

# Comments on EPA's Risk and Exposure Assessment Planning Document for Nitrogen Dioxide

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# ***Abbreviations***

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AERMOD	AMS/EPA Regulatory Model
AHR	Airway Hyper-Responsiveness
CBSA	Core-Based Statistical Area
DM1H	Daily Maximum 1-Hour
ED	Emergency Department
EPA	United States Environmental Protection Agency
NAAQS	National Ambient Air Quality Standard
NO <sub>2</sub>	Nitrogen Dioxide
PPB	Parts Per Billion
REA	Risk and Exposure Assessment
REA PD	Risk and Exposure Assessment Planning Document

# Executive Summary

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The preliminary conclusions of the United States Environmental Protection Agency (EPA) Risk and Exposure Assessment Planning Document (REA PD) for nitrogen dioxide (NO<sub>2</sub>) are that the NO<sub>2</sub> air-quality analysis should be updated, but that neither an updated exposure assessment nor an updated risk assessment are clearly warranted at this time. Rather, a comparison of ambient NO<sub>2</sub> concentrations with health benchmarks would likely suffice, and an updated exposure assessment should be conducted only if the comparison of ambient NO<sub>2</sub> concentrations with health benchmarks indicates a public health concern.

As indicated in the REA PD, sufficient new data exist to warrant an updated NO<sub>2</sub> air-quality analysis for a representative set of core-based statistical areas (CBSAs). However, the analysis plan should be modified so that it:

- Increases emphasis on results at exposure benchmarks where evidence indicates that adverse health effects could occur;
- Improves documentation of the method used to weight the criteria for selecting CBSAs;
- Eliminates the high-NO<sub>2</sub> concentration criterion from the list of primary criteria used to select CBSAs;
- Evaluates the uncertainty in the adjustment factors for NO<sub>2</sub> daily maximum 1-hour (DM1H) concentrations above the 98<sup>th</sup> percentile; and
- Clarifies the use of near-road and on-road NO<sub>2</sub> concentrations and their uncertainties in informing a decision as to whether a new exposure assessment is needed.

Also, although we agree that updated exposure and risk assessments are not clearly warranted at this time, it is important for EPA to consider aspects of the 2008 exposure assessment that resulted in overly conservative exposure estimates. If a new exposure assessment is conducted, we recommend that EPA fully evaluate the modeling strategy and input data to develop a robust assessment based on the best available information. We also note that because results of the 2008 risk assessment were overly conservative, they should not be used to judge the adequacy of the current standard during this review.

# 1 Introduction

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The preliminary conclusions of the United States Environmental Protection Agency (EPA) Risk and Exposure Assessment Planning Document (REA PD) for nitrogen dioxide (NO<sub>2</sub>) are that:

- Uncertainty regarding on- or near-road ambient NO<sub>2</sub> concentrations can be better characterized with updated analyses that compare NO<sub>2</sub> concentrations with health effect benchmarks;
- An updated assessment of population exposures would be useful only if a comparison of ambient NO<sub>2</sub> concentrations with health benchmarks indicates a public health concern;
- Exposure-response information from the controlled human-exposure studies is not sufficient to support a risk assessment; and
- Because recent epidemiology studies (both short-term and long-term) have not adequately addressed uncertainty from the 2008 assessment as to whether effects are related to NO<sub>2</sub> or other traffic-related pollutants, an updated epidemiology-based risk assessment would not improve understanding of, or increase confidence in, NO<sub>2</sub>-related health risks.

The REA PD indicates that the next step in the NO<sub>2</sub> review process is to compare ambient NO<sub>2</sub> concentrations with health benchmarks. If these comparisons indicate that NO<sub>2</sub> exposures are not a concern for public health, then EPA will incorporate the analyses and discussion comparing ambient NO<sub>2</sub> concentrations with health benchmarks into the Policy Assessment for NO<sub>2</sub>, and a separate REA will not be generated.

As Section 2 describes in more detail, an updated air-quality analysis should be conducted, but with modifications to the analysis proposed in the REA PD. We agree with EPA that an updated exposure assessment is warranted only if the air-quality assessment indicates an increased likelihood of exposures above the selected health benchmarks, but we note that EPA should consider conservative aspects of the 2008 exposure assessment. We also agree with EPA that an updated risk assessment is not currently warranted, but note that the previous risk assessment was overly conservative.

## **2 A new analysis of air-quality data is warranted, but with modifications to the analysis proposed in the REA PD.**

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As indicated in the REA PD, new data are sufficient to warrant an updated NO<sub>2</sub> air-quality analysis for a representative set of core-based statistical areas (CBSAs). In particular, the recently installed near-road NO<sub>2</sub> monitors should provide a valuable new set of NO<sub>2</sub> observations that can inform the air-quality analysis. However, the analysis plan should be modified so that it:

- Increases emphasis on results at exposure benchmarks where evidence indicates that adverse health effects could occur;
- Improves documentation of the method used to weight the criteria for selecting CBSAs;
- Eliminates the high-NO<sub>2</sub> concentration criterion from the list of primary criteria used to select CBSAs;
- Evaluates the uncertainty in the adjustment factors for NO<sub>2</sub> daily maximum 1-hour (DM1H) concentrations above the 98<sup>th</sup> percentile; and
- Clarifies the use of near-road and on-road NO<sub>2</sub> concentrations and their uncertainties in informing a decision as to whether a new exposure assessment is needed.

### **2.1 The analysis should focus on results for exposure benchmarks above 100 ppb.**

EPA plans to evaluate NO<sub>2</sub> health benchmark levels of 100-400 parts per billion (ppb) in its updated air-quality analysis, which is an extension of the 100-300 ppb range evaluated in the 2008 NO<sub>2</sub> REA (US EPA, 2015). The range of benchmark levels selected for analysis is critically important, because the new air-quality assessment will tabulate the number of times that benchmark levels are exceeded in each of CBSAs studied, and these tabulated results will inform a decision as to whether a new exposure assessment is warranted.

As the REA PD notes, "important uncertainties" are associated with evidence regarding increased airway hyper-responsiveness (AHR) following exposure to 100 ppb NO<sub>2</sub>, including "the general lack of statistically significant results in individual studies at 100 ppb and the lack of an exposure-response relationship based on individual studies" (US EPA, 2015). Importantly, when considering the fraction of individuals experiencing increased AHR following exposure to NO<sub>2</sub> across all studies and concentrations, this fraction was statistically significant only for non-specific airway challenges, following exposure at rest. This fraction was not significant at any NO<sub>2</sub> concentration for non-specific airway challenges following exposure while exercising, or for specific airway challenges following exposure either at rest or while exercising. Considering the uncertainties associated with the AHR data following exposure to 100 ppb, the paradoxical lack of an effect following exercise, and the lack of an effect on AHR for specific airway challenges (which are more representative of plausible exposure scenarios than non-specific airway challenges), EPA should focus on benchmarks above 100 ppb.

## 2.2 The weighting of the CBSA selection criteria should be quantitatively described.

The REA PD lists criteria that will be used to identify CBSAs for the air-quality data analysis. This list includes criteria of primary importance and lesser importance, both of which will be used for an initial screening of potential sites to include in the analysis, and a separate set of criteria that will be considered after initial screening to determine whether the CBSAs identified should be retained in the final list of study areas (Table 2.1).

**Table 2.1 EPA’s Criteria for Identifying CBSAs for Air-quality Data Analyses**

Criteria of Primary Importance	Criteria of Lesser Importance	Criteria to Be Used After Initial Screening
CBSAs with a maximum number of area-wide monitors and years of monitoring data	CBSAs with data from background or low-concentration monitors	CBSAs that have readily available metadata for the monitoring sites
CBSAs with the highest annual and/or DM1H NO <sub>2</sub> concentrations in the US	CBSAs with data that can be used to characterize non-road emission sources that contribute substantially to measured NO <sub>2</sub> concentrations	CBSAs that include information that can be used to characterize emission sources influencing individual monitors
CBSAs that include areas where large portions of the US population reside		CBSAs with sufficient historical monitoring data to characterize trends
CBSAs that have near-road monitoring data		
CBSAs that are geographically diverse		

Notes:

CBSA = Core-Based Statistical Area; DM1H = Daily Maximum 1-Hour; EPA = United States Environmental Protection Agency; NO<sub>2</sub> = Nitrogen Dioxide.

Source: EPA (2015).

The REA PD clearly describes these criteria and also notes how most criteria will be assessed (*e.g.*, for the criteria focused on the number of monitors, CBSAs with more than three monitors are "strong candidates," and areas with three monitors are considered "possible candidates"). However, the document does not provide the quantitative method that EPA will use to rank the CBSAs based on the criteria, or information on how EPA will select the total number of study areas to analyze. For example, in Tables 2-2 and 2-4, the REA PD lists 12 assessments for each of the CBSAs (*e.g.*, "strong candidate" or "possible candidate"), with each of the 12 assessments related to the number of monitors in the CBSA in specified years, or to the DM1H or annual average NO<sub>2</sub> concentrations in specified years (US EPA, 2015). Based on these 12 assessments, each of the CBSAs is given an overall assessment (*e.g.*, "strong candidate" or "possible candidate"), but no information is provided on the method used to weight the 12 assessments to determine the overall assessment. As shown in Table 2-2 of the REA PD, each CBSA also has six assessments related to the number of area-wide monitors: the total number of monitors for years 2010, 2011, 2012, and 2013, and the average number of monitors for 2010-2012 and 2011-2013. However, no information is given on which of these six assessments are considered most important in the overall assessment of the CBSA. It is also unclear how the overall assessment from these tables is combined with additional assessments in Tables 2-3 and 2-5 of the REA PD to determine the set of "strong," "moderate," and "limited" candidate CBSAs shown in Figure 2-1 (US EPA, 2015).

Establishing a clear and quantitative method for ranking the CBSAs is important to ensure that the resulting air-quality analysis is informative, unbiased, and based on a set of CBSAs that best represents the selection criteria identified. Therefore, EPA should establish and document a clear process for ranking the CBSAs, which at a minimum includes detailed information on the methods for:

- combining the assessments for each CBSA;
- incorporating the geographic diversity and population criteria;
- combining the assessments for the criteria of primary and lesser importance;
- applying the secondary set of criteria after the initial screening to determine which CBSAs are retained for analysis; and
- selecting the total number of CBSAs to analyze.

### **2.3 High NO<sub>2</sub> design values should not be a primary selection criterion for the set of CBSAs to be analyzed.**

As shown in Table 2.1, the REA PD includes the highest annual and/or DM1H NO<sub>2</sub> concentration as one of the primary criteria that will be used to select the CBSAs included in the air-quality analysis. The document provides two justifications for this criterion: these monitors would require the smallest adjustments when estimating NO<sub>2</sub> concentrations that are just over the threshold to meet the existing standard, which could limit uncertainty, and these monitors are likely to represent areas with the highest risk (US EPA, 2015).

First, the possible gains related to limiting uncertainty do not justify this criterion, because the proportional-adjustment approach recommended in the REA PD is likely to have substantial uncertainty regardless of the initial concentration used for the adjustment. This lack of precision is demonstrated by the large variability<sup>1</sup> in the adjustment factors for NO<sub>2</sub> concentrations above the 98<sup>th</sup> percentile DM1H for individual monitors in Philadelphia (US EPA, 2015, Table 2-12). Second, limiting the air-quality analysis to areas with high NO<sub>2</sub> concentrations biases the analysis towards showing that high NO<sub>2</sub> concentrations are present across much of the country, especially if the NO<sub>2</sub> concentration criterion is weighted higher than the geographic diversity and total population criteria.

It is critical for EPA to select a geographically diverse set of CBSAs that have a large amount of ambient and near-road monitoring data and represent a large proportion of the US population. Also, although including CBSAs with a diverse range of maximum NO<sub>2</sub> design values (to represent different conditions across the country) is important, EPA should consider diversity in design values as one of the secondary criteria used to finalize the list of CBSAs analyzed, but not as one of the primary criteria used to select the list of potential CBSAs that could be included in the air-quality analysis.

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<sup>1</sup> Adjustment factors for the first through seventh highest concentrations (*i.e.*, the concentrations above the 98<sup>th</sup> percentile) at the eight monitors ranged from 1.01-1.56.

## 2.4 Uncertainty in the NO<sub>2</sub> concentrations estimated using the proportional-adjustment factors should be quantified.

As described in the REA PD, the air-quality analysis will rely on both adjusted NO<sub>2</sub> concentrations and an evaluation of NO<sub>2</sub> observations (US EPA, 2015). Because current design values<sup>2</sup> fall below the level of the standard, the observed NO<sub>2</sub> concentrations will be adjusted upwards. The proportional adjustment for each CBSA will be based on the lowest ratio of an individual monitor's design value to the level of the standard, considering ratios calculated using both the annual and DM1H standards (US EPA, 2015). In other words, the adjustment factor will be based on the highest design value for a single monitor in the CBSA. Notably, although proportional adjustments will be calculated for both the annual and DM1H standards, the preliminary analysis in the REA PD indicates that the lowest proportional-adjustment factors will be based on DM1H design values because, "currently, the 1-hour standard is the controlling standard in all potential study areas for the 3-years where that 1-hour standard can be calculated" (US EPA, 2015, p. 2-31). EPA proposes to use the single CBSA-wide proportional-adjustment factor described above for all DM1H NO<sub>2</sub> concentrations up to and including the 98<sup>th</sup> percentile DM1H for a given monitor, and then to use individual monitor-based proportional-adjustment factors for all DM1H concentrations above the 98<sup>th</sup> percentile. This approach differs from that employed for the 2008 NO<sub>2</sub> REA (US EPA, 2008), which used the single CBSA-wide proportional-adjustment factor for all DM1H NO<sub>2</sub> concentrations, not just those up to and including the 98<sup>th</sup> percentile. The proposed approach for DM1H concentrations above the 98<sup>th</sup> percentile is intended to address evidence that a non-linear relationship exists between changes in NO<sub>2</sub> emissions and the upper percentile NO<sub>2</sub> concentrations observed at individual monitors.

The REA PD provides example proportional-adjustment calculations for the Philadelphia CBSA. The document proposes that the individual adjustment factors for each monitor should be the ratios of the DM1H NO<sub>2</sub> concentrations above the 98<sup>th</sup> percentile at that monitor in a given year to the 98<sup>th</sup> percentile concentration at that monitor in the same year. Table 2.2 shows these calculations for the eight monitors in the Philadelphia CBSA, with the yearly adjustment factors averaged over the 2003-2013 period. Seven adjustment factors are calculated for each monitor, to represent the seven DM1H concentrations that fall above the 98<sup>th</sup> percentile each year (assuming 365 days of measurements per year).

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<sup>2</sup> A design value is an air-quality statistic calculated for a monitor that is used to determine its status relative to the National Ambient Air Quality Standards (NAAQS).

**Table 2.2 Adjustment Factors for DM1H NO<sub>2</sub> Concentrations Greater Than the 98<sup>th</sup> Percentile for Eight Monitors in the Philadelphia CBSA**

Site ID	Adjustment Factor Derived from Ratio of DM1H Concentrations to 98 <sup>th</sup> Percentile DM1H Averaged Across Years 2003-2013						
	Max. DM1H	2 <sup>nd</sup> DM1H	3 <sup>rd</sup> DM1H	4 <sup>th</sup> DM1H	5 <sup>th</sup> DM1H	6 <sup>th</sup> DM1H	7 <sup>th</sup> DM1H
421010075 <sup>a</sup>	1.38	1.21	1.15	1.09	1.06	1.04	1.01
100031010 <sup>b</sup>	1.44	1.22	1.17	1.10	1.07	1.05	1.02
100032004	1.53	1.22	1.15	1.12	1.08	1.02	–
340070002 <sup>c</sup>	1.21	1.11	1.08	1.05	1.04	1.04	1.01
420170012	1.32	1.18	1.10	1.08	1.04	1.03	1.01
420450002	1.56	1.35	1.15	1.10	1.05	1.03	1.02
421010004	1.38	1.21	1.15	1.09	1.06	1.04	1.01
421010047	1.55	1.35	1.19	1.14	1.09	1.04	1.01

Notes:

CBSA = Core-Based Statistical Area; DM1H = Daily Maximum 1-Hour; NO<sub>2</sub> = Nitrogen Dioxide.

(a) The near-road monitor (421010075) uses the ratios derived from the monitor having the highest design value (42101004).

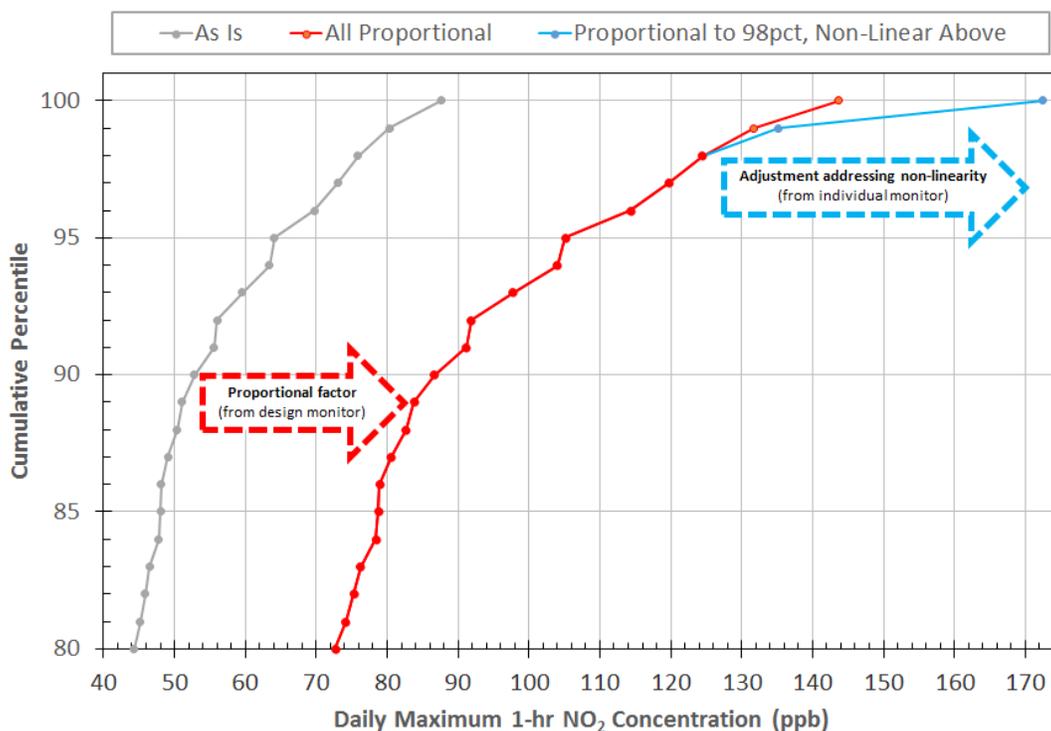
(b) Monitor ID 100031010 is newly sited (2013) and outside urban core of Philadelphia (outside Wilmington, Delaware). Data from a similar monitor (420910013) located outside urban core of Philadelphia (Montgomery County, Pennsylvania, operating 2003-2008) was used to calculate ratios.

(c) Monitor ID 340070003 (operating during 2003-2008) is sited in close proximity to newly sited monitor ID 340070002 (operating during 2012-2013). The data from both monitors were combined to calculate ratios.

Source: Adapted from EPA (2015, Table 2-12).

Figure 1 shows the difference between applying the CBSA-wide proportional-adjustment factor used in the 2008 NO<sub>2</sub> REA (red line) and the individual adjustment factor for the DM1H values greater than the 98<sup>th</sup> percentile (blue line; factors shown in Table 2.1) at Philadelphia monitor 421010004 (US EPA, 2015, Figure 2-9). Note that the figure shows only two data points above the 98<sup>th</sup> percentile (at the 99<sup>th</sup> and 100<sup>th</sup> percentiles), although seven data points actually exist, as shown in Table 2.1.

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**Figure 2.1 Adjusted DM1H NO<sub>2</sub> Concentrations for One Monitor in the Philadelphia CBSA.** Source: EPA (2015, Figure 2-9).

Figure 2.1 shows an exponential increase in the adjusted DM1H concentrations when using the individual monitor adjustment factors plus the CBSA-wide adjustment factors (blue line), as compared to only using the CBSA-wide adjustment factor (red line). However, neither Figure 2.1 nor Table 2.1 show the standard deviation, or any other calculation of uncertainty, for the adjustment factors and the resulting estimated DM1H concentrations. Because the DM1H concentrations greater than the 98<sup>th</sup> percentile will likely be part of the data considered when deciding whether a new exposure assessment is warranted, understanding the uncertainty in the new individual monitor adjustment factors is imperative.

In addition to evaluating and presenting information regarding uncertainty associated with the individual monitor adjustment values, we note that the manner in which the adjustment factors are used for values above the 98<sup>th</sup> percentile DM1H value is not described correctly in the REA PD. Specifically, statements such as the following quotation are made throughout the REA PD:

To estimate ambient concentrations that just meet the existing standard for years evaluated in this illustrative example, for each year of ambient monitoring data and at all monitors, the appropriate year proportional factor described above and found in Table 2-10 is applied to all DM1H concentrations up to and including the 98<sup>th</sup> percentile DM1H. Then, the remaining upper percentile concentrations above the DM1H 98<sup>th</sup> percentile are adjusted for each of the eight monitors in the Philadelphia CBSA (the seven area-wide and one near-road monitor) using the individual monitor-based adjustment factors provided in Table 2-12. (US EPA, 2015, p. 2-56)

This statement indicates that the DM1H concentrations above the 98<sup>th</sup> percentile are adjusted using only individual monitor adjustment factors (*e.g.*, as in Table 2.1). However, as is evident from Figure 2.1 and

the method used to calculate these factors, the individual monitor adjustment factors are actually applied on top of the CBSA-wide proportional-adjustment factors. The language related to this use of the adjustment factors should be corrected when documenting the new air-quality analysis.

## **2.5 The use of near-road and on-road data should be clarified, and robust uncertainty analyses should be conducted.**

As described in Section 2.4, the REA PD presents an example set of proportional-adjustment calculations for the Philadelphia CBSA. The document first shows proportional-adjustment factors calculated using the area-wide monitor design values. It then calculates DM1H values using the near-road data, with the goal of comparing these values to the DM1H design values calculated using the area-wide monitors. However, the near-road data are available only for three quarters in 2014, so comparing the near-road DM1H values to the DM1H design values, which are calculated using three years of data, is not appropriate. Therefore, EPA calculated additional DM1H values for the area-wide monitors based only on the 2014 data and compared these values with the near-road DM1H values. Note that these are not DM1H design values, which are based on three years of data, but rather are daily maximum statistics for 2014. The REA PD states that the adjustment factor calculated using the area-wide monitors was less than the adjustment factor calculated using the near-road data, and therefore the near-road adjustment factor is not being used to inform the CBSA-wide proportional-adjustment factor. As indicated by this analysis and as stated elsewhere in the REA PD, EPA proposes to use the available near-road monitoring data to calculate adjustment factors if these data show greater concentrations (*i.e.*, lower adjustment factors) than the area-wide monitor with the highest concentration values. Although using the near-road monitors (which are generally assumed to measure higher NO<sub>2</sub> concentrations than area-wide monitors) to determine the proportional-adjustment factor may be appropriate in some CBSAs, it will be necessary to explain precisely how the near-road data will be used to quantify adjustment factors, given that most CBSAs will yield, at most, one year of near-road data for analysis. Using values derived from a one-year dataset instead of design values based on three years of data will introduce additional uncertainty to the proportional-adjustment calculations, and this uncertainty should be quantified.

How the near-road data will be used to estimate DM1H concentrations if those concentrations just meet the NO<sub>2</sub> National Ambient Air Quality Standard (NAAQS) is also unclear. For example, in Table 2.1, site 421010075 is a near-road monitor, but the ratios shown for this monitor are simply copied from the monitor with the highest design value (monitor 421010004). As described in Section 2.4, the analysis in the REA PD demonstrated that the proportional-adjustment factor calculated using the near-road monitor data in the Philadelphia CBSA was lower than the proportional-adjustment factor calculated using the highest design value monitor (US EPA, 2015, Table 2-10). Given that comparison, applying the highest design value monitor-adjustment factors to the near-road monitor data is not appropriate. Overall, EPA should clarify how the near-road data will be used to estimate DM1H concentrations when they just meet the NO<sub>2</sub> NAAQS, and how the uncertainty of using a limited near-road dataset will be addressed in calculations.

The estimates of on-road NO<sub>2</sub> concentrations will be even more uncertain than the near-road NO<sub>2</sub> data. The REA PD suggests three possible methods for estimating on-road NO<sub>2</sub> concentrations: using observed on-road to near-road NO<sub>2</sub> concentration ratios; using a statistical model; and using an air-quality model (US EPA, 2015). However, each of these methods has a high degree of uncertainty, and therefore it is unclear how the estimated on-road concentrations can be used to determine whether a new exposure assessment is warranted.

Table 2.3 shows the estimated increase in NO<sub>2</sub> concentrations when comparing near-road and on-road data from three studies (US EPA, 2015, Table 2-6), as would be used to estimate on-road concentrations

based on observed on-road to near-road ratios. As this table shows, the relationship between near-road and on-road concentrations varies widely (e.g., the percent increase of on-road to near-road NO<sub>2</sub> concentrations across all studies and study periods ranges from -12% to 183%, with the percent increase in mean concentrations for individual studies/study periods ranging between 15-88%). In addition, the REA PD states that the data in Table 2.3 are one-week averages, which indicates that the data likely are not representative of one-hour concentrations. Given all of this information, a high degree of uncertainty is likely in any estimate of on-road NO<sub>2</sub> concentrations using the on-road to near-road NO<sub>2</sub> ratios observed in these studies.

**Table 2.3 Comparison of On-road and Near-road NO<sub>2</sub> Concentrations from Observational Studies**

Study Author	Road Description/ Season	On-Road/Near-Road Site Distance (m)	Mean On-Road/Near-Road Concentration (ppb)	Percent increase of on-road to nearest-road			Comments
				Mean	Median	Range (min to max)	
Bell and Ashenden (1997)	Rural/Summer	<1/20	16/9	88%	90%	27% to 183%	Summer data: May-September
	Rural/Not Summer	<1/20	15/11	48%	34%	-12% to 143%	
Cape et al. (2004)	Two-way Trunk/Annual	1/10	19/15	35%	26%	21% to 65%	Site distances are variable based on actual road shoulder width
	Single-way Trunk/Annual	1/10	7/5	44%	46%	31% to 51%	
	Non-Trunk/Annual	1/10	7/6	15%	21%	-7% to 30%	
Monn et al. (1997)	Urban/Unknown	0/20	43/38	15%	19%	-3% to 24%	

Notes:

ppb = Parts Per Billion.

Source: EPA (2015, Table 2-6).

The REA PD also describes the possible use of statistical models developed from near-road monitoring data collected in Las Vegas, Nevada (US EPA, 2015). These statistical models were developed for various meteorological conditions and were used to develop a set of factors that could be applied to near-road NO<sub>2</sub> concentrations (collected 10-20 m from the road) to estimate on-road NO<sub>2</sub> concentrations. These factors show that the upwards adjustment needed to estimate on-road NO<sub>2</sub> concentrations from near-road concentrations collected 10 m from the road varies from 10-17%, and from concentrations collected 20 m from the road, it varies from 13-22%. Based on these factors, EPA concluded that a 15-20% factor would be reasonable (US EPA, 2015). However, the REA PD does not provide any validation of the statistical model results when the model is applied to areas outside of Las Vegas, and therefore applying this range of factors to other US regions would result in highly uncertain estimates of on-road NO<sub>2</sub> concentrations. The REA PD also suggests that on-road NO<sub>2</sub> concentrations could be estimated using results from recent studies that used air-quality models (e.g., the AMS/EPA Regulatory Model [AERMOD]). However, given the limited number of these studies, applying the results to other geographic areas would also generate highly uncertain results.

Overall, there will clearly be a high degree of uncertainty in any estimate of on-road NO<sub>2</sub> concentrations that is based on the methods proposed in the REA PD. Therefore, EPA should quantitatively assess the uncertainty associated with the methods used in the air-quality analysis for estimating on-road NO<sub>2</sub> and use this uncertainty assessment to determine whether the on-road NO<sub>2</sub> concentrations can inform the decision to perform a new exposure assessment. Although the near-road data likely will be more useful in informing this decision, if near-road data are used, the uncertainty associated with these data will have to be appropriately characterized.

### **3 At this point, updated exposure and risk assessments are not warranted.**

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#### **3.1 An updated exposure assessment should be conducted only if the analysis of new air-quality data indicates an increased likelihood of exposures above appropriate benchmark levels.**

As discussed in Section 2.5, a large degree of uncertainty is associated with the near-road NO<sub>2</sub> data and the estimated on-road NO<sub>2</sub> concentrations, and with the proportional-adjustment factors used to estimate NO<sub>2</sub> concentrations above the 98<sup>th</sup> percentile when these concentrations just meet the NO<sub>2</sub> NAAQS. Whether new data would reduce these uncertainties enough to warrant developing a new NO<sub>2</sub> exposure assessment remains unclear. We agree with EPA that an updated exposure assessment should not be conducted at this time and that this decision should be re-evaluated after the air-quality analysis is completed.

Although we don't recommend an updated exposure assessment at this time, it is important for EPA to consider aspects of the 2008 exposure assessment that resulted in overly conservative exposure estimates. For example, this assessment relied on benchmarks below 200 ppb, which are not supported by the evidence. It also relied on air-quality data that was adjusted upwards to meet the current and other potential standards. This combination of factors resulted in the number of days that exceeded health benchmarks, according to the air-quality model used in the REA, being greater than the number of days based on actual data. Finally, the exposures calculated from the AERMOD model were over-estimated (as EPA acknowledged). Taken together, these findings indicate that the exposure assessment conducted in 2008 was overly conservative.

#### **3.2 If an exposure assessment is warranted, EPA should evaluate the modeling strategy and input data to develop a robust assessment based on the best available information.**

If the new air-quality data analysis demonstrates that a new exposure assessment is needed, EPA should fully document its plan for developing the exposure assessment. Describing all of the features that an updated exposure assessment should include is premature, because much of the data that would be considered in that assessment will be documented in the new air-quality data analysis. However, an updated exposure assessment would have to include a robust method for estimating personal exposure to NO<sub>2</sub>, given that many people spend a high proportion of their time indoors and away from major sources of NO<sub>2</sub>. If a new exposure assessment is conducted, it should incorporate realistic assumptions and also consider alternative averaging times and statistical forms.

### **3.3 The 2008 risk assessment should not be used to judge the adequacy of the current standard.**

The concentration-response function derived from the epidemiology evidence contributes to overly conservative results in the 2008 risk assessment. This assessment was based on the results of a single epidemiology study by Tolbert *et al.* (2007), which analyzed over 10 million emergency department (ED) visits recorded between 1993 and 2004 in the Atlanta metropolitan area. EPA used NO<sub>2</sub> coefficients derived from single- and multi-pollutant models in this study to inform concentration-response functions in the risk assessment of respiratory-related ED visits attributable to short-term NO<sub>2</sub> exposure. Using concentration-response functions based on single-pollutant models, EPA estimated that if air quality in Atlanta was adjusted so that it just met the existing annual standard, approximately 8-9% of all respiratory ED visits in the region would be attributable to NO<sub>2</sub> exposures. However, when EPA used coefficients derived from the multi-pollutant models reported by Tolbert *et al.* (2007) in the risk assessment, risks were substantially lower in magnitude.

As EPA noted in the REA, substantial uncertainties limit the accuracy of single- and multi-pollutant models alike, so determining whether models based on single- or multi-pollutant analyses better represent the true risk of respiratory-related ED visits is difficult. However, EPA misleadingly implied that coefficients of single-pollutant models are biased high, whereas those from multi-pollutant models are likely biased low. Although it is true that collinearity and concavity between co-pollutants may cause some coefficients to be biased towards the null as multiple exposures "compete" in regression analyses, the presence of differential exposure measurement error between pollutants in multi-pollutant models greatly complicates the issue. It has been demonstrated that when different pollutants are measured in a study region with varying degrees of measurement error, the pollutant that is measured most accurately may act as a proxy pollutant for one that is measured with more error (Sarnat *et al.*, 2005). In other words, the pollutant with the largest coefficient in multi-pollutant models is not necessarily associated with the greatest health risks.

Given the unpredictability of multi-pollutant models, it is possible that all the concentration-response functions used in the 2008 epidemiology-based risk assessment were biased away from the null. Notably, the original investigators themselves concluded that measured associations between pollutants and respiratory disease likely were affected by differential exposure measurement error and should be interpreted with great caution. These uncertainties preclude the use of the 2008 risk assessment results in the current review.

Finally, EPA's 2008 REA did not adequately consider the potential for a threshold in the concentration-response function derived from Tolbert *et al.* (2007). If a threshold exists, any risk estimates calculated using a concentration-response function with no threshold would have been biased high. Depending on the level of the true threshold, the magnitude of this conservative bias could be substantial. For example, in the 2014 Ozone REA, EPA found that including a threshold in concentration-response functions used to model relationships between long-term ozone exposure and mortality resulted in a 98% reduction in estimated deaths (US EPA, 2014).

## References

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