Preliminary Draft Text to Assist CASAC Oxides of Nitrogen Primary NAAQS Panel Deliberations at the August 10, 2009 Public Teleconference Call

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Health Standards-Related Issues

Appropriateness of the proposed range of standard levels (≥ 80 ppb and <100 ppb), the rationale supporting that range, and alternatives described in the proposal including: The weight placed on the epidemiologic evidence, the controlled human exposure evidence, the exposure/risk information, and the uncertainties associated with each of these.

As noted in the Federal Register (July 15, 2009, pg. 34436):"In making judgments regarding the weight to place on the scientific evidence and exposure/risk information, the Administrator has considered the results of epidemiologic studies, controlled human exposure studies, and exposure/risk analyses as well as the uncertainties associated with this evidence and these analyses. Specifically, she notes the following: The ISA concluded that epidemiologic studies provide the strongest support for the relationship between short-term exposure to NO_2 and respiratory morbidity. "

While it is recognized that the epidemiologic studies likely included people exposed along roadways among those affected populations, those epidemiologic studies that are relied upon by the Administrator (e.g., those displayed in Figures 4 and 5 of the Federal Register) did not generally use near-roadway exposure data, but instead usually relied upon conventional area-wide monitoring in developing their reported NO2-health effects associations relied upon by the Administrator. As such, in the face of a lack of sufficient near-roadway health effects studies to develop direct exposure-health effects relationships, CASAC has concerns about including near-roadway concentrations in the standard-setting process at this time, feeling that the standard would better be set on the same area-wide monitoring basis as employed in the epidemiologic studies upon which it now relies.

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As indicated in the Federal Register on the proposed Rule with regard to the level and form of a new short-term NO_2 standard, the Administrator indicated that in using the results of the epidemiological studies, controlled human studies, and exposure/risk analyses to inform her decisions, the uncertainties associated with these analyses were considered. Issues of both confounding by co-occurring pollutants as well as the clinical significance of NO_2-associated changes in airways responsiveness in asthmatics are reported to have played important roles in the Administrator's decisions. CASAC similarly considered these issues in its deliberations. These considerations led to our original suggestions that because there did not appear to be a threshold for the occurrence of excess risk in the epidemiological studies and greater than 50% of asthmatics exposed to 100 ppb of NO_2 in clinical studies had increases in airways responsiveness and that such changes in asthmatic children would be considered an adverse outcome, that the maximum proposed standard should not exceed 100 ppb. Thus, the issue of uncertainty relates to the degree of protection below 100 ppb that should be considered.

As part of the rule making consideration, with regard to alternative approaches to setting the standard (page 44438) the Administrator has sought comments as to how uncertainty should be treated if either the standard were to exceed 100 ppb or be below the level of 65 ppb. There

seems little biological question or uncertainty that the occurrence of increased airways responsiveness in a substantial fraction of asthmatic children results in clinically significant exacerbation of their disease. Raising the standard to above 100 ppb (proposed for consideration is 150 ppb) would with a high degree of certainty only increase the fraction of asthmatic subjects who would be responsive and thus cannot be justified. Since below 100 ppb there are no clinical studies, the only information that can be used is that those individuals studied at 100 ppb necessarily represented mostly mild asthmatic subjects. Thus, it is likely with a moderate degree of certainty that more severe asthmatics would be more responsive and potentially more likely to respond at levels below 100 ppb. .

With regard to a lower bound of the potential range of the standard the Administrator requested comments on essentially two issues. One relates to how the monitoring site would affect exposure (see para xx of this letter). The second is how the uncertainty regarding the issue of co-pollutants would affect the consideration of level. The data on co- pollutants presented in the ISA and considered in the REA suggest that despite the potential for confounding, the estimates for NO_2 effects remain robust in the multi-pollutant models, "…and that the evidence supports a direct effect of NO_2 exposures on respiratory morbidity, independent of associations with other traffic-related pollutants" (page 34436). Since there does not appear to be evidence for a threshold risk in the epidemiologic data, the uncertainly with regard to the lower bound is much more impacted by the judgment of the appropriateness of the monitoring site in its translation to the population exposure estimates, rather than an issue of co-pollutants. Given the potential for mixing in ambient atmospheres, there is little likelihood to suggest that the directionality of the correlation of co-pollutants would substantially change at lower levels of NO_2 exposure (they might change at higher levels depending upon local sources). Further, given what is known about the additive responsiveness of the respiratory tract to multiple environmental agents, and that no threshold can be identified, the risk from NO_2 would appear to remain linearly related to the shape of the response curve. Thus, consideration by the Administrator of what level would afford an adequate margin of safety should not be impacted by uncertainty of effects of co-pollutants.

<u>Appropriateness of the proposed forms for a 1-hour daily maximum standard (pp. 34429-34430), which are (i) a three-year average of the 99th percentile of the annual distribution of daily maximum 1-hour average concentrations and (ii) a three-year average of the annual 4th-highest daily maximum 1-hour average concentrations.</u>

CASAC recognizes the importance of considering the combination of form and level in setting the NO_x NAAQS. As requested, we have considered the Administrator's alternate proposal for an area-wide standard with a proposed range of 50 to 75 ppb. Based upon the epidemiologic and controlled human studies described in the ISA and REA, we maintain our previously communicated opinion that an area-wide standard should be below 100 ppb and the standard should be set at the lower end of a range from 80 to 100 ppb. Previously (Samet 2008), we recommended that the percentile which is chosen for a one-hour standard must be appropriate for a health protective level and propose that 98th and 99th percentile forms would be appropriate for a standard level at the lower and upper boundaries of the proposed range, respectively. In

considering the current annual standard, we concur with the Administrator's recommendation that the annual standard be retained. This is based upon the limited evidence related to potential long-term effects of NO_2 exposure and the lack of evidence that a new short-term standard of 1-hour would protect against long-term effects.

Monitoring/Network Design

I. General Comments on Proposed NO_2 Monitoring Requirements

Uniformly uncomfortable with using a new roadside monitoring network for attainment demonstration. In addition to concerns that past epidemiological studies and recent CASAC deliberations were based on measurements from monitors more representative of areal NO_2 levels, a number of additional issues were raised that are specific to roadside monitoring and their use in attainment demonstration, including issues specific to the proposed rule:

A. Roadside monitors will be more susceptible to very extreme events because they are nearer to sources and more susceptible to periods of episodically high emissions, low dispersion and other events that could lead to high peak monitored levels that are not reflective of more widespread levels (e.g., heavy congestion near a monitor, trucks idling near the monitor, etc.). In the absence of more detailed roadside measurements, it would be difficult to identify the causes of extreme near-road NO_2 concentrations, or to understand how such extreme values are reflected in exposures of near-by urban populations. Further analyses are needed to determine the causes and frequencies of extreme, concentrations monitored by near-road monitors and to understand how such peak concentrations relate to those measured in the current, population-orientated network.

B. The concentrations monitored will be very sensitive to the specific location of near-road monitors, including exact distance from the roadway, height(s) of monitor inlet(s), orientation with respect to prevailing wind directions (during peak traffic periods), etc. Differences in the microscale environments of different roadside monitors may result in one area being out of attainment even though it actually has similar, and possibly lower, maximum NO_2 levels to another. This possibility also exists for area-representative monitoring, but the likelihood is reduced since the monitors are not trying to capture the extreme end of the distribution. Various practical logistical considerations are likely to further constrain the options for establishing new roadside monitoring sites. This could lead to an area trying to "follow the rules" but settling for a location that has lower maximum values. Unless siting criteria are very tightly constrained, data will not be directly comparable across different sites, and the value of a large multi-site network will be limited.

C. Identifying the location of maximum NO_2 levels will be quite difficult, and the proposed approach will likely miss where the maxima would occur. The proposed approach is insufficient, being based primarily on traffic count. Diesel trucks emit more NOx than cars, and it would be expected that the actual maximum levels would be found in areas of

high diesel activity (including rail yards and shipping) with reduced dispersion (e.g., street canyons). Open freeways that have high usage by light duty vehicles would not necessarily have the highest levels. In the design of a network to identify the maximum NO_2 levels in an area, we would support a more broad assessment to locate the locations of the likely highest NO_2 levels based upon investigation of model results (e.g., CMAQ and LUR, and Gaussian plume, if available) and emissions inventories. One could also use diesel truck activity as well (the traffic data bases include activities by various classes of vehicles)

D. The expected high spatial variability of roadside NO_2 concentrations also raises questions about the spatial representativeness of roadside monitor results. How large a non-attainment area is defined by a roadside violation? What population (if any) is assumed to be affected by the roadside concentrations? What is the public health message (avoid this state, AQCR, county, roadway, intersection, sidewalk)? Will the daily AQI for the county be driven by the relatively highest measurement from among neighborhood-scale (8-hr) ozone, (24-hour) PM2.5 monitors and roadside 1-hour NO_2 – the latter of which by design does not represent the populations covered by the PM and O3 monitors? Would an effective control strategy be to reroute traffic from the high-speed urban freeway (with the monitor) onto low speed urban residential streets (without monitors)?

E. A new roadside monitoring network with hundreds of sites with just NOx monitors and meteorological instrumentation would provide significantly less information than a smaller roadside network with more comprehensive measurements to better characterize near-road exposures to and gradients for the complex mixture of mobile source pollutants. In addition to NO_2, NO and meteorology, such monitoring should include CO, continuous PM, with speciation as possible (e.g., include EC or BC, continuous nitrate and sulfate, as possible, and possibly CO2 and gaseous VOCs). Such an alternative network, as discussed below, would not be designed to have all monitors necessarily placed in locations with the highest NO_2, but would also include locations that are impacted by heavy duty vehicle emissions, light duty vehicle emissions and suspended road dust, as well. It may, or may not, be oriented towards areas with minimal dispersion (street canyons).

F. The justification for the meteorological measurements is unclear in regards to assessing attainment. The need for, and uses of, such data should be better supported. CASAC would find such monitoring very useful at comprehensive monitoring sites.

CASAC strongly supports a special purpose monitoring network oriented towards roadside monitoring that is not used for attainment purposes at this point, and it would not be designed specifically to identify the locations of maximum NO_2 in an area. It would be designed to characterize pollutants in areas with high exposure to traffic-derived pollutants of all types, including heavy duty and light-duty vehicle emissions, tire and break wear and road dust, and would include pollutants beyond NO and NO_2 as discussed above. Detailed meteorological measurements would be well justified at these more intensive sites, as would automated traffic counters. These data would not be used for attainment demonstration.

Further, such a special network would specifically include variability in terms of site location (different distances to the facility, different highway characteristics) and type of monitoring done to provide the type of data that would better inform our understanding of pollutant dynamics, control strategy effectiveness and how a future road-side network should be designed for use in attainment decisions and standard setting. Further, such a network should go in quickly to capture the changes in emissions that are occurring in response to various controls. Funding for such special purpose monitoring may have to come predominantly from EPA. One approach would be through competitive grants to state and local agencies. The network would likely be much more limited in number (possibly on the order of 20 to 50 sites: the network could evolve with time), which would be appropriate given the objectives. A single city might have multiple near-road special purpose monitors to address issues in siting near-road monitors, and to understand relationships between roadside concentrations and larger population exposures. Cities with various characteristics should be chosen for assessing near-road monitoring issues. This approach appears to fit well with a recent EPA document, "Ambient Air Monitoring Strategy for State, Local, and Tribal Air Agencies," that states:

> "With this background, EPA's Strategy currently recognizes (1) the importance of near roadway exposures, and (2) the need for further exploration of the meaning of these exposures to both NAAQS-oriented monitoring networks and air toxics networks. Monitoring near roadways has, to date, been limited to research-level monitoring. As monitoring networks evolve, it is vital that monitoring near roadways be further investigated and eventually integrated into the monitoring networks. Currently, EPA and others continue to evaluate strategies for incorporating this monitoring into the other components of the monitoring Strategy primarily as a means of determining health risks and impacts on urban attainment. EPA intends to consult with SLTs and other stakeholders about the eventuality of developing the near-roadway component of ambient monitoring. The primary consideration would be to operate a small number of sites spaced in varying geographical areas of the country in an initial attempt to address near-roadway issues. Outcomes from EPA's Office of Research and Development's (ORD) near-roadway studies that began in 2006 and extend through 2009 or 2010 would heavily influence where, how, and when a near-roadway monitoring pilot would occur."

Assuming that the decision is made to not use near-road monitors for attainment demonstration, CASAC strongly supports further analysis of the current NO_2 data, diesel truck activity data, model results and emissions inventories to identify where area-representative sites might be placed to capture more broad areas of higher NO_2 levels. For example, CMAQ results, if available at a 4 or 12 km resolution, could be used to help inform analyses of locations with likely higher area-wide NO_2 levels (though would be less informative of locations of the very highest NO_2 levels in a city).

We question the need for monitoring in cities down to a population of 350,000. To be supportive of this choice, we would need to see additional analysis to suggest that such locations have area-

wide concentrations approaching 100 ppb. The population cut-off should be further justified, e.g., by using related monitoring results or modeling.

A concern raised in regard to the current proposal was the suggestion that building tops may be used. This should be done with caution as building tops may not be informative of much higher levels in areas just below where dispersion is inhibited.

1. Appropriateness of the Proposed two-tier monitoring network design

If an appropriate level of further analysis and review were conducted to support a primary NO_2 NAAQS using roadside monitoring, the utility of a two-tier approach for attainment demonstration is not apparent. The area-wide monitoring would support showing progress in reducing NO_x for NO_2, ozone and PM control programs, and would also continue to support health analyses. Whereas new roadside measurements of NO_2 alone, would provide minimal information on near-road multi-pollutant exposures, and would have questionable value in supporting future health studies.

If there is a mechanism to begin roadside monitoring, but not include such data in attainment determination, then a two tier mechanism is potentially attractive for support of health studies that could be used in future NAAQS reviews. However, such monitoring should not be for just NO and NO_2, but should include CO, continuous PM mass, and continuous TC/EC (or BC). Without this additional data, the results would be significantly less informative. If, as part of the current CO and PM reviews, a network of roadside monitoring of all of these species were proposed, it would be very attractive and could potentially be used in supporting a future NAAQS revision for those species and would be more readily used in a multi-pollutant air quality control program and determination of control effectiveness. NO/ NO_2 alone would not be overly informative.

2. Appropriateness of proposed requirements for near major roads

Again, a similar problem exists (that a roadside monitoring network for attainment demonstration is not currently supported). The determination should be based on modeling of peak NO_2 levels, and related air quality data analysis, and should take in to account population density. Specific criteria to be followed by the RA and the State/Local agencies should be further developed and reviewed, e.g., by the CASAC Ambient Air Quality Standards Committee (AAMS).

3. Giving the RA some discretion is appropriate, though it is not apparent that further area-wide monitoring is needed, and any changes and additions should largely come from analysis of NO_2 data and modeling results. Specific criteria to be followed by the RA and the State/Local agencies should be further developed and reviewed, e.g., by the AAMS.

3. Data quality objectives are fine.

II. Alternative Approach.

First, we prefer the alternative approach, and the standard should be, as CASAC advised, about 0.10 ppm. (We should look up how it was phrased.)

1. Area wide monitoring is appropriate, and would be similar to the system currently employed. Preferably the NO/ NO_2 monitoring would be done in locations that include CO, ozone and PM species monitoring as well.
2. We should follow the past CASAC recommendation.
3. Having the state/local air quality managers assess how the current network satisfies the goal of providing data representative or area-wide (not maximum) concentrations is appropriate. As noted above, the population threshold may be too low, and such a choice needs further support and review. One could consider requiring that removing NO/ NO_2 monitors is not allowed, and repositioning would need to have RA approval. Having the RA also have discretion to require additional monitoring to address community impacts is justified.
4. The definition of "area-wide" is not very specific, though reflects the realities of monitoring. It is now possible to use annual modeling to assess how representative a monitor location is of more area-wide levels, and this should be employed to demonstrate reasonableness of site locations. It would be good to specify a minimum distance that a monitor could be placed from a major facility (including freeways and highways), e.g., that a monitor that is representative of area-wide NO/ NO_2 should not be placed within 100 m of a major facility (with a further definition of major facility in terms of expected NOx emissions. For roads this could be in terms of NOx per 100m).

III. Monitoring Method

1. The chemiluminescent approach is appropriate. It would be good to improve and extend the technique to give both true NO_2 as well as NO_y. However, that would not be viable within the time frame of this rulemaking.
2. It is not apparent what the meteorological measurements contribute in terms of attainment demonstration or understanding the processes leading to peak values as those processes are already understood. The desire to have three dimensional winds, and the associated standard deviations, appears more research-oriented. Further, there is no detail as to the data quality requirements of the wind measurements. I did not find the desired time scale used for determining the fluctuations in the wind velocities. It should also be noted that sonic anemometry may suffer from instrument durability.