 case, can be successful, do we not.
 12 DR. CRAPO: The asthmatic has a more
 13 responsive airway, and greater responsive inflammation,
 14 and the NO2 is an irritant, so it could easily be an
 15 oxidant. So, it could easily be - -
 16 DR. POSTLETHWAIT: That one's easy. Some
 17 of the others may not be so easy. And we can't - -
 18 DR. LARSON: Are we doing, dealing with a
 19 likely causal, and that term. I mean - -
 20 DR. POSTLETHWAIT: Yeah - -
 21 DR. LARSON: - - causal is a diff-, is a
 22 higher standard than likely causal. My understanding
 23 was, you don't need the biological plaus-, I mean, you
 24 don't need the detailed mechanism to go to likely
 25 causal.

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1 DR. POSTLETHWAIT: Well, in a perfect
 2 world, the detailed mechanisms would be wonderful, but
 3 I'm not sure we're there yet, or even close.
 4 DR. HENDERSON: And regulations have to
 5 be decided on, you know, even in the absence of
 6 mechanisms for sure.
 7 DR. COTE: The second question I had is
 8 in the next bullet, the word unique. I wasn't and sure
 9 what was intended. So, it says a unique and probably
 10 susceptible - -
 11 DR. POSTLETHWAIT: Hey, Jim Ultman,
 12 you're up.
 13 DR. HENDERSON: Jim, are you there. You
 14 were there. Not answering.
 15 DR. POSTLETHWAIT: He sent me this. I
 16 cut and pasted it in, so it's his fault.
 17 DR. HENDERSON: Oh, okay.
 18 DR. COTE: That's o-, it's not, it's not
 19 a deal breaker either way, so that's okay.
 20 DR. HENDERSON: Well, I - -
 21 DR. COTE: Thank you anyway.
 22 DR. HENDERSON: Okay. We can find out.
 23 DR. POSTLETHWAIT: I mean, there is some
 24 uniqueness in children because of the superimposition
 25 of exposure on top of growth and development. So,

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1 you've got injury, repair, growth, and development.
 2 DR. COTE: Okay.
 3 DR. POSTLETHWAIT: And, which is not, two
 4 of those factors are, don't occur in the adult.
 5 DR. HATTIS: Yeah, if you want to back
 6 off from unique, you might say distinctive.
 7 DR. POSTLETHWAIT: Sure.
 8 DR. COTE: Thank you.
 9 DR. HENDERSON: Okay. Did you get that,
 10 Angela, distinctive. Let's look at charge question
 11 eight and, uh - -
 12 DR. AVOL: Could we just go back.
 13 DR. HENDERSON: Oh, sure.
 14 DR. AVOL: I'm actually, I mean, I think
 15 that Ed is right. It is unique because of the growth
 16 aspect. The tissues are in the period of growth and
 17 are more sensitive. And I think that is a unique
 18 attribute. But it's not a unique population, anything
 19 in the population that makes them unique, susceptibles
 20 population.
 21 DR. HENDERSON: I think we can work that
 22 in. Let's see.
 23 DR. LARSON: The first part of the
 24 sentence refers to the children's health, California
 25 health studies. The second part refers to children in

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1 general.
 2 DR. HENDERSON: Yes.
 3 DR. COTE: I thought the concept of the
 4 injury, repair, growth, development was what was useful
 5 for me.
 6 DR. HENDERSON: Yes, I, and, maybe, we
 7 can put that in, that children, I don't know, are
 8 unique in that, you know, injury, growth and repair.
 9 DR. POSTLETHWAIT: Actually, you could
 10 throw in a fifth variable, which would be dose, 'cause
 11 their running around breathing harder, we hope.
 12 DR. HENDERSON: Okay, now can we go on to
 13 eight, and I, Doug wrote this. It just seemed like it
 14 was very clear and captures many of the concerns that
 15 the committee had. The, a multi-pollutant aspect, I
 16 think, it will be something we'll bring up at the end
 17 of the letter as a, you know, general concern we have
 18 for all airborne pollutants, and maybe we'll suggest
 19 the need for, in the future, striving to address, you
 20 know, multi-pollutants, rather than one pollutant at a
 21 time, a one atmosphere approach, which the Agency is
 22 trying to take anyway.
 23 DR. LARSON: But, I also thought, based
 24 on the discussions yesterday, that there was a general
 25 scientific consensus that nitric oxide was not a



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1 confounder either in the palliative, its palliative
 2 effects, or its, you know, irritant effects. There
 3 was no, really no information at these concentrations.
 4 I guess, we don't really have the EPA summary of all
 5 the nitric oxide concentrations, but it just seemed
 6 like we had, sort of, generally, concluded that if, in
 7 fact, it is a mixture, it's, it doesn't seem to be the
 8 nitric oxide that's doing much of anything. And then,
 9 when you, when you, if you eliminate that, you're, sort
 10 of, the next most abundant thing is NO2, and then you
 11 start going way down in abundant for these other
 12 species that we don't know much about in terms - -
 13 DR. HENDERSON: I agree, or what I was
 14 thinking of multi-pollutant was ultra fines and ozone
 15 and - -
 16 DR. LARSON: I agree with that, but I'm
 17 just saying that, even though we can't, necessarily,
 18 say much about that, I think we can say something about
 19 the biological plausibility or the lack of it for
 20 nitric oxide. Because that seemed to be a point of
 21 confusion early on in yesterday's discussion.
 22 DR. HENDERSON: Okay, I think it's pretty
 23 clear in the document. That's where I read it, so in -
 24 -
 25 DR. LARSON: Yeah, I mean, we're just

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1 re-, I mean, I was just reading it. It seems, it still
 2 seemed to be a point of confusion.
 3 DR. HENDERSON: Okay, I got it. We're
 4 coming to the end here, and as again, this is the first
 5 time we've tried this sort of process. And I need to
 6 know if everyone on the phone and sitting around the
 7 table is co-, if we modify as we have discussed here
 8 this morning extensively, if we modify the content of
 9 these points, are you comfortable with these, this
 10 being the substance of the letter that we send to the
 11 Administrator. Now, I'm not talking about
 12 wordsmithing, et cetera. Because, what will happen is
 13 that this draft letter will go to all of you, so if,
 14 you know, if you have wordsmithing problems, don't
 15 worry about it. It's the substance of what's in the
 16 letter that I want to know if you're comfortable with.
 17 And Mary, why are you raising - -
 18 DR. ROSS: May I ask one final, about
 19 question number eight.
 20 DR. HENDERSON: Okay.
 21 DR. ROSS: We had actually intended that
 22 the entire ISA be the document that serves as support
 23 for risk and exposure assessment. If it is intended
 24 that only the conclusions chapter be the resource for
 25 risk and exposure assessment, what that's going to lead

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1 to is a major reorganization of the document to move a
 2 lot of information from the earlier parts into chapter
 3 five. That's not what we intended, though.
 4 DR. CRAWFORD-BROWN: I need to answer
 5 that, though. I mean, I certainly would agree that the
 6 entire document is the resource to which people need to
 7 turn, but I just don't know what findings and
 8 conclusions mean if it isn't a summary of the most
 9 important and relevant points from the previous
 10 chapters. I, you know, I would think that there will
 11 be people who are going to say, look, I don't have time
 12 to read your whole document.
 13 Tell me what I really need to know as a
 14 policy maker, as somebody who's going to try to do a
 15 risk assessment, and so forth. Tell me what I really
 16 need to know in order to be able to make those
 17 determinations. You're the scientist. I'm not the
 18 scientist. So, I just, you know, that chapter needs to
 19 be a chapter that does summarize everything from the
 20 past as far as relevant conclusions are.
 21 DR. COTE: You know, I was going to, I
 22 meant to ask this yesterday, if there were specific
 23 examples where there were more important conclusions in
 24 the body than in the chapter five. If somebody could
 25 note those, just when you see them. Things were

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1 actually were written by the same people, and I think
 2 chapter five reflected, as we were working, perhaps,
 3 more refinement of thinking, and so, it's a little
 4 disturbing if it was better the first, rather than the
 5 second round of thinking, so if you ju- -
 6 DR. CRAWFORD-BROWN: If we combine a
 7 list
 8 of the things that are back in the earlier chapters
 9 that - -
 10 DR. COTE: That should be - -
 11 DR. CRAWFORD-BROWN: But I think the
 12 main
 13 issue had to do, also, with the fact that the writing
 14 of chapter five does need to be the bridge to the user
 15 of this document, and what that user needs, as
 16 important information, for the kinds of decisions he
 17 or she is going to make. And that's where I didn't,
 18 you know, I, personally, I know Ellis felt the same,
 19 didn't feel that that connection was quite there, where
 20 somebody at chapter five began to ask, what are people
 21 actually going to use this for in the end. And that's
 22 why I raise this issue of integrated. I don't think
 23 there's such a thing as integrated outside of the
 24 context of the question that somebody is trying to
 25 address.
 26 DR. COTE: Was it that there weren't



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1 of information were missing, or both?
 2 DR. CRAWFORD-BROWN: I, but I mean, my
 3 personal opinion is that what happens with chapter five
 4 is that, it is, what often happens with concluding
 5 chapters in theses, for example, where it's just a
 6 compilation of things from the earlier chapters.
 7 Here's a thing from chapter one, and here's a thing
 8 from chapter two. Rather than somebody,
 9 systematically, sorting through and saying, what do we
 10 think we really learned from the earlier chapters that
 11 are relevant to the kinds of applications that we
 12 thought we were directing this report towards.
 13 DR. CRAPO: I think a good example is the
 14 issue I was talking about a lot this morning about the
 15 dose metrics being annual average, and not telling you
 16 what the people, the populations were exposed to,
 17 actually, in terms of the more toxic elements of the
 18 high level exposures. And then, a discussion of that,
 19 so that the person who tries to interpret the health
 20 effects data, in relationship to the possible
 21 exposures, both for what they know and don't know, is
 22 not there in chapter five. A person that would read
 23 that and just think you had, it would just jump right
 24 from the exposure data, think it had totally supported
 25 all the findings. And so, I think, that disconnect

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1 that we struggled with for two days here needs to be
 2 obvious in chapter five.
 3 DR. HENDERSON: And I lay a few, John
 4 Samet had quite a bit to say about chapter five in his
 5 comments. And he had the, since so many people had the
 6 same conclusion that it was really just a listing of
 7 the, what, of items from the previous chapters,
 8 excluding some, because several people said that, and
 9 not an integration of, you know, all five. So, I think
 10 that it really does need attention.
 11 DR. COTE: Clearly.
 12 DR. HENDERSON: You don't have that many
 13 people giving almost the same comments without there
 14 being something that - -
 15 DR. COTE: No, no, I wasn't disagreeing.
 16 I was just trying to get more - -
 17 DR. HENDERSON: Just get more examples
 18 and - -
 19 DR. COTE: Yeah.
 20 DR. HENDERSON: Yes, Ellis.
 21 DR. COWLING: I would offer two comments.
 22 One is George's suggestion yesterday that, and it's
 23 relevant to what Doug was just saying about, what is
 24 relevant to the decisions that were made next. And it
 25 seems to me that he was suggesting that a scan be made

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1 of these 47 statements, or however many it becomes, and
 2 that those that are directly relevant to the issue of
 3 making a judgment about the standard be highlighted or
 4 marked in some way, and that the, so that's the first
 5 point. And the second point, in chapter two, you were
 6 asking for examples of then something that was
 7 mentioned in chapter two, but didn't show up in the
 8 summary that was in chapter five. And all of the nine
 9 statements in chapter five are relevant to the issue of
 10 monitoring alone.
 11 DR. COTE: Right, I heard that, yes.
 12 DR. COWLING: So, I was just thinking to
 13 mention those examples.
 14 DR. COTE: Thank you, and what you
 15 provided on criteria for judgment, I thought was very
 16 good, too.
 17 DR. CRAPO: I'd like to add one more
 18 thing. I think the biggest thing that might come out
 19 of this review of NO cycle is a recommendation that we
 20 go to a one-hour daily average instead of an annual
 21 average. And, no matter what the level is set at, it
 22 would totally change our science. But, we ought to
 23 set, I think that's what's needed more than anything
 24 else, because I think that we're measuring the wrong
 25 thing. And, I would argue that our document ought to

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1 set the, ought to, appropriately, set the background
 2 for that type of a recommendation, 'cause that's where
 3 I think we're headed. And it's not in there now.
 4 DR. HENDERSON: Has the shorter averaging
 5 time been considered in the, by the Agency, because in
 6 our discussion, I had the same thought, James, and I
 7 thought, well, gee, maybe we're looking at the wrong
 8 averaging time.
 9 DR. CRAPO: Well, both daily and, sure, I
 10 mean, one-hour and dailies is, those are two changes to
 11 it.
 12 DR. HENDERSON: I'm just curious if the
 13 Agency has, that's ever come up.
 14 DR. ROSS: Well, I mean, you can look in
 15 the history of the rule making, and in 1993, actually,
 16 you'd have to ask Karen Martin the specific history,
 17 but we made an effort to try to breakdown into short-
 18 term and long-term exposure discussions. And within a
 19 short term, there are a range of different levels.
 20 Many of the epi studies use 24 hour, but we did try to
 21 discuss the evidence at, related to averaging time.
 22 Tox studies use a whole variety of different exposures.
 23 And then, we try to make that available, to the extent
 24 we can say something about peak exposures, we will.
 25 There aren't many epi studies that look at peak



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1 exposures. I'm not even sure there are many tox
 2 studies, but we'll try to bring that up as much as we
 3 can. I mean, we're taking that ho-, as a comment that
 4 we need to address.
 5 DR. CRAPO: Remember if the ozone field
 6 goes that direction, for shorter averaging times and
 7 it's, because it's been there for decades, it has
 8 really influenced the thinking of the evolution in that
 9 field. This data would suggest that NO2 has a toxic
 10 profile similar to ozone. In fact, it interacts with
 11 ozone to make it this toxic product. So, there's no
 12 rationale for having a different, an annual averaging
 13 time for NO2, and a short averaging time for ozone. I
 14 would just argue that you can use the science of the
 15 ozone science to justify a lot more evaluation of why
 16 NO2 ought to have the same type of short-term
 17 evaluation on it. And part of our problem is we set it
 18 up wrong thirty years ago, and we've got a bad
 19 collection of data to compare everything to.
 20 DR. BALMES: I guess the other point that
 21 we should emphasize, this is John Balmes, is that if
 22 asthma exacerbation is one of the major endpoints that
 23 we feel the epidemiology supports, and I certainly
 24 think it does, then it makes no, you know, an annual
 25 average does not protect asthmatics from exacerbation.

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1 DR. HENDERSON: Okay, thank you. I was
 2 thinking of the ozone and, you know, the eight hour
 3 standard make sense because it's much higher during the
 4 daylight hours.
 5 DR. CRAPO: And so NO2 is the same- -
 6 DR. HENDERSON: Is, is NO2 in the same -
 7 -
 8 (WHEREUPON, there was a discussion off the record.)
 9 DR. CRAPO: NO's shorter than the ozone
 10 peak, isn't it?
 11 DR. RUSSELL: It's actually a very
 12 different shape.
 13 DR. HENDERSON: Yeah, I think we'd have
 14 to be a little careful, but you know, I - -
 15 (WHEREUPON, there was a discussion off the record.)
 16 DR. HENDERSON: Terry, Terry has his hand
 17 up, or you want to go to Dale?
 18 DR. GORDON: I had a feeling that this
 19 conversation was going to go this way, and I was
 20 wondering if it did, we went to shorter term. Are we
 21 going to lose something. It sounds like people are
 22 leaning toward a short term, not a long term, and how
 23 would that effect the true long-term studies, such as
 24 the children's lung growth studies, which might be more
 25 correlated epi wise with annual averages. I mean, to

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1 me, the epi drives it. We'd, logically, might think,
 2 oh, it's a short term for that day that really drives
 3 it, but we have to come up with a value, and if all the
 4 epi is driven by lo-, the annual averages, we got a
 5 tough task.
 6 DR. HENDERSON: That's a good point.
 7 DR. CRAPO: For particulates, we have
 8 two, so we could keep both, then. We could put a
 9 short-term and a long-term standard in. Well, we
 10 couldn't, but the Administrator could.
 11 DR. COTE: And if you were, if you're
 12 thinking about two different kind of health effects,
 13 like lung growth and asthma, there's no reason to think
 14 it would be the same. It might be, but I'm not sure, I
 15 don't know.
 16 DR. BALMES: And, there's also no reason
 17 to have the same type of siting criteria for your
 18 monitors if you're going to go to a short-term
 19 standard. Because, I can walk down a street canyon for
 20 an hour and get a completely different exposure than I
 21 will at a EPA monitoring site for an hour.
 22 DR. ROSS: Just to remind people, we're a
 23 little ahead of the process here, talking about the
 24 standards already and the sited criteria.
 25 DR. HENDERSON: No, we tend to jump over

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1 to the endpoints, so let's, but, I really would like to
 2 draw this together so that we complete our peer review
 3 of the ISA document, and Ellis, would, I'll give you
 4 the last call before I ask.
 5 DR. COWLING: Well, I would just like to
 6 support what Jim Crapo has suggested here, with the
 7 additional suggestion, and this is where they did do
 8 what Karen Martin told us yesterday. What was in the
 9 mind of the Administrator, and what are the policy
 10 implications of having an annual standard, and what are
 11 the policy implications of having a daily standard, or
 12 any other standard. And it seems to me that we ought
 13 to know what was the rationale in 1971, when an annual
 14 standard was selected. And now, and then, we have the
 15 other iterations in '93 and so on, what was in the mind
 16 of those who made the decisions at that time. And I
 17 think if that is clarified, it would provide a more
 18 rational basis for a decision about what is the proper
 19 averaging time.
 20 DR. BALMES: Ellis, I can tell you one
 21 thing. I was, way back in my youth, I was in the
 22 public health service at EPA. And the very first
 23 criteria document, as you know, were very thin, and
 24 committees were about five or six people, and the
 25 process took a day, so.



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1 DR. HENDERSON: Oh, you're making us all
 2 jealous. Anyway, I do want, we are skipping way ahead.
 3 We're going to the next step. And we, before we go
 4 there, we need to complete our review of the ISA, which
 5 is looking at the science. So, I want to know if
 6 everyone in the room and on the phone is comfortable
 7 with the substance of what we're going to put in the
 8 letter. And you will see this, the draft come-, the
 9 letter come out, and you will get to, we will seek
 10 concurrences.
 11 We always do, so, is there anyone who is not
 12 comfortable with it? John Samet, are you on the phone?
 13 Oh, he's coming this afternoon, okay. Well, we have a
 14 quorum of the chartered members of CASAC here who
 15 are
 16 all comfortable with this, so I consider that the
 17 charter members have approved this, the substance of
 18 this letter that's going to go out.
 19 What comes out next is going to be the draft
 20 letter, and with Angela's able help, I hope we can get
 21 it out fairly soon. And then, you must look at it very
 22 carefully, and we will seek concurrence before it
 23 actually goes in. And any questions about that
 24 process? Well, I thank everybody for cooperating so
 25 well with this new way of doing things. We'll see if
 it works out. I don't know if it, it hasn't quite

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1 reached it conclusion, but all of you, by participating
 2 so readily, I think have helped it, and we may continue
 3 to do this.
 4 The next thing on our agenda was to move on
 5 to the next document. I think maybe it's time for a
 6 break, and we'll take a fifteen minute break, then
 7 we'll come back and we'll hear from the Air office.
 8 And they are going to move us in the direction we keep
 9 trying to go.
 10 (WHEREUPON, a break was taken.)
 11 DR. HENDERSON: If everybody could take
 12 their seats. Thank you, Doug. Okay. We're going to
 13 be moving on, here comes Ron, if others could take
 14 their seats. We're going to be moving on to a
 15 consultation now for our next document, which is the
 16 exposure risk assessment methods document. And, as
 17 we've been saying, we keep jumping in this direction
 18 from going from the science assessment to wanting to
 19 participate in this part of the process. And this is
 20 our opportunity. As a consultation, this is where we
 21 can, early on in the development of this process,
 22 provide advice to the Agency on the methods for
 23 exposure and risk assessment. So, we had quite a bit
 24 of discussion on exposure assessment this morning. It
 25 is, we're going to hear first, then, from the Agency,

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1 and I would ask, the first speaker is going to be
 2 Lydia?
 3 MS. WEGMAN: Yeah.
 4 DR. HENDERSON: Okay, and Lydia, maybe,
 5 you know, as you go through, you can introduce the
 6 others from the Air office who are going to be
 7 participating. So, it's a real privilege to have Lydia
 8 with us. She always clarifies things.
 9 MS. WEGMAN: Well, I don't know about
 10 that, Rogene, but thank you very much. My name's Lydia
 11 Wegman, and I am the Director of the Health and
 12 Environmental Impacts Division in the Office of Air
 13 Quality Planning and Standards. And we are the folks
 14 who will be working on the exposure and risk
 15 assessment, and ultimately, the advanced notice of
 16 proposed rule making and the proposed rule and final
 17 rule. And I do want to introduce the folks who are
 18 with me, or the ones who have done the real work on the
 19 scope and methods plan for the exposure and risk
 20 assessment. And Dr. Karen Martin, who will speak in a
 21 moment after I'm done, Dr. Scott Jenkins, Dr. Stephen
 22 Graham, and Dr. Harvey Richmond.
 23 MR. RICHMOND: I'm no doctor.
 24 MS. WEGMAN: Oh, no doctor, you should be
 25 a doctor, though. You do the work of a doctor. So,

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1 this is our team on the exposure and risk planning for
 2 the NOx review, the primary NOx review, and we'll be
 3 coming to talk with some of you next week about our NOx
 4 and SOx secondary review.
 5 I first want to say thank you all for taking
 6 the time to review the work we've done, and to spend
 7 the couple of days you're spending here in RTP, either
 8 in person or by phone, to offer us your comments. Your
 9 comments are invaluable to us, and without the work of
 10 CASAC, we would not be able to perform our work.
 And I
 11 just want to say how very important your work is to us,
 12 to the Agency as a whole, and to public health. And
 13 thank you very much for all the work that you do.
 14 I, also, just want to make one point, as you
 15 offer us comments on the scope and methods plan. As
 16 you have seen, and I know several of you have
 17 commented
 18 on, we've got a tiered assessment, both for the
 19 exposure and risk assessments. And, one of the reasons
 20 we have the tiering is that, we don't know whether
 21 we'll have the scientific evidence to go through all
 22 tiers of these assessments, and we are very much
 23 looking to you for advice on how to prioritize these
 24 assessments, and what we do need to do, based on what



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1 are the resource constraints that we face in our
 2 office. We have constraints, not only in terms of
 3 people and money, which are constraints that we always
 4 face, and it does seem that we face them more every
 5 year with declining budgets. But, we also have a time
 6 constraint in this case. As you know, we have a court
 7 order. It's currently under review by the public, but
 8 we very much anticipate having a final court order that
 9 gives us firm dates by which we do have to complete the
 10 proposed and final rules, as well as the ISA. And,
 11 that does limit what we can do. And I want to alert
 12 you to that, because I know that there is a desire on
 13 all of our parts to do the maximum amount of assessment
 14 that we possibly can do with the science that we have.
 15 But we will, in fact, be facing some constraints, and I
 16 want to seek your help in knowing what is the most
 17 important thing to do within the time and resource
 18 constraints we have. So, as you think about these
 19 issues and give us your advice today, I'd appreciate it
 20 if you kept that in mind.
 21 And now, I'm going to turn it over to Karen,
 22 who is going to offer a few thoughts on multi-pollutant
 23 assessments.
 24 DR. MARTIN: Just, while this is, you all
 25 have been talking some about the issue of multi-

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1 pollutant approaches, and multi-pollutant standards,
 2 and multi-pollutant interpretations of scientific
 3 evidence, and the question is, the tangentially
 4 related to the subject we're here to talk about, our
 5 plan for doing exposure and risk assessment, but it's,
 6 obviously, more broadly related to our ultimate review
 7 of these primary and of two standards, and our review
 8 of standards in general. And I just wanted to take a
 9 moment and make a few observations about the
 10 discussion, and sort of, our view of it.
 11 In the context of science assessment
 12 documents, it's clearly extremely important that those
 13 assessment documents do everything they can to tease
 14 out, what do we know about any individual pollutants
 15 effects, and what do we know about the interactions of
 16 that pollutant with other pollutants, and to what
 17 extent can we define specific effects related
 18 individual pollutants versus to what extent does the
 19 evidence limit us to only making more general
 20 observations about associations of air pollution more
 21 broadly.
 22 All those issues are extremely important, and
 23 your discussions are helping, I think, to sharpen the
 24 science assessment document in that regard. It becomes
 25 important for us, of course, at least as an initial

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1 step, in deciding how to approach our exposure and risk
 2 assessments; what is it we're assessing the risk of.
 3 We can, obviously, make some up-front assumptions, and
 4 my comments yesterday were intended to help get your,
 5 at least, preliminary thinking to help us do that. But
 6 our assumptions can, then, be further refined, as we go
 7 through the process of doing a first phase and a second
 8 phase of a risk assessment, so that, in the end, we
 9 can, are in the best position to characterize what, in
 10 fact, we think our quantitative assessments reflect the
 11 risk of, in this case, only SO₂, SO₂ in combination
 12 with other pollutants, SO₂ as a surrogate for other
 13 pollutants. All those things are things we are, in the
 14 end, going to have to speak very clearly to. So the
 15 more you help us, at this early stage in the game, with
 16 some of your thinking at this stage, and recognizing we
 17 can further refine that as we go about characterizing,
 18 in the end, the results that we do produce.
 19 Beyond that, the issue of multi-pollutant
 20 standards and multi-pollutant strategies, obviously,
 21 has much broader implications for all of our NAAQS
 22 reviews, and for what the Office does in implementing
 23 programs to address the NAAQS. And I would just make
 24 the observation that, some of the comments I heard, I,
 25 perhaps, unintentionally, have the, sort of sounded

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1 like, there is an inherent mismatch between setting
 2 standards for individual pollutants, and crafting
 3 control strategies that most efficiently and
 4 effectively get at the mix of pollutants that are, in
 5 fact, of concern.
 6 And I would offer the observation that I
 7 don't, really, perceive that to be a mismatch. It's
 8 clearly a distinction, but one can, clearly, have
 9 standards for individual pollutants in conjunction with
 10 air quality management programs that are very multi-
 11 pollutant oriented, and seek to find the most efficient
 12 strategies for addressing all the pollutants for which
 13 we have standards. And, you all, I mean, different
 14 people have different views on that, but I just wanted
 15 to make the observation that there isn't, necessarily,
 16 an inherent mismatch, or contradiction in doing those
 17 things.
 18 The one pollutant that we truly have a multi-
 19 pollutant standard for is, of course, particulate
 20 matter, which is a collection of thousands of
 21 pollutants. And if you think about it, we have
 22 established that as a multi-pollutant standard under
 23 the guise of PM mass, and a great deal of the research
 24 right now is focused on trying to tease out what are
 25 the differing relative toxicities of the individual



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1 components within that mix. So, when we
 2 do find ourselves faced with what truly is a multiple
 3 pollutant standard, what we set about to do is trying
 4 to figure out how to separate it out. And I think
 5 that's sort of informative as to what utility there
 6 might be in trying to aggregate all the other
 7 pollutants into one standard, with interaction terms,
 8 wouldn't our next step, logically, be trying to sort
 9 out the relative toxicity.
 10 So, I just wanted to offer those
 11 observations, in terms of, the issue is really an
 12 important one, but perhaps, it's not as much of a
 13 mismatch or contradiction as one might originally
 14 think.
 15 Those were the points, observation points I
 16 wanted to offer before we get into it, so if there's
 17 nothing else we need to deal with, why don't we just
 18 jump in to the overview presentation we wanted to make.
 19 DR. HENDERSON: I think that's, that
 20 would be good. Donna has a question.
 21 DR. KENSKI: Well, just a response, I
 22 guess, to the idea that single pollutant standards
 23 don't, necessarily, preclude multi-pollutant controls.
 24 Well, I, you know, it's clear that, you know, a control
 25 on one pollutant will almost always, you know, have an

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1 states, it's the Saint Louis area. And so, we, in
 2 fact, are very mindful of that issue. As far as the
 3 planning goes, I think Karen is addressing, you know,
 4 the way in which we set standards right now, which does
 5 not, in fact, preclude multi-pollutant planning. And
 6 we can set-, you know, at this point, we do need to
 7 look at the pollutants individually, but that doesn't
 8 prevent us from moving forward to multi-pollutant
 9 planning. And that's, definitely, what we are trying
 10 to do.
 11 DR. HENDERSON: Thank you. And so,
 12 Karen, are you going to, who is our first speaker for
 13 the - -
 14 DR. MARTIN: Scott's going to take the
 15 lead in covering the opening, and Stephen and Harvey
 16 will round out the opening presentation.
 17 DR. HENDERSON: Okay.
 18 DR. JENKINS: Okay, thanks. My name is
 19 Scott Jenkins, and I'm the health lead for the NO2
 20 review and OAQPS. And I'm going to be talking through,
 21 probably, three or four slides on giving a little bit
 22 of background on the current approach that we have
 23 proposed in the scope and methods plan. And then,
 24 Stephen is going to talk through the exposure part of
 25 it, and Harvey is going to talk through the risk part

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1 effect on other pollutants, it still, you know, the
 2 burden on the states to comply with the single
 3 pollutant standard requires that they produce a, you
 4 know, state implementation plan. And in that plan,
 5 they have to provide for how they're going to control
 6 that single pollutant, not multi-pollutants. So, I
 7 think the, you know, it would, while we get these, sort
 8 of, indirect, you know, controls on other pollutants,
 9 it would be more straightforward, I think, to, you
 10 know, have a multi-pollutant approach that really, you
 11 know, dictated this, you know, need to control all
 12 pollutants, not just single pollutants. So, while, you
 13 know, while, yes, we do get controls, still the burden
 14 on states is to demonstrate their control of a single
 15 pollutant for a single standard.
 16 MS. WEGMAN: Yeah, and I'll just respond
 17 briefly. We are very mindful of the air quality
 18 manager port that the NRC issued, and we did, there is,
 19 in fact, a subcommittee of the Clean Air Act Advisory
 20 Committee that has looked at all the recommendations
 21 coming out of the air quality management report,
 22 including the one to develop multi-pollutant plans, and
 23 we, in fact, have a project going on in our office to
 24 pilot multi-pollutant planning with three states, North
 25 Carolina, New York, and Illinois, Missouri, four

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1 of it.
 2 Okay, so we're all aware, by now, that our
 3 purpose here to solicit feedback on our proposed
 4 approach to assessing risks and exposures. I just went
 5 through this, so I'm going to talk through, a little
 6 ahead on the schedule a little bit, talk about the
 7 previous review, and give a little bit of what, I hope,
 8 is historical perspective. And then, talk about the
 9 scope of the plan.
 10 Okay, first schedule, and Mary presented the
 11 same slide yesterday, so I'm not going to go through
 12 anything in detail, other than to point out that the
 13 next time we will be soliciting, or will be meeting
 14 with CASAC will be Spring of '08, where we'll be asking
 15 for feedback on the second draft of the ISA, and the
 16 first draft of the risk and exposure assessment, and
 17 then, again, September of '08, for the second draft of
 18 the risk and exposure assessment. And then, the final
 19 date here, this is our, the date that we anticipate
 20 will become our court ordered date. This is about five
 21 months earlier, just to point out, five months earlier
 22 than the dates we had originally proposed.
 23 Okay, so a little bit of background, and
 24 this, and I'm going to expand on this side a little
 25 bit, just based on the conversation that we just had



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1 prior to the break, and that is, providing a little bit
 2 of historical perspective for how the original standard
 3 was set.
 4 So, the original standard was based on
 5 epidemiology studies that were conducted in
 6 Chattanooga, Tennessee, basically, where the long-term
 7 annual average levels of NO2 were correlated with
 8 health effects. The issue that arose later with those
 9 studies was that the issue of confounding with other
 10 pollutants, an issue of the measurement approach to,
 11 for, from measuring NO2 in the studies.
 12 So, what happened was that, the original
 13 standard was set based on those long-term epi studies.
 14 And then, every review since then has focused,
 15 essentially, on the short-term issues. And the crux of
 16 the decisions that the Administrator has made are how
 17 well does that existing long-term annual standard
 18 protect against short peak exposures.
 19 So, I think that'll become clear when I go
 20 through the slide a little bit, but that just gives you
 21 a little bit of a historical context.
 22 So, and their talk-, specifically, about the
 23 last review of the NO2 NAAQS, and the Administrator
 24 had
 25 a, made a couple of conclusions regarding the
 sufficiency and the necessity of the existing annual

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1 standard. The first conclusion was that the existing
 2 annual standard will maintain annual NO2 concentrations
 3 well below levels, long-term levels that are of
 4 potential concern. And those long-term levels of
 5 potential concern were derived from the animal tox
 6 literature. And this is, basically, a fi-, based on
 7 findings that if you expose animals for relatively
 8 long periods of time to relatively high levels of NO2,
 9 you get emphysema-like lesions in the lung. And then,
 10 we're talking about, at least months of exposure to,
 11 say, at least 5 ppm NO2 here.
 12 So, it's pretty much, it's pretty easy to see
 13 that, yes, the existing annual standard of .053 ppm
 14 will protect against those sorts of long-term effects.
 15 The other conclusion, and this is, really,
 16 more of the focus of the last review, the other
 17 conclusion was that the existing annual standard will
 18 provide protection against the short-term peak NO2
 19 levels that are of concern. And those short-term
 20 levels of concern were derived from the human clinical
 21 literature. This came from a set of studies showing
 22 that, in asthmatics, if you expose asthmatics to levels
 23 as low as, say, .2 to .3 ppm NO2, you can get increased
 24 airway response in this.
 25 So, the way that the second conclusion was

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1 arrived at was that we conduct-, we and OAQPS
 conducted
 2 an air quality assessment, essentially, evaluating the
 3 relationship between the annual average NO2 levels and
 4 short-term one-hour average NO2 levels. And, as part
 5 of that evaluation, we looked at the number of
 6 exceedance as a very short-term benchmark values, with
 7 the assumption that were just meeting the current
 8 standard.
 9 So, those benchmark values were derived,
 10 again, from these clinical studies that I just
 11 mentioned, and, basically, the result was that, if you
 12 assume that the existing annual standard is being
 13 attained, the short-term levels of NO2 of potential
 14 concern would be very unlikely in most parts of the
 15 country. I think Los Angeles had a few exceedances at
 16 the .2 ppm level, but that was the only spot where
 17 those exceedances were found.
 18 So, that was, this was the structure of the
 19 la-, the con-, of the decision framework for the last
 20 review. And now, I'm going to move to the current
 21 review, and talk just for just a minute about the scope
 22 of the planned risk and exposure assessment, and then
 23 I'm going to turn it over to Stephen.
 24 We hit on this a little bit yesterday, this,
 25 using NO2 versus other oxides of nitrogen. Obviously,

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1 NO2 is but one of the oxides of nitrogen that include
 2 both gaseous and particulate species.
 3 There are really two issues, I think,
 4 embedded in this. And that is, first, that is using
 5 NO2 as a surrogate for the gaseous nitrogen oxide, and
 6 the other issue is using, is focusing this review on
 7 the gaseous nitrogen oxide.
 8 So, regarding the first, the first statement,
 9 you know, and I think this was borne out yesterday,
 10 we're thinking-, we're planning to use NO2 as a
 11 surrogate for the gaseous species, basically, because
 12 the lack, relative lack of health effects data, and
 13 actually, it came out yesterday, also, the relative
 14 lack of monitoring data for gaseous species other than
 15 NO2.
 16 In the case of the particulate, the second
 17 point that I made, the particulate nitrogen oxide, and
 18 we made this point in our integrated review plan, and
 19 we, this point, also, came up at our last consultation
 20 with you last spring, that the particulate species are
 21 addressed by the current NAAQS, and the rationale
 22 provided right here, basically, the last review for
 23 the, of the PM standard concluded that size
 24 fractionated particle mass, rather than chemical
 25 composition was the most appropriate way to address



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1 ambient PM.
 2 This conclusion, obviously, is going to be
 3 reassessed in the next review, or I should say, the
 4 current review, since it's already kicked off. We had
 5 the opening workshop. But at present, it would be
 6 redundant to, also, use the NO2 NAAQS to protect
 7 against the health effects of particulate nitrogen
 8 oxide.
 9 Other than that, I just want to point out
 10 that the assessment is going to evaluate, this will be
 11 a recurring theme throughout Stephen and Harvey's part
 12 of the talk, that the current assessment, we're
 13 planning to assess both recent ambient levels of NO2,
 14 ambient levels that are associated with just meeting
 15 the current standard, and ambient levels that are
 16 associated with just meeting the potential alternative
 17 standards, which will be identified as we move forward.
 18 And the assessment's going to focus on both short- and
 19 long-term exposures.
 20 So, that's all that I had to say in the way
 21 of background and introduction. I'm going to turn it
 22 over now to Stephen, who is going to talk us through
 23 the proposal, proposed plan for the exposure
 24 assessment.
 25 DR. GRAHAM: Thank you, Scott. Could you

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1 work the clicker? Sometimes I have a habit of talking
 2 with my hands. Okay, all right, thank you. So, of
 3 course, the general, broad goals of this exposure
 4 assessment are to estimate both short-term and long-
 5 term exposures, short-term being hourly, and that is
 6 associated with these current levels of ambient NO2,
 7 and assuming alternative levels of NO2.
 8 Also, to develop these quantitative
 9 relationships, based on the form of the current
 10 standard, which is long-term, annual average and the
 11 relationship between that average and the short-term
 12 peak concentrations, which was done in the prior review
 13 as well. But in addition, I want to, also, consider
 14 local source influences, which we saw was important in
 15 the review of the ISA, and the impact on the exposure
 16 estimates.
 17 As far as the approach, it's already been
 18 mentioned that we have three tiers. The tier one is
 19 air quality characterization. And I'll go through each
 20 of these in greater detail, I guess, or of course, it's
 21 been in greater detail in the scope of methods
 22 document. Populations considered include the general
 23 population, as well as the individuals identified as
 24 susceptible or vulnerable. And the assessment of
 25 uncertainty is also going to be approached in a tiered

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1 fashion, that is going from, in a sense, a qualitative
 2 evaluation and progressing to a quantitative evaluation
 3 if, of course, data exists to support that type of an
 4 evaluation.
 5 So, the tier one, as I mentioned, is a air
 6 quality characterization, and the purpose there is to
 7 estimate the potential exposures, using the current, as
 8 well as historical air quality data that we have
 9 available to us, and use that as a surrogate for
 10 exposure. In addition, we are proposing to take a
 11 glance at some of these near roadway exposures, using
 12 the ambient data, using enhancement factors. And then,
 13 of course, any available concentration data and
 14 emissions data that may be available to look at the
 15 influence from sources, particular sources that may be
 16 outdoors or indoors.
 17 The locations that we considered are
 18 outlined, based on the, those criteria that is, air
 19 quality trans data availability, you know, number of
 20 monitors, whether the data are quality assured and
 21 comprehensive, and in addition, to some other criteria.
 22 And we've selected Los Angeles, Houston, Atlanta,
 23 Philadelphia, and Chicago, and possibly, aggregation,
 24 based on some of the analyses that are going to be
 25 performed here.

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1 The expected output is, of course,
 2 descriptive statistics for NO2 in some of these
 3 selected locations; relationships between the short-
 4 term peak levels and the long-term average levels; and,
 5 of course, identification of additional areas to be
 6 modeled in the tier two and tier three, dependent on
 7 the analysis outcome.
 8 Uncertainty will, primarily, be qualitative
 9 at this stage, and of course, these tier one exposure
 10 assessment, the outcome is going to be used for
 11 comparison with some of the health benchmarks, once
 12 they are identified.
 13 So, in tier two, we've got, the purpose is to
 14 improve that relationship. So, now, we're trying to
 15 link the actual concentrations, themselves, to persons,
 16 to humans. And we are going to, of course, consider
 17 both the on roadway and, as well as, near roadway,
 18 using dispersion modeling and or enhancement factors as
 19 well.
 20 The model concentrations for other outdoor
 21 sources, if there are any identified, as well as the
 22 indoor sources, if they are identified as being
 23 important in influencing these exposure estimates or,
 24 shall I say, the relationship between, I'm sorry, the
 25 contribution, the relative contribution between the



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1 two, that will be done as well. And, of course,
 2 consider influential factors, that is, time that people
 3 do spend in particular microenvironments, as well as
 4 the limited decay of NO2 indoors, and populations
 5 residing near roadways.
 6 The locations, of course, are going to be,
 7 it's going to be a more focused analysis, and it's
 8 going to be focused on the locations that have been
 9 identified in the tier one analysis.
 10 And the output is going to be broken up into
 11 two different exposure metrics. We've got short-term
 12 exposure outcome, where we have, in addition to the
 13 temporal and spatially resolved ambient air quality
 14 concentration fields, that account for local sources,
 15 like emissions from roadways and other sources that are
 16 identified as important. We've got estimates of the
 17 number of individuals who may experience exposures of
 18 concern. Not to suggest that it's an individual
 19 analysis. It's more of a cohort-based analysis.
 20 And then, of course, long-term exposure
 21 estimates will include annual average exposure levels
 22 within a given census tract, and could be considered at
 23 a more finer resolution, say a block group or block.
 24 And it's not just the annual, but also, I believe,
 25 we'll be able to estimate the daily average.

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1 And, in addition, we've got the ratios of
 2 exposure to ambient, which could be useful for
 3 extrapolating to other areas that we had not modeled.
 4 And uncertainty would be addressed, of course, through
 5 various sensitivity analyses, limited sensitivity
 6 analyses, based on input distributions and other model
 7 inputs, as well as measured comparisons, if there are
 8 data that exist for particular microenvironments. That
 9 would be compared to model estimates.
 10 In tier three, of course, it's a more refined
 11 approach, and here we are focusing on addressing more
 12 particulars about human physiology, including time,
 13 well, that's not physiology, but time, location,
 14 activity patterns, and their physiology. Using the air
 15 concentration fields developed from a tier-two
 16 approach, that is where we have the on and near roadway
 17 concentrations, and using the EPA's APEX model for
 18 estimating exposures.
 19 Locations, of course, are built upon what had
 20 been identified in the tier one and used in the tier
 21 two analysis. And, oh, I forgot to mention, of course,
 22 the APEX model is capable of estimating individual
 23 exposure estimates. It's a time series exposure model.
 24 And we also have capabilities to estimate indoor
 25 sources using that model.

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1 So, as I said, the locations are the same as
 2 those identified previously. The expected output is
 3 going to be the counts of people exposed one or more
 4 times to several NO2 levels, based on, of course,
 5 health information obtained from the ISA, and because
 6 APEX is a time series model, and the averaging time,
 7 that is of interest, can be taken out of the, or shall
 8 I say developed as an exposure metric. And we also
 9 have counts of personal occurrences of a particular
 10 exposure.
 11 And the uncertainty can be a little bit more
 12 quantitative in a sense. We can look at, again, model
 13 inputs, where data exists for describing both a
 14 variability and the uncertainty in them, and of
 15 course, model formulation. If we have estimates of
 16 personal exposure that are available to compare that,
 17 as well as microenvironmental concentrations. That's
 18 it. Thank you.
 19 MR. RICHMOND: Thank you, Stephen. I'm
 20 going to walk you through a few slides on the risk
 21 assessment. First of all, overview goals of the risk
 22 assessment are to estimate the number of occurrences of
 23 short-term air quality events and number of people
 24 exposed at, or above, various potential health effect
 25 benchmarks associated with alternative NO2 scenarios.

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1 If a tier two assessment is conducted, we'd also
 2 provide health risk estimates for NO2 health endpoints
 3 associated with alternative scenarios. And for any
 4 tier, we'll, of course, identify and characterize key
 5 assumptions and the variability and uncertainty
 6 associated with the assessments.
 7 As Scott and Stephen have said, the scenarios
 8 evaluated are for both recent air quality, simulating
 9 the current standard, which is a difficult challenge,
 10 given the levels are much lower than the current
 11 standard; and air quality levels just meeting potential
 12 alternative standards, which could be short- or long-
 13 term standards.
 14 There's a two tiered approach here. Proposed
 15 one is the, in tier one, potential health effect
 16 benchmark levels, which will be based on a review of
 17 the revised ISA, would be compared to, first, air
 18 quality and then, exposure estimates generated by the
 19 tiers that Stephen's gone through.
 20 Tier two, if it's judged feasible, and
 21 they're, and of sufficient utility for decision making,
 22 we involve combining concentration response, if it's
 23 based on epi; or exposure response based on controlled
 24 human exposure data, with exposure estimates to
 25 generate population risk estimates. It's what we'd



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1 like to have, ideally. We may or may not be able to
 2 get there.
 3 And next slide, okay. The tier one, as I've
 4 said, the air quality levels from a tier one exposure
 5 assessment, or estimated exposure levels from tier two
 6 or three, would be compared to potential health effect
 7 benchmark levels for several example urban areas.
 8 Those would be the same areas that Stephen's talked for
 9 the air quality and exposure tiers.
 10 We have identified, very tentatively, in a
 11 benchmark of, in the .2 to .3 ppm one-hour averaging
 12 time range, based on the controlled human exposure
 13 studies, of effects that have been observed in
 14 asthmatic, both children and adult asthmatic. There's
 15 uncertainty about those health effect benchmarks that
 16 we see, we'd be using alternative benchmark levels to
 17 illustrate the impact of alternative choices about the
 18 lowest exposure levels of concern.
 19 In terms of variability, we address that by
 20 doing the analysis in different geographic areas.
 21 Population variability in response but it would have to
 22 be addressed qualitatively. We don't have, I think,
 23 data to distinguish that very well. And the projected
 24 outcomes would be the number of occurrences of air
 25 quality levels at or above several benchmarks, or

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1 number of times in a given year that a population or
 2 individual experiences various exposure levels of
 3 concern.
 4 To our next slide. And a tier two, if
 5 conducted, would estimate the number of individuals in
 6 selected populations for several example urban areas
 7 expected to experience specified health effects more
 8 similar to the ozone and PM risk assessments that we've
 9 completed in the last couple of years.
 10 We judged that it would be more likely that
 11 would be based on the epidemiological literature.
 12 Preliminary judgment is that controlled human exposure
 13 studies don't provide enough information to identify
 14 credible exposure response relationships. There's
 15 enough information to judge benchmarks for the health
 16 endpoints, but it's difficult to see how to get
 17 exposure response relationships across the range of
 18 interest.
 19 We're still evaluating. We're, obviously,
 20 listened carefully to what you've said over the last
 21 day and a half. And look forward to seeing how the
 22 revised ISA responds to those, in terms of whether
 23 there's sufficient epidemiological evidence adequate to
 24 conduct a credible quantitative risk assessment.
 25 The criteria listed here for determining if a

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1 tier two assessment would be conducted, including the
 2 outcome and insights gained from the tier one
 3 assessments, both with the exposure and risk
 4 assessment, and availability of information and data
 5 required to conduct a tier two assessment on the
 6 adequacy of concentration response functions, baseline,
 7 and getting baseline incidents data for things like
 8 hospital admissions and emergency department visits for
 9 the example urban areas.
 10 Then, the utility or value added to the
 11 decision process beyond the insights provided by a tier
 12 one assessment, and the feasibility of conducting the
 13 assessment within the time constraints that we have.
 14 Next slide. Based on our preliminary
 15 analysis of the first draft ISA, the most likely
 16 candidate endpoints are listed here. I think that was,
 17 generally, in agreement with what I heard yesterday in
 18 the discussion on ISA. But the strongest evidence from
 19 the epi would be for respiratory related morbidity
 20 endpoints, including hospital admissions, especially
 21 for asthmatics; respiratory related emergency
 22 department visits; and respiratory symptoms, such as
 23 cough and wheeze, particular in children and
 24 asthmatics.
 25 Risk estimates, if we do proceed to this

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1 stage, we would propose to conduct both sing-, use both
 2 single and multi-pollutant models. And uncertainty
 3 would be addressed similar to how we've handled in PM,
 4 the statistical or sample size uncertainty, that we
 5 would provide confidence intervals around point
 6 estimates of risk, and representing a range of results,
 7 based on different epidemiological studies.
 8 Expected outputs are listed here, in terms of
 9 we would look at estimated incidents that can express
 10 the results in a number of different ways. Incidents
 11 per hundred thousand and or percent of incidents. And
 12 this would address hypothetical change in incidents
 13 associated with moving from just meeting the current
 14 standard to just meeting potential alternative
 15 standard.
 16 The final part of the risk characterization
 17 is several things that we've tried to either put the
 18 more limited example, like, you know, urban areas
 19 analysis, is one to summarize U.S. air quality
 20 information, and discuss the various health effects
 21 that we were not able to quantify from the ISA. So,
 22 that would certainly be part of the exposure risk
 23 report to provide context for those things that we do
 24 deal with quantitatively, and would include those air
 25 quality statistics for all air as the U.S. based on the



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1 NO2 monitoring data. And that we'd also provide
 2 information, national scale information on the size of
 3 potentially susceptible or vulnerable populations as
 4 part of that.
 5 DR. JENKINS: Okay and this slide just
 6 has the charge questions to CASAC. This is actually a
 7 condensed version of those charge questions, because we
 8 actually had too many to fit on a single slide, but I
 9 think this captures them.
 10 DR. HENDERSON: Thank you. Karen, do you
 11 have more to present?
 12 DR. MARTIN: I don't believe so, unless
 13 there are some specific questions.
 14 DR. HENDERSON: Okay, now, Lianne, you're
 15 on the phone?
 16 DR. SHEPPARD: I am.
 17 DR. HENDERSON: When are you leaving?
 18 I'm just trying to - -
 19 DR. SHEPPARD: I have two more hours.
 20 DR. HENDERSON: Oh, okay. I was going-
 21 that's good, Lianne. I just wanted to allow you to ask
 22 questions if you were leaving.
 23 DR. BALMES: Rogene?
 24 DR. HENDERSON: Yes.
 25 DR. BALMES: This is John Balmes. I'm

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1 lot of concern about this morning. But let's start in
 2 on the discussion of the air quality section, which is
 3 very brief in this report, and has lots of discussants.
 4 So, we may have more discussion and, than there is
 5 text, here.
 6 SPEAKER: Than material.
 7 DR. HENDERSON: But, what I'd like to do
 8 is run through, you know, there's three, the air
 9 quality section, the exposure section, and the risk
 10 assessment section. We're going to have, open the
 11 discussion up to anyone who has any questions. We
 12 tried to group people as to their interest, rightly or
 13 wrongly, so let's start out with, on the air quality,
 14 Ellis, did you have some comments you wanted to make,
 15 or you know.
 16 DR. COWLING: I must say that the general
 17 impression I have is that the approach is being, that
 18 is being proposed is reasonable, and that I have
 19 confidence that it will be pursued within the limits of
 20 time available that were mentioned. The five months
 21 shorter time frame, I'm sure has caused some anxiety
 22 within the staff about how to get all the things done
 23 that they had hoped that they can accomplish. But, I'm
 24 satisfied that the approach being proposed is
 25 reasonable.

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1 going to have to leave to teach in a few minutes, and I
 2 will be returning in time for the health effects
 3 discussion, which is currently scheduled for, what is
 4 it, 2:15 your time?
 5 DR. HENDERSON: We may be getting to that
 6 a little earlier, because I plan to have a working
 7 lunch.
 8 DR. BALMES: Well, I just, I have to
 9 teach, so I won't be able to join the call till a
 10 little bit after 2:00 your time.
 11 DR. HENDERSON: Okay.
 12 DR. BALMES: Just so you know.
 13 DR. HENDERSON: Okay.
 14 DR. BALMES: I don't have a specific
 15 question right now, though, just letting you know.
 16 DR. HENDERSON: Okay, and if you, let us
 17 know when you join in. Okay, I found it fascinating
 18 our discussion just before we started this about, you
 19 know, the annual average standard and how that relates
 20 to peak exposures. And this group has, obviously,
 21 addressed that, and I, in a statement, if the existing
 22 annual standard is obtained, short-term NO2 levels of
 23 potential concern would be unlikely in most parts of
 24 the country.
 25 That, would, addresses some things we had a

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1 DR. HENDERSON: Thank you, Ellis. Donna,
 2 do you have any comments on this, the proposed methods
 3 for air quality evaluation?
 4 DR. KENSKI: Well, I guess I have a
 5 question.
 6 DR. HENDERSON: You need to get close to
 7 your mike.
 8 DR. KENSKI: Okay, sorry. In answer to
 9 the, I guess, the charge question about whether it was
 10 appropriate to use historic data, I thought that was
 11 the logical approach. I, the question I had was in
 12 the, how you're modeling expected exceedances, and it
 13 gives an exponential model here, and I just wondered if
 14 there were any discussion about that choice of model,
 15 and whether you considered other models.
 16 DR. GRAHAM: That's a good question,
 17 thank you. We've got, that, actually, had been used in
 18 the previous review. So, as I was looking to, I guess,
 19 duplicate that effort, but in addition to that, we are
 20 also going to look at an alternative model that looks
 21 at, like a logistic regression, so it'd be more
 22 probability based.
 23 DR. KENSKI: Okay, yeah, I think that's
 24 appropriate.
 25 DR. GRAHAM: Thanks.



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1 DR. HENDERSON: Is that all, though, or
 2 did you - -
 3 DR. KENSKI: Oh, well, another question
 4 about your choice of, and I'm not sure if this really
 5 fits in, maybe it does. Your choice of cities, New
 6 York wasn't on this list, and that seemed odd to me
 7 that, 'cause it was one of the higher, definitely one
 8 of the higher concentration cities. So, if you're
 9 looking for peak exposures, it seems like you'd choose
 10 those urban locations, and it has lots of monitors.
 11 DR. GRAHAM: Right, I think Philadelphia
 12 was selected over New York, per se, because of, it was
 13 representative of a northeastern region, but the key
 14 feature there was the availability of additional data,
 15 including very refined roadway counts, and other data
 16 that had been developed previously through other
 17 research. So, I thought it would be a slam dunk, per
 18 se.
 19 DR. KENSKI: Okay.
 20 DR. HENDERSON: Is that all? Tim Larson,
 21 are you on the phone?
 22 DR. LARSON: Yes, I am.
 23 DR. HENDERSON: Okay, did you have
 24 comments on the methods for the air quality section?
 25 DR. LARSON: Yes, a couple. It wasn't, I

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1 guess, I have to calibrate my thinking here. The
 2 short-term standard, the health effects for that are
 3 based on the analysis of existing monitoring sites for
 4 short-term NO2 levels, I assume.
 5 Is that the, I mean, is, it seems to me that
 6 the relationship between the short-term values and the
 7 long-term values, and how you do that, depends on what
 8 sort of the health basis you're deriving, using to
 9 derive that short-term value. If it's the epi, then
 10 that's one thing, and then, would you just, sort of,
 11 use the statistics from existing sites.
 12 If it's independent toxicology clinical human
 13 exposures, et cetera, then it seems like, potentially,
 14 there are different relationships between the long-term
 15 and short-term values for parts of urban areas that may
 16 be more relevant than ones at the monitoring sites.
 17 So, I'm not clear, it's not clear to me which is the
 18 basis for your health risk assessments.
 19 To the extent that it's the epi, then I
 20 suspect that the existing monitoring statistics are
 21 relevant. To the extent it's other, then I would
 22 suggest that the relationship, I mean, in the extreme
 23 case, for instance, the one-hour peak exposure is while
 24 you're commuting, which has nothing to do with any of
 25 the statistics or distributions at the monitoring. So,

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1 I guess, the question is, how do you see that going
 2 down?
 3 MR. RICHMOND: Okay, this Harvey
 4 Richmond. Let me try to address that. In, if we can,
 5 the risk assessment has said, at first one tier,
 6 there's, if we're looking at results of either the air
 7 quality in tier one or exposure, either from a tier two
 8 or tier three, either APEX or otherwise exposure
 9 estimates, we're comparing, we're using all of the air
 10 quality information.
 11 We're using the monitoring, but also,
 12 enhancing that with additional information to try to
 13 estimate, either, a surrogate for exposure or getting
 14 the distribution of exposures. That's then going to be
 15 compared with a health benchmark levels that are based
 16 on the controlled human exposure studies.
 17 So, we're trying to match exposure with an
 18 exposure response or an exposure, you know, an effect
 19 observed in a clinical setting. That's one use of it.
 20 And separately, if the epidemiology is deemed that it's
 21 sufficiently one that is likely causal, or you know,
 22 whatever we decide to go down on that continuum of
 23 causality, that we're going to quantify, if we quantify
 24 an effect from the epidemiological literature, those
 25 studies, I agree with you, are based on the ambient

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1 monitoring fixed site monitors, usually the average
 2 across several monitors.
 3 And if we were to do a risk assessment, based
 4 on epi, it would not be based on the exposure analysis.
 5 It would be based on the ambient fixed site monitors.
 6 I hope that clarifies it.
 7 DR. LARSON: Yeah, that helps, thank you.
 8 Well, at least to the extent that it's based on the
 9 human clinical studies, I would suggest caution here
 10 using your near roadway or traffic related impact as
 11 models, because I think you get very different
 12 relationships spatially and temporally in a flat road,
 13 than you would in a built up urban area. So, I mean,
 14 the residential areas of Philadelphia or parts of
 15 Chicago or Houston maybe that's, your approach is fine.
 16 But we're doing studies in Chicago, and I
 17 know for a fact that, is part of our cohort lives in
 18 downtown Chicago, and we can't and don't have any
 19 success using those kinds of approaches in that area.
 20 So, if there was some way to qualitatively screen those
 21 parts of the urban areas that are subject, is more
 22 complicated confinement effects, so that you would
 23 limit your exposure assessment in some way, based on
 24 that.
 25 I would think that's more defensible. You



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1 get a qualitatively different in a distribution and
 2 it's not only, then becomes determined by the geometry
 3 of your urban area, but also you end up with this
 4 question about the vertical distributions within those
 5 confined areas.
 6 And then it, then you really up, you really,
 7 you know, it's an open question as to where the,
 8 whether you've got buildings with open windows, or
 9 whether you've got inlets of a building in a
 10 residential apartment on the roof or on the ground or
 11 whatever, and it gets real complicated in a hurry. And
 12 the, I guess, the basic point is that a simple, sort
 13 of, Gaussian dispersion model do not have much skill in
 14 those parts of the urban area.
 15 So, I mean, maybe it's a qualitative way to
 16 assess, you know, there are methods for doing that.
 17 You know, you can look at building footprints, and
 18 overlay building heights. We've done that in New York,
 19 and we're doing it in Chicago. And you can, sort of,
 20 identify the areas that are, you can just look at
 21 Google, actually, and probably do the same thing, but
 22 more quantitatively, you could do it that way. But I
 23 would say your proposed approach air mod, et cetera, is
 24 fine as long as it's, sort of, single family
 25 residential, but otherwise, it's questionable.

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1 DR. HENDERSON: Do you have a response to
 2 that, I mean, to that, Harvey?
 3 MR. RICHMOND: One thing is I'll note
 4 historically, it's one of the reasons why there hasn't
 5 been an NO2 exposure analysis in the reviews that I was
 6 involved in '85 and '93, is doing this is much more
 7 challenging than doing an ozone exposure assessment.
 8 And we acknowledge that.
 9 I think we're, you know, we're saying, we're
 10 trying to push the envelope as far as we can, and we're
 11 still in the learning phases as to how far that is, and
 12 we'd certainly be interested in the kind of information
 13 that, Tim, that you've cited that, you know, if we, for
 14 some of the example cities, if you have relevant
 15 information, or ideas on how best to do it, or if we,
 16 simply, you think if the advice of this committee is
 17 we, simply, aren't able to credibly do certain parts of
 18 the analysis.
 19 Obviously, from a public health standpoint,
 20 you'd be interested in those levels in those places
 21 where you're saying it's most difficult to conduct the
 22 assessment.
 23 So, that's the challenge we face, and this is
 24 a general road map. We'll see as we get into it, but
 25 we look to the advice of this committee and experts in

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1 the exposure field as to what they think about that.
 2 DR. HENDERSON: And that brings me to a
 3 point that I had meant to bring up earlier. For all of
 4 you who have not yet submitted your individual comments
 5 on this methods document, that's just essential in this
 6 case, because the letter will not, it will be more pro
 7 forma when it's not going to list the consensus. So,
 8 the advice that you want to give to the Agency in this
 9 consultation will come in the form of your individual
 10 written comments, so that increases their importance.
 11 Tim, is that, are you, have you completed your comments
 12 on the air quality section?
 13 DR. LARSON: Well, I, yeah, I think
 14 that's, wait a minute. It certainly, EPA, I think, is
 15 sponsoring some of the work I mentioned, so, you know,
 16 we certainly can do our best to work with the, provide
 17 whatever information we have. We have quite a bit of,
 18 Lianne is involved with this, too. We have quite a bit
 19 of NO2 passive monitoring data, saturation data in
 20 several cities that we're talking about.
 21 DR. HENDERSON: I'm sure they'd
 22 appreciate having all the information you can give
 23 them. Ted, would you - -
 24 MR. RICHMOND: Can I just ask one
 25 clarifying question?

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1 DR. HENDERSON: Sure.
 2 MR. RICHMOND: Tim, that saturation data,
 3 is it for short-term averaging?
 4 DR. LARSON: It's, no, it's two-week
 5 average - -
 6 MR. RICHMOND: Two-week average.
 7 DR. LARSON: Yeah, so that's a problem,
 8 but, yeah, it's a problem. But it - -
 9 MR. RICHMOND: Okay, I just wanted to
 10 clarify it.
 11 DR. LARSON: It can identi-, I mean,
 12 we've done models, though. We, in New York,
 13 specifically, we've done, we've implemented the OSPM
 14 model for New York City, which is kind of an
 15 interesting exercise. And, to do that, you have to do,
 16 or you have to have information on building footprints.
 17 It's a massive undertaking, but so, we have, we have
 18 hourly predictions compared to our measurements. And
 19 they compare pretty well.
 20 I mean, it is reasonably, if you expect to
 21 model that. So, they do have skill, and they, and we
 22 do have predictions on an hourly basis, both as an
 23 urban background model, and superimposed on that is a,
 24 is an OSPM model, and using Mobile Six and the traffic
 25 - - model for New York City.



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1 DR. HENDERSON: Okay, let's move on to
 2 Ted.
 3 DR. RUSSELL: Okay, very much like the
 4 prior individuals, I was, generally, pleased with the
 5 scope document. One of the things, I think, that comes
 6 out of just recognizing that you're going to be doing a
 7 number of these, if you look at it more than one a
 8 year, to get it down to a well-oiled, sort of,
 9 approach, is one of my first recommendations.
 10 And I realize you all are, may not have tons
 11 of resources or whatever, but just something that could
 12 be done such that these things become very automatic.
 13 You know, I look at where we've come in other areas of
 14 the modeling world, and I think that this could be done
 15 when you're looking at exposure and risk analysis as
 16 well, just to make it so it's not as, such a huge
 17 effort every time.
 18 A few things, one of them was, in regards to
 19 what you, when you were presenting this morning, you
 20 said something about locations considered, and you have
 21 the five cities, and then, an aggregation of others.
 22 And then you said, possibly, or maybe you said possibly
 23 before you said that. And I, it brings back what we
 24 discussed in the lead panel was that, we're, I think,
 25 as a whole, more interested in the U.S. than in

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1 read this, it wasn't just peak exposures. It was all
 2 exposures. So, I'm just hoping that you're looking at
 3 doing the exposure analysis at a national level, not
 4 just for five cities, both peak as well as long term.
 5 DR. GRAHAM: The air quality data is
 6 going to be evaluated nationally. When we look at the
 7 focused exposure analyses, that's going to be on
 8 individual cities that had been identified.
 9 DR. RUSSELL: I think we would have some
 10 interest in, maybe I'm not, maybe I'm singular here, of
 11 really the interest at a national level somehow
 12 extrapolating or doing something to get, to give us an
 13 idea of what's happening nationally, not just at those
 14 cities. Because it came up in the lead. It came up in
 15 the ozone, as well, that that would be some important
 16 information.
 17 And, let's see, one, just a minor comment, in
 18 your model, in terms of how to go away from roads use-
 19 -
 20 DR. MARTIN: Just, if I may?
 21 DR. RUSSELL: Yes.
 22 DR. MARTIN: Just to come back to the
 23 point you just made. I can't not make the observation
 24 that, as we move to exposure modeling, what we and you
 25 both are looking for is to develop enhancements to

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1 individual cities.
 2 I'm just wondering how you can, how you would
 3 plan not to do an aggregation of others, because I
 4 think that would be somewhat more instructive to us, to
 5 show us, on a national basis, the exposures of concern.
 6 So, do you want to respond to that, how you're going to
 7 make that decision not to do an aggregation of others,
 8 or?
 9 DR. GRAHAM: Delete possible.
 10 DR. RUSSELL: Okay.
 11 DR. GRAHAM: No, the intent was, in the
 12 original analysis, they had done Los Angeles as a
 13 separate area, and everything else was just lumped
 14 together. And here I was proposing, okay, we can do
 15 multiple locations, and if it's of value, we can look
 16 at these other locations as well. And the criteria, in
 17 a sense, for selecting the individual areas is based on
 18 the fact that, we do have some information on the fact
 19 that there are more peak occurrences.
 20 In these other locations, there may not be.
 21 So, in a sense, the model for predicting peak exposures
 22 over a particular level, it just may fall apart,
 23 because there are no peak exposures. So, that's why I
 24 say possible.
 25 DR. RUSSELL: Okay, though, the way I

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1 those models to be, to address the location-specific
 2 issues that are so central to understanding exposures
 3 to NO2.
 4 Once you zoom out and now say, oh, let's do
 5 that on a national scale, you lose all your local
 6 specificity, which is why we would approach a national
 7 look on the basis of air quality, recognizing it's a
 8 pretty gross approximation, and looking on the local
 9 level, to try to tease out the nuances of exposures
 10 around roadways and building canyons and those sorts of
 11 things that we couldn't possibly do on a national
 12 scale.
 13 So, I mean, we're not trying to be resistant
 14 to say, yes, it would be nice to know exposures on a
 15 national scale, but I think the best we can reasonably
 16 do is to do the more generalized air quality, look on
 17 the national scale and to tease out the details
 18 locally.
 19 DR. RUSSELL: Dale has a comment, I
 20 think, in response.
 21 DR. HATTIS: Yeah, but, yes, essentially,
 22 you've got three legs of a parallelogram approach here,
 23 at least, in your plan. You've got the local
 24 assessment of air quality. You've got the local
 25 assessment of exposure. You've got the national



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1 assessment of air quality.
 2 I think it's not too much to hope that you
 3 apply the lessons from the comparison of the local
 4 assessment of air quality and the local assessment of
 5 exposure to make, at least, a preliminary national
 6 projection of the exposures, if the regularities you've
 7 observed in your fully analyzed cases apply to some
 8 portion of the national air quality data.
 9 I mean, you, probably, wouldn't apply the
 10 Philadelphia comparison directly to South Dakota, but
 11 you, probably, want to apply it to some portion of
 12 South Dakota, maybe, in a fraction of Fargo or
 13 whatever, and, to some extent, get.
 14 But anyway, that's the basic idea, is that
 15 it's, it might not be a tremendous expense and of
 16 effort to do that distributional projection for an
 17 appropriate fraction of the country, or the country as
 18 a whole, you know, even though you don't want to do,
 19 in detail, the country as a whole. You can get an
 20 approximation from that, from the comparison.
 21 DR. MARTIN: And then, of course, you're
 22 left with making the judgment, does the approximation
 23 so assume away all the details that are important that
 24 you're left with, clearly we could create numbers, but
 25 would they be meaningful. And if they're not going to

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1 be meaningful, then we would argue, they're not worth
 2 creating in the first place.
 3 So, that's what we have to deal with, and we
 4 can clearly look at it, but that's always the tension,
 5 as you point to with lead as well. And, I didn't want
 6 to just slip by this and so.
 7 DR. CRAPO: I wanted amplify what you're
 8 saying, and maybe, even take it further the other
 9 direction, which is that, your data on local data is
 10 really still coming from your primary monitoring
 11 stations, I assume. That's correct? I mean, your,
 12 like your, near roadway monitoring stations, and things
 13 like that, gives you local data that you'll use for
 14 looking at some of the variation at the more local
 15 level.
 16 But, in fact, what we're learning, as we, or
 17 the mornings is, or what we're learning is that there,
 18 the local level has even tremendous variability within
 19 that. There's each gra-, I mean, gradients across the
 20 roadway are falling away as a, you know, being 10 feet
 21 versus 100 feet versus 1,000 feet for roadway has a
 22 huge impact on the levels. And even being in a car
 23 dramatically changes the level.
 24 I was told during the break that the school
 25 buses are 4.6 times higher than ambient inside the bus,

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1 as opposed to standing by the roadside. So, I guess
 2 that I'm thinking that a lot of your, most of your key
 3 data that's going to explain health effects are going
 4 to come from understanding local variability.
 5 And I, and it's where I'm going with this is,
 6 is the, you need to associate locally, but you'd
 7 probably have to have wide, a careful thought and
 8 discussion about the variances even locally, 'cause
 9 you're only very, barely touching that, that part of
 10 the parameter.
 11 Sounds to me like the, if you're doing a near
 12 roadway, for example, comparison, you might have
 13 various people that are experiencing that for which,
 14 that have levels that are many, many times others that
 15 are in the same environment because of the way they,
 16 the way they were exposed to it. And so, I'm curious
 17 how you'd handle that variability as you let that
 18 average out.
 19 And that's just, actually, taking exactly
 20 your comment and taking it the other direction, even
 21 more extreme at the local level that we, actually, need
 22 to understand the health effects.
 23 DR. GRAHAM: Well, that is part of the
 24 plan.
 25 DR. CRAPO: Yeah, I like that part, that

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1 you had one-hour average, I just really compliment you
 2 on the fact that your, you did have the one-hour
 3 averaging goals in there.
 4 DR. GRAHAM: Well, and to take into
 5 account, specifically, roadway, on roadway and within,
 6 given buffer distances of the roadway.
 7 DR. CRAPO: And what about inside cars?
 8 DR. GRAHAM: Sure, on road equals in
 9 vehicle.
 10 DR. CRAPO: 'Cause that could've, that
 11 could, actually, do you have, are you going to have
 12 personal monitoring measurements to give you that data?
 13 DR. GRAHAM: No, based on modeling.
 14 DR. CRAPO: You're just going to model
 15 it, okay. That would be key to this whole thing.
 16 DR. HENDERSON: Okay, Ted, did you have
 17 more to - -
 18 DR. RUSSELL: I think that was,
 19 primarily, it, and I'm not sure where we ended up on
 20 it.
 21 DR. HENDERSON: Well, I heard that we
 22 need the local data to be able to relate it to health
 23 effects. I mean, that's, to me, that's, but - -
 24 DR. RUSSELL: Right, I think we want the
 25 local data, and, just, when we sit here and talk about



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1 things later, I think we're going to want to know what
 2 are the national implications. And maybe I'm one of
 3 those who says, if you give me an approximate number
 4 and say it's really approximate, that's a fine thing.
 5 You know, I don't, that doesn't bother me, because I
 6 know what I'm basing my discussions on.
 7 That is, it's a number and there's
 8 significant uncertainty, but it, at least, it's
 9 something that gives me an idea of what's happening
 10 nationally. So that was the, that's my major concern
 11 there. And, let's see. Also, one of the other issues
 12 that I, or thoughts I had on this was, how do you plan
 13 to provide ambient versus total exposure risks, total
 14 exposures and related risks in your assessment, 'cause
 15 I think having that comparison would be insightful.
 16 MR. RICHMOND: Well, in the past, and
 17 we've addressed this in the CO exposure model, where we
 18 included passive smoking in gas stoves, we're able to,
 19 since it's driven by a model, the exposure part, at
 20 that tier of the assessment, to both report total, as
 21 well as, just with the ambient.
 22 In other words, basically, turn the indoor
 23 sources off in the model, and how much is the ambient,
 24 both including ambient outdoors and the ambient that
 25 penetrated indoors, but in the absence of those indoor

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1 sources. So, we do try to provide that perspective of
 2 how much is due to the ambient problem, as opposed to
 3 indoor concentrations as well.
 4 DR. RUSSELL: And that will be included
 5 in this?
 6 MR. RICHMOND: Yes.
 7 DR. HENDERSON: Okay, Christian, do you
 8 have?
 9 DR. SEIGNEUR: Yes, I only have one point
 10 I want to address. It's, when it does a tier two
 11 exposure assessment and the use of the model used to
 12 calculate the air quality concentrations, in your
 13 document, you mentioned you plan to use AERMOD.
 14 You,
 15 also, mentioned the model CALINE4.
 16 My understanding is that AERMOD was the route
 17 for stacks, dispersion of protons from stacks. CALINE4
 18 is most specific to roadways. So, could you clarify
 19 why you're planning to use AERMOD other than
 20 CALINE4?
 21 DR. GRAHAM: Absolutely. While it had
 22 been recommended to me that I use CALINE for, I'm
 23 sorry, AERMOD for few reasons, CALINE, from what I
 24 understand is, the developer of that model had recently
 25 retired, and Air B has no initiative to continue on
 developing that model. So, we can consider that an

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1 DR. GRAHAM: In a sense, it's no longer
 2 supported, so it may have been used traditionally, and
 3 it may look like a reasonable approach now. I guess,
 4 I'm trying to think of the future. And AERMOD is
 5 actually a little bit more advanced. It's based on
 6 boundary layer theory versus stability classes, and has
 7 additional capabilities addressing turbulence and
 8 meandering.
 9 And, I know that the AERMOD doesn't have a
 10 line source option right now, but it is something that
 11 is being considered in the near future, not in time for
 12 this particular review, but it will have that
 13 capability. Right now, what we are proposing is to do
 14 link-based emissions, so, and I think it is being
 15 applied right now in New Haven, Connecticut, and there
 16 has been a paper published recently using CALPUFF,
 17 which is a similar type of dispersion model, to do this
 18 near roadway estimation.
 19 So, it's, I think, not an unreasonable
 20 approach, and there will be, I guess, portions of it
 21 that, of CALINE that may be investigated. I think you
 22 had also mentioned in your comments earlier about the
 23 conversion from NOx to, or shall I say NO to NO2. So,
 24 that may be an important feature there.
 25 But, again, it was to look for, look towards

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1 the future, and, in addition, the fact that we are,
 2 also, going to look at additional sources, some of
 3 which are stationary type sources. So, why not use one
 4 model to head all the emission sources.
 5 DR. SEIGNEUR: Okay, yeah, that will be
 6 fine. My recommendations, though, would be that if
 7 you're going to use AERMOD for roadways, that it would
 8 be evaluated prior to, with data graded near roadways
 9 prior to its application. 'Cause EPA, typically,
 10 requires people to evaluate the models before they are
 11 applied. So, in this case, since AERMOD has not been
 12 formerly evaluated for roadway application, that, you
 13 know, EPA would do that.
 14 DR. GRAHAM: Right, yeah, and I did
 15 forget to mention that, that AERMOD is the
 16 recommended
 17 model, at least for dispersion.
 18 DR. HENDERSON: Now, does anyone else
 19 have something they want to comment on the air quality
 20 section, 'cause after this, we'll move on to the
 21 exposure. Yeah, Ron.
 22 DR. WYZGA: I have some questions. Let
 23 me say that, I'm very impressed by the approach, and, I
 24 think, a really good understanding of the exposures
 25 here, and I think you're, really, getting it.
 I think you, it's going to be a challenging



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1 job, but my question was, when you talk about just
 2 meeting the current standard scenario, I just want to
 3 see if I understand it.
 4 The current standard is 0.053 ppm, and let's
 5 say, that you come up with a health benchmark, a new
 6 one, of .05. And that, if, let's say, one of your
 7 cities, your concentration is .04. Does this mean
 8 that, in your risk assessment, you're going to assume
 9 that the people are exposed to .053, as opposed to .04?
 10 DR. GRAHAM: That's a tough one.
 11 MR. RICHMOND: Our dilemma is, for our
 12 purpose, not an impact assessment. We're looking at,
 13 in the country, we have levels, typically, down at .03
 14 and below. So, we're well below the current standard,
 15 annual averages for the current standard.
 16 How do we assess what the risk is for meeting
 17 the current standard. It's not the risk from recent
 18 air quality, which is lower. Is there a scenario, you
 19 know, that we look at as a hypothetical scenario, that
 20 matches exactly the current standard at the monitoring
 21 network, in the design monitor just meets the 53, you
 22 know, ppb.
 23 There are two, you know, sort of, basic
 24 choices, and I'd be interested in comments from the
 25 committee. The one we put forward but were, like to

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1 hear views on, is to use recent, meaning recent the
 2 last time places did not attain or were just in
 3 attainment of standard. In L.A., it wasn't that long
 4 ago, had levels that were approximately the current
 5 standard.
 6 That's one approach to use historical air
 7 quality in the '90's, generally, when some of these
 8 locations were just meeting the current standard. The
 9 other choice is to use some kind of roll up approach.
 10 And then, the question is, do you do it proportionately
 11 and roll all the monitors up from current levels to
 12 just meeting standard. And, I believe, UARG had some
 13 comments about that very issue, so I'd encourage you to
 14 look at that.
 15 They were actually arguing not to use the
 16 historical approach, but that it would be better
 17 rolling up the monitors that were nearest the road, and
 18 then, rolling up the other monitors not as much based
 19 on relationships between near roadway monitors and the
 20 other monitors. So, that's an alternative approach.
 21 And I don't think we're fixed, yet, on exactly which
 22 approach, but we put forward as, to get reaction, at
 23 least. You know, how else are you going to do it.
 24 Otherwise, we don't have any results for risk or
 25 exposure or air quality that approximate the current

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1 standard.
 2 DR. WYZGA: My only concern is that, I
 3 think, the risk estimate that you come up with is going
 4 to be misread as to, this is the current risk, and - -
 5 MR. RICHMOND: Right, and it's not, and I
 6 appreciate that.
 7 DR. WYZGA: - - and I think that's
 8 something that, really, if it's done this way, you need
 9 a very strong statement telling people what it is not.
 10 MR. RICHMOND: Right, and we agree. It's
 11 a very hypothetical, and I agree, sort of, with your
 12 comments that if we go down this path, whichever way we
 13 do to simulate the current standard, we need to make it
 14 clear how unlikely that is, given current NOx
 15 stationary controls, given NOx vehicle controls, you
 16 know, that's a very unlikely scenario. But, that is,
 17 sort of, the baseline if you're looking at, what are
 18 the risks that would be, if you were just meeting the
 19 current standard.
 20 DR. HENDERSON: Important point. Yes,
 21 Kent.
 22 DR. PINKERTON: Although this may be
 23 somewhat of a trivial question, I noticed in figure
 24 two, when it shows the NOx emissions that, where
 25 they're coming from, and I understand that the focus

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1 has been, primarily, on urban areas and near roadways,
 2 but I noticed that close to 20 percent of NOx emissions
 3 come from off highways. And so, I'm just curious if
 4 rural areas or areas of high agricultural activity, do
 5 they contribute to NOx emissions, and are we missing
 6 something by only focusing on urban areas or near
 7 highways?
 8 MR. RICHMOND: I don't know if we're
 9 prepared to say much. The one thing I will note, I
 10 think we were going to look at an air quality tier one,
 11 was major power plants sometimes are sited. I know in,
 12 I think it was Charlotte Mecklenburg, I know the case
 13 where it was sited, just outside the ozone non-
 14 attainment area, coal-fired power plant. And we have
 15 the ability of modeling to see what kind of NOx levels,
 16 NO2 levels would we expect around some of those point
 17 sources.
 18 They may or may not be peaks of concern.
 19 Maybe they're still, with controls that we have on,
 20 don't reach those levels. I don't know if on, have any
 21 information on that, but that's the kind of thing we
 22 will look at in the screen analysis, do we have any
 23 potential problems outside due to some of these may be
 24 that we know which sources from the emission inventory
 25 are major contributors to that.



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1 DR. KENSKI: Kent, maybe I could clarify
 2 a little bit. That off-highway category includes
 3 sources like construction equipment and marine, you
 4 know, boats, lawnmowers, all those things. And so, you
 5 could make the assumption that they, generally, follow,
 6 sort of, a population distribution. I mean, the
 7 distribution of emissions in that category would be
 8 highly correlated with population. So, to that extent,
 9 you could assume that it was more urban and less rural.
 10 Although, certainly, you know, farm equipment is a part
 11 of that category.
 12 DR. PINKERTON: Okay, thanks.
 13 DR. HENDERSON: Okay, I think we've,
 14 actually, already moved into the second section, the,
 15 our exposure section, and - -
 16 DR. SHEPPARD: Rogene, before we
 17 continue, I wanted to comment a little bit more on the
 18 air quality modeling.
 19 DR. HENDERSON: Go right ahead.
 20 DR. SHEPPARD: You know, well, before I
 21 start, if everybody who's on the phone could mute their
 22 line. That would be really helpful. You can press
 23 star six if you don't have a mute button. So, the
 24 complexity of the modeling, I think, is ex-, of the air
 25 quality model is extremely challenging. And Tim

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1 important again, depending upon the purpose of what,
 2 what the analysis is trying to do.
 3 The other comment I have, beyond that, is, if
 4 it could simplify the work, or at least make it clearer
 5 to those of us who are reviewing it, how much each tier
 6 is completely conditional on the previous tier, and to,
 7 perhaps, take out anything that's overlapping. For
 8 instance, between tier one and two, that looks like
 9 there's some different overlapping efforts that are
 10 going to be done, and can those, can some of that be
 11 removed and done in only one tier.
 12 DR. HENDERSON: Do you have a response,
 13 anybody want to respond to a question about the
 14 overlapping of the tiers. Again, we've gotten into the
 15 exposure area, but that's fine. That's where we're
 16 supposed to go. No comments.
 17 DR. GRAHAM: We'll take a look at that.
 18 DR. HENDERSON: You'll take a look at,
 19 okay. That's all we need. Thank you, Lianne. Did you
 20 have more to, comments to make?
 21 DR. SHEPPARD: I do, but maybe I'll wait
 22 until other people talk about exposure, and then chime
 23 in later.
 24 DR. HENDERSON: Okay, well, I know you
 25 still have, you'll still be there another hour or so?

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1 touched on that a bit with the street canyon issue.
 2 And there's so many assumptions that are in here. And
 3 it, it's, also, I was, it really hit home, the comment
 4 about the resource limitations. And this is a,
 5 potentially, a huge effort to get it right.
 6 I think simplifications are possible,
 7 depending on the purpose of the analysis, and I'm, it
 8 strikes me as this air quality modeling is being done
 9 for many different purposes, which means that
 10 simplifications, if you had only one purpose, may not
 11 be as easy.
 12 You know, if you just want exceedances, you
 13 might be able to simplify in different ways, than if
 14 you wanted predictions. Because you're going to be
 15 using the predictions, for instance, in the APEX model.
 16 If you're focusing just on long-term exposure, there
 17 are simplifications; but if you want the short-term,
 18 one-hour, that means a lot more complex model.
 19 It's not so clear that temporal and spatial
 20 variation in NOx are separable in the sense that, when
 21 you're really near roads, the temporal patterns are,
 22 probably, really different than locations far away from
 23 roads.
 24 So, thinking about which monitors are
 25 representative for the analysis becomes really

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1 DR. SHEPPARD: Yeah, right.
 2 DR. HENDERSON: Doug, you have comments
 3 on the exposure method, the tiered approach, et cetera.
 4 DR. CRAWFORD-BROWN: There's no lunch
 5 first, then?
 6 DR. HENDERSON: No.
 7 DR. CRAWFORD-BROWN: Just wanted to
 8 know
 9 where we stood with lunch, that's all.
 10 DR. HENDERSON: Oh, well, lunch is coming
 11 in thirty minutes. Oh, lunch is ready. I suggest we
 12 have a working lunch. I thought, maybe, according to
 13 our schedule, we would go to, we would have lunch at
 14 12:30, that we might make a little more progress, but
 15 if hunger pangs are striking, I don't mind.
 16 DR. CRAWFORD-BROWN: I'm not taking the
 17 rap for this here. I just wanted - -
 18 DR. GORDON: Let me take the rap.
 19 DR. HENDERSON: When you said to know,
 20 it's good to know what the plan is. Let's work a
 21 little longer, I feel like.
 22 DR. CRAWFORD-BROWN: Okay, I don't care.
 23 DR. HENDERSON: I'm not hungry yet.
 24 DR. CRAWFORD-BROWN: Is this on? Is this
 25 one on? I'm not, is there a reason you're holding the?
 DR. HENDERSON: It's just because I can't



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1 reach and yeah, it's on.
 2 DR. CRAWFORD-BROWN: Okay, well, first, I
 3 like the exposure section, as I mentioned in my
 4 comments. It, really, is very much in the line of a
 5 wide range of other kinds of assessments that the EPA
 6 has done over the years. And it, really, is, I would
 7 say, you know, partially in answer to Ted's issue, the
 8 exposure and the risk side is starting to get pretty
 9 automated these days.
 10 The models are not quite plug and chug,
 11 because situations change quite dramatically. I was
 12 very comforted when you said that you would use the
 13 epidemiological results with air quality information
 14 and the clinical studies for the, I hope I'm getting
 15 this right, for the actual inter-subject variability
 16 kinds of calculation, 'cause I always worry about using
 17 the epidemiological results to get your slope factor,
 18 or whatever, and then, also, doing inter-subject
 19 variability.
 20 Because the epi results, in fact, already
 21 have that convolved inside of it. And so, I hope I'm
 22 understanding that correctly.
 23 MR. RICHMOND: That is correct. And if
 24 you'll look at the ozone staff paper, and risk
 25 assessment, you'll see that's exactly what we say - -

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1 you could do is, you could imagine that the different
 2 tiers are different levels of uncertainty, or you can
 3 imagine that the different tiers address different
 4 kinds of questions of one, the lower tiers having to do
 5 with questions about the upper percentiles of exposure.
 6 And the other ones covering the whole exposure realm.
 7 And then, the only other comment I would make now, the
 8 rest are all in my written comments, is, I do think on
 9 the uncertainty side, you've got a significant amount
 10 of work to do there.
 11 You always will have that. You've got this
 12 challenge of combining the, what are going to be
 13 necessarily qualitative aspects of uncertainty with
 14 more quantitative aspects of uncertainty, aspects of
 15 uncertainty that have to do with scenario
 16 specification, and so forth, and other aspects having
 17 to do with uncertainty in parameter values.
 18 And I'll be interested to see how you fold
 19 those things together into some, sort of, overall
 20 judgment of uncertainty here. I agree with the
 21 direction you were, sort of, heading, which is to make
 22 it, you know, to leave this sort of expert judgment as,
 23 and sort of semi-quantitative uncertainty bounds in the
 24 assessment.
 25 I think that will be important, rather than

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1 DR. CRAWFORD-BROWN: Yeah, exactly the
 2 same thing, yeah.
 3 MR. RICHMOND: - - where we had clinical
 4 data and epi data. We made that point.
 5 DR. CRAWFORD-BROWN: Yeah, good,
 6 okay. I
 7 wasn't quite clear on one thing, which has to do with,
 8 as you move from tier to tier, are you moving from tier
 9 to tier because of things that you see in the previous
 10 tiers assessment, like a screening method, for example,
 11 that say, oh, if I look at the upper 95 percentile,
 12 boy, that's really large.
 13 So, I, that risk is large, so I better do a
 14 more detailed one. Or I look at it and it's very
 15 small, so I don't need to do the more detailed one. Or
 16 are you moving from tier to tier based on whether the
 17 data are available to move to the next tier. I'm
 18 assuming, maybe, a little bit of a combination of
 19 those.
 20 DR. GRAHAM: Right, I'd say both. And
 21 the hope would be that the prior tier is, in a sense,
 22 more conservative or, well, I don't want to say,
 23 hopefully, it's more uncertain, but we want to reduce
 24 the uncertainty in progression from going from, say, a
 25 tier one to a tier two or tier three.
 DR. CRAWFORD-BROWN: Okay, 'cause is

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1 thinking that everything can be reduced entirely to the
 2 kind of more quantitative probability density functions
 3 on uncertainty. But, in the end, you'll just have to
 4 figure out how you're going to present that as a story,
 5 the overall uncertainty. But I thought the
 6 methodologies were quite good. That's all.
 7 DR. HENDERSON: Thank you. Terry Gordon,
 8 do you have some assessment, or advice to give on the
 9 exposure section?
 10 DR. GORDON: Well, I'd say quantitative
 11 risk assessment is a weak point of mine, so I don't
 12 have really much to say, except exposure.
 13 DR. HENDERSON: Well, this is exposure,
 14 yes.
 15 DR. GORDON: Well, see my confusion of
 16 the terms shows - -
 17 DR. HENDERSON: Well, we're talking about
 18 the exposure section, not the risk assessment. I mean,
 19 the tiered exposure approach.
 20 DR. GORDON: So, not the-, we're on the
 21 health effects or not?
 22 DR. HENDERSON: No.
 23 DR. GORDON: Oh, no.
 24 DR. HENDERSON: So, are you still, are
 25 you just still, okay, that's fine.



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1 DR. GORDON: Well, I was going to read
 2 Ellis' comment.
 3 DR. GORDON: I have no experience in
 4 which to basically form judgment.
 5 DR. CRAWFORD-BROWN: That didn't stop me
 6 from talking.
 7 DR. GORDON: Well.
 8 DR. HENDERSON: I got the message. Okay,
 9 Jim Ultman, are you on the phone? Have to wait for
 10 people to un-mute. Lianne, you said you wanted to save
 11 your comments. Do you have any further comments, and
 12 then I'll open it up to the whole group.
 13 DR. SHEPPARD: Well, you know, I'm
 14 looking over what I wrote. And I prepared an extensive
 15 set of comments, but a lot of them are fairly detailed,
 16 and probably aren't worth discussing now. But the, my
 17 comment about the purpose of the tiers, and I also, it
 18 resonated with me, the previous comment about, exactly,
 19 what is the goal of each tier, and are they
 20 representing different kinds of questions, or are they,
 21 really, just progressions of better information.
 22 Because, in the exposure tier, it states pretty clearly
 23 that they'll be using interpolated hourly NO2
 24 concentrations.
 25 It says measurements, but presumably,

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1 there'll also be predictions, because they'll be over
 2 space as well. And, you know, that is just a, I mean,
 3 we're, as Tim alluded to, we're struggling with that
 4 here in the project we're doing.
 5 That's a huge, huge undertaking to do that
 6 well. So, there has to be a number of simplifying
 7 assumptions to even do it at all. And, of course, you
 8 know, then you start to question how good it is. And,
 9 again, it depends on the purpose. I guess the only
 10 other comment, with respect to the exposure modeling
 11 is, it seems to me that the, well, when it moves to the
 12 level of the Monte Carlo simulation with the APEX
 13 model, that could be expanded to incorporate some key
 14 assumptions.
 15 So, not just doing sensitivity analyses,
 16 looking at one or two different assumptions; but
 17 incorporating explicit structure for what those
 18 different assumptions or models could be. And, then,
 19 getting a more explicit estimate of the uncertainty
 20 that has to do with more than just the distribution, or
 21 just the underlying assumptions, but also variability
 22 in what those assumptions are.
 23 DR. HENDERSON: Thank you, Lianne. Now,
 24 do others, as I say, these names listed here are just,
 25 trying to divide up according to interest. Obviously,

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1 I missed it on Terry, but anyone should have, should
 2 feel free to comment on the approach they're using for
 3 exposure assessment, particularly the tiered approach.
 4 Do we have any more comments?
 5 DR. HATTIS: Yeah, I just want to just
 6 reinforce that, you know, I do think that if you stop
 7 at the some of the lower tiers, you'll probably not
 8 produce the kind of information that will later be
 9 needed in, at least, impact assessments, if not the
 10 primary decisions.
 11 DR. HENDERSON: Good, and I believe Frank
 12 Speizer had a similar comment that he would be
 13 disappointed if you stopped at tier one.
 14 DR. GORDON: Rogene, I - -
 15 DR. HENDERSON: Okay, Terry.
 16 DR. GORDON: I might be making myself
 17 more confused, but on page 22, it has a long-term
 18 exposure approach, as if it's going to be using annual
 19 averages. And then, when I get to page 31, I was going
 20 to talk about some, one health comment. It says
 21 they're not going to use that in the health risk
 22 assessment. So, if that's true, why are you going to
 23 do this work? I don't agree with not doing it,
 24 actually.
 25 DR. GRAHAM: It was probably found, I

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1 don't want to say probably. It was founded in the
 2 current form of the standard. That is, it's a annual
 3 average.
 4 DR. HENDERSON: Is that the answer
 5 you're, I mean, does that answer your question?
 6 DR. GORDON: Tradition, yeah.
 7 DR. HENDERSON: Yeah, okay.
 8 MR. RICHMOND: Well, one of the, I mean,
 9 this is sort of the linkage to get back and forth
 10 between the exposure and risk. One could envision
 11 doing a long-term, addressing long-term air quality in
 12 the tier one, or long-term exposure, doesn't mean that
 13 quantitatively that we have enough information to
 14 address, or we don't, you know, depending on both
 15 causality and the level of information on concentration
 16 response relationships from the epidemiology, do we
 17 have enough to make a credible quantitative risk
 18 assessment, not qualitative con-, you know, concerns
 19 about the health endpoints that may be shown, but
 20 enough to, basically, move to that next step
 21 quantitatively. And, so I mean, there could be very
 22 much a distinction between whether we do long-term air
 23 quality or exposure, as opposed to a tier two,
 24 quantitative, long-term risk assessment.
 25 The question on benchmark is it's difficult,



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1 given the issue that Doug and others have brought up,
 2 the epi studies long-term don't tell you, like the
 3 clinical studies, what's a benchmark exposure level.
 4 You don't know what the exposure was. You know what
 5 the ambient monitors were. That's all.
 6 DR. HATTIS: Well, because you don't,
 7 they don't directly tell you about it, they certainly
 8 give you a clue, from which you can reason, given your
 9 other information about what they're likely to have
 10 been.
 11 MR. RICHMOND: It, again, depends,
 12 there's all sorts of questions about is it really the
 13 cumulative long-term average, or is it, as Dr. Crapo
 14 mentioned earlier, is it that someone sees a peak so
 15 many times per week. There's all sorts of
 16 possibilities, from a health standpoint, in terms of
 17 what the real, underlying cause of those long-term
 18 effects are.
 19 DR. HATTIS: Yeah, and I think you need
 20 to fairly characterize those uncertainties by doing it
 21 a couple of different ways, and say, okay, what are the
 22 differences in expectations that we get from these
 23 different possible states of the world.
 24 DR. HENDERSON: Thank you, Ed?
 25 DR. AVOL: I submitted some written

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1 the current standard?
 2 DR. HENDERSON: Yeah, go ahead, Harvey.
 3 We talked about that earlier.
 4 MR. RICHMOND: Yeah, I thought we had
 5 discussed that about twenty minutes ago, but - -
 6 DR. HENDERSON: Yeah.
 7 DR. SHEPPARD: Yeah. Well, maybe, okay,
 8 maybe I just missed it.
 9 MR. RICHMOND: Oh, okay, but, well, what
 10 I laid out is, it is a problematic challenge to, you
 11 know, to deal with how do you assess the exposures or
 12 risk just meeting the current standard. There are
 13 different approaches. One is to use historical air
 14 quality when the levels were just meeting the current
 15 standard back typically in the 90's for some of these
 16 example urban areas.
 17 The other approach would be to rec-, you
 18 know, do some statistical adjustment just like we've
 19 done in ozone and PM, where it's been to ra-, you know,
 20 adjust things, air quality adjustment procedures to
 21 adjust the distributions downward to meet a standard,
 22 but effectively, rolling up distributions to just meet
 23 the standard. And there are different ways you could
 24 do that, as to whether it's proportionately all the
 25 monitors, or whether we make distinctions between the

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1 comments. I won't go through all those, but one area I
 2 did want to ask about was the issue of the Tiger
 3 mapping, in terms of the road designations, and in
 4 terms of modeling and assessing the portion of
 5 population that may be within or near roadways.
 6 There are ways, I point out one way that we,
 7 sort of, found out there was a problem and what we did
 8 about it, but there are other ways to do it. But I
 9 just wanted to get some confirmation that, in fact,
 10 you're either going to ground troop it or do some
 11 sensitivity analysis or something, or move to something
 12 other than that.
 13 DR. GRAHAM: I'm sorry, I was looking at
 14 my notes. Yeah, we are aware of that data as well.
 15 And, it's not to say that we were just going to look at
 16 the one data source that I mentioned, but the Tiger
 17 road, it wouldn't be exclusive. But the Tele Atlas
 18 would be used.
 19 DR. HENDERSON: Are there any other
 20 comments or questions people have about the exposure
 21 assessment section?
 22 DR. SHEPPARD: Yeah, this is Lianne
 23 Sheppard. I have another question, and what does it
 24 mean to look at exposure for just meeting current
 25 standard, when so many of the measurements are below

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1 near roadway and non-near roadway monitors.
 2 So, we were looking for feedback from the,
 3 particularly, the air quality experts on this
 4 committee.
 5 DR. SHEPPARD: So, I guess, my question,
 6 then, is, should we even do that, since the mo-, since
 7 the current data are below the standard.
 8 MR. RICHMOND: Right, the other
 9 alternative is, then, we, otherwise, have no exposure
 10 or risk associated with the current standard. It would
 11 really be the recent air quality and what standard that
 12 would be associated. So, if a place that only maximum
 13 has .03 today annual average, that they were,
 14 basically, looking at standards at that level and
 15 below. That's the choices we face, and you know.
 16 DR. CRAWFORD-BROWN: Rogene, may I,
 17 several points have touched on that.
 18 DR. HENDERSON: Yes, go ahead, Doug.
 19 DR. CRAWFORD-BROWN: This worries me
 20 just
 21 a little bit, because the question comes up as to what
 22 do you mean by meeting the standards. If what you mean
 23 by meeting the standards is that everybody goes to
 24 0.053, then that's one thing.
 25 But my argument is going to be, that when
 people meet the standards, kind of like in water, it's



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1 the same issue, they put in place mitigation strategies
 2 that do drop significant areas well below the
 3 regulatory limit, and that is part and parcel with
 4 meeting the standard.
 5 So, I don't think that a scenario in which
 6 everybody has gone up to .053 is, in fact, a scenario
 7 that is meeting the standard in the way that meeting
 8 the standard actually plays itself out.
 9 MR. RICHMOND: Yeah, let me clarify that.
 10 When we say meeting the standard, standards, typically,
 11 have been implemented by, for example, large regional
 12 areas. The CMSA basis, it's not just L.A. County, but
 13 it's the L.A. at CMSA is, typically, a definition for a
 14 non-attainment area. When we say adjusting the air
 15 quality, we mean at the highest monitor in that area.
 16 We're not talking about using or adjusting air quality
 17 so that every single monitor in an area is just at the
 18 current standard. It is the design monitor within that
 19 urban area. So, it's like, for the whole New York
 20 area, if we did New York, or Philadelphia.
 21 DR. CRAWFORD-BROWN: Okay, so in your - -
 22 MR. RICHMOND: So that, so none of it,
 23 nowhere have we ever adjusted air quality in any of our
 24 analyses in the past so that all monitors with an area,
 25 when we do just meeting standard scenarios, it means

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1 only at the design monitor, and what are the
 2 relationships at the other monitors as they flow up and
 3 down.
 4 DR. CRAWFORD-BROWN: Oh, okay, okay.
 5 Okay, there's something you said earlier that made me
 6 think it was different from that. Thank you.
 7 MR. RICHMOND: All right, okay.
 8 DR. HENDERSON: Well, and, I think Ron
 9 brought up the important point. You wouldn't want to
 10 say that the risk associated with meeting the current
 11 standard, or the current risk when it's, actually,
 12 lower. So, I, that's, you could misinterpret that.
 13 Dale, did you have something?
 14 DR. HATTIS: Yeah, I think the concern is
 15 to have a realistic scenario. And in the, the
 16 realistic scenario that could get you to back up to the
 17 roll up, type methodology that you want to think about,
 18 is imagine a future of possible growth in traffic or
 19 other things that you could reasonably imagine, where
 20 you could be deteriorating the air quality enough to
 21 get you to near the, near compliance with the current
 22 thing. So, I think it may well be that your roll up
 23 scenarios are the easiest thing to do along those
 24 lines.
 25 MR. RICHMOND: Right, and in that vein,

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1 one of the things, having looked at your comments, we
 2 may want to, at least, take maybe the worst case
 3 situation, maybe it's Los Angeles, and look, you know,
 4 look at the mobile models. What if we were to double
 5 vehicle things, would we still have a problem?
 6 We still might not come up to that level
 7 given control technologies and given stationary
 8 technologies, that was the industry argument, that even
 9 given what's in place and can't be rolled back, that
 10 you can't envision the scenario that gets there, but
 11 that's something we could look through modeling in a
 12 more limited number of areas.
 13 DR. HATTIS: Yeah, and I think that's a
 14 reasonable alternative, to say, okay, what is the worst
 15 possible deterioration that we can reasonably imagine
 16 under the current scenario. I mean, that can include,
 17 you know, non-attainment of ideal compliance with
 18 everything, but.
 19 DR. LARSON: Harvey, this is Tim again.
 20 When your scenario of just meeting the standard is
 21 going to based on the actual location of the, the
 22 worst, the highest EPA monitor in that area?
 23 I mean, what if you did your modeling
 24 exercise and found that there were a whole bunch of
 25 places that currently don't meet that standard within

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1 the urban area.
 2 MR. RICHMOND: Well, what you, are you
 3 talking about the exposure modeling, air qu-, I'm a
 4 little lost as to which point - -
 5 DR. LARSON: Yeah, I mean, your, yeah. I
 6 mean, is it based on the current, the - -
 7 MR. RICHMOND: Whether you meet the
 8 standard, by definition, is at the monitors. It, you
 9 know, the mo-, we're supposed to be, have taken that
 10 into account.
 11 We realize in setting the CO standard and the
 12 ozone standard that, no, the highest level may not, you
 13 know, depending on the pollutant, may not be at the
 14 monitor, but designing scenarios for alternative
 15 standards is based on the monitoring network, not,
 16 we'll then look at the implications through exposure
 17 analysis in modeling to see what's the distribution of
 18 exposures in the population, no matter where they are,
 19 but it is based on simulating standards that are met at
 20 the monitoring network and by definition of the
 21 standard at the design monitor.
 22 DR. LARSON: Okay.
 23 DR. HENDERSON: Okay, does anyone who is
 24 on the phone have any comments? I don't want to ignore
 25 you. I've already heard from Lianne and Tim. Okay, I



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1 suggest that there seems to be a strong move towards
 2 lunch. We have lunch next door. I would like for us
 3 to use this as sort of a working lunch. Maybe be
 4 prepared to start our discussions again at 1:00 in
 5 here. You can bring your lunch in here and eat, or you
 6 can eat there, or do whatever you want to do. But I'd
 7 like to start the discussions at 1:00 and Vanessa has
 8 something.

9 DR. VU: Since we are short of time, I'd
 10 also like to invite OAR representatives to join, grab a
 11 lunch here so you can quickly go back here.

12 DR. CRAWFORD-BROWN: With us?

13 DR. VU: No, no, I mean, get the lunch
 14 and come back here at 1:00, since it's a, you know,
 15 sandwich buffet, whatever.

16 DR. CRAWFORD-BROWN: They get in line
 17 first, then.

18 DR. HENDERSON: Well, I think that's
 19 great, so we will begin our discussions here at 1:00,
 20 and you can use your time now to eat in there or eat
 21 in, to bring it in here, whatever you want.
 22 (WHEREUPON, the morning session was concluded.)

23 DR. HENDERSON: We want to, very good.
 24 Doug is my bell ringer. We want to get started
 25 discussing this last section of the methods document.

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1 is data from several studies looking at children's lung
 2 function, for example, which is a long-term, sort of,
 3 exposure. And so, it seems like there needs to be some
 4 reconciliation.

5 Yesterday, we had some discussion about,
 6 well, perhaps maybe there is a need for a short-term
 7 NO2 standard. But, so, I just want to offer that up as
 8 a comment for discussion, or at least for
 9 consideration. In any case, here, it just, sort of,
 10 says, well, so, we're just not going to do it. But I
 11 think it needs to be, at the very least, it needs to
 12 be, sort of, just supported or substantiated or
 13 something.

14 The other comment, which is a small comment.
 15 I, also, have some small written comments. But,
 16 there's a, in section 4.3, there's a discussion about
 17 health responses. And again, it, sort of, focuses more
 18 on short-term effects. And, sort of, disregards long-
 19 term losses in lung function. And yet, based on what
 20 we talked about yesterday and today, one of the
 21 conclusions in the ISA is going to be that long-term
 22 lung function is an important issue. So, it seems like
 23 the two documents are not going to be quite consistent.

24 MR. RICHMOND: In response, we said
 25 preliminary, based on what we saw in the first draft

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1 That is the one on the health risk assessment. And I
 2 think there'll be a lot of comments on that. A lot of
 3 people interested in it. John Samet is calling in a
 4 1:45, so we'll have his comments later.

5 But, we have all of our Air Office crew here.
 6 Well, that was a great lunch, and I thank Vanessa and,
 7 who has already left for arranging it for us. That was
 8 a nice way of handling things.

9 So, now, we're going to open our discussion
 10 on the health risk assessment approach, and what, and
 11 offer it, our advice to the Agency as to whether we
 12 think they're using the right approach, or if it could
 13 be improved. And Ed, you are one of the first
 14 discussants.

15 DR. AVOL: Okay, thank you. I have, I
 16 guess, two comments. One has to do with the risk
 17 assessment scope overview itself. The, what's laid out
 18 on page 31 talks about how the draft ISA leads to a
 19 suggestion that the strongest health findings are for
 20 one-hour and twenty-four-hour averaging times, so
 21 there's not going to be any risk assessment for longer
 22 term exposures. And that's disquieting, I guess.

23 The current standard is an annual, long-term
 24 standard. The document says, or this document says,
 25 we're only going to look at short-term exposure. There

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1 ISA, which we're waiting, and we said we will make the
 2 assessments based on the second draft ISA that will be
 3 coming out before the risk assessment. So, we will
 4 look at and work closely with and see it to see how
 5 those issues are addressed in the second draft ISA.

6 DR. HENDERSON: Okay, now, is, John
 7 Balmes, are you on the phone?

8 DR. SHEPPARD: Rogene, I think he said he
 9 was coming back at 2:15.

10 DR. HENDERSON: Oh, that's right. I knew
 11 that. I'm sorry.

12 DR. SHEPPARD: Can I take his place? I'm
 13 leaving kind of earl-, soon.

14 DR. HENDERSON: So, would you like to
 15 make your comments now?

16 DR. SHEPPARD: Yeah, and I'd like to
 17 follow up on Ed's comment, because one of my main
 18 concerns was for each of the tiers of the risk
 19 assessment is that, I think we need to have very
 20 clearly stated criteria for what particular outcomes
 21 and populations and so on will be used. And those
 22 should be specified in advance. And presumably, they
 23 will come from the results of the ISA, as has been
 24 stated. But, the criteria for choosing them, for
 25 instance, would it be only the out-, the outcomes that



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1 are measure-, assessed as likely causal, as an example.
 2 Those, then, get brought forwarded to the risk
 3 assessment.
 4 My other, fairly major comment, with respect
 5 to the risk assessment is, I think it needs to be
 6 expanded to have three tiers. And the first tier
 7 should be the qualitative risk assessment. And, so,
 8 that it doesn't, it becomes as important as the other
 9 tiers, and it also becomes the foundation for the
 10 quantitative risk assessment.
 11 So, all the different outcomes are reviewed,
 12 but some of them, presumably, can't be easily
 13 quantified in a quantitative risk assessment, but
 14 they're still important, and they get discussed in the,
 15 in what I would suggest would be the first tier, which
 16 is the qualitative assessment. And then, some of them
 17 meet the criteria for being brought forward for
 18 quantitative assessment, and they, therefore, go up to
 19 the next levels. So, I think that's a fairly major
 20 change in the organization that I recommend.
 21 I think the criteria for even discussing the
 22 quantitative or even conducting the quantitative risk
 23 assessment need to be specified in advance as well in
 24 this document. And I, actually, recommend that all
 25 tiers of all, both the exposure and the risk

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1 I guess, looking back at the ozone criteria
 2 document, when we had a fair amount of discussion about
 3 the linear versus logistic function, you ended up
 4 using, doing a new analysis, which had different
 5 weights for the linear and the logistic function.
 6 That is an example of moving in that
 7 direction. It was presented more as a sensitivity
 8 analysis, but the, you know, that's the, that's what
 9 I'm thinking, that a lot of, a number of different
 10 assumptions and uncertainties of those would be
 11 incorporated into the estimates that are produced.
 12 MR. RICHMOND: But again, that was a
 13 sensitivity analysis. There wasn't an assignment of
 14 how much weight to put on the different choices. We
 15 put forth a base case assumption, and we looked at the
 16 impact of alternative assumptions. I'm hearing you say
 17 that you want us to do more than that. I'm still left
 18 puzzled as to what you would be recommending us to do
 19 differently.
 20 DR. SHEPPARD: Okay, I'll try to
 21 articulate that more clearly in writing.
 22 DR. HENDERSON: Okay, is that all you had
 23 to say right now, Lianne?
 24 DR. SHEPPARD: Yes.
 25 DR. HENDERSON: Okay, thank you. And

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1 assessment, be discussed, even if the discussion is
 2 that these are the reasons why we can't do this, if
 3 that is the ultimate decision.
 4 From what I've seen, I think that all tiers
 5 should be done, at least so far, but that remains to be
 6 seen.
 7 And then my last, fairly major comment is the
 8 quantitative risk assessment needs to, also,
 9 incorporate some integrated uncertainty assessment that
 10 goes beyond the sensitivity analysis.
 11 DR. HENDERSON: Okay.
 12 MR. RICHMOND: Just on the last point,
 13 this is Harvey Richmond. Could you clarify what
 14 approaches, either in written comments or today, when
 15 you use the word integrated uncertainty assessments,
 16 what you would envision that, what approaches being
 17 used to carry out such integrated assessments?
 18 DR. SHEPPARD: Yeah, and the devil of
 19 those, that kind of thing is in the details, of course.
 20 I'm sure that's why you asked the question. And I
 21 guess, the idea here is that the, and I'll try to
 22 expand a little bit more than I have already. The idea
 23 is that the, we go beyond sensitivity where we assume a
 24 different set of fixed assumptions to allowing for
 25 multiple different assumptions.

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1 then, James Crapo, do you have something?
 2 DR. CRAPO: Yeah, I think I've made most
 3 of the points, so to make the, I like the risk
 4 assessment model and the health endpoints. I thought
 5 you were choosing the appropriate ones, and I like,
 6 particularly, that you were, included a focus on short-
 7 term exposures and short averaging times.
 8 And, I assume, if I read it correctly, you're
 9 going to continue that as you do the tier two
 10 epidemiology. You're also going to look at the
 11 possibility of using correlations with something other
 12 than the national average, annual average, but rather
 13 the short-term exposure peaks, which I'd really
 14 encourage that.
 15 Because I think that one of the most
 16 important outcomes that can come out of this analysis
 17 to help us develop data that would convince us it's
 18 important to change the form of the standard or not.
 19 Because I think that, I think form of the standard is,
 20 probably, one of the more important questions to
 21 address at this point in time. And I'd like to see the
 22 risk assessment provide us better information to make
 23 an informed decision on that. But I think that's
 24 already part of your goal as I read it, so I'm very
 25 pleased with what I see.



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1 DR. HENDERSON: Thank you, James. Is
 2 Steve Kleeberger still here? I don't see him. He's
 3 not, he wasn't going to be on the phone, was he?
 4 DR. NUGENT: That's correct, and he did
 5 send an email this morning saying he may be unlikely to
 6 be here.
 7 DR. HENDERSON: Oh, okay. Then we'll go
 8 on to Kent Pinkerton.
 9 DR. PINKERTON: Okay, again, I think this
 10 is a really well-executed document. I think the
 11 concern that I have is one that was also expressed by
 12 Frank Speizer. And that's just the concern that with
 13 the tiered approach, that one may be tempted to stop at
 14 tier one and not go beyond. And I think that becomes
 15 problematic, because there's such rare occurrences of
 16 excursions of above the set standard, that one could
 17 argue, well, there is no need to go to tier two and
 18 look at these potential health effects.
 19 But since we see so many instances of
 20 significant health effects associated with ambient
 21 concentrations of NO2 that are well below the
 22 established standard, that I think it's just important
 23 that that be really emphasized, that many of these
 24 studies really need to go beyond just tier one and go
 25 on to tier two and, occasionally, to tier three.

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1 But, again, I think the way it is written,
 2 the health endpoints seem to be very appropriate.
 3 Again, keep in mind, as you look at susceptible
 4 populations, again, to keep in mind children, those who
 5 have asthmatic conditions. Also, I don't know if we've
 6 really reached a point at this point in time, but are
 7 there potential differences based on gender, with
 8 regard to the health effects associated with nitrogen
 9 oxide exposures.
 10 Again, I think, some of my questions about
 11 why only cities and not areas that are not city or
 12 population based are not being included, but I think,
 13 Donna, you helped me understand that a little bit
 14 better. So, and I think those are, pretty much, the
 15 extent of my comments.
 16 DR. HENDERSON: Thank you, Kent. Dale
 17 Hattis observed that I'm not too sharp here this
 18 morning. I skipped him. That was not intentional,
 19 Dale. So, we'll hear from Dale right now.
 20 DR. HATTIS: That's all right. Anyway, I
 21 want to second the thing that some of the, many of the
 22 comments that, in fact, Kent Pinkerton has just made.
 23 But just to say, a little more strongly. I'm going to
 24 be really disappointed if you stop at tier one. Of
 25 course, avoiding disappointing me is not a huge

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1 national priority - -
 2 DR. HATTIS: - - but I do think that
 3 getting an idea of the quantitative significance of the
 4 health effects that you think are likely is important
 5 from a national priority setting standpoint. You know,
 6 one, of course, your main job is to inform on decisions
 7 about the revision of the criteria, this particular
 8 criteria standard.
 9 But, also, it seems to me, that you are also
 10 feeding into a national discussion about how we should
 11 devote our resources to changing the mix of air
 12 pollutants that we are exposed to, and, as well as
 13 other problems. And so, trying to be as thorough as
 14 you can about allowing people to project national
 15 impacts is an important function, okay.
 16 Because this isn't going to stop at the, with
 17 your meeting of the deadlines that you have in front of
 18 you. And, you know, people are going to continue to
 19 try to understand how, you know, how they should be
 20 devoting resources to this problem. Because of that,
 21 in part, I think you ought to really, seriously,
 22 consider stretching a bit to include the kind of
 23 effects that are based upon the chronic observations,
 24 particularly the children's lung function growth.
 25 Let me say that that's important because it

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1 sets, if, in fact, it's true that the NOx or NO2
 2 changes that, that sets the baseline for lung function
 3 over a lifetime, which deteriorates, which grows
 4 through childhood and early adulthood, and then starts
 5 to deteriorate over time until you get to less and less
 6 function as you get to our age. And so, that's, and
 7 that is, in fact, directly related to mortality as
 8 well.
 9 So, that has, sort of, long term implications
 10 for lifetime function and survival that might not be
 11 apparent from just saying, okay, well, we're going to
 12 lose X percent of FEV1 for kids who have more than they
 13 need to begin with, you know.
 14 So, I think that's, so I think that's a
 15 reason to take that possibility seriously, and to, it's
 16 worth a little bit of a stretch, if you have to admit
 17 that you have three or four or even tenfold uncertainty
 18 in that, well, okay, it might still be important.
 19 DR. HENDERSON: Thank you, Dale. I'm
 20 going to ask Ronald Wyzga to make his comments, and
 21 then we'll open it up, and everybody can make comments.
 22 DR. WYZGA: Thank you. I think the plan
 23 as written is a very good plan. I think it's very
 24 thorough, very thoughtful. I think the difficulties
 25 are going to be in the implementation. It's a



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1 formidable task. You have a tremendous challenge, and
 2 I think that to come up with something that's going to
 3 be, with your resources available and with the data
 4 available, is going to be, accepted by a wide community
 5 is going to be a challenge.
 6 But, I applaud the approach you've taken. I
 7 think, when I think, you know, particularly, tier
 8 three, and you look at the current epidemiology
 9 studies, they tend to look, they tend to use linear
 10 models, which suggest that there's no threshold. And,
 11 that's one area, what worries me particularly, where
 12 you're looking at the just meeting current standard, in
 13 the sense that if an area is still well below any
 14 standard or proposed standard, because you're using a
 15 linear model, you're going to overestimate the risks
 16 for that area.
 17 And I really worry that that could be
 18 misinterpreted, and I urge you to, sort of, think about
 19 both how you present that, and is there some way to get
 20 around that problem. I don't have an obvious solution
 21 to it. I think you've done some thinking about it, but
 22 I urge you to think further about it, and to the extent
 23 that you can't resolve it, it's going to be very
 24 important how you present the results so that they
 25 don't mislead the public. But, otherwise, thank you, I

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1 point in time.
 2 DR. HENDERSON: I think that's the
 3 problem of double counting, are we double counting. I
 4 mean, how many deaths, how many times can a man
 die. I
 5 mean, I'm just joking, of course, but what I mean is -
 6 -
 7 DR. HENDERSON: - - is there any double
 8 counting. I think that's a logical question.
 9 MR. RICHMOND: No, Rogene, no, we didn't,
 10 really, indicate mor-, we didn't include mortality in
 11 that preliminary list. It's morbidity endpoints, and
 12 the hospital admission studies, that have NO2 may, or
 13 may not, be some of the same studies that pointed to
 14 ozone or PM where they were using - -
 15 DR. CRAWFORD-BROWN: Yeah, I don't
 know.
 16 I just get a sense that I keep seeing the same kinds of
 17 studies appear in documents, and, you know.
 18 DR. HENDERSON: Yeah, you're right, it's
 19 the morbidity we're concerned about, but, okay. Is
 20 there anybody on the phone who wants to make a
 comment
 21 and has not? We are - -
 22 DR. POSTLETHWAIT: I think Ted wants to
 23 comment.

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1 think you've done a great job.
 2 DR. HENDERSON: Are there other people
 3 who want to make comments on the health effects. Doug,
 4 I think does.
 5 DR. CRAWFORD-BROWN: Just one small one,
 6 and it's more of a medid issue. As we've been having
 7 this discussion about the epidemiological studies, and
 8 the contribution of NOx and ozone and PM and so forth,
 9 this, probably, is a time for you to start thinking
 10 about looking at, what I would sort of call, the mass
 11 balance of the various risk studies that you're doing
 12 to see if they add up to something more than the total
 13 decrement that's seen in the epidemiological studies.
 14 I just wonder, if you add it up, what you calculate for
 15 NOx, and what you calculate for ozone, and what you
 16 calculate for PM.
 17 They're all based on, sort of, the same kind
 18 of epidemiological results from which, we hope, we're
 19 tearing apart the various relevant contributions, but I
 20 just don't know. I don't know. If you added them up,
 21 would this be something like TRIM, for example, where
 22 TRIM had problems with more stuff coming out of a
 23 compartment than ever went into the compartment, you
 24 know. It's sort of a mass balance, kind of, thing
 25 there, that I thought I would find interesting at some

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1 quick. We've got all the time in the world.
 2 DR. RUSSELL: No, I prefer making it
 3 quick. Just, carrying on something from what James
 4 said is that, if we're going to be looking at a,
 5 possibly, a new standard, when you look at your table
 6 two, or any of the other analyses, just keep in mind
 7 that, maybe look at various alternative standards and
 8 forms of standards for our assessment.
 9 DR. HENDERSON: Yes, I think that would
 10 be very good for the analysis to see. Well, it's been
 11 a very productive day and a half. I'm, I really want
 12 to thank everybody for working so hard, and for
 13 staying, most of you staying to the end of the meeting.
 14 And, I hate that we're going to miss John Samet,
 15 apparently, but he has written, has he sent in his
 16 comments, his written comments?
 17 DR. NUGENT: I don't think we have
 18 comments on the methods document, but his assistant
 19 said he'd be on the line at 1:45. This was scheduled
 20 for 2:15 on the agenda.
 21 DR. HENDERSON: Oh, I know, I know the
 22 problem, but I'm just sitting here. I don't think
 23 people want to sit fifteen minutes to wait, I mean.
 24 DR. HATTIS: He can sign on and say his
 25 piece and that's fine, but we won't hear it.



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1 DR. HENDERSON: But you all will be a the
 2 airport.
 3 DR. CRAWFORD-BROWN: I think it's \$14.38
 4 we'll earn during that time, so keep at it.
 5 DR. HENDERSON: Okay, well, it, I do
 6 value John and, the two Johns comments, but I think
 7 that they have, since we're not trying to reach a
 8 consensus, I mean, we're trying to get all of
 9 everybody's comments, that we can just get their
 10 written comments, which is what is needed. And again,
 11 if you haven't turned in your written comments, well,
 12 be sure you do that. Ed is wanting to say something.
 13 DR. AVOL: Yeah, I would just ask that if
 14 the Agency staff have any questions, based on what
 15 they've heard, that they would like to get
 16 clarification on.
 17 MR. RICHMOND: I have one.
 18 DR. HENDERSON: Okay.
 19 MR. RICHMOND: We put forth, I know it's
 20 preliminary for putting aside the long-term children's
 21 health study, but for short-term, from the clinical, we
 22 identified a preliminary range of .2 to .3. Are we in
 23 the right ballpark, or do the people who are familiar
 24 with the clinical evidence think it's something other
 25 than that range for one hour, based on the controlled

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1 we're - -
 2 DR. CRAPO: - - and homes and things like
 3 that. So, you're going to extrapolate that that might
 4 be there and use that. I like that idea.
 5 MR. RICHMOND: But I'm saying, on the
 6 health side, are we in the right range - -
 7 DR. CRAPO: On the health side, but the,
 8 so you're going to, actually, look to see if there's
 9 health effects, and you're going to model with that,
 10 perhaps, might be that will be - -
 11 MR. RICHMOND: Well, we're going to see
 12 if there are exposures of, what we call, our term is
 13 exposures of concern, which doesn't mean that everyone
 14 who sees that exposure will, necessarily, be affected,
 15 and we've explained - -
 16 DR. CRAPO: I know, and I understand
 17 that. But this going to be all extrapolation data,
 18 based on modeling from - -
 19 MR. RICHMOND: Model data that's a
 20 combination of both ambient and modeled inputs through
 21 the exposure model.
 22 DR. CRAPO: I think that's a very good
 23 idea. I'd love to see the data, 'cause it addresses
 24 exactly what I've been talking about.
 25 DR. HENDERSON: And I think he was,

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1 studies that we have, based on the evaluation in the
 2 ISA.
 3 DR. CRAPO: I have a question, what do
 4 you mean by .2 or .3. Are you looking for, are you
 5 going to model the - -
 6 MR. RICHMOND: A level of concern, if
 7 you're going to compare either air quality or
 8 exposures. We did this in ozone, as you remember.
 9 DR. CRAPO: Right.
 10 MR. RICHMOND: But we had .06, .07, .08,
 11 so we don't have to settle on a single level, but is
 12 that lev-, a range at which we, at least, are
 13 interpreting our evaluations, because - -
 14 DR. CRAPO: All right, well, let me be
 15 sure I unders- -
 16 MR. RICHMOND: - - I think that that's
 17 where the clinical studies start to, kind of, you know,
 18 the lowest level at which effects in asthmatics are
 19 being observed.
 20 DR. CRAPO: I like this, except I'm not
 21 sure how you're going to model it. Because, in fact,
 22 we don't have any documented exposures at that level
 23 from the air monitoring stations. You have to
 24 extrapolate into cars and buses and - -
 25 MR. RICHMOND: Well, that's what

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1 Harvey was probably asking Ed clinically that was what
 2 you would consider appropriate levels. Haven't you
 3 done studies with children?
 4 DR. AVOL: Not children in chambers at .2
 5 or .3, no. I mean, the work we did in chambers was a
 6 higher, was with adults. So, I don't know that it's, I
 7 can directly relate to this.
 8 MR. RICHMOND: You talking about, there
 9 were a number, there's a table summarizing a number of
 10 asthmatic studies that go down as low as .2.
 11 DR. AVOL: And so, I mean, in that sense,
 12 again, as James said, I mean, I think, what you lay out
 13 is fine. My, not withstanding my previous comment
 14 about long-term studies, long-term is more - -
 15 DR. HATTIS: Let me make a somewhat
 16 modest further comment on that, and that is that, you
 17 should, when you measure a statistically significant
 18 decrement at lung function, or a change in the
 19 responsiveness, you're talking about, not necessarily,
 20 a uniform response or a uniform susceptibility within
 21 that group that's measured.
 22 And we have prior information about how
 23 variable people are in their susceptibility in a large
 24 number of other context. We have a database of that
 25 that's on our website.



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1 But, anyhow, so, in pharmacodynamic
 2 variability, in that kind of local responsiveness,
 3 happens to be, tend to be more variable than lots of
 4 other stuff, basically, of the order of geometric
 5 standard deviation of three or a bit more for that kind
 6 of variability, if I remember correctly.
 7 But, you know, so, you can, in fact, by
 8 imposing a, kind of a log-probit function, with that
 9 amount of spread, you can make a, just as you can make
 10 distributional characterizations of the exposures, you
 11 can make distributional characterizations of the likely
 12 variability in susceptibility, and get something more
 13 that may, in fact, you know, say, you know, for your
 14 first percentile population, you might have sensitivity
 15 that's outside of the range that you've measured for
 16 the average concentration that's capable of changing
 17 this group, right.
 18 And so, anyhow, so, it is possible to do a
 19 slightly more involved analysis that, maybe, take you
 20 half hour rather than fifteen minutes, that you might
 21 do for the una, with single variable analysis.
 22 You also asked the question about how do we
 23 do an integrated, you know, characterization of
 24 uncertainty. And there's a, this is, perhaps, a longer
 25 answer, but basically, you characterize the

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1 there are ways of dealing with this, although, they do
 2 require a bit of creativity and maybe creativity is a
 3 bad word.
 4 MR. RICHMOND: A lot of creativity on
 5 work.
 6 DR. HATTIS: Yeah, you know, but,
 7 nevertheless, you know, it's possible. And I think
 8 it's possible without inordinate resources. I mean, I
 9 think of the, you know, the poor guy who's over in the
 10 other part of ORD dealing with trichloroethylene and
 11 he's having to deal with Markov chain Monte Carlo
 12 simulations of to do uncertainties and variability for
 13 trichloroethylene and project from animal data to
 14 people. And, you know, and he's large-, mostly one
 15 guy, you know. So, lots of people have, you know,
 16 resource constraints, but you know, it's a hard problem
 17 to do quantitative assessments. But it can, you know,
 18 it's not impossible.
 19 DR. HENDERSON: Thank you, Dale. You
 20 almost took up the fifteen minutes, but not quite.
 21 DR. HATTIS: I'm sorry.
 22 DR. HENDERSON: No, it's okay.
 23 Yeah, I can just change it. Kent, go ahead.
 24 DR. PINKERTON: This is a, just a
 25 question about, under the risk assessment overview, you

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1 uncertainties in the exposure, and it's faster to say
 2 that than to do it, and the uncertainties in the
 3 susceptibility and concentration response slopes and
 4 other things of that sort, and you, basically, convo-,
 5 you know, basically, convolute those two with a Monte
 6 Carlo simulation.
 7 But you do have to, you know, sometimes these
 8 are better done than other times, and it is a matter of
 9 an evolving art as to how to choose the distributions
 10 that you use to characterize each of the uncertainties.
 11 MR. RICHMOND: And in this area, it is
 12 not straightforward. The clinical data, even when I'm
 13 suggesting .2 to .3, some asthmatic studies, controlled
 14 studies, have found effects. Some have them have been
 15 repeated, and haven't found the same level under the
 16 same kind of conditions. So, this is no easy matter to
 17 assign probability or simply pick distributions out.
 18 DR. HATTIS: Right, and so, you might
 19 want to, you know, do some combined analysis that says,
 20 well, there's some chance that the population
 21 distribution of susceptibilities is in this range, and
 22 some with this kind of mean in standard deviation, and
 23 some chance that it's in some other range that would be
 24 compatible with the observation that, you know, was not
 25 found in a particular population. So, anyhow, so,

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1 had mentioned there that the EPA would not develop risk
 2 estimates for NO2 related effects associated with long-
 3 term NO2 exposures. And, I think you stated that you
 4 wouldn't do that, based on the fact that the findings
 5 are inconclusive, or at best, suggestive. And I'm just
 6 wondering, does that mean that you think that in doing
 7 short-term exposure assessments, you might be able to
 8 address issues that may have, with regard to NO2
 9 exposures, that may have long-term effects?
 10 MR. RICHMOND: No, I don't think that's
 11 what we're saying. One, as Lianne mentioned, there, we
 12 have applied in the past and was envisioning here,
 13 it's, selecting which health endpoint is first looking
 14 at causality, and in the past, we have and proposed
 15 here to do things that were likely causal, not to
 16 quantitate risk, or develop risk, quantitative risk
 17 estimates for things that were only suggestive or
 18 limited whatever final terms the ISA ends up.
 19 So, we are, that is, part of the screening
 20 criteria in terms of determining how far we go, and
 21 then, looking at what kind of information we have as
 22 well, in terms of even once you get past. There were
 23 endpoints for ozone like inflammation, which were
 24 clearly likely causal, or causal.
 25 But we didn't have sufficient information to



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1 generate, we felt, a credible exposure response
 2 relationship, and we still considered that in the
 3 review, that endpoint, in the discussion and
 4 evaluation, but we didn't do a quantitative, let's
 5 produce how many people have different degrees of
 6 inflammation.
 7 So, just because we don't quantitate
 8 something in terms of producing some number of people
 9 have this many health effects, doesn't mean we're
 10 ignoring the other health endpoints.
 11 DR. HENDERSON: I have a question that
 12 has occurred to me as I sit here. I seem to remember
 13 that some of the toxicology studies suggested
 14 development of a tolerance to NO2, am I right, does
 15 that happen, or am I getting it confused with ozone
 16 or - -
 17 MR. RICHMOND: I'll defer to Ed.
 18 DR. HENDERSON: Are there development,
 19 are there animal tox studies showing development of
 20 tolerance?
 21 DR. PINKERTON: I think there are, yes.
 22 Oftentimes, NO2, as people are likely to be aware,
 23 behaves in a similar manner to ozone. It's just that
 24 you have to have much higher concentrations to get the
 25 equivalent response. But I do believe that there is a

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1 tolerance that is developed with persistent exposure to
 2 NO2.
 3 DR. HENDERSON: And that's very hard to
 4 take into account at setting any standard, I'm sure,
 5 but. Well, okay, I think we, now. I will do as Ed did
 6 earlier. Anything, any advice or that you were
 7 expecting to get that you haven't gotten and would like
 8 for us to comment while you have this great group of
 9 investigators here?
 10 DR. GRAHAM: After your other comment, I
 11 did have a question specifics about, we had selected, I
 12 think, five locations, and I briefly said there were
 13 criteria in their selection. And, I think it was Ed
 14 had commented, why not Phoenix and Denver, and I was
 15 just wondering, why those might want to be included?
 16 DR. AVOL: I picked those two in looking
 17 at previous annual standards in violations of the
 18 standards, and just thinking about distribution and
 19 representation of the national picture that Phoenix and
 20 Denver offered other sorts of geography and exposure
 21 issues than just the urbanized cities like New York and
 22 Philadelphia, sort of thing.
 23 DR. HENDERSON: Any more advice for the
 24 Agency. We will be seeing this again, of course, but
 25 the consultation comes first, and then there's the

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1 first draft of the actual document and the second
 2 draft. So, we should be seeing this document two more
 3 times, and - -
 4 MR. RICHMOND: Just to clarify, no, you
 5 won't be seeing this document. You'll be seeing a
 6 draft exposure risk assessment report.
 7 DR. HENDERSON: Oh, okay.
 8 MR. RICHMOND: I mean, there's a huge
 9 difference. This was the road map, this plan. We
 10 don't, we plan to take into account your comments and
 11 the comments of the public in figuring out what we
 12 ultimately do. But the revised methods and what we
 13 actually do will be in, along with the results, in the
 14 first draft risk assessment, that's targeted for March.
 15 DR. HENDERSON: Your report. Okay,
 16 that's good, and I'm glad you - -
 17 MR. RICHMOND: I just want to make sure
 18 they do, and on the scheduling and we don't, under the
 19 new process, we don't produce a final of this plan.
 20 DR. HENDERSON: Oh, no.
 21 MR. RICHMOND: The plan is a living - -
 22 DR. HENDERSON: No, no, no, no. I'm
 23 just, but this is leading to a document that will be
 24 reviewed two more times.
 25 MR. RICHMOND: Right.

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1 DR. HENDERSON: But thank you for
 2 correcting. This has gotten so complicated with the
 3 new process, but it's good to be precise, so I'm glad
 4 you corrected that. And, perhaps, we can - -
 5 DR. MARTIN: If I might, perhaps, it
 6 might be worth saying, just a little bit of
 7 clarification about what you can expect to see in the
 8 first draft - -
 9 DR. HENDERSON: Good.
 10 DR. MARTIN: - - of the risk assessment
 11 report versus what you can expect to see in the second
 12 draft of the risk assessment report. And I'll just
 13 layout an initial major distinction, and you folks can
 14 add to it as you will. We talked about estimating
 15 exposures and risks associated with various alternative
 16 standards.
 17 And first of all, looking at just air
 18 quality, current levels of air quality, and then, just
 19 attaining the current standard. Those are the
 20 scenarios that we anticipate putting into the first
 21 draft of the risk report, and that you will be seeing
 22 those results and estimates associated with those two
 23 scenarios in the Spring, at the same time you see the
 24 second draft integrated science assessment.
 25 Subsequent to that, in the second draft, we



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1 would then, at that point, decide what alternative
 2 standards we would then, additionally, do exposure and
 3 risk estimates for. Because at that point, we would
 4 have the benefit of the second draft science
 5 assessment, and the benefit of your review of that
 6 document, to help inform an appropriate range of
 7 alternative standards that would reasonably be applied
 8 to finish out the exposure and risk assessment.
 9 So, those results you'll see in the second
 10 draft assessment.
 11 DR. HENDERSON: Okay, that's helpful.
 12 DR. MARTIN: And I wanted to make that
 13 point, because in the past, when we've come out with
 14 the first draft assessment, what everyone's looking for
 15 is, what is the risk associated with the range of
 16 alternative standards, and that, that's what we'll do
 17 in the second draft.
 18 DR. HENDERSON: Second draft, in the
 19 first draft, you'll have the risks associated with the
 20 current exposures and the, if you reach the higher
 21 levels of the - -
 22 DR. MARTIN: And it relates to the
 23 comment I made yesterday. We really don't want to get
 24 ahead of ourselves. We don't want to start projecting
 25 to what alternative standards may be appropriate to

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1 consider until we've had the benefit of your review of
 2 the second draft of the science assessment, where the
 3 inferences and conclusions are more sharply defined.
 4 DR. HENDERSON: Good advice, Karen.
 5 DR. MARTIN: Did you offer anything.
 6 SPEAKER: No, that's okay, well stated.
 7 DR. HENDERSON: Good.
 8 SPEAKER: Rogene, somebody may have
 9 just - -
 10 DR. HENDERSON: That's what I thought.
 11 Is there someone that had come on the phone?
 12 DR. BALMES: ;Yeah, this is John, hi.
 13 DR. HENDERSON: Oh, you have no idea how
 14 happy we are to hear from you, John.
 15 DR. BALMES: Yeah, no, I just listened.
 16 DR. HENDERSON: Okay, well, we would like
 17 your comments on the risk assessment part of this
 18 methods document. And, I'll tell you that the response
 19 before you has been generally positive. You probably
 20 didn't get to hear all that, but - -
 21 DR. BALMES: No, I, you know, I'll tell
 22 you, Rogene. I don't, I didn't provide written
 23 comments on it at this point. I didn't have, I guess,
 24 very much to say, because, in a sense, it was such a
 25 general template that I didn't see too much to say

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1 until I guess receive sort of the next step. So, as a
 2 starting point, I think it was fine. And then, I think
 3 we'll have to see what comes.
 4 DR. HENDERSON: Okay, John. Yeah, and
 5 we've had a very good clarification of what the next
 6 steps will be. Did you get to hear that?
 7 DR. BALMES: Yeah, I did hear that. I
 8 heard that, yeah.
 9 DR. HENDERSON: Okay, so that was very
 10 informative. And, okay, John. Well, we hope you
 11 didn't rush over to, we were just waiting for you to,
 12 in order to adjourn, to tell you the truth.
 13 DR. BALMES: Oh, okay, well, then. I'm
 14 sorry to hold anybody up from adjourning.
 15 DR. HENDERSON: Well, we've had
 16 interesting discussions. Really, this last discussion
 17 was most helpful, and we wouldn't have had it if we
 18 hadn't have been kind of waiting for you.
 19 DR. BALMES: Oh, okay, okay.
 20 DR. HENDERSON: So you contributed.
 21 DR. BALMES: I'll be in person next time.
 22 DR. HENDERSON: Okay. Thanks a lot,
 23 John, for calling in.
 24 DR. BALMES: Okay, bye.
 25 DR. HENDERSON: Okay, I think we are

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1 finished in our, it is the job of our DFO to adjourn
 2 us.
 3 DR. NUGENT: Well, thank you all for
 4 being here, and then the next steps will be for me to
 5 send around a draft of the document we spoke about this
 6 morning, and send a draft of the minutes around for
 7 your comments. And I guess, even before I do that,
 8 I'll be contacting you about scheduling the May meeting
 9 to get your availability, so, I look forward to seeing
 10 you again and thank you. Meeting's adjourned.
 11 (WHEREUPON, the PUBLIC MEETING was
 12 adjourned at 1:45
 13 p.m.)
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<p>1 CAPTION</p> <p>2 The foregoing matter was taken on the date,</p> <p>3 and at the time and place set out on the Title page</p> <p>4 hereof.</p> <p>5 It was requested that the matter be taken by</p> <p>6 the reporter and that the same be reduced to</p> <p>7 typewritten form.</p> <p>8 Further, as relates to depositions, it was</p> <p>9 agreed by and between counsel and the parties that</p> <p>10 the reading and signing of the transcript, be and</p> <p>11 the same is hereby waived.</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<p>1 CERTIFICATE OF REPORTER</p> <p>2 COMMONWEALTH OF VIRGINIA</p> <p>3 AT LARGE:</p> <p>4 I do hereby certify that the witness in the</p> <p>5 foregoing transcript was taken on the date, and at</p> <p>6 the time and place set out on the Title page hereof</p> <p>7 by me after first being duly sworn to testify the</p> <p>8 truth, the whole truth, and nothing but the truth;</p> <p>9 and that the said matter was recorded</p> <p>10 stenographically and mechanically by me and then</p> <p>11 reduced to typewritten form under my direction, and</p> <p>12 constitutes a true record of the transcript as</p> <p>13 taken, all to the best of my skill and ability.</p> <p>14 I further certify that the inspection, reading</p> <p>15 and signing of said deposition were waived by</p> <p>16 counsel for the respective parties and by the</p> <p>17 witness.</p> <p>18 I certify that I am not a relative or employee</p> <p>19 of either counsel, and that I am in no way</p> <p>20 interested financially, directly or indirectly, in</p> <p>21 this action.</p> <p>22</p> <p>23</p> <p>24 MARK REIF, COURT REPORTER / NOTARY</p> <p>25 SUBMITTED ON OCTOBER 25, 2007</p>	



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