Responses to Significant Comments on the 2023 Proposed Rule for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter

Docket Number OAR-2015-0072

U.S. Environmental Protection Agency

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Frequently Cited Documents

The following documents are frequently cited throughout the EPA's response to comments, often by means of the short names listed below:

2019 Integrated Science Assessment (2019 ISA)

> Integrated Science Assessment for Particulate Matter: Final Report. Center for Public Health and Environmental Assessment-RTP Division, Office of Research and Development, Research Triangle Park, NC. EPA/600/R-19/188. December 2019. Available: *https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=347534*.

2022 Supplement to the 2019 ISA for PM (ISA Supplement)

> Supplement to the 2019 Integrated Science Assessment for Particulate Matter (Final Report). Center for Public Health and Environmental Assessment-RTP Division, Office of Research and Development, Research Triangle Park, NC. EPA/600/R-22/028. May 2022. Available: *https://www.epa.gov/naaqs/particulate-matter-pm-standards-integrated-science-assessments-current-review.*

2022 Policy Assessment (2022 PA)

> Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA 452/R-20-002. January 2020. Available: *https://www.epa.gov/naaqs/particulate-matter-pm-standards-policy-assessments-current-review-0*.

Proposed Rule (Proposal or Proposed Action)

> Reconsideration of the National Ambient Air Quality Standards for Particulate Matter: Proposed Rule. 88 FR 5558, January 27, 2023.

Preamble to the Final Rule (Final Action)

> Reconsideration of the National Ambient Air Quality Standards for Particulate Matter: Final Rule. To be published in the *Federal Register*.

I. Introduction

This Response to Comments (RTC) document, together with the preamble to the final rule (or final action)[1] on the reconsideration of the national ambient air quality standards (NAAQS) for particulate matter (PM), presents the responses of the Environmental Protection Agency (EPA) to significant public comments received on the 2023 PM NAAQS proposal notice (88 FR 5558, January 27, 2023). This document also includes the EPA's provisional consideration of "new" studies submitted during the public comment period (i.e., those studies considered to be within the scope but published after the literature cutoff date for the Integrated Science Assessment (2019 ISA; U.S. EPA, 2019) and the Supplement to the 2019 ISA for PM (ISA Supplement, U.S. EPA, 2022b), and as such, not considered as part of the EPA and CASAC review of the air quality criteria (see Appendix A). The responses presented in this document are intended to augment the responses to comments that appear in the preamble to the final rule and to address comments not discussed in that preamble. Although portions of the preamble to the final rule are paraphrased in this RTC document, the preamble itself remains the definitive statement of the rationale for revising the level of the primary annual $PM_{2.5}$ standard to 9 $\mu g/m^3$ and retaining all other PM NAAQS.

Accordingly, this RTC, together with the preamble to the final rule and the information contained in the 2019 ISA, ISA Supplement, the 2022 PA, and the Notice of Proposed Rulemaking, should be considered collectively as the EPA's response to all of the significant comments submitted on the EPA's 2023 PM NAAQS proposed rule. This document incorporates, directly or by reference, the significant public comments addressed in the preamble to the PM NAAQS final rule, as well as other significant public comments that were submitted on the proposed rule.

Due to the large number of comments received overall and the number of comments that addressed similar issues, this RTC does not generally cross-reference responses to a particular commenter or commenters. However, commenters are identified in some cases where they provided particularly detailed comments that were used by the EPA to frame the overall response on an issue.

Comments on the health effects evidence and quantitative risk assessment are addressed in this document in sections II and III, respectively. Comments on the primary standards for $PM_{2.5}$ and PM_{10} are addressed separately in this document in sections IV and V, respectively. Comments on secondary standards for fine and coarse particles are addressed below in section VI. Comments related to the communication of public health and the Air Quality Index (AQI) are addressed in section VII. Comments on amendments to ambient monitoring and quality assurance requirements are addressed in section VIII. Comments related to implementation are addressed in section IX. Comments on other topics, including legal, administrative, procedural, or miscellaneous comments, are addressed in section X.

II. Comments on the Health Effects Evidence

[1] Consistent with CAA section 307(d)(2), we at times refer to the final "action" as a "rule" in the preamble to the final action and in this RTC document.

A. General Comments on the Integrated Science Assessment (ISA) and ISA Supplement

(1) **Comment:** A number of commenters question aspects of the EPA's process of ISA development, broadly, and some of the decisions made by EPA in the development of the Supplement to the 2019 PM ISA. Specifically, commenters assert that: (a) the ISA's framework for reviewing and interpreting the evidence and making causality determinations lacks specificity and detail, and is flawed; (b) the ISA lacks several critical features of modern systemic review practices and as a result the EPA does not use an unbiased and transparent systematic approach to reviewing the evidence as reflected in EPA's process of evaluating and interpreting studies, which includes the lack of detailed explanations of the protocol used to review the literature, the approach used to evaluate study quality, the methods and quality control approaches used to extract data, and the processes used to evaluate that data; and (c) the EPA does not clearly articulate the scope of the ISA and Supplement, and specifically decisions around the exclusion of some studies (e.g., non-U.S. studies, studies conducted at high [above typical] ambient concentrations, biochemical and histological studies [and more broadly in vitro studies]) and that the scope of the Supplement is too narrow.

Response: The EPA disagrees with each of the points raised by the commenters. Specifically for point (a), the EPA disagrees with the commenter's assertion regarding criticisms of the causal framework used to make key science judgments in the ISA. Since the inception of the ISAs in 2008, the EPA has relied on a weight-of-evidence approach to assessing the causal nature of relationships between exposure to criteria pollutants and health and welfare effects, which is similar to frameworks used by numerous scientific organizations (e.g., Institute of Medicine, Centers for Disease Control and Prevention, International Agency for Research on Cancer). Over time, this framework has evolved through substantive interactions with the CASAC, as well as ad hoc panels developed to support the chartered CASAC members during numerous public meetings. In addition, the EPA disagrees with commenters that the framework is inappropriate to use, either in being overly cautious or not detailed enough. With respect to the criticism that the EPA's causal framework is overly cautious, the EPA notes that the key science judgments (i.e., causality determinations) developed using the causal framework are the main pillars used in subsequent policy and technical documents that inform the Administrator's decision on the adequacy of the NAAQS. As such, the causal framework relies on the collective body of evidence spanning scientific disciplines to assess the consistency of evidence within a discipline, the coherence of effects across disciplines, and whether there is evidence of biological plausibility. Therefore, the degree of certainty conveyed using the causal framework in the ISAs in the assessment of the causal nature of relationships between health effects and criteria pollutants, including PM, is needed to fully inform additional steps of the NAAQS review process. It is important to accurately characterize uncertainties in the evidence so those uncertainties can be taken into account in decision making on the NAAQS, recognizing that the NAAQS are intended to provide a degree of protection against uncertain risks.

In addition, the EPA's conclusion that the causal framework is appropriate for use in NAAQS reviews is supported by the overall conclusions of the National Academies of Science, Engineering, and Medicine (NASEM) ad hoc committee convened to provide

independent advice to the EPA on the causal framework used in forming causality determinations in the ISA. This NASEM committee, consisting of 12 subject matter experts with expertise spanning disciplines including decision analysis, epidemiology, toxicology, dosimetry, biostatistics, experimental sciences, toxicokinetics, exposure-dose-response modeling, atmospheric sciences, ecology, and risk analysis, was tasked with reviewing the EPA's causal framework and making recommendations as to its development and use in ISAs. In October of 2022, NASEM released the report of the committee "Assessing Causality from a Multidisciplinary Evidence Base for National Ambient Air Quality Standards" (NASEM, 2022). While the committee provided recommendations that the EPA could address to improve the framework, overall, the committee concluded that "… the fundamental structure of the weight of evidence approach described in the 2015 Preamble allows effective determination of causality for both health and welfare effects." This conclusion, in combination with the origins of the EPA's causal framework being some of the leading scientific organizations in the world, as previously noted, provides additional support for its overall structure and the EPA's application of the framework in making key science judgments within ISAs.

For point (b), the EPA disagrees with the commenter's contention that the ISA development process is biased and lacks transparency. As a direct result of the substantive interactions with the CASAC over many years, ad hoc panels developed to support the chartered CASAC members and the public during numerous public meetings, the EPA has continuously strived to increase transparency in the ISA development process. Ultimately, the advice of the CASAC and the public contributed to the EPA publishing a separate document, titled Preamble to the ISA (U.S. EPA, 2015) (hereafter "Preamble"), with the sole purpose of clearly articulating each phase of the ISA development process to ensure transparency. The process for developing ISAs was summarized in the Preface and the Executive Summary of the 2019 ISA, referring readers to the Preamble for greater detail. In addition, in the final 2019 ISA, the EPA added an Appendix that provided detailed steps on the development of the PM ISA to address comments on the draft ISA from the CASAC and the public (U.S. EPA, 2019). This Appendix provides more detailed information that the commenters contend is lacking from the 2019 ISA. Specifically, the Appendix provides extensive details on all phases of the development of the 2019 ISA, including the literature search and initial screening and documentation of studies, the detailed evaluation of individual study quality (e.g., study scope, design, and methods), the peer review and public participation process, and the quality assurance steps that were taken to ensure accuracy. Also, as noted in the Appendix to the 2019 ISA, the EPA has undertaken a rigorous process of evaluating individual studies. As part of this process, the Agency relies on various scientific considerations, detailed in Table A-1 of the Appendix (U.S. EPA, 2019). These considerations allow the Agency to evaluate the strength of inference from studies spanning scientific disciplines and, ultimately, their utility in informing causality determinations. It is based on these individual study quality evaluations that the strength of the evidence base is assessed. If there are instances where there are inherent limitations in individual studies and in the overall body of evidence, this is reflected in the causality determination for a health effect category.

Lastly, with respect to point (c), the EPA disagrees with the commenters as the 2019 ISA clearly articulates the scope in Section P.3.1 while Section A.2 and A.3 of the Appendix

details the process of screening and selecting studies. The EPA also disagrees with the commenter's assertion that studies at higher concentrations should also be included in the 2019 ISA and ISA Supplement. Within the 2019 ISA, the focus is on assessing the causal nature of relationships between health effects and PM at relevant ambient concentrations. As such, Section P.3.1. of the 2019 ISA states that one of the areas of focus is on studies "conducted at concentrations of PM that are relevant to the range of human exposures across ambient microenvironments (up to 2 mg/m^3, which is one to two orders of magnitude above ambient concentrations)" (U.S. EPA, 2019). However, "the scope is broader for experimental studies when examining biological plausibility for PM health effects, and in some cases, includes in vitro studies, studies that use intratracheal (IT) installation, studies examining relative toxicity, and studies conducted at concentrations >2 mg/m^3" (U.S. EPA, 2019).

With respect to biochemical and histological studies, and more broadly, in vitro studies, the Preamble to the ISAs states "in vitro studies may provide mechanistic insight for effects examined in vivo or in epidemiologic studies" (U.S. EPA, 2015). It additionally states that "experimental results from in vivo studies involving animal models and humans, as well as from in vitro studies when appropriate, may be used to establish biological plausibility and to interpret other lines of evidence (e.g., health effects from epidemiologic studies)" (U.S. EPA, 2015). Therefore, in vitro studies are sometimes used in the process of assessing biological plausibility, but they do not encompass the main evidence base used to assess causality as the focus is on studies of inhalation exposures.

With respect to the ISA Supplement, the scope is described in detail in section 1.2 (U.S. EPA, 2022b). The scope of both 2019 ISA and ISA Supplement is rooted in identifying those studies that "address policy-relevant questions" as noted in the Integrated Review Plan (U.S. EPA, 2016). In the 2019 ISA, studies conducted across the world were considered and included in the evaluation of the scientific evidence. As described in section 1.2 of the ISA Supplement, studies considered for inclusion in that document were limited to U.S. and Canadian studies. The rationale for this approach is noted in section 1.2 of the ISA Supplement:

> "In addition to focusing on studies for health effect categories for which the 2019 PM ISA concluded *causal* or a *likely to be causal relationship*, as noted above, the 2020 PM PA also focused on a narrower set of studies conducted in locations that are most relevant to informing the level, form, averaging time, and indicator of the NAAQS for PM. Specifically, the 2020 PM PA states that the emphasis is on "multicity studies that examine health effect associations in the U.S. or Canada, as such studies examine potential associations over large geographic areas with diverse atmospheric conditions and population demographics (e.g., U.S. EPA, 2019 , sections 11.1 and 11.2). Additionally, studies examining associations outside the U.S. or Canada reflect air quality and exposure patterns that may be less typical of the U.S., and thus less likely to be informative for purposes of reviewing the NAAQS" (U.S. EPA, 2022a). Therefore, within this Supplement the studies considered for inclusion are limited to those studies conducted in the U.S. and Canada. However, it is the combination of the scientific evidence detailed in the 2019 PM ISA and this Supplement that forms the complete scientific record informing the reconsideration of the 2020 PM NAAQS."

The EPA also disagrees with the commenter's assertion that narrow scope of the ISA Supplement is inadequate and that the CASAC viewed the limited scope of the ISA Supplement as a flaw in the process of reconsidering the 2020 PM NAAQS. The EPA has a longstanding practice of supplementing ISAs with select, important additional studies that have been reviewed by CASAC, when appropriate (see, e.g., the discussion of this practice in the 2012 PM NAAQS final rule, 78 FR 3095-96). In the CASAC's consensus letter to the EPA Administrator for its review of the 2021 draft ISA Supplement, it noted that this limited scope is "appropriate for the targeted purpose of the Draft ISA Supplement." However, the CASAC did state that:

> "[t]his limitation should be explicitly acknowledged. It should also be noted in the Draft ISA Supplement that this limiting of scope applies only to this document and is not intended to establish a precedent for future ISAs."

As a result, based on this advice from the CASAC, the EPA in the ISA Supplement added text to reflect the point that the limited scope of the ISA Supplement does not influence decisions regarding the scope of future ISAs. This text states: "This targeted approach to developing the Supplement to the 2019 PM ISA for the purpose of reconsidering the 2020 PM NAAQS decision does not reflect a change to EPA's approach for developing ISAs for NAAQS reviews" (U.S. EPA, 2022b, section 1.2).

(2) **Comment:** Some commenters who support revising the primary PM_{10} standard state that the EPA needs to properly consider the most recent scientific evidence in reaching decisions regarding the adequacy of the current standard. In so doing, these commenters note that in determining the scope of the 2022 ISA Supplement to support the reconsideration, the EPA did not include an evaluation of scientific evidence of $PM_{10-2.5}$-related health effects published since the literature cutoff date of the 2019 ISA because the evidence at that time did not support a causal relationship. These commenters also cite to the CASAC's advice in their review of the 2019 draft PA that there is a "clear progression" in the strength of the evidence, including for mortality, cardiovascular effects, and cancer. These commenters further cite two new studies that they assert have demonstrated links between $PM_{10-2.5}$ and respiratory effects, nervous system effects, and reproductive and developmental effects.

Response: The EPA disagrees with commenters that the most recent scientific evidence was not properly considered in reaching conclusions regarding the adequacy of the current primary PM_{10} standard. As an initial matter, as noted by the commenters and described in section I.D.6, above, the scope of the 2022 ISA Supplement focused on those health effect categories for which the 2019 ISA concluded a "causal relationship" and subsequently the 2020 PA deemed to be of most importance in assessing the adequacy of the PM NAAQS. Similar to the 2009 ISA, $PM_{10-2.5}$ studies evaluated in the 2019 ISA had some of the same inherent limitations, resulting in the ISA concluding "uncertainties in the evidence regarding biological plausibility for health effects related to $PM_{10-2.5}$ exposure and in the methods used to assign $PM_{10-2.5}$ exposure in epidemiologic studies contributed to causality determinations of *suggestive of, but not sufficient to infer, a causal relationship* or *inadequate to infer the presence or absence of a causal relationship*" for health effect categories for both short- and long-term exposure. Therefore, the 2022 ISA Supplement did not include an evaluation of studies related to $PM_{10-2.5}$ exposures published since the literature cutoff date of the 2019

ISA. Further, we note that in CASAC's review of the 2021 draft PA, they did recognize that more scientific evidence has become available since the 2009 ISA that could potentially support an upgrading of some causality determinations in the 2019 ISA (Sheppard, 2022, p. 18 of consensus responses). While we agree with the commenters and the CASAC that the body of evidence related to $PM_{10-2.5}$ exposures and health effects has expanded since the 2009 ISA, there are still inherent limitations and uncertainties in the evidence base, as described above, that contributed to causality determinations of "inadequate to infer the presence or absence of a causal relationship" and "suggestive of, but not sufficient to infer a causal relationship" in the 2019 ISA. As a result, consistent with Agency recommendations in the 2012 review and the 2020 final decision, additional research is needed to address these uncertainties. Finally, we disagree with the commenters that the studies they provided support revising some causality determinations for health effect categories for $PM_{10-2.5}$. The studies by Kollath et al. (2022) and Herrera-Molina et al. (2021) are out of scope because these studies examine associations between PM_{10} and health outcomes, which is important because the 2019 ISA reached conclusions regarding causality based on studies that examined short- and long-term $PM_{10-2.5}$ exposures and health effects, and not PM_{10}. Additionally, while the study by Enders et al. (2018) did examine associations between $PM_{10-2.5}$ exposures during gestation and low birthweight, and would be considered to be within the scope of the 2019 ISA, the EPA has provisionally considered this study and concludes that this one single study on its own would not be sufficient to warrant the changing of this causality determination, in light of the collective body of evidence that is considered in making conclusions regarding causality as detailed in the Preface to the 2019 ISA (U.S. EPA, 2019) and the Preamble to the ISA (U.S. EPA, 2015). Specifically, during the process of forming causality determinations, the EPA considers the broader body of scientific evidence and not only one line of evidence (e.g., epidemiology). As such, in evaluating a body of evidence the EPA considers the pattern of results across a scientific discipline, such as epidemiology, to assess whether there is consistency and the coherence of results across scientific disciplines including toxicological studies and controlled human exposure studies.

(3) **Comment**: Some commenters assert that, in assessing the evidence in the 2019 ISA and the ISA Supplement, the EPA ignored studies that reported no association with $PM_{2.5}$.

Response: The EPA also disagrees with the commenters' assertion that the Agency has not considered epidemiologic studies that did not report associations between $PM_{2.5}$ exposure and mortality in determining the adequacy of the current standard. As detailed in section 11.2 of the 2019 ISA, all studies of long-term $PM_{2.5}$ exposure and mortality that were within the scope of the 2019 ISA (as detailed in the Preface) were considered and included in the 2019 ISA. In assessing the full body of evidence in forming a causality determination, the EPA focuses on the pattern of results across studies and does not focus solely on statistical significance as described in detail in the Preamble to the ISAs (U.S. EPA, 2015). This is because statistical significance is an indicator of the precision of a study's results, which is influenced by a variety of factors including, but not limited to, the size of the study, exposure and measurement error, and statistical model specifications. As a result, in developing an integrated assessment of the health effects evidence for PM, the EPA has emphasized the importance of examining the pattern of results across various studies, not statistical significance. Therefore, in assessing the adequacy of the PM NAAQS within the 2022 PA, the EPA relies on the full suite of evidence used to inform causality determinations detailed

in the 2019 ISA, which includes studies that report no evidence of an association, but only pulls forward those studies of most relevance.

(4) **Comment**: Some commenters express concern about the difference in the strength of the associations for respiratory and cardiovascular morbidity compared to respiratory and cardiovascular mortality. Specifically, the commenters state that associations/coherence for respiratory and cardiovascular morbidities are less consistent than the associations for respiratory and cardiovascular mortality. These commenters state that if $PM_{2.5}$ concentrations were associated with respiratory and cardiovascular mortality, then one would expect the association with respiratory and cardiovascular morbidity to be as strong or stronger, but this is not the case as stated in the 2019 ISA and 2022 PA. Commenters state that the EPA does not explain this difference and requests the EPA provide an explanation. In addition, with respect to the causality determination for short-term $PM_{2.5}$ exposure and respiratory effects, the commenters contend that the causality determination is not supported because of the lack of observed respiratory effects in controlled human exposure studies. Commenters request the EPA provide an explanation as to why such direct study results were not considered to be more relevant than the epidemiologic studies.

Response: As an initial matter, the commenters do not define what they mean by "strength of the associations". Strength could be implied to mean either associations larger in magnitude or associations that are more precise. In the context of the 2019 ISA, which directly informed the 2022 PA, strength of the association is one of multiple key aspects to aid in judging causality considered as part of EPA's causal framework that is used to make causality determinations for the health effect categories evaluated in the 2019 ISA (U.S. EPA, 2015, Table I). Strength of the association on its own is not considered to be a greater attribute to inform causality than any of the other key aspects evaluated. As noted in the Preamble to the ISAs, the EPA states:

> "In evaluating the strength of the observed association, the U.S. EPA considers both the magnitude and statistical precision (i.e., width of confidence interval) of the association in epidemiologic studies. In a large study that accounts for several potential confounding factors, a strong association can serve to increase confidence that a finding is not due to a weak unmeasured confounder, chance, or other biases. However, in a study that accounts for several potential confounding factors and other sources of bias, a weak association does not rule out a causal connection. The health effects evaluated in the ISAs tend to have multiple risk factors that likely vary in strength of effect, and the magnitude of effect of air pollution exposure will depend on the prevalence of other risk factors in the study population. Further, a small effect size can be important from a public health impact perspective. The air pollution-related change in a health effect observed in a study can represent a shift in the distribution of responses in the study population and potentially an increase in the proportion of individuals with clinically important effects" (U.S. EPA, 2015, section 5).

In addition, when evaluating the different aspect considered in the process of assessing causality "it is important to note that the aspects…cannot be used as a strict checklist, but rather to determine the weight of evidence for inferring causality. Consistency of findings across studies is informed by the repeated observation of effects or associations across

multiple independent studies. Further strength is provided by reproducibility of findings in different populations under different circumstances" (U.S. EPA, 2015). Therefore, in assessing the causal nature of relationships between short- and long-term PM exposure and the health effects categories evaluated in the 2019 ISA, the totality of the evidence is considered. As a result, the causality determinations rely on different lines of evidence, by integrating evidence across scientific disciplines, including epidemiologic, animal toxicological, and controlled human exposure studies to assess consistency of effects within a discipline, coherence of effects across disciplines, and whether there is evidence of biological plausibility.

In providing this background, the EPA disagrees with the commenter's contention that the strength of the association should be the same for studies of morbidity and mortality. First, the commenters provide no basis for their assumption that the strength of the association should be different between outcomes. Second, as noted above multiple factors within each individual study can influence the strength of the association. Last, the outcomes within respiratory and cardiovascular morbidity that provide some of the strongest evidence in support of the causality determination for each health effect category report evidence of generally consistent positive associations as reflected in 2019 ISA (asthma; COPD; myocardial infarction/ischemic heart disease; heart failure). In addition, studies of respiratory and cardiovascular mortality, in combination with the morbidity evidence indicate a continuum of effects that could lead to mortality, which ultimately supports the causality determination for total mortality. Causality determinations are not made for individual cause-specific mortality outcomes. In conclusion, strength of the association is one of multiple key aspects considered in assessing causality, and therefore should not be given more weight than other aspects as suggested by the commenters.

In addition, the EPA disagrees with the commenters' contention that the causality determination of a "likely to be causal relationship" for short-term $PM_{2.5}$ exposure and respiratory effects is not appropriate because of the lack of evidence from controlled human exposure studies. In fact, the reason the causality determination is likely to be a causal relationship (and not a causal relationship) is because of the inconsistent evidence of respiratory effects in controlled human exposure studies. As detailed in Table II of the Preamble to the ISAs, a likely to be causal relationship can be concluded if:

> "Evidence is sufficient to conclude that a causal relationship is likely to exist with relevant pollutant exposures. That is, the pollutant has been shown to result in health effects in studies where results are not explained by chance, confounding, and other biases, but uncertainties remain in the evidence overall. For example: (1) observational studies show an association, but copollutant exposures are difficult to address and/or other lines of evidence (controlled human exposure, animal, or mode of action information) are limited or inconsistent, or (2) animal toxicological evidence from multiple studies from different laboratories demonstrate effects, but limited or no human data are available. Generally, the determination is based on multiple high-quality studies."

As described in section 1.4.1.1.1 and further expanded upon in section 5.1.12 of the 2019 ISA, the EPA states the conclusion of a "likely to be causal relationship" for short-term $PM_{2.5}$

exposure and respiratory effects "is based on multiple recent epidemiologic studies demonstrating generally consistent, positive associations with ED visits and hospital admissions for asthma, COPD, and combined respiratory-related diseases, as well as with respiratory mortality. Evidence from animal toxicological studies, although limited, is supportive of and provides biological plausibility for the associations observed in the epidemiologic studies related to exacerbation of asthma and COPD as well as respiratory infection." Therefore, the EPA also disagrees with the commenters assertion that the Agency has not clearly articulated the rationale and scientific basis supporting the "likely to be causal relationship" for short-term $PM_{2.5}$ exposure and respiratory effects.

B. Comments Related to Epidemiologic Studies

(1) **Comment:** Some commenters contend that while the EPA recognized a number of areas of uncertainty associated with the epidemiologic studies, confounding was not adequately addressed or considered in reaching conclusions regarding the strength of the scientific evidence or the adequacy of the primary $PM_{2.5}$ standards. Specifically, the commenters highlight copollutant confounding, unmeasured confounding, and temporal and spatiotemporal confounding. The commenters cite to a number of studies that evaluate confounding in epidemiologic studies (e.g., Janes et al., 2007; Greven et al., 2011; Pun et al., 2017; Eum et al., 2018) in support of their comments related to confounding. Some commenters contend that the EPA did not appropriately take into account the finding of these studies in reaching conclusions regarding causality for long-term $PM_{2.5}$ exposure and mortality in the 2019 ISA and ISA Supplement, and recommend that the EPA consider confounding more comprehensively in NAAQS reviews.

Response: The EPA disagrees with the commenter's contention that the Agency did not consider studies that evaluate confounding in epidemiologic studies, including those cited by the commenters (Janes et al., 2007; Greven et al., 2011; Pun et al., 2017; Eum et al., 2018) in the process of concluding a "causal relationship" between long term PM2.5 exposure and mortality. The EPA initially addressed public comments on the studies conducted by Janes et al. (2007) and Greven et al. (2011) as a part of the 2012 final decision. As noted in the Responses to Comments document for the 2012 review, (U.S. EPA, 2012a, p. II-4) the Agency stated:

> The EPA evaluated the study by Janes et al. (2007) in the ISA (U.S. EPA, 2009, p. 7-88) and evaluated the study by Greven et al. (2011) (an extension of the study by Janes et al. (2007) incorporating three additional years of data) in the Provisional Science Assessment (U.S. EPA, 2012b). In the EPA's evaluation of the relationship between long-term exposure to $PM_{2.5}$ and mortality, the Janes et al. (2007) study was included in the body of evidence that supported the determination that a causal relationship existed (U.S. EPA, 2009, section 7.6.5.1). For the reasons discussed below, the EPA does not agree with the commenters' views that these two studies call into question the scientific merit or the consistency of the results of long-term exposure studies of mortality that contribute to this body of evidence. Both studies used nationwide Medicare mortality data to examine the association between monthly averages of $PM_{2.5}$ over the preceding 12 months and monthly mortality rates in 113 U.S. counties and examined whether community-specific trends in monthly $PM_{2.5}$ concentrations and mortality declined at the

same rate as the national rate. The investigators examined this by decomposing the association between $PM_{2.5}$ and mortality into two components: (1) "national" trends, defined as the association between the national average trend in monthly $PM_{2.5}$ concentrations averaged over the previous 12 months and the national average trend in monthly mortality rates and (2) "local" trends, defined as county-specific deviations in monthly $PM_{2.5}$ concentrations and monthly mortality rates from national trends. The EPA does not question the results of the national trends analyses conducted by Janes et al. (2007) and Greven et al. (2011).[2] Both Janes et al. (2007) and Greven et al. (2011) observed positive and statistically significant associations between long-term exposure to $PM_{2.5}$ and mortality in their national analyses. However, Janes et al. (2007) and Greven et al. (2011) eliminated all of the spatial variation in air pollution and mortality in their data set when estimating the national effect, focusing instead on both chronic (yearly) and sub-chronic (monthly) temporal differences in the data (Dominici et al., 2012). Janes et al. (2007) (Table 1) highlighted that over 90 percent of the variance in the data set used for the analyses conducted by both Janes et al. (2007) and Greven et al. (2011) was attributable to spatial variability, which the authors chose to discard. The focus of the analyses by Janes et al. (2007) and Greven et al. (2011) was on two components: (1) a temporal or time component, i.e., the "national" trends analysis, which examined the association between the national average trend in monthly $PM_{2.5}$ concentrations averaged over the previous 12 months and the national average trend in monthly mortality rates and (2) a space-by-time component, i.e., the "local" trends analysis, which examined county-specific deviations in monthly $PM_{2.5}$ concentrations and monthly mortality rates from national trends. These two components combined comprised less than 10 percent of the variance in the data set. The authors included a focus on the space-by-time component, which represented approximately 5 percent of the variance in the data set, in an attempt to identify, absent confounding, if $PM_{2.5}$ was associated with mortality at this unique exposure window. Thus, the national effects reported in these studies are not directly comparable to other cohort studies investigating the relationship between long-term exposure to $PM_{2.5}$ and mortality, which make use of spatial variability in air pollution and mortality data.[3] Indeed, the study authors noted expressly that "when one considers that this wealth of [spatial] information is not accounted for in that study, it is not as surprising that we see vastly different estimates of the $PM_{2.5}$/mortality relationship than in other studies that do exploit that variability" (Dominici et al., 2012, p. 2).

[2] In its evaluation of Janes et al. (2007) in the 2009 ISA, the EPA did not identify limitations in the statistical methods used per se (U.S. EPA, 2009, p. 7-88) and included the results of the national-scale analyses in that study in the body of evidence that supported the determination that there is a causal relationship between long-term $PM_{2.5}$ exposure and mortality.

[3] Though not directly comparable, the effect estimates for mortality reported by Janes et al. (2007) and Greven et al. (2011) were coincidentally similar in magnitude to those previously reported in other long-term cohort studies. It is important to note that previous cohort studies focused on identifying spatial differences in $PM_{2.5}$ concentrations between cities, while Janes et al. (2007) and Greven et al. (2011) primarily focused on temporal differences in $PM_{2.5}$ concentrations. In fact, Greven et al. (2011) stated, "We do not focus here on a third type [of statistical approach] used in cohort studies, measuring the association between average $PM_{2.5}$ levels and average age-adjusted mortality rates across cities (purely spatial or cross-sectional association)."

For the local analyses, both Janes et al. (2007) and Greven et al. (2011) observed associations between exposure to $PM_{2.5}$ and mortality that are near the null value, often negative, and not statistically significant. The fact that the authors did not observe an association in the local analyses is not surprising. As stated in Janes et al. (2007), they were estimating "associations between temporal changes in exposure and outcomes within counties relative to the national trend." However, a limitation of the analysis conducted by Janes et al. (2007) [and subsequently by Greven et al. (2011)], and recognized in a commentary by (Pope and Burnett, 2007) is the use of monthly average $PM_{2.5}$ concentrations to examine associations at the local scale. This is a limitation because such an exposure assignment approach does not provide enough exposure contrast to observe temporal changes in mortality. The ISA (U.S. EPA, 2009, p. 7-88) recognized comments made by (Pope and Burnett, 2007) that pointed out that the conclusions of Janes et al. (2007) "are overstated. . . their analysis tells us little or nothing about unmeasured confounding in those and related studies because the methodology of Janes et al largely excludes the sources of variability that are exploited in those other studies. By using monthly mortality counts and lagged 12-month average pollution concentrations, the authors eliminate the opportunity to exploit short-term or day-to-day variability."

Furthermore, the EPA disagrees with commenters that Janes et al. (2007) and Greven et al. (2011) provide evidence that other studies of long-term exposure to $PM_{2.5}$ and mortality are affected by unmeasured confounding. As noted above, the design of the studies conducted by Janes et al. (2007) and Greven et al. (2011) are fundamentally different than those used in other studies of long-term exposure to $PM_{2.5}$ and mortality, including the ACS cohort and the Harvard Six Cities study. Studies, such as the ACS and Harvard Six Cities studies, used the spatial variation between cities to measure the effect of long-term (annual) exposures to $PM_{2.5}$ on mortality risk, and did not conduct any analyses relying on the temporal variation in $PM_{2.5}$. The opposite is true of the Janes et al. (2007) and Greven et al. (2011) studies which first removed the spatial variability in $PM_{2.5}$ and then examined the temporal variation at both the national and local scale to measure the effects of temporal differences in $PM_{2.5}$ on mortality risk. Janes et al. (2007) and Greven et al. (2011) focus on changes in $PM_{2.5}$ concentrations over time and therefore control for confounders would be based on including variables that vary over time rather than over space. As a result, any evidence of potential confounding of the $PM_{2.5}$-mortality risk relationship derived from Janes et al. (2007) and Greven et al. (2011) cannot be extrapolated to draw conclusions related to potential spatial confounding in studies based on the spatial variation in $PM_{2.5}$ concentrations.

As detailed in the 2009 ISA (U.S. EPA, 2009, section 7.6), and recognized by the authors of Janes et al. (2007) and Greven et al. (2011), the cohort studies that informed the causality determination for long-term $PM_{2.5}$ exposure and mortality "have developed approaches to adjust for measured and unmeasured confounders" (Dominici et al., 2012). These approaches were specifically designed to adjust for spatial confounding. The hypothesis that the authors of Janes et al. (2007) and Greven et al. (2011) chose to examine was that differences in the local and national effects indicate unmeasured temporal confounding in either the local or national effect estimate. This hypothesis was specific to these two studies that examined temporal variability in exposure to air

pollution and did not include known potential confounders at either the national or local scale as covariates in the statistical model. The authors acknowledged that the interpretation of either the national or local estimates needs to occur with an appreciation of the potential confounding effects of national and local scale covariates that were omitted from the model (Dominici et al., 2012). It is important to recognize that because Janes et al. (2007) and Greven et al. (2011) focused on variations in $PM_{2.5}$ over time and not space, the results from these two studies do not provide any indication that other studies of long-term exposure to $PM_{2.5}$ and mortality exhibit spatial confounding, or that $PM_{2.5}$ does not cause mortality.[4] The authors of Janes et al. (2007) and Greven et al. (2011) recognized "it is entirely possible that these papers are looking for an association at a timescale for which no association truly exists" (Dominici et al., 2012, p. 3).

In summary, the EPA does not question the quantitative results presented by Janes et al. (2007) and Greven et al. (2011); however, the EPA disagrees that the results of these studies are comparable to the results of other cohort studies of long-term exposure to $PM_{2.5}$ and mortality, or that the results presented in these two studies invalidate either the results themselves, or the consistency of the results observed across other cohort studies of long-term exposure to $PM_{2.5}$ and mortality. Janes et al. (2007) and Greven et al. (2011) chose to eliminate the spatial variability in the air pollution and mortality data. Thus, the results of these studies cannot be directly compared to time-series studies of short-term exposure to $PM_{2.5}$ and mortality (which rely on day-to-day changes in $PM_{2.5}$ concentrations and mortality) because the authors only use temporal variability measured on a monthly scale. Nor can the results of these studies be directly compared to cohort studies of long-term exposure to $PM_{2.5}$ and mortality (which rely on the spatial variability of air pollution concentrations and mortality) because their analyses include a fixed effect for county in the regression model which eliminates spatial variability when estimating the national effect. Additionally, Janes et al. (2007) and Greven et al. (2011) use a different time scale in their analyses compared to the timescales used in other cohort studies. Janes et al. (2007) and Greven et al. (2011) examined whether an association exists at a sub-chronic (i.e., monthly) time scale. Thus, the results of the study by Janes et al. (2007) are included in the ISA and contributed to the body of evidence for an association between long-term $PM_{2.5}$ exposures and mortality but are not directly comparable to other cohort studies that rely on a different timescale and focus on spatial variability.

As demonstrated in the ISA, there is a large body of evidence supporting the association between long-term exposure to $PM_{2.5}$ and mortality that generally reports consistent relative risks between 1.0 and 1.5 (U.S. EPA, 2009, Figures 7.6 and 7.7). Based on this large body of evidence, the EPA concluded that a causal relationship exists between long-term exposure to $PM_{2.5}$ and mortality (U.S. EPA, 2009, section 7.6.5.1). The results presented by Janes et al. (2007) and Greven et al. (2011) are not comparable to the results of these studies on long-term exposure to $PM_{2.5}$ and mortality. Therefore, the EPA concludes that these studies do not invalidate the large body of epidemiological evidence

[4] Further, the EPA notes that Janes et al. (2007) and Greven et al. (2011) provide no information relevant to examining confounding in studies of short-term exposure to $PM_{2.5}$.

that supports the EPA's determination that a causal relationship exists between long-term $PM_{2.5}$ exposure and mortality.[5]"

In addition to the previous evaluation of Janes et al. (2007) and Greven et al. (2011), the EPA evaluated Pun et al. (2017) in the 2019 ISA (U.S. EPA, 2019, section 11.2.2.4) and Eum et al. (2018) in the ISA Supplement (U.S. EPA, 2022b, section 3.2.2.6). With respect to the 2019 ISA, the EPA stated "studies [such as Pun et al. (2017)] contribute to the body of epidemiologic evidence that informs the *causal relationship* between long-term $PM_{2.5}$ exposure and total mortality. Observing consistent results for this relationship across studies using different analytic techniques (i.e., difference-in-difference approach) increases our confidence in the relationship." Subsequently, in the evaluation of studies published since the literature cutoff date of the 2019 ISA, the EPA evaluated Eum et al. (2018) in the context of the studies published by Janes et al. (2007), Greven et al. (2011), and Pun et al. (2017). In addition to Eum et al. (2018), additional studies were evaluated that also examined the role of potential unmeasured confounders on the relationship between long-term $PM_{2.5}$ exposure and mortality. In considering all of these studies together in the ISA Supplement, the EPA concluded, "recent studies that further evaluate the potential implications of unmeasured confounders on the association between long-term PM2.5 exposure and mortality indicate that bias can occur in either direction. However, across the studies evaluated, the control for unmeasured confounders, as detailed in Eum et al. (2018), Wu et al. (2020), and Erickson et al. (2019) do not result in the elimination of the association, but instead provide additional confirmation that an association between long-term $PM_{2.5}$ exposure and mortality exists when accounting for additional confounders (U.S. EPA, 2022b, section 3.2.2.2.6)." In conclusion, the EPA disagrees with the commenter's assertion that the EPA did not consider these studies in forming the causality determination for long-term $PM_{2.5}$ exposure and mortality, when in fact, these studies were thoroughly evaluated and considered as part of the body of evidence that supported the conclusion of a "causal relationship."

(2) **Comment:** Commenters also assert that the effect estimates from the key epidemiologic studies in the 2022 PA are of "questionable reliability" because of the "modest" association between $PM_{2.5}$ exposure and mortality as a result of the use of Cox proportional hazards models that "cannot adequately control for strong time-varying confounding." These commenters contend that the Cox proportional hazard model poorly controls for a time-dependent strong risk factor (e.g., smoking), which yields unreliable relative risk estimates unless detailed, time-varying information is incorporated into the modeling.

Response: We disagree with commenters' assertion that the risk estimates from epidemiologic studies examining long-term $PM_{2.5}$ exposure and mortality are unreliable because they are of "modest size." This comment insinuates that the magnitude of the association must be large to support the conclusion of a "causal relationship." While the strength of the observed association is an important aspect to aid in judging causality, and "while large effects support causality, modest effects therefore do not preclude it" (U.S. EPA, 2009, Table 1-2, section 1.5.4). The weight of evidence approach used by the EPA

[5] We note that the EPA's conclusion with regard to the interpretation of the results from Janes et al. (2007) and Greven et al. (2011) is supported by the study authors' conclusion that "[o]ur results do not invalidate previous epidemiologic studies" (Dominici et al., 2012, p. 1).

encompasses a multitude of factors of which the magnitude of the association is only one component (U.S. EPA, 2009, Table 1-3). An evaluation of the association across multiple investigators and locations supports the "reproducibility of findings [which] constitutes one of the strongest arguments for causality" (U.S. EPA, 2009, Table 1-2). Even though the risk estimates for air pollution studies may be modest, the associations are consistent across hundreds of studies as demonstrated throughout the 2009 ISA (U.S. EPA, 2009, Figures 2-1, 6-27, and 7-7) as well as the 2019 ISA (U.S. EPA, 2019, Figures 11-17 and 11-18). Furthermore, the causality determinations rely on different lines of evidence, by integrating evidence across disciplines, including animal toxicological studies and controlled human exposure studies. The EPA recognizes that the population potentially affected by $PM_{2.5}$ is considerable, including large subgroups of the U.S. population that have been identified as at-risk populations (e.g., children, older adults, persons with underlying cardiovascular or respiratory disease). While individual effect estimates from epidemiologic studies may be modest in size, the public health impact of the mortality and morbidity associations can be quite large given that exposure to airborne $PM_{2.5}$ is ubiquitous. Taken together, this information indicates that exposure to ambient $PM_{2.5}$ concentrations has substantial public health impacts.

In citing potential issues in accounting for time-varying confounders in the Cox proportional hazards models often used in long-term $PM_{2.5}$ exposure epidemiologic studies, the commenters cite a study by Moolgavkar et al. (2018) that used a simulated cohort to mimic the structure of the American Cancer Society – Cancer Prevention Study II cohort used by Pope et al. (1995). In this study, the authors focus on the confounding structure between cigarette smoke and covariate X. However, the authors note "[o]ur analysis did not account for the use of ecologic measures of exposure (such as fine PM)." Therefore, it is unclear how the commenters can contend that the results of Moolgavkar et al. (2018) are applicable to studies examining air pollution exposures.

In addition, as noted in the 2004 PM AQCD, confounding is defined as "…a confusion of effects. Specifically, the apparent effect of the exposure of interest is distorted because the effect of an extraneous factor is mistaken for or mixed with the actual exposure effect (which may be null)" (U.S. EPA, 2004b, p. 8-10). The commenters do not indicate how smoking status can be a confounder if smoking status is not correlated with $PM_{2.5}$ concentrations. In order for smoking status to be a confounder, it would need to vary across locations as $PM_{2.5}$ concentrations vary. However, as was shown in the extended follow-up of the Harvard Six Cities study (Laden et al., 2006), the rank order of cities remains the same even as $PM_{2.5}$ concentrations decline (i.e., the cities with the highest concentrations continue to have the highest concentrations and those with the lowest concentrations continue to have the lowest). Therefore, the rate of smoking in each city would need to change in the same way in order for smoking to have a confounding effect on the association between $PM_{2.5}$ exposure and mortality.

Recent studies evaluated in the 2019 ISA, as well as the ISA Supplement, provide evidence that effect estimates from Cox proportional hazards models yield similar results to effect estimates from other statistical models (i.e., Poisson regression models). This evidence does not support the commenter's argument that effect estimates from Cox proportional models are of "questionable reliability". As detailed in section 11.2.2.1 of the 2019 ISA, Kloog et al.

(2013) and Shi et al. (2015) in studies conducted in Massachusetts and New England, respectively, used a 365-day moving average, which is similar to the statistical analyses used in short-term exposure time-series studies. Both studies reported positive associations with mortality, which were then confirmed in a larger national analysis conducted by Di et al. (2017) using the same $PM_{2.5}$ concentration data but a Cox proportional hazards model. Lastly, the similar results reported by Kloog et al. (2013), Shi et al. (2015), and Di et al. (2017) were further confirmed in a study by Wu et al. (2020) which also used the Medicare cohort and was evaluated in the ISA Supplement (U.S. EPA, 2022b, sections 3.2.2.2.1 and 3.2.2.3). Wu et al. (2020) examined associations between long-term $PM_{2.5}$ exposure and mortality using both a Cox proportional hazards model and a Poisson regression model, as well as three different alternative approaches developed to further account for potential confounders. Across all models the results were similar. This series of epidemiologic studies using different statistical approaches and reporting evidence of positive associations of similar magnitude and precision between long-term $PM_{2.5}$ exposure and mortality does not support the commenter's claim. The EPA disagrees with the commenter's assertion that there is a flaw in the use of the Cox proportional hazards model in epidemiologic studies of long-term $PM_{2.5}$ exposure and mortality.

(3) **Comment:** Some commenters recommend that the EPA should more comprehensively consider the impact of uncertainty in exposure estimates on effect estimates from epidemiologic studies. These commenters contend that epidemiologic studies that use monitor-based or hybrid model-based estimates of exposure can lead to exposure misclassification, which can bias the results of the studies. They further note that the use of one method of exposure assignment versus another may impact the degree to which exposure is accurately estimated because PM composition is spatially variable. Finally, the commenters assert that the reduced ability of exposure estimation methods in hybrid modeling studies at low concentrations (because of lack of monitoring data) may lead to differential exposure concentrations that may bias the results.

Response: The EPA agrees with the commenters that an assessment of exposure measurement error is an important aspect of assessing the results from epidemiologic studies as reflected by the fact there is an entire chapter devoted to a full evaluation of studies that inform our understanding of exposure issues that are specific to PM in the 2019 ISA (see U.S. EPA, 2019, chapter 3). However, the EPA disagrees with the commenters assertion that exposure misclassification can bias epidemiologic results to the point that the results of studies are uninterpretable. In the 2019 ISA, there is a section that focuses on the "Influence of Exposure Errors on Results from Epidemiologic Studies of Different Designs" (U.S. EPA, 2019, section 3.4.5). Within this section, the EPA states: "Exposure error can bias epidemiologic associations between ambient pollutant concentrations and health outcomes and tends to widen confidence intervals around those estimates (Sheppard et al., 2005 ; Zeger et al., 2000)." However, the EPA also notes that "exposure error tends to underestimate health effects associations in epidemiologic studies of PM exposure" (U.S. EPA, 2019, p. 1-16). While it is plausible that bias can occur in either direction, bias away from the null only occurs under the unique circumstance where a monitor or model underestimates population exposure in long-term exposure studies (U.S. EPA, 2019, p. 3-1). Although exposure measurement error can influence individual epidemiologic study results, in assessing the collective body of evidence for a particular health outcome (e.g., respiratory-related ED

visits, mortality), the EPA evaluates the pattern of associations across studies. As a result, if across studies the direction of the association is consistent, even in the face of potential underestimation of the health effect association and widening confidence intervals, it provides support for a relationship between PM exposure and the health outcome of interest.

With respect to different exposure assessment methods, since the 2009 ISA, new approaches (e.g., hybrid models) have been developed and applied to assign exposure in epidemiologic studies, specifically for PM. These approaches generally increase/refine spatial and temporal coverage of exposure estimates and therefore errors in exposure estimates have been reduced. This is reflected by hybrid models typically having good cross-validation, especially for $PM_{2.5}$, and therefore having the potential to reduce exposure measurement error and resulting bias and uncertainty in the health effect estimates produced by epidemiologic models of long-term exposure to PM, even for spatially varying size fractions and components (U.S. EPA, 2019, p. 3-120). As a result, the 2019 ISA concluded that: "New developments in PM exposure assessment methods, including hybrid spatiotemporal models that incorporate satellite observations of aerosol optical depth (AOD), land use variables, surface monitoring data from Federal Reference Methods (FRMs), and/or chemical transport models (CTMs), have reduced bias and uncertainty in health effect estimates by improving the spatial resolution and accuracy of exposure predictions" (U.S. EPA, 2019, p. 3-1).

The EPA recognizes that exposure to ambient air pollutants, including PM, can be estimated using multiple approaches. The applicability of each approach in an epidemiologic study depends on the study design, as detailed in Table 3-5 of the 2019 ISA, which summarizes exposure estimation methods, their typical use in PM epidemiologic studies, and related errors and uncertainties (see U.S. EPA, 2019, p. 3-45). The 2019 ISA examined epidemiologic studies that used multiple exposure estimation methods (i.e., Dionisio et al., 2013; Mannshardt et al., 2013; McGuinn et al., 2017) and reported relatively consistent results across the different approaches used although some approaches did exhibit greater spatial variability in exposures.

Last, with respect to commenters assertions of exposure estimation methods in hybrid modeling studies at lower concentrations, studies using hybrid modeling methods have reduced exposure measurement error and uncertainty in the health effect estimates, as detailed in section II.A.2.d of the notice of final rulemaking, using a variety of approaches to estimate $PM_{2.5}$ concentrations and to assign exposure to assess the association between health outcomes and $PM_{2.5}$ exposure. The EPA recognizes that this variability in methodology has inherent limitations and uncertainties, as described in more detail in section 2.3.3.1.5 of the 2022 PA, and the performance of the modeling approaches depends on the availability of monitoring data which varies by location. However, the key U.S. epidemiologic studies that use hybrid modeling that were identified and used to inform the Administrator's conclusions (as detailed in section II.B.4 of the notice of final rulemaking) were nationwide or region-wide studies, rather than studies completed only in rural areas with limited monitoring data and thus less reliable estimates of $PM_{2.5}$ concentrations in the hybrid model study. These key studies reported a thorough model performance evaluation for core years of the study (U.S. EPA, 2022a, p. 3-89). As such, the EPA considers that the potential for reduced ability of exposure estimation methods in hybrid modeling studies at low concentrations (due to a lack

of monitoring data), is unlikely to bias the results in the nationwide or region-wide, population-weighted epidemiologic studies.

(4) **Comment:** Some commenters argue that exposure measurement error makes it difficult to determine the true shape of the C-R function and that such errors do not allow for the determination of a $PM_{2.5}$ threshold, if one even exists. These commenters further assert that because of these issues, assessing risks associated with low $PM_{2.5}$ concentrations and exposures at these levels are not reliable. In addition, the commenters state that the long-term epidemiologic studies assessed in the 2019 ISA and ISA Supplement did not assess the risks of lifetime $PM_{2.5}$ exposures or how those exposures would impact the interpretation of the study results. Because of these uncertainties, the commenters conclude that there is a high degree of uncertainty in the C-R relationships for long-term $PM_{2.5}$ concentrations below the current level of the primary annual $PM_{2.5}$ standard.

Response: The EPA disagrees with the commenter's assertion regarding the role of exposure measurement error on assessing the concentration-response (C-R) relationship and whether a threshold exists for long-term $PM_{2.5}$ exposure and mortality. As noted in an earlier response, the 2019 ISA notes that "exposure error tends to underestimate health effects associations in epidemiologic studies of PM exposure, [and] although bias in either direction can occur" (U.S. EPA, 2019, p. 1-16), bias away from the null occurs under the unique circumstance where a monitor or model underestimates population exposure in long-term exposure studies (U.S. EPA, 2019, p. 3-1).

In addition, the EPA notes in an earlier comment that we disagree with commenters that there is greater exposure measurement error at lower concentrations which would impact the ability to assess the C-R relationship. There is no evidence showing that exposure estimation at low concentrations leads to differential exposure error. Although the impacts of nonambient sources on personal total exposure might increase at low ambient PM concentrations, nonambient sources impacts are Berkson-like errors, which will not bias health effect estimates. This is in the 2019 ISA, where the EPA stated that: "Berkson error may occur when personal monitors used in a panel study capture ambient and nonambient exposures, when the objective of the study is to evaluate the effect of ambient exposures on health and the ambient and nonambient exposures are independent of each other" (U.S. EPA, 2019, p. 3-4). However, the Agency does note in assessing that C-R relationship between long-term $PM_{2.5}$ exposure and mortality that there is a point below which we have less confidence in the shape of the C-R relationship. In the ISA Supplement, the EPA stated "consistent with the conclusions of the 2019 PM ISA, recent studies provide evidence that continues to support a linear, no-threshold C-R relationship for long-term $PM_{2.5}$ exposure and all-cause or cause-specific mortality across the range of exposure concentrations observed in North American cohort studies, with some studies characterizing the C-R relationship with certainty down to 4 $\mu g/m^3$ (i.e., the confidence intervals become relatively wide and in some instances the lower 95% CI crosses the null at this concentration). Generally, the evidence remains consistent in supporting a no-threshold relationship, and in supporting a linear relationship for $PM_{2.5}$ concentrations > 8 $\mu g/m^3$. However, uncertainties remain about the shape of the C-R curve at $PM_{2.5}$ concentrations < 8 $\mu g/m^3$, with some recent studies providing evidence for either a sublinear, linear, or supralinear relationship at these lower concentrations" (U.S. EPA, 2022b, section 3.2.2.2.7, p. 3-112).

The EPA also disagrees with the commenters contention that because cohort studies do not estimate lifetime exposures to $PM_{2.5}$ there is a high degree of uncertainty in the assessment of the C-R relationship. In the 2009 ISA, the EPA evaluated an analysis of the extended Harvard Six Cities Study by Schwartz et al. (2008) that used model averaging (i.e., multiple models were averaged and weighted by probability of accuracy) to assess exposure periods prospectively. The exposure periods were estimated across a range of unconstrained distributed lag models (i.e., same year, one year prior, two years prior to death). In comparing lags, the authors reported that the effects of changes in exposure to $PM_{2.5}$ on mortality were strongest within a two-year period prior to death (U.S. EPA, 2009, p. 7-92, Figure 7-9). More recently, Crouse et al. (2020) within the CanCHEC study examined associations between long-term $PM_{2.5}$ concentrations over different averaging times (i.e., 1-, 3-, and 8-year average $PM_{2.5}$ concentrations) and spatial domains (i.e., 1, 5, and 10 km). Whereas Schwartz et al. (2008) reported associations larger in magnitude for more recent years of $PM_{2.5}$ data, Crouse et al. (2020) showed that associations increased in magnitude as the averaging time increased (U.S. EPA, 2022b, Figure 3-20). This observation indicates that longer time periods of annual $PM_{2.5}$ concentrations may increase the magnitude of the association and studies that examine shorter averaging times may be underestimating the magnitude of the association; it does not indicate the epidemiologic studies are misrepresenting the association.

C. Comments Related to Controlled Human Exposure Studies

(1) **Comment:** Some commenters disagree with the EPA's conclusion that controlled human exposure studies provide support for the biological plausibility of health effects observed at the $PM_{2.5}$ concentrations observed in epidemiologic studies. They argue that the few available studies evaluate exposure concentrations well above ambient levels and that the observed outcomes are not consistent or coherent. They also note that the studies include small sample sizes that are not representative of the larger population in the U.S. Specifically, these commenters contend that many of the respiratory and cardiovascular effects assessed in controlled human exposure studies have threshold modes of action and do not occur at lower $PM_{2.5}$ concentrations, and if that threshold is above ambient concentrations, these studies do not provide support for effects at ambient concentrations.

Response: As discussed in the 2022 PA, the EPA notes that controlled human exposure studies provide support understanding the effects of exposure to $PM_{2.5}$, and support for biologically plausible mechanisms through which adverse human health outcomes could occur (U.S. EPA, 2022a, p. 3-175). In addition, controlled human exposure studies have consistently reported that $PM_{2.5}$ exposures lasting from less than one hour up to five hours can impact cardiovascular function and provide some insight into how short-term exposure to $PM_{2.5}$ may impact cardiovascular function in ways that could lead to more serious outcomes. Additionally, while assessing plausible biological pathways is an important step in evaluating potential causal determinations, the degree of biological plausibility for different mechanisms and endpoints can also vary depending on ambient concentrations being evaluated (U.S. EPA, 2020a).

The 2019 ISA concludes that, when taken as a whole, controlled human exposure studies demonstrate that exposure to $PM_{2.5}$ may impact cardiovascular function in ways that could

lead to more serious outcomes (U.S. EPA, 2019, section 6.1.16). Thus, such studies can provide insight into the potential for specific $PM_{2.5}$ exposures to result in physiological changes that could increase the risk of more serious effects, though the health relevance of the occurrence of these acute effects is less certain (U.S. EPA, 2022a, p. 3-175). However, in reaching his proposed and final conclusions, the Administrator recognized that the concentrations reported in these studies are for observed effects that signal a change in the body likely due to short-term exposure to $PM_{2.5}$ and which may be the prelude to more adverse effects following longer duration and/or higher concentration exposures but typically would not, by themselves, be judged as adverse (88 FR 5620, January 27, 2023).

The EPA recognizes that while controlled human exposure studies provide support for the biological mechanisms and plausibility of the serious cardiovascular effects associated with ambient $PM_{2.5}$ exposures in epidemiologic studies (U.S. EPA, 2019, chapter 6), the exposures evaluated in most of these studies are well-above the ambient concentrations typically measured in locations meeting the current primary standards, and the results are variable across some of the controlled human exposure studies evaluated at near ambient $PM_{2.5}$ concentrations (U.S. EPA, 2022a, p. 3-176). The Administrator has taken these limitations and uncertainties into account in reaching his conclusions regarding the appropriate weight to place on these studies in reaching his final decisions.

D. Other Comments on the Health Effects Evidence

(1) **Comment:** A few commenters believe the EPA is overestimating the health risks of exposure to $PM_{2.5}$ and in so doing question the relationship between short-term $PM_{2.5}$ exposure and health outcomes, specifically mortality. In support of this point they state that if the EPA is correct about the acute deadliness of $PM_{2.5}$, we should witness smokers dropping dead as they inhale tobacco smoke. Because a single cigarette exposes a smoker to levels of $PM_{2.5}$ well over 100 times higher than present $PM_{2.5}$ standards allow for an entire day. In order for the epidemiologic studies linking $PM_{2.5}$ pollution to acute illness and death to be true, smoking would also have to trigger acute illness and death in addition to the long-term health effects primarily associated with smoking. Furthermore, in expressing doubt in the relationship between short-term $PM_{2.5}$ exposure and mortality, the commenters focus on a study conducted by Young et al. (2017). In reference to this study, the commenters state:

> "[A] study of air pollution in California, which has the highest non-attainment of $PM_{2.5}$ standards in the country, did not find conclusive connections between $PM_{2.5}$ and acute deaths: Our analysis finds little evidence for association between air quality and acute deaths. These results are consistent with those for the widely cited [National Morbidity and Mortality Air Pollution Study] dataset when the latter are restricted to California. The daily death variability was mostly explained by time of year or weather variables; Neither $PM_{2.5}$ nor ozone added appreciably to the prediction of daily deaths. These results call into question the widespread belief that association between air quality and acute deaths is causal/near-universal."

The commenters also suggest that the fact that some Americans smoke cigarettes suggests the Administrator should not place as high a value on addressing mortality risks from ambient $PM_{2.5}$ exposures.

Response: Broadly, the EPA disagrees with the commenters contention that the scientific evidence does not support a relationship between short-term $PM_{2.5}$ exposure and mortality. With respect to the commenter's comparison of the risks of smoking with those of ambient PM2.5, the EPA disagrees as previous studies conducted at higher concentrations provide evidence of a relationship between short-term $PM_{2.5}$ exposures and mortality. The most prominent and earliest example of this stems from the work of Schwartz and Marcus (1990) on the London Fog episode, which was evaluated in the 1996 PM AQCD. Although the study focused on British Smoke, this information was relevant in establishing the Air Quality Index (AQI), 500 breakpoint. As noted in section IV of the proposal:

> "Due to limited ambient $PM_{2.5}$ monitoring data available at that time, the decision on the 500 breakpoint concentration for $PM_{2.5}$ was based on the stated assumption that PM concentrations measured by the British Smoke method were approximately equivalent to $PM_{2.5}$ concentrations (64 FR 42530, August 4, 1999)" (88 FR 5539, January 27, 2023). Additionally, "particle concentrations during these episodes, measured by the British Smoke method were in the range of 500 to 1000 $\mu g/m^3$" (88 FR 5539, January 27, 2023).

While the relationship between British Smoke and $PM_{2.5}$ is not one-to-one, the analysis of daily mortality during the London Fog episode, which is at much higher concentrations than those in question by the commenters, shows that high $PM_{2.5}$ concentrations can have detrimental impacts on public health, including mortality.

With respect to the commenter's contention that the causality determination for short-term $PM_{2.5}$ exposure and mortality is not supported by the current science, the EPA disagrees with this notion. As described in detail in section 11.1.12 in the 2019 ISA:

> "Recent multicity studies evaluated since the completion of the 2009 PM ISA continue to provide evidence of primarily positive associations between short-term $PM_{2.5}$ exposures and total (nonaccidental) mortality from studies conducted mostly in urban areas using traditional exposure assignment approaches (i.e., average of all available monitors) as well as studies with a larger spatial coverage (i.e., urban and rural areas) employing new methods using all available $PM_{2.5}$ data (i.e., combination of monitoring, satellite, and LUR). Additionally, the evidence from recent studies further substantiates the relationship between short-term $PM_{2.5}$ exposure and mortality by providing additional information on potential copollutant confounding; effect modification (e.g., stressors, pollutants, season); geographic heterogeneity in associations; and the shape of the C-R relationship, which collectively reaffirms that a *causal relationship* exists between short-term $PM_{2.5}$ exposure and mortality. The body of evidence for total mortality is supported by generally consistent positive associations with cardiovascular and respiratory mortality. Although there is coherence of effects across the scientific disciplines (i.e., animal toxicological, controlled human exposure studies, and epidemiologic) and biological plausibility for $PM_{2.5}$-related cardiovascular (Chapter 6) and respiratory (Chapter 5) morbidity, there is strong evidence indicating biological plausibility for $PM_{2.5}$-related cardiovascular mortality with more limited evidence for respiratory mortality." (U.S. EPA, 2019, p. 11-53 to 11-54)

The conclusion of a "causal relationship" between short-term $PM_{2.5}$ exposure and mortality was based on the collective body of evidence evaluated in the 2019 ISA. As such the results of one individual study are evaluated in the context of the results of the other studies evaluated. Within the 2019 ISA, Young et al. (2017) was evaluated and presented in Figure 11-1, which summarized results across all the multi-city studies included in the 2019 ISA as well as key multi-city studies evaluated in previous science assessments in support of the PM NAAQS. Across the studies evaluated in the 2019 ISA, Young et al. (2017) was one study that did not report evidence of a positive association between short-term $PM_{2.5}$ exposure and mortality. However, the results of Young et al. (2017) were at odds with the results of Ostro et al. (2006) that examined the same geographic location. Upon further evaluation of these two studies, the 2019 ISA noted:

> "The difference in results between these two studies could be attributed to: (1) the larger spatial domain over which exposure was assigned in Young et al. (2017), (i.e., an air basin [encompassing multiple counties]) compared with Ostro et al. (2006), (i.e., a single county); (2) the use of only the monitor with the highest concentration on each day to assign exposure (Young et al., 2017) versus the averaging of all monitors over the spatial domain examined (Ostro et al., 2006); and (3) the different statistical models used in the studies." (U.S. EPA, 2019, p. 11-9 to 11-10)

In conclusion, there is extensive scientific evidence indicating a relationship between short-term $PM_{2.5}$ exposure as detailed in the 2019 ISA, and reaffirmed in the ISA Supplement, which supports the conclusion of a causal relationship. However, for purposes of this reconsideration, "short-term $PM_{2.5}$ exposure" generally refers to exposures of 24-hours or less and is not intended to include exposure from a single cigarette. The commenter has not provided any scientific study establishing concentrations from cigarette smoke, nor has the EPA proposed or adopted a C-R function that purports to provide a comparison of the effects of a single cigarette with that of ambient $PM_{2.5}$ in this reconsideration. Thus, the EPA disagrees that the effects of a single cigarette undermine the conclusions of the 2019 ISA and ISA Supplement. In addition, for the reasons explained in the preamble, the Administrator judges that the current primary $PM_{2.5}$ NAAQS do not provide requisite protection for public health, including the risk of mortality. The Administrator does not find that the current prevalence of smoking leads him to conclude that less weight should be placed on avoiding mortality risks from $PM_{2.5}$, particularly given that those levels are relatively low and may be influenced by addictive properties of nicotine.

(2) **Comment:** Commenters contend that the available health effects evidence is consistent with that considered in the 2012 review and the 2020 final decision. Specifically, they assert that the available scientific evidence in this reconsideration does not add any new findings of health effects with a causal or likely causal association with $PM_{2.5}$ exposure, and causal determinations have remained the same since 2009. Furthermore, they contend that evidence in the ISA Supplement is consistent with the 2019 ISA and that the previous Administrator took into account the 2019 ISA in the reaching his final decision in 2020, and that the proposal fails to adequately explain why the current Administrator now finds that the same evidence warrants a more stringent annual primary $PM_{2.5}$ standard. They claim that the only difference in this reconsideration is the weight that the current Administrator places on the available epidemiologic evidence. Some commenters also suggest that there is minimal new

information available to inform decisions regarding the primary $PM_{2.5}$ standards, particularly because of the short amount of time between the 2020 final decision and the reconsideration, and as reflected by the EPA's development of the ISA Supplement – rather than a full ISA – to support the reconsideration.

Response: The EPA disagrees with the commenters' assertion that the health effects evidence has not changed since the 2012 review, that new scientific evidence does not warrant changing any of the causality determinations presented in the 2019 ISA, and that the Administrator did not adequately explain the basis for his decision. Since the completion of the 2009 ISA there has been an extensive body of new studies spanning scientific disciplines, as detailed in the 2019 ISA, that further informs our understanding of the relationship between both short- and long-term $PM_{2.5}$ exposures and health. Ultimately these new studies reaffirmed and extended the evidence base supporting the conclusion of a "causal relationship" between both short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality and supported the "likely to be causal relationship" between short- and long-term $PM_{2.5}$ exposure and respiratory effects conclusions from the 2009 ISA.

The EPA also disagrees with the commenter that the completion of the ISA Supplement reflects that there is only "minimal information" available to inform the Administrator's conclusions in the reconsideration. As an initial matter, we note that the Administrator considers the full body of scientific evidence, as assessed in both the 2019 ISA and ISA Supplement, in reaching his decisions on the current standard. As noted in the ISA Supplement, the EPA states "the evidence presented within the 2019 ISA, along with the targeted identification and evaluation of new scientific information in this Supplement, provide the scientific basis to support a robust and thorough reconsideration of the 2020 PM NAAQS" (U.S. EPA, 2022b, section 1.1, p. 1-1). Furthermore, the EPA also disagrees with the commenter that the scientific evidence published since the literature cutoff date of the 2019 ISA does not provide any new information to support a revision of the primary annual $PM_{2.5}$ standard. Numerous new studies, including multiple studies of long-term $PM_{2.5}$ exposure and mortality (U.S. EPA, 2022b, section 3.2.2.2, Figure 3-20), that were conducted at lower annual averages, lower than those studies evaluated in the 2019 ISA (U.S. EPA, 2022b, Figure 3-19), continue to report evidence of consistent, positive associations. For comparison, the EPA notes that one member of the CASAC who advised on both the 2019 draft PA and the 2021 draft PA changed his views as to whether the current primary annual $PM_{2.5}$ standard is adequate after review of the draft ISA Supplement and 2021 draft PA. This member of the CASAC recommended retaining the primary annual $PM_{2.5}$ standard in their review of the 2019 draft PA, but recommended revising the level of the primary annual $PM_{2.5}$ standard from its level of 12.0 $\mu g/m^3$ to within the range of 10-11 $\mu g/m^3$ in their review of the 2021 draft PA.

The previous Administrator concluded that, based on the available scientific evidence, quantitative risk assessment, CASAC advice, and public comments, the primary annual $PM_{2.5}$ standard was adequate and should be retained. In reaching this conclusion, the previous Administrator emphasized a number of uncertainties associated with the available information, as described in the 2020 notice of final rulemaking (85 FR 82714, December 18, 2020) and summarized in section II.A.1 of the notice of final rulemaking for this reconsideration. In so doing, the previous Administrator's conclusions "reflect[] the fact that

important limitations in the evidence remain" and "that these limitations lead to considerable uncertainty regarding the potential public health implications of revising the existing suite of $PM_{2.5}$ standards (85 FR 82718, December 18, 2020). The EPA notes that in reaching the conclusion that the existing $PM_{2.5}$ standards are requisite to protect public health with an adequate margin of safety, the then-Administrator concluded that it was appropriate to consider the study-reported means collectively and placed weight on the fact that the mean of the study-reported means (or medians) from key U.S. epidemiologic studies that are monitor-based (i.e., 13.5 $\mu g/m^3$) is above the level of the current primary annual $PM_{2.5}$ standard of 12.0 $\mu g/m^3$, which is a departure from how the EPA has considered study-reported means relative to the primary annual $PM_{2.5}$ standard in other recent PM NAAQS reviews (and from how the current Administrator has considered them in this reconsideration) (e.g., the individual study-reported mean $PM_{2.5}$ concentrations rather than an average of the study-reported means from all studies).

As recognized by the current Administrator in announcing the reconsideration of the 2020 final decision, the available scientific evidence and technical information indicate that the current standards may not be adequate to protect public health and welfare, as required by the Clean Air Act.[6] The Administrator reached this decision in part based on the fact that the EPA noted that the 2020 PA concluded that the scientific evidence and information called into question the adequacy of the primary annual $PM_{2.5}$ standard and supported revising the level to below the current level of 12.0 $\mu g/m^3$ while retaining the primary 24-hour $PM_{2.5}$ standard (U.S. EPA, 2020b). Thus, as described further in the preamble, the Administrator's decision to revise, rather than retain, the existing PM NAAQS was based on additional scientific evidence and information, and advice from the CASAC and public comment based on that additional evidence and information, as well as the Administrator's independent judgments regarding how to weigh the evidence, which in some ways differed from how the prior Administrator weighed the evidence that was before him.

(3) **Comment:** In their comments in support of retaining the current primary $PM_{2.5}$ standards, some commenters contend that because the EPA is relying on a mass-based indicator for the primary $PM_{2.5}$ standards, it raises questions about the usefulness of the available scientific evidence in differentiating and addressing the components associated with health effects. These commenters assert that a mass-based standard is a poor toxicity surrogate for $PM_{2.5}$ and a poor basis for a nationwide standard, citing to heterogeneity in responses to $PM_{2.5}$ exposures and geographical and seasonal differences in risk based on the available epidemiologic evidence. In so doing, these commenters conclude that the available scientific evidence suggests that PM mass is not equally toxic across the country or over time, and therefore, because of the heterogeneity in risk and $PM_{2.5}$ composition across the U.S. nationwide estimates or NAAQS based on $PM_{2.5}$ mass are scientifically inappropriate. Other commenters who support revising the primary $PM_{2.5}$ standards also reiterate that a mass-based standard does not distinguish between the toxic profiles of various components or sources of PM.

[6] The press release for this announcement is available at: https://www.epa.gov/newsreleases/epa-reexamine-health-standards-harmful-soot-previous-administration-left-unchanged.

Response: The EPA notes that the scientific evidence in this reconsideration, as in previous reviews, continues to provide strong support for health effects associated with $PM_{2.5}$ mass, and in its review of the 2021 draft PA, the CASAC reached consensus that the $PM_{2.5}$ mass-based indicator should be retained, without revision (Sheppard, 2022, p. 2 of consensus letter). In evaluating the latest scientific evidence in the 2019 ISA, the EPA assessed whether individual PM components or sources were more strongly associated with health effects than $PM_{2.5}$ mass. In that assessment the EPA concluded: "Overall, recent studies continue to demonstrate that many $PM_{2.5}$ components and sources are associated with health effects ranging from subclinical (e.g., changes in heart function, such as HRV, or circulating biomarkers) to the more overt (i.e., ED visits, hospital admissions, and mortality). The results of these studies confirm and further support the conclusion of the 2009 PM ISA that many $PM_{2.5}$ components and sources are associated with many health effects and that the evidence does not indicate that any one source or component is consistently more strongly related with health effects than $PM_{2.5}$ mass" (U.S. EPA, 2019, section 1.5.4). As discussed in the 2022 PA, the available information continues to support the $PM_{2.5}$ mass-based indicator and remains too limited to support a distinct standard for any specific $PM_{2.5}$ component or group of components (U.S. EPA, 2022a, section 3.6.3.2.1)..

(4) **Comment:** Some commenters that support revising the primary $PM_{2.5}$ standards also disagree with the use of a $PM_{2.5}$-mass based indicator, stating that ultrafine particles (UFPs) are the most toxic fraction of $PM_{2.5}$. These commenters assert that a particle number concentration is a more common metric for measuring UFPs and a better marker of UFP concentrations, and therefore, would be a better marker of health hazards.

Response: As discussed in the proposal (88 FR 5572, January 27, 2023), the EPA notes that compared to $PM_{2.5}$ mass, there is relatively little data on U.S. particle number concentrations, which are dominated by UFP. Long-term trends in UFP are not routinely available at U.S. monitoring sites. At one background site in Illinois with long-term data available, the annual average particle number concentration declined between 2000 and 2019, closely matching the reductions in annual $PM_{2.5}$ mass over that same period (U.S. EPA, 2022a, section 2.3.2.6). In addition, a small number of published studies have examined UFP trends over time. While limited, these studies also suggest that UFP number concentrations have declined over time along with decreases in $PM_{2.5}$ (U.S. EPA, 2022a, section 2.3.2.6). However, the relationship between changes in ambient $PM_{2.5}$ and UFPs cannot be comprehensively characterized due to the high variability and limited monitoring of UFPs (U.S. EPA, 2022a, section 2.3.2.6). As summarized here and discussed in the 2022 PA, the available information continues to support the $PM_{2.5}$ mass-based indicator and remains too limited to support a distinct standard for the ultrafine fraction.

The EPA also disagrees with the commenters' contention that the UFP size fraction is the most toxic fraction of $PM_{2.5}$. As discussed in the 2019 ISA, there are numerous challenges associated with examining the health effects attributed to UFP exposure. These challenges are reflected in the Preface of the 2019 ISA when outlining the scope of the evaluation of the health effects evidence for UFP, which states:

> "UFPs have often been defined as particles <0.1 μm (U.S. EPA, 2009), but depending on the scientific discipline, the methods used and the particle sizes examined to assess the

> UFP-health effects relationship varies. UFP exposures in animal toxicological and controlled human exposure studies typically use a particle concentrator, which can result in exposures to particles <0.30 μm (Section 2.4.3.1). Whereas toxicological studies typically rely on examining UFP mass, epidemiologic studies examine multiple UFP metrics, including particle number concentration (NC), mass concentration (MC), and surface area concentration (SC). However, depending on the monitor used and the metric, the UFP size distribution included within each of these ranges can vary. Some studies that examine NC use no additional size classification and instead measure NC over the entire size range of the particle counter. If the entire size range is measured, limited available measurement data in the U.S. and Europe indicates that approximately 67 to 90% of NC consists of particles <0.1 μm (Section 2.4.3.1). Studies that examine MC or SC often include a range of particle sizes up to 0.3 μm. Currently, there is no consensus within the scientific community on the metric that best represents exposure to UFPs (Baldauf et al., 2016)." (U.S. EPA, 2019, section P.3.1)

Based on the scope for the evaluation of the health effects evidence for UFPs, the EPA stated in section 1.4.3 of the 2019 ISA:

> "Recent studies have further explored the relationship between short-and long-term UFP exposure and health effects; however, the assessment of study results across experimental and epidemiologic studies is complicated by the size distribution examined in each discipline and the nonuniformity in the exposure metric examined (i.e., the particle size range and indicators (e.g., particle number concentration [NC], surface area concentration [SC], and mass concentration [MC)]; see Preface). Specifically, experimental studies include size ranges up to 200 nm or higher. Epidemiologic studies often focus on various size ranges below 100 nm. However, if an epidemiologic study is focusing on NC it can include larger particle sizes, but it has been shown that 67−90% of NC represents particles <100 nm (section 2.4.3.1)
>
> Although there is some evidence of positive but imprecise associations across epidemiologic studies examining a range of health effects (e.g., cardiovascular and respiratory effects, and mortality), study results are difficult to interpret. This difficulty arises because most of the studies rely on a single monitor, which is inadequate, as shown in some monitoring campaigns that demonstrate a high degree of spatial variability in UFP concentrations and the fact the size distribution of UFPs changes with distance from a source (U.S. EPA, 2019, section 2.5.1). As noted above, examining coherence and biological plausibility of UFP-related health effects is complicated by the larger size distribution of UFPs examined in experimental studies compared with the size distribution examined in epidemiologic studies. However, animal toxicological studies provide emerging evidence for nervous system effects resulting from short-and long-term UFP exposure, including brain inflammation and oxidative stress, morphologic changes, behavioral, and neurodevelopmental effects.
>
> Based on the overarching uncertainties and inconsistency across studies in the characterization of UFP with respect to size distribution and exposure metric, across most health effects categories the collective evidence contributed to causality determinations

that did not exceed suggestive of, but not sufficient to infer, a causal relationship (Table 1-4)" (U.S. EPA, 2019).

In its review of the 2018 draft ISA, the CASAC found that there is inadequate evidence to revise the causality findings for UFP to "likely to be causal" (Cox, 2019b, p. 1 of consensus responses) and in its review of the 2021 draft PA, the CASAC recommended additional research on UFP health effects because of the significant uncertainties in the existing evidence, as well as the limited number of studies of UFP-related health effects in the U.S., and also noted that there are differing definitions of UFP in the research community (Sheppard, 2022, p. 15 of consensus responses). Therefore, we disagree with the commenters that there is a sufficient scientific basis to adopt a primary PM standard based on UFP at this time or that UFP number concentration would be a more appropriate indicator than the current $PM_{2.5}$ mass-based indicator for the primary $PM_{2.5}$ NAAQS.

(5) **Comment:** Some commenters assert that the EPA relies on studies that examine a relationship between $PM_{2.5}$ exposure and COVID-19 health outcomes, but fails to explain how these studies can support revising the NAAQS. The commenters identify a number of methodological uncertainties associated with these studies, consistent with those identified by the EPA in the ISA Supplement and the 2022 PA (e.g., timing of the studies, impact of "stay-at-home" orders). The commenters assert that these studies are not sufficient to suggest that a more stringent standard is necessary.

Response: The EPA would like to clarify that although assessments of short- and long-term $PM_{2.5}$ exposure and SARS-CoV-2 infection and COVID-19 death were within the scope of the ISA Supplement, these studies were not relied upon to inform decisions regarding the adequacy of the PM NAAQS because the EPA concluded that, while there is initial evidence of positive associations with SARS-CoV-2 infection and COVID-19 death, uncertainties remain due to methodological issues that require additional exploration.

Under the circumstances of a global pandemic and based on initial evidence, as well as a number of public comments on the 2020 notice of proposed rulemaking that cited such studies, the EPA decided to include studies assessing $PM_{2.5}$ exposure and SARS-CoV-2 infection and COVID-19 death within the scope of the ISA Supplement. As described in the ISA Supplement, the scope was defined to "focus on specific PM-related health and welfare effects most pertinent to EPA in support of the reconsideration of the primary and secondary PM NAAQS… [specifically] "the health effects evidence for which the 2019 PM ISA concluded a causal relationship." (U.S. EPA, 2022a, pp. 1-2 to 1-3)". In addition, the "this Supplement also considers recent health effects evidence that addresses key scientific topics for which the literature has evolved since the 2020 PM NAAQS review was completed, specifically since the literature cutoff date for the 2019 PM ISA" including "studies that assess the relationship between PM2.5 exposure and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and coronavirus disease 2019 (COVID-19) death" (U.S. EPA, 2022b) .

"Given the scope of this Supplement (i.e., not focusing on the broader body of experimental studies), it is important to recognize the evaluation conducted does not encompass the full multidisciplinary evaluation presented within the 2019 ISA as

described in the Preamble to the Integrated Science Assessments (U.S. EPA, 2015) that would result in weight-of-evidence conclusions on causality (i.e., causality determinations). Additionally, this scope does not allow for the evaluation of recent studies for health effect categories from the 2019 ISA for which a likely to be causal relationship was concluded nor an assessment as to whether recent evidence may strengthen the causality determination to a causal relationship.9 Therefore, this Supplement critically evaluates and provides key study-specific information for only those recent studies deemed to be of greatest significance for impending regulatory decisions regarding the PM NAAQS in the context of the body of evidence and scientific conclusions presented in the 2019 ISA. As such, the Supplement indicates whether recent evidence supports (is consistent with), supports and extends (is consistent with and reduces uncertainties), or does not support (is not consistent with) the causality determinations described in the 2019 ISA" (U.S. EPA, 2019; U.S. EPA, 2022b)

This context is important in responding to the commenters' criticism regarding the use of studies that examine the relationship between short- and long-term $PM_{2.5}$ exposure and SARS-CoV-2 infections and COVID-19 deaths in evaluating the adequacy of the PM NAAQS. As the ISA Supplement does not conduct a full weight-of-evidence evaluation and the ISA Supplement only focused on those health effect categories for which the 2019 ISA concluded a "causal relationship", studies examining short- and long-term $PM_{2.5}$ exposure and respiratory effects were not considered. It is within the evaluation of respiratory effects that studies of SARS-CoV-2 infection and COVID-19 death would be evaluated because they inform our understanding of the relationship between short- and long-term $PM_{2.5}$ exposure and respiratory infections.

III. Comments on the Quantitative Risk Assessment

(1) **Comment:** Some commenters contend that it was inappropriate to limit the risk assessment to mortality risk and to not consider morbidity risk.

Response: The EPA disagrees with the commenters that it was inappropriate to limit the risk assessment to mortality risk and to not consider morbidity risk. As discussed in Appendix C of the 2022 PA, in determining the scope of the risk assessment, we first considered the health effects for which the 2019 ISA concluded that the evidence supports either a "causal" or a "likely to be causal" relationship with short- or long-term $PM_{2.5}$ exposures. These health effects include mortality, cardiovascular effects, and respiratory effects associated with long- and short-term $PM_{2.5}$ exposures, as well as cancer and nervous system effects associated with long-term $PM_{2.5}$ exposures. As detailed in Appendix C of the 2022 PA, we focused the risk assessment on short- and long-term PM exposure-related mortality, reflecting its clear public health importance, the large number of epidemiologic studies available for consideration, and the broad availability of baseline incidence data (U.S. EPA, 2022a, section C.1.1). The EPA believes that, although the risk assessment focuses on mortality risks, these risks also generally reflect the distribution and magnitude of risks of other health outcomes, including morbidity risks as raised by the commenters. That is, the results of the risk assessment indicate that the current primary $PM_{2.5}$ standards could allow a substantial number of $PM_{2.5}$-associated deaths in the U.S., but revising the level of the primary annual $PM_{2.5}$ standard is

also expected to reduce not only $PM_{2.5}$-associated mortality risks, but also other health risks as well.

(2) **Comment:** A few commenters stated that it is inappropriate to assign outcomes from controlled human exposure studies with relatively young, healthy study subjects to sensitive groups (i.e., infants, children, the elderly, pregnant people, persons with chronic diseases, or developing fetuses). The commenters assert that the EPA should include studies that examine health outcomes in these populations in the risk assessment for $PM_{2.5}$.

Response: As an initial matter, we note that as a part of this reconsideration, we conducted an epidemiologic-based risk assessment that uses C-R functions from epidemiologic studies and is not informed by controlled human exposure studies. It is not possible to use controlled human exposure study data in this type of analysis of risk. The EPA agrees with the commenters that because the controlled human exposure studies tend to include generally healthy adult individuals, these studies are somewhat limited in their ability to inform at what concentrations effects may be elicited in at-risk populations (88 FR 5594, January 27, 2023). Furthermore, we generally note that the cohorts examined in the key epidemiologic studies considered in this reconsideration include large numbers of individuals in the general populations, and often also include those populations identified as at-risk (i.e., children, older adults, minority populations, and individuals with pre-existing cardiovascular and respiratory disease) (U.S. EPA, 2022a, p. 3-78). With respect to the risk assessment, we note that the C-R functions selected are from large, multicity U.S. epidemiologic studies that evaluate the relationship between $PM_{2.5}$ exposures and mortality. The specific epidemiologic studies and C-R functions used in the risk assessment were identified using criteria that take into account factors such as study design, geographic coverage, demographic populations, and health endpoints (U.S. EPA, 2022a, Table 3-13 and section C.1.1; U.S. EPA, 2021a). Further, in the 2022 PA, we conducted an at-risk analysis as a part of the risk assessment that considered estimated risks among potentially at-risk populations specifically. In this analysis, we assessed long-term $PM_{2.5}$-attirbutable exposure and mortality risk, stratified by racial/ethnic demographic groups. In so doing, we evaluated exposure and risk, stratified by race-specific C-R functions from the Di et al. (2017) study of Medicare enrollees, which is a large, multicity U.S. epidemiologic study.

(3) **Comment:** Some commenters disagree with the study areas that were included in the risk assessment. These commenters specifically express concern about the exclusion of study areas that are frequently affected by wildfire smoke which results in certain geographic areas (i.e., Pacific Northwest, Northern Rockies, and Northern California), and thereby their populations, from being represented in the risk assessment. The commenters assert that the selection criteria result in the study areas primarily representing urban areas and populations and representing different pollution sources than those of areas not included in the risk assessment, many of which contribute to short-term peaks in $PM_{2.5}$ exposures because of topography and meteorological conditions, and also note the CASAC's statements regarding this point in their review of the 2021 draft PA. Further, these commenters state if areas from the geographic regions that are not represented in the risk assessment had been included, there would have been more CBSAs in the risk assessment where the daily standard is controlling.

Response: As discussed in detail in Appendix C of the 2022 PA, specific criteria were used to select study areas for inclusion in the risk assessment. Study areas were selected based on the availability of ambient air quality monitors, geographic diversity, and ambient $PM_{2.5}$ air quality concentrations. Using these criteria, 47 CBSAs were identified for inclusion in the risk assessment (U.S. EPA, 2022a, Figure 3-16 and section C.1.3), including 30 study areas where just meeting the current standards is controlled by the annual standard, 11 study areas where just meeting the current standards is controlled by the 24-hour standard, and 6 areas where the controlling standard differed depending on the air quality adjustment approach (U.S. EPA, 2022a). The 47 urban study areas include many highly populated CBSAs and represent approximately 30% of the total U.S. population (roughly 58.4 million people) above the age of 30. The risk assessment in this reconsideration includes study areas that are considerably more geographically representative compared to the risk assessment in 2012.

In designing the risk assessment and selecting study areas, the EPA excluded areas where air quality may be influenced by wildfires because wildfire influence is often excluded when determining attainment of the NAAQS. This is because wildfires can be identified as exceptional events, which are unusual or naturally occurring events that can affect air quality but are not reasonably controllable using techniques that Tribal, state or local air agencies may implement in order to attain and maintain the NAAQS. Based on this criterion, seven of the original areas identified for inclusion in the risk assessment were excluded from further consideration in the selection of study areas (U.S. EPA, 2022, section C.1.4.2).

While we generally agree with the commenters and the CASAC that excluding areas influenced by wildfires reduced the number of areas included in the risk assessment whether the 24-hour $PM_{2.5}$ standard is controlling, we believe that the 47 study areas provide a broad geographical representation of areas in the country.

(4) **Comment:** Some commenters contend that because the risk assessment does not reflect risks associated with current air quality that the risk assessment does not allow for an evaluation of whether a revised standard would lead to public health improvements. These commenters further state that the air quality adjustment approach used in the risk assessment does not reflect current air quality or ambient conditions and therefore results in overstating the public health benefits of an alternative standard level. The commenters also note that very few areas included in the risk assessment have $PM_{2.5}$ design values above the current primary annual and 24-hour $PM_{2.5}$ standards and that there are several programs in place that would prevent an area from degrading air quality. Because of these reasons, the commenters assert that the risk assessment does not provide the Administrator with a basis for revising the current primary $PM_{2.5}$ standards, with some commenters clearly stating that the risk assessment does not support revision of the level of the primary annual $PM_{2.5}$ standard to below 10 $\mu g/m^3$.

Response: We disagree that the EPA did not provide information on our assessment of risks associated with recent air quality conditions. As the commenters appear to be aware, Appendix C of the 2022 PA, and in particular Figure C-24 presents mortality estimates from the full 47 study areas under recent conditions (as well as from just meeting an annual standard of 12 $\mu g/m^3$ and of just meeting an annual standard of 10 $\mu g/m^3$), while Figures C-30 and C-31 present distributions of mortality and premature death, respectively, for recent conditions, and just meeting the current standards and various alternative standards. The EPA

disagrees that these data are insufficient to provide insight into the magnitude of risks presented by the current standard in areas with elevated ambient $PM_{2.5}$ concentrations and the potential benefits of a revised standard.

We also disagree with the commenters that the approach for adjusting air quality to "just meet" the standard is not an appropriate method to evaluate the risk allowable under the current and alternate standards. Inclusion of these areas that are below, but near, the levels of the standards requires an upward adjustment to $PM_{2.5}$ air quality concentrations in order to simulate just meeting the current standards (U.S. EPA, 2022a, section 3.4.1.5). This approach aligns with the CAA requirements for evaluating the adequacy of the current and potential alternative standards. In setting a NAAQS the Administrator is cognizant of his responsibility to provide requisite protection for those likely to be exposed to concentrations just meeting the level of the standard, while also recognizing that most areas of the country will not experience ambient $PM_{2.5}$ concentrations just meeting the levels of the standard. Thus, as noted in the 2022 PA, in performing a risk assessment, the purpose is to understand the exposures and risks associated with meeting a given level of a standard (see U.S. EPA, 2022a, p. 3-146 & footnote 56). In evaluating the adequacy of a primary annual $PM_{2.5}$ standard level of 12.0 $\mu g/m^3$, the exposures and risks must be estimated for air quality meeting a level of 12.0 $\mu g/m^3$ – that is to say, if we estimated exposures and risks for air quality that was above or below that level, we would not be able to directly evaluate the exposures and risks for a level of 12.0 $\mu g/m^3$. The same is true for any alternative standard levels. We take this approach in part because we do not believe that we can assume with confidence that if we retain the current standard then ambient concentrations will not increase but will remain well below the standard on a nationwide basis and we find this approach to be the most appropriate basis for comparing alternative standards. We note that the most recent air quality trends report, cited by commenters, shows a trend of increasing national average $PM_{2.5}$ concentrations for 2020 and 2021, although that reflects contributions from wildfires as well other sources. We further note that, in the 2012 review, the RIA projected that by 2020 all but seven counties would attain the revised primary annual $PM_{2.5}$ standard with its level of 12.0 $\mu g/m^3$. However, the final data indicate that in 2020, there were 21 counties that did not meet the 2012 primary annual $PM_{2.5}$ NAAQS.[7] Furthermore, there are nine monitors located within areas that were initially designated attainment/unclassifiable but have 2020-2022 design values that currently exceed the annual $PM_{2.5}$ standard. While again recognizing the contributions wildfires may have had in at least some of these areas, the EPA finds it would be inadequately protective of public health to assume that $PM_{2.5}$ concentrations will stay stable or trend down across the country for the foreseeable future. Similarly, the EPA does not agree that the existence of CAA programs such as New Source Performance Standards and emissions standards for motor vehicles justifies a conclusion that $PM_{2.5}$ emissions will not increase in the future. These programs may reduce emissions as compared to a baseline in which they did not exist but new industrial sources and additional vehicle miles traveled will continue to generate additional $PM_{2.5}$ emissions. We disagree that this approach results in overstating the public health

[7] A few of these counties represent areas that were unmonitored or had incomplete data in 2012 and therefore were not included in the original projection from the RIA in the 2012 review. The 2020 design values may include air quality data that could potentially be eligible for exclusion under the Exceptional Events Rule.

benefits of alternative standard levels. Furthermore, we agree with the commenters that there were a limited number of study areas with design values that exceed the level of the primary $PM_{2.5}$ standards (see U.S. EPA, 2022a, Table C-3). This is one of the primary reasons that the EPA selected additional study areas that had design values that were below, but near, the levels of the standards – to expand the number of study areas and include a greater proportion of the U.S. population in the risk assessment.

In reaching his final decisions regarding the primary $PM_{2.5}$ standards, the Administrator considers the results of the quantitative risk assessment, along with his consideration of and conclusions regarding the scientific evidence, to inform his conclusions regarding the appropriate level for the primary $PM_{2.5}$ standards. As described in more detail in section II.B.4 of the notice of final rulemaking, the Administrator recognizes that the risk estimates can help to place the evidence for specific health effects into a broader public health context, but should be considered along with the inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with $PM_{2.5}$ exposure and related health effects. The Administrator recognizes that the overall risk assessment estimates suggest that the current primary annual $PM_{2.5}$ standard is allowing a substantial number of $PM_{2.5}$-associated deaths in the U.S. (and could allow substantially more if ambient concentrations increased to higher levels permitted under the current standard), but considers the results of the risk assessment along with the full body of scientific evidence available in this reconsideration in reaching his decision to that the current standards are not requisite to protect public health with an adequate margin of safety. However, because of the uncertainties associated with the risk assessment, as described in greater detail in section II.B.4 of the notice of final rulemaking, the Administrator places little weight on the absolute results of the risk assessment, including the at-risk analysis, for purposes of selecting the level of the annual standard that is requisite.

(5) **Comment:** Some commenters contend that the EPA inappropriately equated hazard ratios with relative risks, and hazard ratios should not be used in the risk assessment calculations unless the EPA demonstrates that such an approach is appropriate. The commenters quote the 2022 PA, where the EPA justifies the use of hazard ratios by stating, "As noted in Sutradhar and Austin (2018), the HR [hazard ratio] associated with a Cox-proportional hazard model may approximate the RR [relative risk] when the effect estimate (and consequently the β) is relatively small. This is the case with the effect on mortality modeled for long-term exposure to ambient $PM_{2.5}$ (i.e., the size of the effect estimate supports an assumed equivalency between HR and RR). The near equivalency between the HR and RR, allows us to utilize the β derived above in a C-R function based on a log-linear functional form of the type presented earlier, to model changes in mortality related to changes in ambient PM" (U.S. EPA, 2022a, p. C-6). The commenters contend that the EPA incorrectly interpreted this paper, noting that Sutradhar and Austin (2018) state that "The odds ratio is close in value to the relative risk if the event probability is small." The commenters also quote from the abstract of Sutradhar and Austin (2018) , noting that "This article demonstrates that although the direction of the HR can be used to explain the direction of the relative risk, the magnitude of the HR alone cannot be used to explain the magnitude of the relative risk," and in the summary, "Authors should refrain from using the magnitude of the HR to describe the magnitude of the relative risk – this is incorrect." The commenters further argue that the study authors stated that the magnitude of the hazard ratio is not comparable to

the magnitude of the relative risk 13 times. The commenters assert that the relative risk and hazard ratios are not mathematically equivalent, and therefore, the EPA should use a method that appropriately captures the mathematical nature of the estimates, noting that this is of particular importance because a small difference in the magnitude of the effect estimate can have a substantial impact when it is applied to the population size (60 million people) included in the risk assessment.

Response: The EPA agrees with the commenter that the hazard ratio (HR) and the relative rate (RR) are not mathematically equivalent. However, when the baseline mortality rate is low, the two are roughly commensurate. In Table 1 of Sutradhar and Austin (2018) the authors illustrate this point. Here, the estimated difference between the HR and RR diminishes as the baseline rate of the event at time *t* among the controls declines. In that table, the smallest baseline event rate at time *t* is 0.1 and the difference between an HR of 1.5 and the corresponding RR is 0.039. Though the authors do not separately report the RR for a baseline event rate at time *t* for values smaller than 0.1, we can infer that the HR and RR would begin to converge. Within the U.S., the baseline rate of death for individuals ages 75-84 is 0.027. Hence, the EPA believes that it is reasonable to infer that when estimating the risks of PM-attributable mortality among such a population that the HR and RR are roughly commensurate.

(6) **Comment**: Some commenters who support retaining the current $PM_{2.5}$ annual primary standard raised concerns about the underlying long-term mortality studies selected by the EPA for its $PM_{2.5}$-associated risk assessment. They contend that the EPA's risk assessment does not provide sufficient evidence of causation to support revising the primary annual $PM_{2.5}$ standard and contend that the risk assessment and the underlying long-term mortality studies (e.g., Di et al. (2017) and Turner et al. (2016)) violate four steps for appropriately quantifying how reducing exposure to $PM_{2.5}$ would affect public health. They contend that the four steps necessary to appropriately quantify how reducing exposure to including: (1) using appropriate study designs to collect data that can support valid causal inferences (e.g., quasi-experiments, intervention studies); (2) appropriate causal analysis methods are used to estimate and validate causal impacts; (3) model assumptions are appropriate for the data analyzed; and (4) control for confounding. As such, the commenters argue that the quantitative risk assessment does not provide sufficient evidence of causation to support revising the level of the primary annual $PM_{2.5}$ annual standard and suggest that the EPA revise its risk assessment using data from quasi-experiments and intervention studies, as well as controlling for key confounding variables (such as income and weather variables). They contend that until these steps are taken, that there is not a scientifically sound basis for predicting that reductions in $PM_{2.5}$ concentrations in ambient air will have any causal effect on reducing mortality rates.

Response: The EPA disagrees with the commenters assertion regarding how the Agency uses epidemiologic evidence in the assessment of causality. First, it is important to recognize that the assessment of causality is conducted within the Integrated Science Assessment (ISA), not the quantitative risk assessment. In assessing causality in the ISA, as discussed in the Preamble to the ISAs (U.S. EPA, 2015) and the Appendix of the 2019 ISA (U.S. EPA, 2019), the EPA uses a weight-of-evidence approach. As such, the 2019 ISA focuses on evaluating the causal nature of relationships between both short- and long-term $PM_{2.5}$

exposure and various health effect categories, including mortality, by evaluating and integrating evidence across scientific disciplines (i.e., animal toxicological studies, controlled human exposure studies, and epidemiologic studies) and assessing whether there is consistency of evidence within a discipline, coherence of effects across disciplines, and evidence of biological plausibility.

In assessing the evidence that informed the causality determinations for both short- and long-term $PM_{2.5}$ exposure and mortality, some studies were evaluated that employed statistical approaches that attempted to more extensively account for confounders (i.e., used alternative methods for confounder control).[8] As an individual study on its own cannot inform causality, these studies represent an additional piece of evidence to evaluate when assessing causality and should not be misconstrued to represent a gold standard or viewed as a replacement for the large body of epidemiologic studies that have used more traditional statistical approaches. The role of individual studies in informing causality was also reiterated by the National Academies of Science, Engineering, and Mathematics (NASEM) in one of their conclusions in their assessment of the EPA's causal framework:

> "A single study will rarely definitively and comprehensively address issues associated with the determination of causality that are examined in ISAs. A weight of evidence approach—combining assessment of study quality with expert judgment—allows EPA to draw conclusions that integrate scientific findings across multiple study designs and disciplines, as required by the CAA" (NASEM, 2022, p. 2).

Within the 2019 ISA, as well as the ISA Supplement, many epidemiologic studies were evaluated that examined the relationship between short- and long-term $PM_{2.5}$ exposure and mortality. Across these studies different time periods, populations with different demographic characteristics, various statistical approaches, and a variety of well-known confounders were examined. In light of these differences across studies there was evidence of generally consistent, positive associations for both short-term and long-term $PM_{2.5}$ exposure and mortality (U.S. EPA, 2019, short-term $PM_{2.5}$ exposure: Figure 11-1; long-term $PM_{2.5}$ exposure: Figure 11-18 and 11-19). The consistency in results across studies, in light of the different study designs, populations, statistical approaches, and confounders examined, argues against there being fundamental flaws in the epidemiologic studies evaluated as the commenters insinuate.

Second, while the assessment of causality for mortality relies heavily on epidemiologic studies, the causality determination builds on the evidence for both cardiovascular (U.S. EPA, 2019, sections 6.1.9 and 6.2.10) and respiratory morbidity (U.S. EPA, 2019, sections 5.1.9 and 5.2.10). This evidence provides support for the continuum of effects that could ultimately lead to mortality. Therefore, the EPA disagrees with the commenters assertion that

[8] In the peer-reviewed literature, these epidemiologic studies are often referred to as causal inference studies or studies that used causal modeling methods. As noted in the ISA Supplement this terminology is not used by the EPA to prevent confusion with the main scientific conclusions (i.e., the causality determinations) presented within an ISA. In addition, as is consistent with the weight-of-evidence framework used within ISAs and discussed in the Preamble to the ISAs, an individual study on its own cannot provide the evidence needed to make a causality determination, but instead represents a piece of the overall body of evidence.

only epidemiology studies were relied upon in concluding a "causal relationship" for both short- and long-term $PM_{2.5}$ exposure and mortality.

Third, studies that examine reductions in air pollution concentrations and corresponding impacts on health, often termed accountability studies, are evaluated and included within the 2019 ISA and ISA Supplement. As noted above, these studies represent one line of evidence evaluated in assessing causality and similar to the epidemiologic studies that use alternative methods for confounder control should not be misconstrued to represent a gold standard. Additionally, as noted in Dr. John Vandenberg's (EPA) response[9] to CASAC chair Tony Cox regarding these types of studies he states:

> "The draft ISA builds on a long and extensive record of epidemiological and experimental studies and conveys the available evidence on the relationship between exposures and response, including studies that indicate the occurrence and extent of reduction in responses observed with reductions in PM exposures. Such studies, often termed accountability studies, are evaluated and discussed within the ISA if they fit the scope of the ISA as detailed in the Preface."

Therefore, the EPA disagrees with the commenter's assertion that the EPA's assessment of causality in the 2019 ISA is flawed because it should focus only on studies that show reducing $PM_{2.5}$ concentrations leads to a reduction in health impacts.

Lastly, the EPA disagrees with the commenters suggestion that the Agency should redo the quantitative risk assessment in light of the publication by Burns et al. (2020). We believe that the multiple C-R functions used in the risk assessment appropriately reflect variation in epidemiologic studies, such as the population (e.g., geographic locations and demographics), exposure estimation methods (e.g., monitor-based or hybrid techniques), and potential confounders included in the epidemiologic model (e.g., ozone). The EPA also disagrees that data from quasi-experiments and intervention studies should be used in the risk assessment, as these approaches are attempting to answer a different question then we are asking in the risk assessment and do not necessarily inform the relationship between exposure and health effects.

(7) **Comment**: A number of commenters argue that the EPA should use the National Academy of Science's (NAS) integrated uncertainty analysis (IUA) to evaluate overall uncertainty in the risk assessment. These commenters state that the EPA's approach uses qualitative and quantitative uncertainty assessments, but this approach only considers the statistical uncertainty and not the model uncertainty associated with the risk estimates. Some commenters also assert that if the EPA is unable to complete a full probabilistic analysis, the Agency should consider doing a site-specific, partial probably analysis. These commenters further note that while the EPA says that they conducted sensitivity analyses in evaluating uncertainties in the risk assessment, the 2022 PA did not include a description of such analyses. The commenters also suggested specific methods for investigating quantitative

[9] Available at: *https://casac.epa.gov/ords/sab/r/sab_apex/casac/0?mm_id=5324&request=APPLICATION_PROCESS%3DMEETING_FILE&session=5686427276509*

uncertainty of the risk estimates in support of their comments (i.e., Smith, 2020; Smith and Gans, 2015).

Response: The EPA agrees that given sufficient time and resources, and appropriate information to develop key input factors, application of an IUA has the potential to provide a more rigorous and complete characterization of uncertainty. However, we determined that in the absence of those resources, a defensible IUA would not be possible to include in the 2022 PA and that such an analysis was outside of the scope of this reconsideration. Application of IUA requires specification of confidence distributions of key input parameters representing important sources of uncertainty. The specification of these confidence distributions is a critical step in implementing an IUA since these drive the outcome of the simulation. In addition, it is also important to specify any correlations between key inputs since these can also significantly impact the uncertainty analysis. The method used to establish confidence distributions (and any potential correlations between parameters) is critical to both the outcome of the IUA as well as the scientific defensibility of the overall analysis. Depending on analysis involved, experts can differ in their characterization of confidence for key input factors. For many important inputs to the risk assessment, there was insufficient information available to provide defensible specifications of distributions around those key input parameters. Thus, we determined that a defensible IUA would not be possible to include in the 2022 PA. Separately, the EPA disagrees with the commenters that the 2022 PA "did not include a description" of "sensitivity analyses" that evaluate uncertainties, as both the use of multiple C-R functions and approaches for estimating exposures are forms of sensitivity analyses.

(8) **Comment:** Some commenters contend that the uncertainty analysis for the risk assessment in the 2022 PA should be based on more than just two exposure scenarios and C-R functions from just two studies. The commenters contend that the EPA does not explain how using two exposure scenarios and multiple C-R functions can account for uncertainty and variability in the risk estimates. The commenters suggest that expanding the quantitative uncertainty analysis by using more C-R functions, particularly because the EPA relies on this analysis as the basis for their conclusion that the C-R functions have little impact on the risk estimates. These commenters note that the 2021 Technical Support Document includes 19 studies that provide 19 risk estimates for adults and older adults and 64 risk estimates for older adults alone, and that while not all of these studies would meet the EPA's preferred inclusion criteria, more than one risk estimate for the two age groups would have met the criteria and should have been selected.

Response: While there were additional high-quality epidemiology studies providing C-R functions relating $PM_{2.5}$ exposure to mortality effects identified in the 2021 Benefits TSD (U.S. EPA, 2021a), two studies were determined to best characterize risk in the U.S.. The EPA used all available C-R functions deemed to best characterize risk across the U.S., for both short- and long-term effects. The EPA disagrees that the risk assessment should be based on C-R functions from other studies, as the use of additional C-R functions would have been associated with additional uncertainties, such as study locations that do not cover the contiguous U.S. The EPA also disagrees that the risk assessment should be based on other exposure scenarios, as the two exposure scenarios used reflect two outcomes that could represent a potential range of $PM_{2.5}$ concentration changes in the study areas and the two

adjustment approaches used to guide the generation of these modeled surfaces were selected to span a wide range of possible $PM_{2.5}$ spatial response patterns.

(9) **Comment:** Some commenters assert that the EPA did not appropriately emphasize the impact of data error and biases on the shape of the C-R relationship in its evaluation of uncertainties associated with the risk estimates. In so doing, these commenters argue that this uncertainty has the potential to alter the results of the risk assessment and impact conclusions regarding the adequacy of the current primary $PM_{2.5}$ standards because they are based on a lack of a threshold in epidemiology studies. The commenters contend that, in the 2022 PA, the EPA reiterates that studies continue to show linear trends with no evidence of a threshold, and state that the EPA does not acknowledge the known error in the variables in the study may obscure thresholds. The commenters suggest that the EPA's failure to conduct analyses to address their concerns about the impact of data error and biases on the shape of the C-R provides support for concluding that the risk assessment does not support the proposed revisions to the PM NAAQS.

Response: The EPA performed both qualitative and quantitative assessments of uncertainty in the risk assessment, which can be found in Appendix C, section C.5, of the 2022 PA (U.S. EPA, 2022a). Uncertainty is also thoroughly considered in the 2019 ISA and 2022 ISA Supplement U.S. EPA, 2019; U.S. EPA, 2022b). In the 2022 PA, especially in Tables B-4 and C-1, the EPA explicitly considers the impacts of data error and biases for epidemiologic studies evaluated (U.S. EPA, 2022a). Furthermore, as described in responding to comments earlier in this section, the EPA notes that, in reaching his final decisions regarding the primary $PM_{2.5}$ standards, the Administrator considers the results of the quantitative risk assessment, along with his consideration of and conclusions regarding the scientific evidence, to inform his conclusions regarding the primary $PM_{2.5}$ standards. Because of the uncertainties associated with the risk assessment, as described in greater detail in section II.B.4 of the notice of final rulemaking, the Administrator places little weight on the absolute results of the risk assessment, including the at-risk analysis, for purposes of selecting the level of the annual standard that is requisite.

(10) **Comment:** A few commenters suggest that there is an error in the long-term risk estimates in the risk assessment. They note that the difference between the absolute risk between the total mortality estimates compared to the difference in the change in risk for short-term mortality estimates are comparable, but the difference for the long-term estimates is inflated. As an example, the commenters note that the difference in absolute risk based on the Di et al. (2017) study between the current primary annual $PM_{2.5}$ standard level of 12 $\mu g/m^3$ and an alternative standard level of 10 $\mu g/m^3$ is 5,200 and for the Turner et al. (2016) study is 5,800, compared to a change in risk of 5,630 and 6,120 for Di et al. (2017) and Turner et al. (2016), respectively. The commenters contend that because these differences are not observed with the short-term estimates or the estimates for the primary 24-hour $PM_{2.5}$ standard that the EPA should further evaluate these results and explain how their concerns regarding the validity of the long-term risk results impact the EPA's conclusions.

Response: The EPA does not agree there are errors in the risk assessment results. However, it should be noted that numbers may not sum/subtract accurately due to rounding of results.

Also, due to rounding, proportionally similar differences may not be visible in numbers that are smaller in absolute terms.

(11) **Comment:** Commenters who support retaining the current primary $PM_{2.5}$ standards suggest that the available scientific evidence does not support using long-term mortality as an endpoint for assessing risk disparities in different racial groups, as was done in the at-risk analysis in the 2022 PA. The commenters state that the ISA Supplement, in summarizing the conclusions of the 2019 ISA, noted that the evidence for race/ethnicity-specific differences in all-cause mortality were "inconsistent" (U.S. EPA, 2022b, p. 3-153). They further note that the ISA Supplement concluded that the since the literature cutoff date of the 2019 ISA, the recently available evidence continues to suggest that there is less consistency when evaluating $PM_{2.5}$ exposure and all-cause or total (nonaccidental) mortality (U.S. EPA, 2022b, section 3.3.3.2). The commenters contend that because of these conclusions, the EPA's selection of a single study for use in the at-risk assessment obscured the uncertainties and inconsistencies associated with the evidence. The commenters argue that there were other endpoints for which the results were more consistent that should have been considered in the at-risk analysis instead of long-term mortality.

Response: The 2019 ISA and the 2022 ISA Supplement noted that the available scientific evidence provides strong support for minority populations, and particularly Black/African American populations, being at increased risk from $PM_{2.5}$-related health effects, in part due to disparities in exposure, giving the EPA confidence in performing the quantitative at-risk analysis. The EPA also noted the various uncertainties associated with this analysis, including that there is higher confidence estimating race-stratified $PM_{2.5}$ health effects for Black and White populations than for other races/ethnicities and that using hazard ratios from a single study, even that of a large, high-quality study, comes with certain uncertainties (U.S. EPA, 2022a, section 3.4.1.8). The EPA also notes that the commenter's reference to evidence for race/ethnicity-specific differences in all-cause mortality being "inconsistent" is inaccurate and does not acknowledge the full sentence. This sentence, as written in the 2022 ISA Supplement, reads "While the studies that evaluated all-cause or total (nonaccidental) mortality were inconsistent, there was stronger evidence to indicate a greater risk of cause-specific mortality and some other health endpoints among people of color" (U.S. EPA, 2022b, p. 3-153). The EPA believes that the all-cause mortality hazard ratios stratified by race/ethnicity in the 2022 PA at-risk analysis best reflect race/ethnicity-stratified mortality impacts, due to the large cohort size (>60 million), high-quality study design, and sophisticated exposure estimation technique. While the EPA considers the stratified analysis informative, as described more fully in the notice of final rulemaking, the EPA also recognizes that there are a number of uncertainties and limitations associated with the at-risk analysis, including that it was based on one study of mortality risk for older adults (i.e., 65 years and older). Further, the EPA recognized that the results of the at-risk analysis can vary greatly depending on the inputs to the analyses, including the representativeness of the populations and demographics captured by the study areas included in the analysis and the C-R functions that are available from the epidemiologic studies that stratify by race and ethnicity. For these reasons, as well as those discussed more fully in the notice of final rulemaking, the Administrator places little weight on the absolute results of the risk assessment, including the at-risk analysis, for purposes of selecting the level of the annual standard that is requisite.

(12) **Comment:** Some commenters suggest that there are uncertainties in the risk assessment that the EPA has not addressed because the risk estimates between the total population from the risk assessment and sum of the risk estimates for the subpopulations from the at-risk analysis are not the same. The commenters assert that there are 25% more deaths when estimating risks for separate subpopulations compared to the estimates of the total populations, and that this uncertainty should be addressed in the uncertainty analysis section of the 2022 PA.

Response: It is unsurprising that results differ when using a single overall hazard ratio (HR) versus race/ethnicity stratified HR. This is because the majority population, in this case the White population, has a HR very close to the overall/reference population, whereas other populations, such as the Black population, are associated with larger magnitude HRs. This leads to a similar absolute estimate from the majority population and a larger magnitude estimate from the minority population, and an overall larger magnitude total estimate. The EPA believes the larger mortality estimates generated when using race/ethnicity stratified hazard ratios actually suggests that there may be an underestimate of risk when using the overall hazard ratio. As noted in responding the public comments above in this section and in the notice of final rulemaking, while the EPA notes that the risk assessment supports the conclusion that the primary $PM_{2.5}$ standards are not adequate, as detailed further in the proposal and above in section II.A.3, the EPA also cautions against an over-interpretation of the absolute results. For these reasons, the Administrator places little weight on the absolute results of the risk assessment, including the at-risk analysis, for purposes of selecting the level of the annual standard that is requisite.

(13) **Comment:** Some commenters who support revising the primary $PM_{2.5}$ standards suggest that the EPA's risk assessment underestimates the impacts of long-term $PM_{2.5}$ exposure. The commenters assert that recently available scientific evidence provides race-specific C-R functions that should be used to quantify disparity in $PM_{2.5}$ impacts in the risk assessment. Specifically, the commenters cite to a study by Spiller et al. (2021) that found that using race/ethnicity specific C-R functions and race/ethnicity specific mortality rates (compared to current approaches) resulted in increased $PM_{2.5}$-related premature mortality estimates in older populations and older Black populations, as well as three times higher mortality in older Black people than compared to white people.

Response: We disagree with the commenters' assertion that the risk assessment underestimates the impacts of long-term $PM_{2.5}$ exposure. Compared to the full risk assessment, the at-risk analysis estimated larger absolute mortality impacts of long-term $PM_{2.5}$ exposure when using race/ethnicity-stratified hazard ratios from the Di et al. (2017) study of Medicare enrollees (U.S. EPA, 2022a, section 3.4). The Spiller et al. (2021) study cited by the commenters was published after the literature cutoff date of the ISA Supplement. This study was provisionally considered, but does not materially change the scientific conclusions of the 2019 ISA or ISA Supplement in this reconsideration or the Administrator's final decision on the appropriate levels of the primary $PM_{2.5}$ NAAQS, which were set to protect the public health including at-risk populations with an adequate margin of safety. However, we note that this study has the potential to be informative in the next review of the PM NAAQS with regard to quantitative assessments of risk.

(14) **Comment:** Some commenters contend that there is no statistical confidence that reducing the levels of the primary $PM_{2.5}$ standards would reduce $PM_{2.5}$-exposure related mortality risk because the confidence intervals for the current and alternative standard levels overlap and that a lack of effect exists due to this overlap. These commenters assert that the EPA should explain how this lack of health benefits would support the proposed revisions to the PM NAAQS.

Response: First, we disagree with the commenters regarding the overlap of confidence intervals. For example, with the long-term estimates of mortality, there is no overlap between the estimates for Di et al. (2017) Pri-PM for an annual standard with a level of 12.0 $\mu g/m^3$ and a level of 9.0 $\mu g/m^3$ (U.S. EPA, 2022a, Table 3-16). While the commenters acknowledge that the long-term estimates for this study do not have the overlap that they claim is of great importance for interpreting the results of the risk assessment, the commenters then assert that the Di et al. (2017) study itself was preferentially selected by the EPA for this reconsideration and that the estimates do not overlap because of the precision in the C-R function for this study resulting from the substantial size of the database. We agree with the commenters that the Di et al. 2017 study has notably smaller confidence intervals due to its larger sample size but we disagree with the commenters because the risk assessment did not preferentially select a "best estimate" or place more weight on one C-R function over another. The C-R functions used in the risk assessment are from large, multicity U.S. epidemiologic studies that evaluate the relationship between long- and short-term $PM_{2.5}$ exposures and mortality, and the studies selected were based on criteria that take into account a number of factors including study design, geographic coverage, demographic populations, and health endpoints.[10] The risk assessment included multiple C-R functions in order to more fully evaluate the estimated exposures and risks for various cohorts.. Additionally, we disagree with the commenters that the large database for the Di et al. (2017) study somehow artificially influences the precision of the C-R function or the C-R function should be given less weight as a result of the tight confidence interval. Generally, epidemiologic studies with larger sample sizes will have tighter confidence intervals because the standard error is decreased. The Di et al. (2017) study has approximately 60 million people in its cohort, while the Turner et al. (2016) study has approximately 670,000 people. Therefore, we would expect tighter confidence intervals in the Di et al. (2017) compared to the Turner et al. (2016) study, though both studies have statistically significant effect estimates. Although the commenter presents arguments why the EPA should place weight primarily on the Turner et al. (2016) study instead of the Di et al. (2017) study, the EPA finds that both studies have their strengths and it has taken the appropriate approach in considering both of them without trying to choose one as more significant for the reconsideration.

Moreover, we disagree with the commenters' assertion that any overlap in the confidence intervals between estimates of $PM_{2.5}$-associated mortality for the current and alternative standard levels indicates that there is not statistical confidence in exposure and risk estimates and that this indicates a lack of effect that reducing the annual standard would reduce short-

[10] Additional detail regarding the selection of epidemiologic studies and specification of concentration-response functions can be found in Appendix C of the 2022 PA (U.S. EPA, 2022asection C.1.1) and the Estimating $PM_{2.5}$ and Ozone-Attributable Health Benefits TSD (U.S. EPA, 2021a).

and long-term exposure related mortality risk. An overlap of confidence intervals does not in and of itself necessarily demonstrate a lack of statistical confidence nor a lack of effect. Additionally, while some confidence intervals do overlap, there is a shifting of the distribution of estimated mortality impacts under alternative annual standards, which shows that largest possible number of estimated mortality impacts would be smaller than under the current standard. Therefore, we disagree with the commenters that the risk assessment does not provide meaningful information for consideration in reaching conclusions regarding the primary $PM_{2.5}$ standards.

Thus, in light of the full body of evidence, including the risk assessment, the Di et al. (2017) study and other epidemiologic studies and other supporting lines of evidence, as discussed at length in the notice of final rulemaking, the EPA disagrees with the commenter's view that there is practically no statistical confidence that reducing the primary annual $PM_{2.5}$ NAAQS (or the primary 24-hour $PM_{2.5}$ NAAQS) would actually reduce exposure-related mortality risk. To the contrary, while recognizing uncertainties in the evidence, the Administrator concludes that the available evidence indicates that more stringent NAAQS are needed to protect the public health from mortality and other adverse health effects.

Furthermore, as described in the preamble and in responding to comments earlier in this section, the Administrator considers the results of the quantitative risk assessment, along with his consideration of and conclusions regarding the scientific evidence, to inform his conclusions regarding the adequacy of the current primary $PM_{2.5}$ standards. As described in more detail in section II.B.4 of the notice of final rulemaking, the Administrator recognizes that the risk estimates can help to place the evidence for specific health effects into a broader public health context, but should be considered along with the inherent uncertainties and limitations of such analyses when informing judgments about the potential for additional public health protection associated with $PM_{2.5}$ exposure and related health effects. The Administrator recognizes that the overall risk assessment estimates suggest that the current primary annual $PM_{2.5}$ standard could allow a substantial number of $PM_{2.5}$-associated deaths in the U.S., and considers the results of the risk assessment along with the full body of scientific evidence available in this reconsideration in reaching his conclusion that the current standards do not provide requisite protection of public health with an adequate margin of safety. However, because of the uncertainties associated with the risk assessment, as described in greater detail in section II.B.4 of the notice of final rulemaking, the Administrator places little weight on the absolute results of the risk assessment, including the at-risk analysis, for purposes of selecting the level of the annual standard that is requisite.

(15) **Comment:** Some commenters assert that the Administrator did not recognize that the estimated risks from the risk assessment in the 2022 PA have decreased compared to the estimated risks from the risk assessment in the 2020 PA. These commenters contend that the Administrator does not explain why lower risk estimates – or even similar risk estimates – would warrant a more stringent primary annual $PM_{2.5}$ standard than was retained in the 2020 final action.

Response: We note that the commenters are correct that the risk estimates in the 2022 PA are lower than those in the 2020 PA because the EPA used different effect estimates for the two risk assessments. In the 2020 PA, the EPA selected the effect estimate for the single-pollutant

model from the Di et al. (2017) study to be consistent with effect estimates from the other epidemiologic studies (U.S. EPA, 2020b, Table C-1). However, since the completion of the 2020 PA, the EPA finalized the Estimating $PM_{2.5}$ and Ozone-Attributable Health Benefits Technical Support Document (TSD; U.S. EPA, 2021a). In developing the risk assessment for the 2022 PA, the EPA determined that it was most appropriate to follow the best practices outlined in that TSD for estimating risks based on changes in ambient $PM_{2.5}$ concentrations. In so doing, in the risk assessment in the 2022 PA, the EPA selected the copollutant model-based effect estimate from Di et al. (2017) (U.S. EPA, 2022a, Table C-1). Using the lower copollutant model-based effect estimate of 1.073 resulted in lower risk estimates in the 2022 PA than using the single-pollutant model effect estimate (1.084) than in the 2022 PA. On page C-8 of the 2020 PA, the EPA indicated that we anticipated lower risk estimates had the copollutant model-based effect estimate been used in the 2020 PA. We note that this footnote was inadvertently included in the 2022 PA on page C-8, since the 2022 PA did in fact use the copollutant model-based effect estimate.

It is important to note, however, that the then-Administrator placed "little weight on quantitative estimates of $PM_{2.5}$-associated mortality risk in reaching conclusions about the level of the primary $PM_{2.5}$ standards" in reaching his decision to retain the current standards in 2020. (85 FR 82717, December 18, 2020). Likewise, as described in responding to earlier comments in this RTC document and in section II.B.4 of the notice of final rulemaking, because of the uncertainties associated with the risk assessment, the current Administrator places little weight on the absolute results of the risk assessment for purposes of selecting the level of the annual standard that is requisite. Although the Administrator finds the effect estimate based on the copollutant model more appropriate to use, in light of the overall uncertainties associated with the risk assessment and the limited weight he places on the absolute risk assessment results, he does not find that the difference between the risk estimates using the single pollutant model and the copollutant model is materially relevant to his decision-making in this reconsideration. Moreover, the Administrator explains in the notice of final rulemaking that the record before him in this reconsideration is expanded and strengthened in a number of ways, notes the different judgments he has reached after consideration of the full evidence before him (as compared to the judgments of the then-Administrator in 2020), and explains why he finds more stringent standards are necessary to protect public health with an adequate margin of safety.

IV. Responses to Significant Comments on Proposed Primary $PM_{2.5}$ Standards

A. General Comments on Proposed Primary $PM_{2.5}$ Standards

A large number of comments on the proposed primary standards for $PM_{2.5}$ were very general in nature, basically expressing one of two substantively different views: (1) support for revisions to the primary standards to be more public health-protective or (2) opposition to any revision of the current $PM_{2.5}$ standards for a number of reasons. Some commenters expressed that the EPA must follow the best available science and recommend revisions to the standard down to a level with an adequate margin of safety that is scientifically supported. Others opposed to revision note that revision of the standards is not supported by the scientific evidence, while others express that the United States already has some of the cleanest air and revision is not needed. Many of these commenters simply expressed their views without stating any rationale,

while others gave general reasons for their views but without reference to the factual evidence or rationale presented in the proposal notice as a basis for the Agency's proposed decision. The preamble to the final rule in its entirety presents the Agency's response to these very general views.

B. Specific Comments on Proposed Primary $PM_{2.5}$ Standards

A large number of commenters provided more detailed comments regarding the proposal to revise the level and form of the primary annual $PM_{2.5}$ standard in conjunction with retaining the current 24-hour standard. Below, the EPA provides more detailed responses to the full range of significant issues raised in these comments.

1. Comments in Support of Revising the Primary Annual $PM_{2.5}$ Standard

(1) **Comment:** Some commenters suggest that there are no meaningful uncertainties exist in the scientific evidence at or above 8 $\mu g/m^3$. They contend that the EPA itself recognizes that uncertainties have been reduced over time, and that not revising the level of the annual standard to 8 $\mu g/m^3$ is arbitrary. The commenters specifically point to the EPA's consideration of the available epidemiologic evidence in the proposal, noting that the EPA stated that these epidemiologic studies "reduce key uncertainties identified in previous reviews, including those related to potential copollutant confounding" (88 FR 5583, January 27, 2023). The commenters assert that the CAA requires that the EPA take a precautionary, health-protective approach when setting a primary annual $PM_{2.5}$ standard that is requisite to protect public health with an adequate margin of safety.

Response: First, the EPA agrees that uncertainties have been reduced over time and that the scientific evidence supports health effects associated with $PM_{2.5}$ concentrations at lower ambient concentrations than previous reviews. Additionally, the epidemiologic evidence is robust in studies that use a variety of statistical designs and employ a variety of methods to examine exposure measurement error as well as to control for confounding effects. Moreover, a subset of epidemiologic studies has emerged that further inform an understanding of the relationship between $PM_{2.5}$ exposure and health effects, including epidemiologic studies that employed statistical approaches that attempt to more extensively account for confounders and are more robust to model misspecification (i.e., used alternative methods for confounder control). Studies that employ alternative methods for confounder control to assess the association between long-term exposure to $PM_{2.5}$ and mortality reduce uncertainties related to confounding and provide additional support for the associations reported in the broader body of cohort studies that examined long-term $PM_{2.5}$ exposure and mortality.

At the same time, the EPA disagrees with the view that there are no meaningful uncertainties associated with a level of 8 $\mu g/m^3$. The decision of the appropriate standard level, which in conjunction with the other elements of the standard would protect public health with an adequate margin of safety, requires a public health policy judgment, taking into account all of the evidence and its related uncertainties. The EPA agrees that the CAA requires the Administrator to set a health-protective standards but notes that the CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level, but rather at a level that

reduces risk sufficiently so as to protect public health with an adequate margin of safety. As detailed in section II.B.4 of the notice of final rulemaking, in considering the available scientific evidence, quantitative information, CASAC's advice, and public comments, the Administrator concludes that there are remaining uncertainties in the evidence associated with a standard with a level below 9.0 $\mu g/m^3$, and that the extent to which adopting such a standard could result in further public health improvements is sufficiently uncertain that he judges such a standard would be more stringent than requisite.

(2) **Comment:** Some commenters contend that there is substantial scientific evidence that demonstrates $PM_{2.5}$-related health effects, such as mortality and cardiovascular outcomes, occur at concentrations below 9 $\mu g/m^3$, and that uncertainty in the shape of the C-R curve is not uncertainty over whether health effects occur below those levels. These commenters assert that the EPA ignores studies that found statistically significant increases in mortality associated with $PM_{2.5}$ concentrations below 9 $\mu g/m^3$ because the exact increase differs across studies. The commenters state that regardless of uncertainties associated with the shape of the C-R function, the magnitude of the effect is substantial. These commenters cite to a recent meta-analysis in support of their comment (Vodonos et al., 2018). The commenters suggest that the number of studies that report effects at $PM_{2.5}$ concentrations below 9 $\mu g/m^3$ has increased in recent years. Other commenters note that the evidence continues to support a linear no-threshold relationship between $PM_{2.5}$ exposure and numerous health outcomes and that the shape of the C-R function is steeper below concentrations of 8 $\mu g/m^3$. They contend that the EPA acknowledges that the C-R function for $PM_{2.5}$ is well-characterized down to 8 $\mu g/m^3$, with some of these commenters pointing to evidence of a no threshold-relationship down to as low as 5 $\mu g/m^3$. Therefore, these commenters recommend revising the level of the standard to 8 $\mu g/m^3$ to provide requisite public health protection with an adequate margin of safety.

Response: The EPA disagrees with commenters who contend that uncertainty in the shape of the C-R curve is not relevant for setting the standard. First, the EPA has long recognized that the evidence does not identify a threshold below which there are no PM-related health effects. Consistent with the 2012 review, while the EPA recognizes that there likely are individual biologic thresholds for specific health responses, the 2019 ISA concluded that: "Recent studies that focus on the shape of the C-R curve expand upon the health effects evaluated in previous reviews and continue to provide evidence of a linear, no-threshold relationship between both short-and long-term $PM_{2.5}$ exposure and several respiratory and cardiovascular effects, and mortality" (U.S. EPA, 2019, section 1.5.3). However, in past NAAQS reviews, the EPA has never found that lack of evidence of a threshold for health effects is a sufficient basis to lower a NAAQS. Rather, the Administrator must consider the strength of the evidence, and the related uncertainties (including uncertainties about the concentration-response relationship), for adverse effects on public health in deciding the appropriate level at which to set the standard. We disagree with commenters that the shape of the C-R relationship is well-characterized down to 8 $\mu g/m^3$. As detailed in the 2019 ISA and ISA Supplement, there is variability at the point in which there is increased uncertainty in the C-R relationship across studies examining morbidity and mortality outcomes, and there is not a clear demarcation at 8 $\mu g/m^3$ within the scientific evidence evaluated. Studies examining short-term $PM_{2.5}$ exposure and morbidity and mortality outcomes provide evidence of increased uncertainty at long-term mean $PM_{2.5}$ concentrations of 10 $\mu g/m^3$ and 5 $\mu g/m^3$,

respectively (U.S. EPA, 2019, section 1.5.3.1). In addition, studies of long-term $PM_{2.5}$ exposure provide evidence of uncertainty in the C-R relationship within the range of 10 to 12 $\mu g/m^3$ when examining morbidity outcomes and 5 to 8 $\mu g/m^3$ when examining mortality (U.S. EPA, 2019, section 1.5.3.2). In considering this collective body of evidence in this reconsideration, the Administrator recognizes this variability across studies and also recognizes that some recent studies provide evidence for deviations from linearity (i.e., either a sublinear, linear, or supralinear) at the low end of the concentration distribution within the U.S. (U.S. EPA, 2019, section 11.2.4; U.S. EPA, 2022b, section 2.2.3.2). As discussed in section II.B.4 of the preamble, the Administrator has taken this evidence with its variability and uncertainty, as well as information and uncertainties about exposure risks from patterns of air quality under a standard of 9.0 $\mu g/m^3$ compared to 8.0 $\mu g/m^3$, into account in reaching his judgment that a standard more stringent than 9.0 $\mu g/m^3$ would be more stringent than necessary to protect the public health with an adequate margin of safety.

With regard to the study by Vodonos et al. (2018), in developing the ISA Supplement, this study was determined to be out of scope, as it is a meta-regression that includes studies conducted outside the U.S. and Canada. In defining the scope of the ISA Supplement, the EPA states that the focus is on "U.S. and Canadian epidemiologic studies for health effect categories for which the 2019 PM ISA concluded a *causal relationship* (i.e., short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality)" (U.S. EPA, 2022b, section 1.2.2see also section 1.2.1: "studies examining associations outside the U.S. or Canada reflect air quality and exposure patterns that may be less typical of the U.S., and thus less likely to be informative for purposes of reviewing the NAAQS"). As such, because Vodonos et al. (2018) includes studies conducted in Europe and Asia as part of the meta-regression, this study was deemed to be out of scope. However, in the broader assessment of the concentration-response relationship between long-term $PM_{2.5}$ exposure and mortality presented in previous PM science assessments, as well as the 2019 ISA (U.S. EPA, 2019, sections 11.2 and 11.2.4) and ISA Supplement (U.S. EPA, 2022b, sections 3.2.2 and 3.2.2.2.7), the U.S. based studies included in Vodonos et al. (2018) were evaluated and inform the Agency's conclusion regarding the shape of the concentration-response relationship, whether there is a threshold below which effects do not occur, and whether there is a point along the air quality distribution where the data density is lower and there is greater uncertainty in the shape of the concentration-response relationship.
However, the CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety. Moreover, while some studies indicate steeper slopes (e.g., larger effect estimates) at lower concentrations, interpreting the shapes of these relationships, particularly at $PM_{2.5}$ concentrations near the lower end of the air quality distribution, can be complicated by relatively low data density in the lower concentration range, the possible influence of exposure measurement error, and variability among individuals with respect to air pollution health effects (U.S. EPA, 2022a, p. 3-166). As such, these uncertainties are considered by the Administrator in determining the appropriate level of the standard in light of the CAA specifically stating the standard should protect public health with an adequate margin of safety.

(3) **Comment:** As part of their rationale to revise to level of the annual $PM_{2.5}$ standard to a level of 8 $\mu g/m^3$, some commenters cite to additional studies, noting that recent large-scale studies

of $PM_{2.5}$-related health effects, including Di et al. (2017), Di et al. (2019),Vodonos et al. (2018), Wei et al. (2020), Wei et al. (2021),Yazdi et al. (2019), and Yitshak-Sade et al. (2019), are based on very large datasets, unlike those available in previous reviews.

Response: While the public commenters identify additional studies as support for health effects at levels below the reported mean $PM_{2.5}$ concentrations, those studies did not meet the criteria outlined in the 2022 PA to include as key epidemiologic studies used to inform the adequacy and alternative levels of the $PM_{2.5}$ annual standard.[11] These criteria were adopted to identify studies which are most reliable for understanding the association between ambient $PM_{2.5}$ concentrations and reported health outcomes and were reviewed without comment by the CASAC in their review of the 2021 draft PA. Some of these epidemiologic studies (e.g., Wei et al., 2020, Wei et al., 2021, and Yitshak-Sade et al., 2019) employed statistical approaches that attempt to more extensively account for confounders. These studies used alternative methods for confounder control, and as a result they provide further support for the robustness of the associations exhibited in cohort studies but do not meet the criteria for being included in the group of key epidemiologic studies. Moreover, one study Yazdi et al. (2019) identified by commenters does not report a long-term mean $PM_{2.5}$ concentration and as such was not used to evaluate alternative levels of the annual $PM_{2.5}$ standard. Additionally, another study cited by public commenters is a meta-analysis (Vodonos et al., 2018), and in developing the ISA Supplement, this study was determined to be out of scope, as it is a meta-regression that includes studies conducted outside the U.S. and Canada. In defining the scope of the ISA Supplement, the EPA states that the focus is on "U.S. and Canadian epidemiologic studies for health effect categories for which the 2019 PM ISA concluded a causal relationship (i.e., short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality)" (U.S. EPA, 2022b, section 1.2.2). As such, because Vodonos et al. (2018) includes studies conducted in Europe and Asia as part of the meta-regression, this study was deemed to be out of scope. Finally, one study cited by commenters (Di et al., 2019) is not a health-based epidemiologic study, but is rather a publication that explains the development of a hybrid modeling surface of estimated $PM_{2.5}$ concentrations across the U.S. This hybrid modeling surface was used as part of the analysis comparing design values to mean $PM_{2.5}$ concentrations, as described further in the 2022 PA (U.S. EPA, 2022a, section 2.3.3.2.4).

(4) **Comment:** Some commenters suggested that the EPA's proposed rule failed to consider several epidemiologic studies that used restricted analyses (Zhang et al., 2021a; Shi et al., 2016) and that were discussed in the 2022 PA. The commenters disagree that the studies that used restricted analyses should not be included for consideration because they did not

[11] Key U.S. and Canadian epidemiologic studies are those that report overall mean (or median) $PM_{2.5}$ concentrations and for which the years of $PM_{2.5}$ air quality data used to estimate exposures overlap entirely with the years during which health events are reported. For some studies of long-term $PM_{2.5}$ exposures, exposure is estimated from air quality data corresponding to only part of the study period, often including only the later years of the health data, and are not likely to reflect the full ranges of ambient $PM_{2.5}$ concentrations that contributed to reported associations. Additionally, for studies that use hybrid modeling approaches to estimate $PM_{2.5}$ concentrations key studies include those for which recent methods and models were used (e.g., recent versions and configurations of the air quality models); studies that are fused with $PM_{2.5}$ data from national monitoring networks (i.e., FRM/FEM data); and studies that reported a thorough model performance evaluation for core years of the study (U.S. EPA, 2022a, p. 3-89).

expressly report a mean $PM_{2.5}$ concentration for the restricted analysis, and suggest that in doing so, the EPA arbitrarily ignored studies that examined health effects below the proposed range of alternative standard levels. Some commenters also cite to several additional epidemiologic studies that restrict analyses to $PM_{2.5}$ concentrations at or below a level of 12 $\mu g/m^3$ that report associations with $PM_{2.5}$-related morbidity effects (Qiu et al., 2023; Danesh Yazdi et al., 2022, Shi et al., 2021).

Response: The EPA disagrees with commenters that the proposal failed to consider these epidemiologic studies that used restricted analyses and were discussed in the 2022 PA (Zhang et al., 2021a; Shi et al., 2016). These studies do not report the mean $PM_{2.5}$ concentration for the restricted analyses. When a study does not report the mean $PM_{2.5}$ concentration for the restricted analysis, it is not possible to determine what concentration is associated with the health outcomes in those restricted analyses. Therefore, these studies do not provide sufficient information to inform conclusions regarding the level of the primary annual $PM_{2.5}$ standard. However, the EPA notes that the restricted analyses were helpful in providing evidence that even when highest exposure days are excluded from consideration, the association between exposure to $PM_{2.5}$ and morbidity and mortality remains, providing evidence that the association is not driven by the highest exposures.

We further note that the study by Shi et al. (2016) reports a mean $PM_{2.5}$ concentration in their main (unrestricted) analysis by computing the average of all grid cells in their analysis and therefore does not apply aspects of population weighting (U.S. EPA, 2022a, Table 3-8). In studies that use each grid cell to report a mean $PM_{2.5}$ concentration and do not apply aspects of population weighting, the study mean may not reflect the exposure concentrations used in the epidemiologic study to assess the reported association and as such, the reported mean may not reflect the reported association between $PM_{2.5}$ exposure and the health outcome. While the Administrator does not dispute the reported associations of epidemiologic studies that report long-term mean concentrations and do not apply aspects of population weighting, he judges that use of the reported long-term mean concentration from these in informing an appropriate level of the annual $PM_{2.5}$ standard is more uncertain. The study by Shi et al. (2016) reports positive and significant associations with long-term $PM_{2.5}$ exposure and mortality and helps provide overall support that the annual $PM_{2.5}$ standard is not adequate. However, because this study does not report a mean for the restricted analysis and does not apply aspects of populations weighting, it is of limited utility for informing conclusions regarding the appropriate level of the annual standard. We also note that the Zhang et al. (2021a) is a Canadian epidemiologic study. As discussed in more detail below, there are differences between the U.S. and Canadian epidemiologic studies (e.g., exposure environments, population densities) and the long-term means from Canadian epidemiologic studies are a less certain basis for informing the EPA's selection of the annual standard level. Therefore, we disagree with commenters that these studies were excluded from the proposal; rather, they were considered in the context of the broader evidence base but given less weight when reaching the proposed conclusions for all of the reasons discussed in section II.B.3 of the notice of final rulemaking.

With regard to the studies that use restricted analyses cited by the commenters, we first note that these studies (Danesh Yazdi et al., 2022; Qiu et al., 2023; Shi et al., 2022; Shi et al., 2021) were published after the literature cutoff date of the ISA Supplement. These studies

were provisionally considered but do not materially change the scientific conclusions of the 2019 ISA or ISA Supplement in this reconsideration. Secondly, three of the four studies do not utilize restricted analyses. The Shi et al. (2021) and Qiu et al. (2023) studies do not restrict the analysis in their studies of associations between $PM_{2.5}$ concentrations and neurological outcomes. Danesh Yazdi et al. (2022) is a study that employes alternative methods for confounding control, evaluating psychotic disorders associated with $PM_{2.5}$ exposure, using a difference-in-difference approach. As described in more detail in section II.A.2, studies that employ alternative methods for confounder control are more robust to model misspecification and support the robustness of associations exhibited in epidemiologic studies that use standard methods, but are not part of the key epidemiologic studies that are used to support alternative levels of the annual $PM_{2.5}$ standard. Lastly, while Shi et al. (2022) restricts their analysis to $PM_{2.5}$ concentrations of less than 12 $\mu g/m^3$ and reports a mean for the restricted analyses of 7.38 $\mu g/m^3$, this study is still subject to the same types of limitations outlined above, and as such, does not materially alter our conclusions regarding how this information can be used to inform conclusions regarding the primary annual $PM_{2.5}$ standard or the Administrator's decision on the appropriate level.

(5) **Comment:** Multiple commenters contend that the primary annual $PM_{2.5}$ standard should be revised to 8 $\mu g/m^3$ to reduce disproportionate health impacts for minority populations and low SES populations. In so doing, a number of these commenters cite to the importance of considering environmental justice and disparities in exposure and risk when reaching conclusions regard the appropriate level for the primary $PM_{2.5}$ standard. Some of these commenters also cite a recent study that they believe provides additional support for setting the standard at the lowest level that is being considered. The study found greater exposure to PM and greater susceptibility to disproportionate effects from PM exposure among minority populations and low SES populations, and concluded that the increased harm from $PM_{2.5}$ exposure was attributable to social structural forces, rather than any biological differences amongst the study groups (Josey et al., 2023).

Response: The 2019 ISA and ISA Supplement thoroughly evaluate studies examining whether specific populations are at increased risk of $PM_{2.5}$-related health effects including specific racial and ethnic groups or people encompassing different socioeconomic groups. The ISA Supplement builds upon the evidence presented in the 2019 ISA and concluded that: "[r]ecent studies that use a variety of metrics to represent SES, including educational attainment and income, along with studies that used composite metrics to represent neighborhood SES, provide additional support indicating there may be disparities in $PM_{2.5}$ exposure and health risk by SES. These studies indicate that the strongest evidence of a health risk disparity for low SES is for cause-specific mortality and certain health endpoints (i.e., MI and CHF) when compared with higher SES groups (U.S. EPA, 2022b, p. 5-4). The ISA Supplement further stated that: "Building upon the conclusions of the 2019 PM ISA, recent studies continue to support disparities in $PM_{2.5}$ exposure and health risks by race and ethnicity, with the strongest evidence for minority populations, specifically Black populations. Black populations or individuals that live in predominantly Black neighborhoods experience higher $PM_{2.5}$ exposures, in comparison with non-Hispanic White populations. Additionally, there is evidence of health risk disparities for both Hispanic and non-Hispanic Black populations compared with non-Hispanic White populations for cause-specific mortality and incident hypertension" (U.S. EPA, 2022b, p. 5-4).

Therefore, the EPA agrees with the commenters that examining whether there are disparities in health risk and/or exposure to $PM_{2.5}$ by race and income levels is important, and it is important to set the NAAQS to protect at-risk groups with an adequate margin of safety. However, the EPA recognizes that additional studies may become available after the literature cut-off date of the 2019 ISA, or in the case of this reconsideration, the ISA Supplement, that could add to the evidence base detailed in the scientific assessments that underpin the NAAQS review. The EPA has provisionally considered the study submitted by the commenters in support of revising the current standard, and the EPA concluded that this study does not materially change the broad scientific conclusions of the 2019 ISA regarding disparities in risk and exposure and thus would not materially affect decision making on the NAAQS. It is important to recognize that an individual study on its own does not change the broad scientific conclusions of the 2019 ISA or ISA Supplement and it must be considered within the broader body of scientific evidence that informs the key science judgments and conclusions of the 2019 ISA and ISA Supplement. The EPA will thoroughly consider and evaluate this study in the next review of the PM NAAQS.

(6) **Comment:** As support for their recommendation to revise the primary annual $PM_{2.5}$ standard to a level of 8 $\mu g/m^3$, numerous commenters cite a recent analysis by Industrial Economics (IEc) commissioned by the Environmental Defense Fund (EDF) that undertakes an analysis that is similar to the risk assessment in the 2022 PA. These commenters specifically note that, compared to the risk assessment in the 2022 PA, the IEc analysis has an expanded geographical scope, includes a higher population, and assesses morbidity in addition to mortality. These commenters contend that while the results are consistent with the 2022 PA risk assessment, the analyses suggest that 70% of the morbidity impacts are experienced in areas outside of the 47 study areas included in the EPA's risk assessment, and primarily in smaller cities and rural areas with larger minority populations and low SES populations. The commenters suggest that the IEc analyses highlight the importance of evaluating areas beyond the urban areas included in the risk assessment in the 2022 PA in order to fully capture the harmful effects of $PM_{2.5}$.

Response: It is important to note that the IEc analysis employed approaches that are different than those used in the risk assessment presented in the 2022 PA. These differences in methods are important when considering and comparing the results of the IEc analyses and those in the risk assessment in the 2022 PA.

Risk assessments that support PM NAAQS reviews have historically been performed in areas that exceed either or both of the primary $PM_{2.5}$ standards, as adjusting air quality downward is less uncertain than adjusting air quality upward. However, after applying the criteria for study area selection in designing the risk assessment in the 2022 PA, based on 2014-2016 design values, only 16 CBSAs met these criteria. Therefore, to mitigate uncertainties associated with upward adjustment of $PM_{2.5}$ air quality concentrations to simulate just meeting alternative standards while including more areas in the risk assessment, the EPA selected areas requiring a relatively modest upward adjustment (i.e., no more than 2.0 $\mu g/m^3$ for the annual standard and 5 $\mu g/m^3$ for the 24-hour standard, based on the 2014-2016 design value period). Using these criteria, 47 urban study areas were identified, which include nearly 60 million people aged 30-99, or approximately 30% of the U.S population in this age range (U.S. EPA, 2022a, Figure 3-16 and section C.1.3). This approach results in simulated air

quality surfaces for a subset of areas that "just meet" the current and alternate standards and can provide reasonable scenarios in which to evaluate allowable exposures and risk. In contrast, in order to evaluate the contiguous U.S., the IEc analyses defined the baseline as current $PM_{2.5}$ exposures from 2015, as a reflection of conditions under the current NAAQS. To evaluate lower standards, the IEc analyses performed a simplistic "roll back" approach. The EPA does not agree this is an equivalent or superior approach as it involves additional uncertainties in the exposure estimates. Due to these uncertainties, the EPA does not have sufficient confidence in the additional impacts estimated by the IEc analyses, nor do we believe that it is appropriate to compare the results of the IEc analysis to the risk assessment in the 2022 PA or to use the results of the IEc analyses to inform conclusions regarding the appropriate level of the primary $PM_{2.5}$ standards that is necessary to provide public health protection with an adequate margin of safety.

The EPA also believes that the mortality results of the areas evaluated in the risk assessment and at-risk analysis in the 2022 PA lead to the same overall conclusion as the national mortality and morbidity results of the IEc analyses. That is, the current primary $PM_{2.5}$ standards could allow a substantial number of $PM_{2.5}$-associated health impacts in the U.S. and revising the standard to a lower level could reduce $PM_{2.5}$-associated health risks, especially for those populations who may experience disparities in exposure and risk. The EPA appreciates the information from commenters suggesting that the results of the risk assessment are illustrative of risks faced by a wider range of communities across the country. The EPA notes that the risk assessment was never intended to represent the full scope of risk faced by Americans on a national scale, but rather was a quantitative estimation of exposure and risk based on certain parameters of the risk assessment (e.g., certain study areas, air quality years, and C-R functions) to provide a "snapshot" of these estimates in the context of the 2022 PA. However, while the EPA notes that the risk assessment, including the at-risk analysis support the conclusion that the primary $PM_{2.5}$ standards are not adequate, the EPA also cautions against an over-interpretation of the absolute results. For these reasons, the Administrator places little weight on the absolute results of the risk assessment, including the at-risk analysis, for purposes of selecting the level of the annual standard that is requisite.

(7) **Comment:** Some commenters contend that, in the proposal (citing to 88 FR 5616, January 27, 2023), the EPA inappropriately characterized the body of evidence and conclusions of the 2022 PA (citing to U.S. EPA, 2022a, p. 3-55) regarding $PM_{2.5}$ exposures for Hispanic populations.

Response: We disagree with the commenters on this point. On page 3-55 of the 2022 PA where the EPA states that "[t]here is strong evidence for racial and ethnic disparities in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risk…demonstrating that Black and Hispanic populations, in particular, have higher $PM_{2.5}$ exposures than non-Hispanic White populations" (U.S. EPA, 2022a, p. 3-55), the EPA is summarizing the evidence from multiple studies assessed in the 2019 ISA and ISA Supplement. In the proposal, where the EPA states that "White, Hispanic, and Asian populations were exposed to similar average $PM_{2.5}$ concentrations" (88 FR 5616, January 27, 2023), the EPA is summarizing the results of the at-risk analysis from the 2022 PA. These are two different pieces of information – the scientific evidence and the quantitative analyses – and therefore, we disagree with the commenter that the EPA contradicts the evidence and conclusions of the 2022 PA in the proposal. Additionally, the

EPA recognizes that the at-risk analysis is subject to greater uncertainties for various reasons, as detailed more in section II.A.3 of the notice of final rulemaking, including that it incorporates C-R functions from only one study (Di et al., 2017b), which reported associations between long-term $PM_{2.5}$ exposures and mortality, stratified by race/ethnicity, in populations age 65 and older.

(8) **Comment:** As part of support for revising the annual $PM_{2.5}$ standard to a level of 8 $\mu g/m^3$, several commenters provide individual analyses that highlight disproportionate impacts in their own communities. Some cite statistics using EJScreen to highlight health impacts which commenters note is due to disproportionate pollution burdens. Other commenters use handheld monitors (non-FRM/FEM monitors) to evaluate the population below the poverty level at $PM_{2.5}$ concentrations of 8 $\mu g/m^3$, 9 $\mu g/m^3$, 10 $\mu g/m^3$, compared to 12, and contend that a stronger PM standard will impact a larger number of people in poverty and therefore stronger standards will impact more people and help to ultimately drive down PM pollution when standards are translated into implementation. Lastly, some comments, using published literature evaluated the number of premature deaths avoided in their communities if a standard of 8 $\mu g/m^3$ is met, noting the largest benefit would be in areas with the highest percent of poverty.

Response: The primary $PM_{2.5}$ standards are established at levels that are requisite to protect public health with an adequate margin of safety, including the health of at-risk populations. To achieve this, the decisions on the NAAQS are based on thorough and clear assessment of the available scientific evidence and associated risk analyses. In particular, the EPA explicitly considered the available evidence related to health effects among at-risk populations, including minority populations and low SES populations, when determining the primary PM NAAQS. In instances where groups facing disparities in exposure and risk are categorized as at-risk populations, the determination of the primary standards is focused on ensuring protection for these along with other at-risk populations and lifestages.

As detailed in the proposal, the EPA carefully considered the available evidence about the impacts of $PM_{2.5}$ exposure on the health of at-risk populations and determined that the existing set of primary $PM_{2.5}$ standards is not requisite and required revision. Apart from considering and making conclusions on the available epidemiologic and experimental evidence, the Administrator also takes into account the findings of the risk assessment when arriving at his decision on the primary annual $PM_{2.5}$ standard. In his final decision, the Administrator notes that the at-risk analysis, which estimated the potential long-term exposure and mortality risk associated with $PM_{2.5}$ among older adults stratified by racial/ethnic demographics, suggests that revising the annual standard down to 9.0 $\mu g/m^3$ would likely lead to reduction in $PM_{2.5}$ exposures as well as lower risk in at-risk populations.

The EPA also highlights that commenter arguments citing EJScreen statistics and handheld monitors involve setting the primary annual $PM_{2.5}$ NAAQS based on simulation of implementation rather than on health effects evidence. Although the full data explaining the basis of the simulation were not provided to the EPA, the EPA notes it establishes the NAAQS to provide the requisite protection of human health, which includes the health of sensitive sub-populations. However, the standards are not determined based on projections of the number of people living in areas expected to meet or not meet the standards.. This

approach is especially relevant considering the prohibition on considering the costs or feasibility of attaining the NAAQS. With further regard to comments presenting findings derived from analyses using handheld sensor-based air quality data, it is important to mention that the data employed for assessing compliance with the NAAQS must be sourced from FRMs/FEMs. The handheld sensors mentioned in the commenters' evaluation were not FRMs/FEMs. However, the EPA recognizes that sensors can provide useful information and that the revised NAAQS will provide substantial health benefits to many people across the country, including many low SES populations.

(9) **Comment:** Some commenters state that the EPA's approach to setting the level of the primary annual $PM_{2.5}$ standard focuses on what design value will result in levels at or below overall means reported in key epidemiologic studies. They contend that the EPA's approach inflates study-reported means from key epidemiologic studies, then selects the level of the annual standard somewhere below the inflated result. In disagreeing with the EPA's approach they point to the EPA's response to comments in the 2012 notice of final rulemaking, suggesting that at that time the EPA itself dismissed such an approach. The commenters note that, in that review, some past commenters urged the EPA to set a level for the primary annual $PM_{2.5}$ standard by identifying a "mean composite monitor $PM_{2.5}$ level that should be achieved and then identify the maximum monitor level that would result in that composite value" (78 FR 3146, January 15, 2013). The present commenters further assert that one of the EPA's reasons for not agreeing with the commenters in the 2012 review was that "for areas in which the maximum monitor concentration is appreciably higher than other monitor concentrations within the same area, public health would not be protected with an adequate margin of safety if the disproportionately higher exposures of at-risk, susceptible populations around the monitor measuring the highest concentration were in essence averaged away with measurements from monitors in other locations within large urban areas" (78 FR 3146, January 15, 2023). The commenters argue that, in this reconsideration, the EPA is taking an identical approach to the same approach that they disagreed with in the 2012 review.

Additionally, commenters also contend that the EPA has deviated from the approach taken in 2012 where the level of the annual standard was to just below the long-term reported mean $PM_{2.5}$ concentrations of the key epidemiologic studies. As an example, these commenters cite the EPA's rejection in 2012 of other commenters (e.g., industry) opposition to the EPA's proposal to eliminate spatial averaging. They contend that public commenters in 2012 take a similar approach to how the EPA has currently proposed setting the level of the annual standard to between 9-10 $\mu g/m^3$. These commenters further contend that the same commenters in 2012 argued "that because spatial averaging is consistent with how air quality data are considered in the underlying epidemiological studies, such averaging should not be eliminated. Specifically, commenters…pointed out that $PM_{2.5}$ epidemiological studies use spatially averaged multi-monitor concentrations, rather than the single highest monitor, when evaluating health effects. Therefore, these commenters contended that allowing spatial averaging would make the $PM_{2.5}$ standard more consistent with the approaches used in the epidemiological studies upon which the standard is based" (78 FR 3126, January 15, 2013). Commenters further contend that in the current reconsideration that the EPA notes that epidemiologic studies report area-wide mean $PM_{2.5}$ concentrations that are associated with adverse health effects, rather than focusing on the highest monitor in the area, and claim that

the EPA aims to make the results of the study-reported mean more consistent with the design value metric relevant to assessing compliance with the standard. However, they claim that in the 2012 decision, the EPA rejected claims by commenters specifically advocating for this approach and contend that the EPA must adopt the same approach used in 2012 to set the level of the annual $PM_{2.5}$ standard.

Response: As an initial matter and as detailed further in section II.B.4 of the notice of final rulemaking, the Administrator's final decision to set the level of the annual standard at 9.0 $\mu g/m^3$ reflects his judgment that the standard level be set below of the study-reported mean $PM_{2.5}$ concentrations for key epidemiologic studies. Consistent with some previous reviews, the decision on level centers on the average annual concentration observed in key epidemiologic studies, where mean $PM_{2.5}$ concentrations in key U.S. studies are as low as 9.3 $\mu g/m^3$.[12] Setting the annual standard level at 9.0 $\mu g/m^3$, which is below concentrations for which the evidence is the strongest in supporting an association between exposure to $PM_{2.5}$ and adverse health effects observed in the key epidemiologic studies available in this reconsideration, is expected to shift the distribution of $PM_{2.5}$ exposure concentrations in an area such that the area's highest monitor would generally be at or below 9.0 $\mu g/m^3$ annually, and most of the resulting $PM_{2.5}$ concentrations across the area would be even lower. In considering these air quality relationships, the Administrator judges that a revised annual standard level of 9.0 $\mu g/m^3$ would provide requisite protection with adequate margin of safety, for all populations, including those most at-risk.

The Administrator additionally notes that air quality analyses in the 2022 PA demonstrate that areas meeting a revised annual standard of 9.0 $\mu g/m^3$ would be expected to shift the distribution of $PM_{2.5}$ exposure concentrations in an area such that the area's highest monitor would generally be at or below 9.0 $\mu g/m^3$ annually, and most of the resulting $PM_{2.5}$ concentrations across the area would be even further below the study-reported means. Thus, a standard level of 9.0 $\mu g/m^3$ is expected to provide sufficient protection not only in areas where the highest allowable concentration would be located (i.e., near design value monitors) but also in other parts of the area where $PM_{2.5}$ concentrations would be expected to be maintained even lower.

As such, the EPA disagrees with commenters who contend that the EPA's approach to setting the level of the primary annual $PM_{2.5}$ standard focuses on what design value will result in levels at or below overall means reported in key epidemiologic studies. Further the EPA disagrees with commenters who contend that the EPA's current approach is based on evaluating the standard mean composite monitor $PM_{2.5}$ level that should be achieved and then identify the maximum monitor level that would result in that composite value.

[12] As detailed in the notice of final rulemaking, the Administrator acknowledges that in the 2020 final action, the then-Administrator took a somewhat different approach in deciding to retain the standard based in part on concerns about placing reliance on the epidemiologic studies and his judgment that even if he did rely on them, the majority of the studies had means or medians, as well as the mean of all of the key study-reported means or medians, above the level of the current annual standard. However, after considering the evidence, the advice of CASAC, and public comments the Administrator judges that in light of the evidence before him this approach is insufficient to protect public health with an adequate margin of safety.

Additionally, the EPA disagrees with commenters who contend that the EPA has deviated from the approach taken in 2012.

2. Comments in Support of Retaining the Primary Annual $PM_{2.5}$ Standard

(1) **Comment:** Some commenters who support retaining the current primary $PM_{2.5}$ standards contend that while recent studies provide support for exposure disparities for minority populations and low SES populations, these studies do not provide support for $PM_{2.5}$-related health effects associated with these factors. The commenters assert that none of the five studies included in the ISA Supplement that evaluated the dose-response relationship between long-term $PM_{2.5}$ exposure and total mortality stratified by race/ethnicity support the conclusion that there is a disparity in $PM_{2.5}$-related mortality risk associated with race/ethnicity Awad et al. (2019); Lipfert and Wyzga (2020); Parker et al. (2018) Son et al. (2020); and Wang et al. (2020)). The commenters claim that the ISA Supplement's characterization of the Parker et al. (2018) study reported hazard ratios and confidence intervals that were inconsistent with those reported in the study. These commenters also assert that the results of these studies suggest that there were no statistically significant differences in the associations between long-term $PM_{2.5}$ exposure and all-cause mortality among different racial groups.

Response: In evaluating the evidence for potential disparities in $PM_{2.5}$ exposure and health risk by race/ethnicity, the ISA Supplement evaluated studies that examined both short- and long-term $PM_{2.5}$ exposure to inform conclusions. This is important to recognize as the commenters only focus on the results of long-term $PM_{2.5}$ exposure studies. With respect to the studies in question, while some studies did not report evidence of differences in health risk between different races and ethnicities, it is the collective body of evidence that informed ISA Supplement conclusions. In addition, as detailed in the Preamble to the ISAs (U.S. EPA, 2015), in assessing evidence to inform conclusions, the EPA focuses on the pattern of results across studies and does not focus solely on statistical significance as described in detail in the Preamble to the ISAs (U.S. EPA, 2015). This is because statistical significance is an indicator of the precision of a study's results, which is influenced by a variety of factors including, but not limited to, the size of the study, exposure and measurement error, and statistical model specifications. As a result, in developing an integrated assessment of the health effects evidence for PM, the EPA has emphasized the importance of examining the pattern of results across various studies, not statistical significance. Therefore, the EPA disagrees with the commenters that statistical significance is the sole criteria by which conclusions can be made with respect to whether there are disparities in health risks due to $PM_{2.5}$ exposure.

In addition, EPA disagrees with the commenters assertion that the Agency incorrectly presented results from Parker et al. (2018) . The results in Parker et al. (2018) are presented for a 10 $\mu g/m^3$ increase in annual $PM_{2.5}$ concentrations. As noted in Footnote 13 on Page 3-1 of the ISA Supplement, EPA states **"**Throughout this Supplement, as detailed in the Preface of the 2019 PM ISA, risk estimates from epidemiologic studies examining short-term exposures are for a 10 $\mu g/m^3$ increase in 24-hour average $PM_{2.5}$ concentrations and long-term exposures are for a 5 $\mu g/m^3$ increase in annual concentrations, unless otherwise noted" (U.S. EPA, 2022b, section P.3.2.2). Therefore, the difference in results between the ISA

Supplement and Parker et al. (2018) is due to scaling the risk estimate to represent a 5.0 $\mu g/m^3$ instead of 10 $\mu g/m^3$ increase in annual $PM_{2.5}$ concentrations.

(2) **Comment:** Some commenters contend that the current primary annual $PM_{2.5}$ standard should be retained because air quality in the U.S. has improved in recent years, with the exception of wildfires, and note that the current standards are working and show significant improvements in the nation's overall air quality. They claim, therefore, that revising primary $PM_{2.5}$ standards is not needed because the U.S. already has some of the cleanest air.

Response: As described in section I of the notice of final rulemaking, the EPA notes that the Administrator's decision on the primary annual $PM_{2.5}$ standard is constrained by the provision of the CAA that requires that the primary NAAQS be requisite to protect public health with an adequate margin of safety. This requires that his judgments are to be based on an interpretation of the evidence that neither overstates nor understates the strength and limitations of the evidence, or the appropriate inferences to be drawn from the evidence. As discussed in section II.B.4 of the notice of final rulemaking, the Administrator has considered the available scientific evidence, including epidemiologic studies that found associations between health effects and $PM_{2.5}$ concentrations at or below the level of the primary annual $PM_{2.5}$ standard, the quantitative risk assessment information, the advice of the CASAC, public comments in reaching his final decision to revise the level of the primary annual $PM_{2.5}$ standard. The Administrator does not have discretion to set a less stringent standard based on comparison to prior air quality and improvements in recent years.

(3) **Comment:** Some commenters contend that the current primary annual $PM_{2.5}$ standard should be retained because areas that meet the primary annual $PM_{2.5}$ standard level of 12 $\mu g/m^3$ are likely achieving equivalent average exposures of 9.6 to 10.8 $\mu g/m^3$, citing to the 2022 PA evaluation that demonstrated that the maximum annual $PM_{2.5}$ design values are often 10 to 20% higher than annual average concentrations. These commenters assert that this range of annual average concentrations overlaps with the proposed range of alternate levels of 9 to 10 $\mu g/m^3$ and, according to the Administrator, provide the strongest support for adverse health effects. The commenters also cite to a study in the 2022 PA that found that most near-road monitors are report the highest annual $PM_{2.5}$ design values in the metropolitan statistical areas (i.e., on average, 0.8 $\mu g/m^3$ higher than the next highest non-near-road monitor). The commenters suggest that as more near-road monitors are installed, the difference between design values and average exposure concentrations will increase, such that attaining a primary annual $PM_{2.5}$ standard of 12 $\mu g/m^3$ would be well within the proposed range and the mean values of the key epidemiologic studies.

Response: Based on the current scientific evidence and quantitative information, as well as the CASAC's advice and public comments, the Administrator concludes that the current primary annual $PM_{2.5}$ standard is not adequate to protect public health with an adequate margin of safety (see section II.B.4 of the notice of final rulemaking and 88 FR 5624, January 27, 2023). In so doing, among other considerations and public health policy judgments, the Administrator places the most weight on the large number and strength of epidemiologic studies that report positive, and often statistically significant, associations with long-term mean reported $PM_{2.5}$ concentrations well below the current level of the annual standard of 12.0 $\mu g/m^3$, as well as corroborating evidence from U.S. accountability studies

with starting concentrations below 12.0 $\mu g/m^3$ and studies that found positive and statistically significant associations in analyses restricted to concentrations less than 12 $\mu g/m^3$. Based on his interpretation of this evidence, the Administrator judges that the current primary annual $PM_{2.5}$ standard with its level of 12.0 $\mu g/m^3$ does not adequately protect public health with an adequate margin of safety, and therefore, should be revised to a level of 9.0 $\mu g/m^3$.

The EPA acknowledges that it is likely that people living and working in areas meeting a design value of 12 $\mu g/m^3$ likely have patterns of exposure which include areas below 12 $\mu g/m^3$. However, the Administrator has taken this variation into account in setting the standard, since his obligation is to set the standard with an adequate margin of safety, to provide a reasonable degree of protection against less certain or unknown risks. As such, the Administrator notes that setting the annual standard level at 9.0 $\mu g/m^3$, which is below the lowest study-reported mean $PM_{2.5}$ concentration from the key U.S. epidemiologic studies of 9.3 $\mu g/m^3$, would be expected to shift the distribution of $PM_{2.5}$ concentrations in an area such that the area's highest monitor would generally be at or below 9.0 $\mu g/m^3$ annually, when meeting the annual standard. In this situation, the resulting average or mean $PM_{2.5}$ concentration for the entire area (measured across a number of monitors) would be even further below the study-reported means, and will provide adequate protection not only in areas where the highest allowable concentrations would be expected (i.e., near design value monitors) but also in other parts of the area where $PM_{2.5}$ concentrations would be expected to be maintained even lower. As demonstrated by analyses in the 2022 PA, the highest monitored value would be expected to be greater than the study-reported mean values by 10-20% for monitor-based studies and 15-18% for hybrid modeling studies that apply aspects of population weighting. Furthermore, we note that as more or different data becomes available (i.e., from near-road monitors that are not yet installed, as cited by commenters) for consideration in future epidemiologic studies and informing future PM NAAQS reviews, the EPA will consider such data, as appropriate, but the EPA cannot consider data in this reconsideration that do not yet exist. However, the EPA disagrees that it would be appropriate under CAA 109 to conclude the current level of the annual standard of 12.0 $\mu g/m^3$ is providing requisite protection based on the expectation that most exposures would occur at concentrations between 9 and 10 $\mu g/m^3$. For the reasons stated in the preamble, the Administrator has concluded that a standard of 9.0 $\mu g/m^3$, which maintains most exposures below that level, is requisite to protect public health with an adequate margin of safety.

(4) **Comment:** Some commenters claim that the epidemiologic studies that the EPA relies on for informing conclusions on the primary annual $PM_{2.5}$ standard provides little information about the impact of $PM_{2.5}$ at low concentrations. In so doing, the commenters note that the key epidemiologic studies in Figures 1 and 2 in the proposal have mean $PM_{2.5}$ concentrations above 10 $\mu g/m^3$, with none of the studies included in Figure 1 with mean $PM_{2.5}$ concentrations at or below 9.5 $\mu g/m^3$. Therefore, the commenter suggests that it is difficult to extrapolate from the ranges in these studies to support the Administrator's proposed conclusions.

Response: We disagree with the commenters that the key epidemiologic studies presented in Figures 1 and 2 in the proposal do not provide support for the Administrator's decision to revise the level of the primary annual $PM_{2.5}$ standard to 9.0 $\mu g/m^3$. As an initial matter, we note that the Administrator judges that it is most appropriate to examine where the evidence of associations observed in the epidemiologic studies is strongest, and conversely, where he

has appreciably less confidence in the associations observed in the epidemiologic studies. In so doing, as described in more detail in the proposal (88 FR 5625, January 27, 2023) and in section II.B.4 of the notice of final rulemaking, he notes that in most past reviews, evidence-based approaches focused on identifying standard levels near or somewhat below long-term mean concentrations reported in key epidemiologic studies and were supported by previous CASAC advice as well as the CASAC's advice in their review of the 2021 draft PA as a part of this reconsideration (88 FR 5625, January 27, 2023).[13] In adopting this approach, the Administrator considers the long-term mean concentrations reported in two types of key epidemiologic studies: (1) monitor-based studies as shown in Figure 1 of the proposal and (2) hybrid modeling-based studies as shown in Figure 2 of the proposal. As there is no clear way to identify how much below the long-term mean $PM_{2.5}$ concentrations of key epidemiologic studies to set the level of a standard that would provide requisite protection with an adequate margin of safety, the Administrator recognizes that he must use his judgment regarding the appropriate weight to place on the available evidence and technical information, including uncertainties, in reaching his decision. As shown in Figures 1 and 2, for the key U.S. monitor-based epidemiologic studies, the study reported mean concentrations range from 9.9-16.5 $\mu g/m^3$ and for the U.S. hybrid modeling-based key epidemiologic studies, the mean concentrations range from 9.3-12.2 $\mu g/m^3$. The Administrator's proposed range of a level of 9.0 to 10.0 $\mu g/m^3$ for the primary annual $PM_{2.5}$ standard is consistent with the interpretation of the mean $PM_{2.5}$ concentrations from key epidemiologic studies, such that this range is at or just below the mean $PM_{2.5}$ concentrations presented in Figures 1 and 2.

Moreover, the Administrator is required to set primary standards that provide public health protection with an adequate margin of safety. The Clean Air Act does not require NAAQS to be set at zero but does requires a precautionary approach which addresses uncertainties associated with inconclusive scientific information available at the time of standard setting and provides a reasonable degree of protection against hazards that research has not yet identified. The need to provide an adequate margin of safety under CAA 109 contributes to the Administrator's decision to set the standard at 9.0 $\mu g/m^3$ even if many of the key epidemiologic studies have higher means.

Therefore, as discussed in section II.B.4 of the notice of final rulemaking, based on the current evidence and quantitative information, as well as consideration of CASAC advice and public comments, the Administrator concludes that the current annual primary $PM_{2.5}$ standard is not adequate to protect public health with an adequate margin of safety. The Administrator notes that the CASAC was unanimous in its advice on the 2021 draft PA regarding the need to revise the annual standard. In considering the appropriate level for a revised annual standard, the Administrator concludes that a standard set at a level of 9.0 $\mu g/m^3$ reflects his judgment about placing the most weight on the strongest available evidence while appropriately weighing the uncertainties.

[13] As noted above and in the preamble, the EPA recognizes that in providing advice on the 2019 draft PA some members of the CASAC recommended that retaining the current standards would properly weight recent epidemiologic evidence showing positive associations with long-term mean $PM_{2.5}$ concentrations below the level of the annual standard, in light of their concerns (e.g., about the possibility of potential sources of error and bias).

3. Comments in Support of Revising the Primary 24-hour $PM_{2.5}$ Standard

a. *Form*

(1) **Comment:** Some commenters, including those from public health and environmental organizations, state and local elected representatives, and some state and local government agencies, recommend that the 24-hour average should be calculated based on a 24-hour rolling average rather than the current midnight-to-midnight average. These commenters assert that the current midnight-to-midnight average can lead to an underestimation of 24-hour averages of $PM_{2.5}$. They further contend that there are overnight emissions and/or temperature inversions that impact the 24-hour $PM_{2.5}$ concentrations, and that the current midnight-to-midnight approach splits these events across two days, whereas a 24-hour rolling average would capture these events more appropriately. The commenters further suggest that a 24-hour rolling average that would account for these spikes in $PM_{2.5}$ would result in an increased number of days exceeding the standard and increased design values. In support for their recommendation, some commenters point to the CASAC's advice that the EPA should in future reviews consider alternative forms for the primary 24-hour $PM_{2.5}$ standard, specifically noting the advice of an individual CASAC member that suggested a 24-hour rolling average. Other commenters also note that existing continuous $PM_{2.5}$ monitors could support a 24-hour rolling average. In addition, some commenters provided local or regional air quality analyses to demonstrate the differences between the midnight-to-midnight averaging compared to the 24-hour rolling average.

Response: The EPA has considered these comments and the possibility of revising the calculation of the standard to a 24-hour rolling average and finds that there is currently insufficient support for such a change. First, the EPA notes that the health effects evidence for this reconsideration is largely based on the approach of categorizing exposures on a calendar day-basis (i.e., the current 12 am to 12 am calculation). Thus, the Administrator finds that using this calculation as the basis for the NAAQS when deciding how to set the NAAQS to protect public health with an adequate margin of safety is appropriate because it is consistent with the underlying health studies. Second, the Administrator notes that one commenter has provided analyses completed at one monitor (e.g., the Liberty monitor in Allegheny County, PA) for 2018-2020, showing that a rolling 24-hour average results in three more days over 35 $\mu g/m^3$ in 2018, one less day in 2019, and no change in 2020. The EPA does not consider this a sufficient basis for reaching conclusions about the impact of such a change on a nationwide basis, particularly given that it is unclear whether the effect of the change would be, as commenters suggest, to change design values by 7% or whether such a change is warranted. The EPA notes that the CASAC stated that they also considered the available information insufficient to evaluate alternative forms of the 24-hour standard, and for that reason, recommended that the EPA consider potential changes more fully in future reviews (Sheppard, 2022, p.18 of consensus responses). Third, there are practical and policy considerations which weigh against adoption of a rolling 24-hour average, at least in the absence of additional information and analysis (including notice and comment). For example, although many states operate continuous $PM_{2.5}$ monitors which are approved Federal Equivalent Monitors, the current Federal Reference Monitor (FRM) for $PM_{2,5}$ is a filter-based monitor which is only capable of providing a 24-hour measurement from mid-night to midnight under our existing programs. While the EPA could set up other sampling

periods for the FRM to quality assure continuous $PM_{2.5}$ FEMs, doing so may never adequately cover the rolling 24-hour period of interest. Thus, a change to a rolling 24-hour average would not have quality assurance data consistent with the time-period of interest. Also, not having FRM data on a consistent sampling schedule (i.e., midnight to midnight) may necessitate new approaches to data completeness which would benefit from public notice and comment. The EPA also notes that in 2015 it changed the calculation of the 8-hour daily maximum concentration for the ozone NAAQS to avoid a rolling average which overlaps consecutive calendar days (that is, the EPA calculates rolling 8-hour averages, but the calculation for each day starts at 7:00 am, so that 8-hour averages on consecutive days do not overlap). The EPA found this approach more appropriate because it ensures that all hourly concentrations are included in the design value calculation, but avoids the possibility that a single 8-hour period will be treated as two calendar days above the standard (see 80 FR 65292, 65412, December 28, 2015). The EPA notes that similar concerns – to ensure all data is represented but not over-represented – would need to be addressed before adoption of a 24-hour rolling average for the primary 24-hour $PM_{2.5}$ NAAQS. Finally, the EPA notes that as detailed further in section II.B.4 of the notice of final rulemaking, based on air quality analyses at monitors across the entire country, the Administrator finds that the current suite of standards maintains subdaily concentrations of $PM_{2.5}$ in ambient air far below the exposure concentrations in controlled human exposure studies where consistent effects have been observed. Taking all of these factors into consideration, the Administrator concludes that there is insufficient support for revising the calculation method of the 24-hour standard and retaining the current 24-hour standard with its current calculation method is requisite to protect public health with an adequate margin of safety.

b. ***Level***

(1) **Comment:** Some commenters contend that the EPA placed more weight on inconsistencies in the results of the controlled human exposure studies rather than placing weight on the fact that recent studies assessed in the ISA Supplement found effects related to cardiac function at levels at or below the level of the current primary 24-hour $PM_{2.5}$ standard. These commenters point to the 2022 PA statement that intermittent exercise in the 4-hour Wyatt et al. (2020) study would have produced exposure doses similar to those that occur in the 2-hour studies that find effects at higher levels. These commenters speculate that, based on the EPA's statement in the 2022 PA about shorter exposure durations at higher levels, the converse could also be true: longer exposures (e.g., 24 hours) would produce similar doses to those observed in that study at even lower $PM_{2.5}$ concentrations, particularly for people who live or work near sources that produce peak $PM_{2.5}$ concentrations and have some levels of daily activity.

Response: The EPA disagrees with the comments that we focused too much on the inconsistencies associated with recent controlled human exposure studies that investigated the effects of exposure to near ambient concentrations of $PM_{2.5}$ and did not give the findings proper consideration. These studies were assessed in the 2019 ISA (Hemmingsen et al., 2015a; Hemmingsen et al., 2015b) and the ISA Supplement (Wyatt et al., 2020), and considered in the 2022 PA (U.S. EPA, 2022a, sections 3.3.1.2 and 3.3.3.1). As noted in the ISA Supplement, "While Wyatt et al. (2020) provides evidence of some effects at lower $PM_{2.5}$ concentrations, overall there is inconsistent evidence for changes in lung function

(U.S. EPA, 2019, section 5.1.7.2 and section 5.1.2.3.3) and inflammation (U.S. EPA, 2019, section 6.1.11.2.1) in other controlled human exposure studies conducted at higher $PM_{2.5}$ concentrations evaluated in the 2019 PM ISA" (U.S. EPA, 2022b, p. 3-130). It is important to consider the results of individual studies in the context of the larger body of evidence when reaching conclusions and for consideration in reaching conclusions regarding the adequacy of the current standards. Additionally, as noted in the EPA's causal framework, assessing the evidence to inform causality consists of evaluating whether this is consistency in evidence within a discipline, coherence of effects across disciplines, and evidence of biological plausibility (U.S. EPA, 2015). As noted previously, the EPA's evaluation of controlled human exposure studies in the 2019 ISA, as well as in the ISA Supplement, identified inconsistencies in the results across these studies.

Furthermore, we disagree with the commenters' speculation regarding the applicability of the results of the controlled human exposure studies to real world exposures to ambient $PM_{2.5}$ for longer durations. While we do not disagree with the commenters that it might be possible that lower $PM_{2.5}$ concentrations could elicit similar effects to those observed in Wyatt et al. (2020) for longer exposure periods (e.g., 24 hours), particularly while engaged in physical activities, we have no evidence supporting that possibility, as studies of such exposures are not available for consideration as a part of this reconsideration. . In addition, as noted above, this assumption by the commenters is further complicated by the fact the results of Wyatt et al. (2020) are not consistent with other controlled human exposure studies evaluated in the 2019 ISA.

(2) **Comment:** Some commenters who support revising the level of the primary 24-hour $PM_{2.5}$ standard suggest that the EPA did not thoroughly consider evidence from epidemiologic panel studies in concluding that the current standard is adequate. These commenters contend that the EPA did not give sufficient weight to numerous panel studies that reported associations between short-term $PM_{2.5}$ exposure with changes in clinical endpoints that are on the pathway to adverse cardiovascular events. The commenters suggest that these short-term exposure panel studies are able to: (1) evaluate $PM_{2.5}$ exposures for at-risk populations below the current primary 24-hour $PM_{2.5}$ standard, (2) assess effects for multiple (i.e., 1-5) days of exposure, and (3) measure the same endpoints as the controlled human exposure studies. These commenters further state that the panel studies are supported by controlled human exposure studies that observed similar subclinical effects and contend that together these studies find consistent subclinical effects that are risk factors for adverse cardiovascular events. Additionally, they cite to one study (e.g., Zhang et al., 2021b) that linked exposure with adverse cardiopulmonary events. The commenters further contend that the EPA did not consider the implications of a number of panel studies that found cardiovascular effects related to $PM_{2.5}$ exposures that were included in the 2019 ISA and previous ISAs, and did not include relevant panel studies in the ISA Supplement (e.g., Zhang et al., 2021b). Finally, the commenters assert that these studies should have been considered within the body of evidence when reaching conclusions regarding the adequacy of the current primary 24-hour $PM_{2.5}$ standard. They contend that these studies should not only be used to support biological plausibility, and that these studies (including those that restrict concentrations to less than 35 $\mu g/m^3$), in conjunction with controlled human exposure studies, support revision of the level of the 24-hour standard to between 25 and 30 $\mu g/m^3$.

Response: In collectively considering the epidemiologic evidence, the 2019 ISA evaluated panel studies. As described in the Preamble to the ISAs, the EPA considers several categories of epidemiologic evidence, including cross-sectional, prospective cohort, time-series, and panel studies (U.S. EPA, 2015, p.15). We note that the Zhang et al. (2021b) study cited by the commenters was published after the literature cutoff date of the ISA Supplement. This study was provisionally considered but does not materially change the scientific conclusions of the 2019 ISA or ISA Supplement in this reconsideration.

With regard to considering the epidemiologic panel studies for purposes of informing conclusions regarding the adequacy of the current primary $PM_{2.5}$ standards, we note that the 2022 PA does not identify any panel studies as key epidemiologic studies. This is because panel studies, by their design, investigate clinical endpoints similar to those evaluated in controlled human exposure studies, with intermediate effects that are not clearly adverse. Thus, similar to short-term epidemiologic cohort studies, mean $PM_{2.5}$ concentrations from epidemiologic panel studies are an insufficient basis for concluding that the current 24-hour standard with its 98th percentile form is not providing the requisite degree of supplemental protection against peak exposures. However, we note that the experimental evidence, including evidence from epidemiologic panel studies, does inform our understanding of the biological plausibility and pathways for the more serious effects seen in epidemiologic studies of morbidity and mortality. In reaching his final decisions, the Administrator concluded that the combination of an annual standard of 9.0 $\mu g/m^3$ and a 24-hour standard of 35 $\mu g/m^3$ provide requisite protection for at-risk populations with an adequate margin of safety, for the reasons explained in section II.B.4 of the preamble.

(3) **Comment:** Some commenters who recommend that the level of the primary 24-hour $PM_{2.5}$ standard should be revised contend that the controlled human exposure studies provide support for strengthening the standard. In the broader context of considering the controlled human exposure studies and the CASAC's advice regarding these studies in their review of the 2021 draft PA, the commenters specifically ~~In so doing, these commenters~~ cite to the CASAC's advice, where they noted "if the prior 20 hours of ambient exposure and the 2-4 hours of the controlled human exposure were taken as a time-averaged 24-hour concentration, the exposure would likely be in the realm of normal ambient 24-hour exposures" (Sheppard, 2022, p. 7 of consensus responses).

Response: The EPA disagrees with the commenters that effects seen in controlled human exposure studies provide support for a more stringent primary 24-hour $PM_{2.5}$ standard because taking an average of the exposures during the controlled human exposure studies plus ordinary ambient concentrations "would likely be in the realm of normal ambient 24-hour exposures." First, the EPA notes that neither the CASAC nor the commenters present any analysis or data to support the claim either that the mathematical result of this averaging is equivalent to "normal" ambient exposures, or that the available scientific evidence would provide such analysis or data to support this claim. Additionally, the EPA does not believe that it is appropriate to set a standard intended to provide protection against peak concentrations by averaging short but extremely high concentrations (like those observed in the controlled human exposure studies) with much longer typical daily concentrations (like those from typical ambient air exposures). This is because such a pattern of air quality is not likely to be experienced from "normal ambient 24-hour exposures," as there are very few

instances where typical ambient air exposures to $PM_{2.5}$ concentrations similar to those in the controlled human exposure studies occur (much less occurs when ambient concentrations are otherwise normal), and it is unclear whether a standard based on such averaging would provide the requisite level of protection against patterns of air quality that are likely to occur. To the extent commenters and the CASAC are suggesting that it would be normal for people to be exposed to similar concentrations as the study participants in the controlled human exposure studies over short periods of time (e.g., 2-4 hours) because the current standards allow for such exposures, and therefore the 24-hour standard should be revised to be more stringent to prevent such exposures, the EPA disagrees. As noted in section II.B.4 of the notice of final rulemaking, the EPA's air quality analysis demonstrates that occurrences of $PM_{2.5}$ concentrations comparable to the exposure concentrations in the controlled human exposure studies are exceedingly rare. For the reasons stated in the notice of final rulemaking, the Administrator continues to conclude that the annual standard is sufficient to control "normal ambient 24-hour exposures" and that the 24-hour standard provides the requisite degree of supplemental control for peak daily concentrations.

(4) **Comment:** Some commenters who recommend revising the level of the 24-hour primary $PM_{2.5}$ standard to 25 $\mu g/m^3$ emphasize the impacts of particulate matter on children, including from in utero exposures. These commenters express concern over $PM_{2.5}$ exposures associated with early development, including respiratory system impacts and neural development impacts citing a number of recent studies in support of their rationale for revising the level of the current standard.

Response: As an initial matter, the primary (health-based) NAAQS are established at a level that is requisite to protect public health, including the health of sensitive or at-risk groups, with an adequate margin of safety. In so doing, the EPA expressly considers the available information regarding health effects among at-risk populations, including that available for children, in decisions on the primary (health-based) NAAQS.

The 2019 ISA evaluated studies that examined several health outcomes associated with $PM_{2.5}$ exposures during periods of early development, including cancer (Chapter 8), growth (Chapter 9), infection (Chapter 5), eczema (Chapter 5), neurodevelopmental effects including autism (Chapter 8), cardiovascular effects (Chapter 6), and respiratory effects including asthma (Chapter 5) (U.S. EPA, 2019, section 9.1.3). The results from studies examining these outcomes were considered in the causality determinations for long-term (i.e., months to years) $PM_{2.5}$ exposure and respiratory effects, cardiovascular effects, nervous system effects, and birth outcomes. In reaching his conclusions regarding the adequacy of the primary $PM_{2.5}$ standards, the Administrator places the greatest weight on evidence of effects for which the 2019 ISA determined there to be a "causal relationship" or "likely to be causal relationship" with long- and short-term $PM_{2.5}$ exposures. As in the 2020 review, the Administrator recognizes that the strongest evidence, including with regard to quantitative characterizations of relationships between $PM_{2.5}$ exposure and effects, continues to be for mortality and cardiovascular effects. While the Administrator places the greatest weight on evidence associated with these effects, he recognizes that, in setting standards that are requisite to protect public health with an adequate margin of safety against these effects, including protecting at-risk populations (e.g., children) and achieving such a level of protection would also result in air quality improvements that would also reduce other health outcomes.

In addition, the EPA disagrees with the commenters' rationale for why the level of the primary 24-hour $PM_{2.5}$ standard should be lowered. Specifically, the commenters note that evidence indicating reproductive and developmental effects supports revising the 24-hour standard. The 24-hour standard, however, with its 98th percentile form, is designed to protect against peak exposures. However, studies that evaluate effects noted by the commenters s do not examine exposure durations that would inform conclusions regarding the adequacy of the primary 24-hour $PM_{2.5}$ standard as these studies focus on longer-term exposures ranging from multiple months to multiple years, which could be more applicable to evaluating the adequacy of the annual standard. .

Finally, with regard to the studies cited by the commenters, we note that we have provisionally reviewed these studies and found they do not materially change the conclusions in the 2019 ISA and ISA Supplement regarding the health outcomes discussed above. A number of these studies (Johnson et al., 2021, Liu et al., 2018, Brumberg et al., 2021, Lin et al., 2021, and Payne-Sturges et al., 2019) are systematic reviews and are considered out of scope of the ISA as detailed in the Preamble to the ISA (U.S. EPA, 2015). While (Jedrychowski et al. (2013) examined the impact of prenatal exposure to fine particulate matter ($PM_{2.5}$) on recurrent broncho-pulmonary infections in early childhood and would be considered to be within the scope of the 2019 ISA and the evaluation of the relationship between long-term $PM_{2.5}$ exposure and respiratory effects, this one single study on its own would not be sufficient to warrant the changing of a causality determination, as the collective body of evidence is considered in making conclusions regarding causality as detailed in the Preface to the 2019 ISA (U.S. EPA, 2019) and the Preamble to the ISA (U.S. EPA, 2015).

(5) **Comment:** Some commenters contend that the EPA's discussion regarding there being less evidence to inform decisions on the 24-hour standard than the annual standard is arbitrary and capricious, because having less information for decisions on one standard compared to the other does not prevent revisions to either standard. They contend that the decision regarding the 24-hour standard must be based on the protection afforded by both primary $PM_{2.5}$ standards against short- and long-term $PM_{2.5}$ exposures and not on the strength of the evidence for either standard. These commenters assert that, even if the evidence is less compelling for the 24-hour standard than the annual standard, it still provides support for revising the level of the primary 24-hour $PM_{2.5}$ standard.

Response: The EPA agrees that the Administrator is required to make a decision whether to revise or retain the current standards based on his judgment, after considering all of the available evidence, whether the standards together are requisite to protect public health with an adequate margin of safety. The Administrator's decision to revise the annual standard and retain the 24-hour standard takes into consideration the available evidence and information as well as uncertainties. As explained in section II.B.4 of the preamble, his decision is based on his evaluation of the available evidence and how the evidence informs his judgments as to the protection afforded by the annual standard, the 24-hour standard, and the combination of the two, rather than simply considering the quantity of evidence available for evaluating each standard.

(6) **Comment:** With regard to the risk assessment, commenters contend that the analyses are limited in scope and do not provide a full evaluation of a lower primary 24-hour $PM_{2.5}$

standard. The commenters assert that, because the risk assessment does not provide quantitative information on the risk associated with an alternative standard level of 25 $\mu g/m^3$, any assertion regarding the "controlling" standard based on the risk assessment does not apply to a 24-hour standard of 25 $\mu g/m^3$. They state that the design is not particularly helpful in determining whether the 24-hour standard is adequate, and that the EPA's reliance on the risk assessment for asserting that the annual standard is "controlling" for most of the U.S. is arbitrary and capricious. These commenters also note that "the majority of CASAC members are concerned that the current risk assessment may not adequately characterize mortality risks associated with short-term $PM_{2.5}$ exposures" (Sheppard, 2022, p. 11 of consensus responses). Some commenters, in noting that the minority of the CASAC agreed with the EPA that the annual standard is controlling in urban areas, stated that the EPA did not consider the areas where the annual standard is not controlling.

Response: We recognize that the risk assessment did not provide quantitative information on risk impacts associated with an alternative standard level of 25 $\mu g/m^3$. The EPA determined that quantitative limitations associated with air quality modeling would introduce significant additional uncertainties into the risk assessment if alternative standard levels below 30 $\mu g/m^3$ were analyzed. Our fundamental approach to estimating human health risks associated with $PM_{2.5}$ exposure in this reconsideration involved using C-R functions derived from epidemiologic studies. These functions establish a link between ambient $PM_{2.5}$ exposure and mortality risk. Inputs required for risk modeling using C-R functions include the C-R functions themselves, baseline health incidence data and information on population demographics, study areas, and modeled ambient $PM_{2.5}$ concentrations corresponding to air quality scenarios of interest. Air quality modeling is used to develop gridded $PM_{2.5}$ concentration fields and adjustments are made to simulate just meeting the current standards and alternative standards to approximate air quality scenarios (U.S. EPA, 2022a, section C.1). For this reconsideration, linear interpolation and extrapolation was employed to simulate air quality for alternative standard levels for the annual standard below those that were simulated using air quality modeling. However, interpolation and extrapolation were not performed for additional alternative 24-hour standard levels beyond the modeled alternative of 30 $\mu g/m^3$ due to the weak relationship between the 98th percentile of the 24-hour $PM_{2.5}$ concentrations and the concentrations comprising the middle portion of the $PM_{2.5}$ air quality distribution. The 98th percentile 24-hour concentrations are most relevant for simulating air quality that just meets the 24-hour standard while in contrast, the concentrations representing the middle portion of the $PM_{2.5}$ air quality distribution are most relevant for estimating risks based on information from epidemiologic studies (U.S. EPA, 2022a, section C.1.4). Thus, the EPA had greater confidence in interpolation and extrapolation of the mean concentrations for the annual standard and less confidence for the 98th percentile of the 24-hour standard, and concluded that the uncertainties associated with modeling alternative air quality scenarios for a 24-hour standard of 25 $\mu g/m^3$ would be sufficiently large such that the results would be significantly less informative.

To the extent the commenters are suggesting that a standard of 25 $\mu g/m^3$ would result in a greater number of areas where the 24-hour standard was the controlling standard, the EPA acknowledges that this is possible but the EPA disagrees that this would fundamentally undermine any aspect of the Administrator's conclusions on the standards. The Administrator has carefully considered the risks of short-term exposure to $PM_{2.5,}$ as discussed at length in

the preamble (particularly in section II.B.4). The EPA continues to believe, as explained in the preamble, that reducing the annual standard is a more appropriate way to reduce the risks from both typical and peak daily concentrations and that the current level of the 24-hour standard provides the requisite degree of supplemental protection from peak short-term exposures.

(7) **Comment:** Commenters suggest that if the primary annual $PM_{2.5}$ standard is lowered, the primary 24-hour $PM_{2.5}$ standard should also be lowered to maintain the "typical mean ratio" between the two standards (i.e., if the annual standard is revised from 12.0 $\mu g/m^3$ to 8-10 $\mu g/m^3$, a linearly proportional reduction of the 24-hour standard would be 23-29 $\mu g/m^3$).

Response: We disagree with the commenters that the primary 24-hour $PM_{2.5}$ standard should be set proportionally with the primary annual $PM_{2.5}$ standard. We are not aware of data establishing a "typical mean ratio" between the annual mean and 98th percentile concentrations, nor are the Administrator's decisions on the levels of the primary $PM_{2.5}$ standards based on any standard ratio or proportional relationship between the annual mean and 98th percentile concentrations. Broadly speaking, the Administrator recognizes that the annual standard is most effective at limiting exposures to "typical" daily $PM_{2.5}$ concentrations that are commonly encountered throughout the year. Conversely, with its 98th percentile form, the 24-hour standard is most effective at limiting peak daily or 24-hour $PM_{2.5}$ concentrations. In reaching conclusions on the adequacy of these standards, the Administrator considers the public health protection afforded by the standards together against the full distribution of long- and short-term $PM_{2.5}$ exposures. The Administrator finds that a proportional change to the 24-hour standard is not needed to increase protection from peak $PM_{2.5}$ exposures because the available scientific evidence for peak $PM_{2.5}$-related health effects indicates that the current primary 24-hour $PM_{2.5}$ standard with its level of 35 $\mu g/m^3$ in conjunction with a revised annual standard with its level of 9.0 $\mu g/m^3$ provides requisite protection.

(8) **Comment:** Some commenters claim that because of how the primary annual $PM_{2.5}$ standard is calculated – as the 3-year average of annual means, which is the weighted arithmetic mean based on quarterly means – it cannot be the controlling standard, and by design reflects the long-term chronic average daily exposure. The averaging used in calculating the annual standard flattens the daily peak $PM_{2.5}$ concentrations across the three years and does not capture the daily high peak $PM_{2.5}$ concentrations.

Response: As an initial matter, the EPA disagrees with commenters that contend the annual standard cannot be the controlling standard. As detailed more in the 2022 PA (U.S. EPA, 2022a, section 3.4.1.5), for the majority of the study areas included in the risk assessment, the annual standard is the "controlling standard" because when air quality is adjusted to simulate just meeting the current or alternative annual standard levels, air quality in those areas also would meet the current or alternative levels of the 24-hour standard.

The EPA acknowledges that the arithmetic mean form of the annual standard does combine both typical and peak data to produce an average concentration. However, as detailed in section II.B.4 of the notice of final rulemaking, in evaluating what existing or revised standards may be requisite to protect public health, the Administrator's approach recognizes

that the current annual standard (based on arithmetic mean concentrations) and 24-hour standard (based on 98th percentile concentrations), together, are intended to provide public health protection against the full distribution of short- and long-term $PM_{2.5}$ exposures. This approach recognizes that changes in $PM_{2.5}$ air quality designed to meet either the annual or the 24-hour standard would likely result in changes to both long-term average and short-term peak $PM_{2.5}$ concentrations. Further, consistent with the approach adopted in 2012, the Administrator concludes that the most effective and efficient way to reduce total population risk associated with both long- and short-term $PM_{2.5}$ exposures is to set a generally controlling annual standard, and to provide supplemental protection against the occurrence of peak 24-hour $PM_{2.5}$ concentrations by means of a 24-hour standard set at the appropriate level. In reaching this conclusion, the Administrator explicitly recognizes that air quality changes associated with meeting a revised annual standard would result in lowering risks associated with both long- and short-term $PM_{2.5}$ exposures by lowering the overall distribution of air quality concentrations, leading to not only in lower short- and long-term $PM_{2.5}$ concentrations near the middle of the air quality distribution, but also in fewer and lower short-term peak $PM_{2.5}$ concentrations. Similarly, the Administrator recognizes that changes in air quality to meet a 24-hour standard, would result not only in fewer and lower peak 24-hour $PM_{2.5}$ concentrations, but also in lower annual average $PM_{2.5}$ concentrations. However, as noted in 2012, he also recognizes that an approach that relies on setting the level of the 24-hour standard such that the 24-hour standard is generally controlling would be less effective and result in less uniform protection across the U.S. than an approach that focuses on setting a generally controlling annual standard. Thus, he concludes that relying on a revised annual standard as the controlling standard will reduce aggregate risks associated with both long- and short-term exposures more consistently than a generally controlling 24-hour standard. He further concludes that retaining a 24-hour standard at the appropriate level will ensure an adequate margin of safety against short-term effects in areas with high peak-to-mean ratios.

Additionally, in light of the Administrator's emphasis on the annual standard as the controlling standard, with the 24-hour standard providing supplemental protection against peak concentrations, the Administrator considers the potential impact of a revised annual standard of 9.0 $\mu g/m^3$ on the occurrence of peak sub-daily $PM_{2.5}$ concentrations. Specifically, the Administrator takes note of the new air quality analyses[14] where he observes that in areas meeting an annual standard of 9.0 $\mu g/m^3$ and a 24-hour standard of 35 $\mu g/m^3$ concentrations greater than 120 $\mu g/m^3$ and 38 $\mu g/m^3$ occur 0.029% and 0.41%, respectively, of the particular subdaily time period analyzed. For the reasons stated in the preamble, the Administrator concludes that this level of control of peak concentrations will provide requisite protection of public health. Thus, he concludes that the annual standard will continue to effectively limit both typical and peak daily concentrations, and the existing 24-hour standard, with its level of 35 $\mu g/m^3$ and 98th percentile form, will provide supplemental protection as needed against peak concentrations.

[14] Jones et al. (2023). Comparison of Occurrence of Scientifically Relevant Air Quality Observations Between Design Value Groups. Memorandum to the Rulemaking Docket for the Review of the National Ambient Air Quality Standards for Particulate Matter (EPA-HQ-OAR-2015-0072). Available at: https://www.regulations.gov/docket/EPA-HQ-OAR-2015-0072.

(9) **Comment:** A number of commenters who recommend revising the level of the primary 24-hour $PM_{2.5}$ standard contend that a lower standard is especially important for providing public health protection against short-term peak $PM_{2.5}$ concentrations. These commenters often cite specific or local sources that they state contribute to short-term peak $PM_{2.5}$ concentrations, including wildfires, wintertime woodburning, and industrial emissions. The commenters also emphasize inversions, particularly in the wintertime, in areas with these types of sources, which can impact exposure to peak $PM_{2.5}$ concentrations. Some commenters submitted local or regional air quality analyses to support this rationale for revision of the level of the primary 24-hour $PM_{2.5}$ standard and in particular highlight examples of areas where short-term $PM_{2.5}$ concentrations are above the current primary 24-hour $PM_{2.5}$ standard.

(10) **Response:** While the annual standard is the controlling standard for much of the U.S., the EPA recognizes that there are a small number of areas including areas with temperature inversions, wood smoke, and areas that are near manufacturing sources where the 24-hour standard is generally the controlling standard. The EPA's approach has been to focus on the annual standard as the principal means of limiting both long and short-term $PM_{2.5}$ concentrations recognizing that the 24-hour standard with its 98th percentile form, would provide additional protection against short-term peak exposures, particularly for areas with high peak-to-mean rations. Compared to the annual standard, we recognize that the 24-hour standard is less likely to appropriately limit the more typical $PM_{2.5}$ exposures (i.e., corresponding to the middle portion of the air quality distribution) that are most strongly associated with the health effects observed in epidemiologic studies. Thus, as in previous reviews (78 FR 3161-3162, January 15, 2013; 85 FR 82715, December 18, 2020), we focus on the 24-hour standard as a means of providing supplemental protection against the short-term exposures to "peak" $PM_{2.5}$ concentrations, such as can occur in areas with strong contributions from local or seasonal sources. As noted above and for the reasons stated in the preamble, the Administrator has concluded that the annual standard with its level of 9.0 $\mu g/m^3$ will continue to effectively limit both typical and peak daily concentrations, and the existing 24-hour standard, with its level of 35 $\mu g/m^3$ and 98th percentile form, will provide supplemental protection as needed against peak concentrations, including in areas subject to the conditions identified by the commenters. The 24-hour standard is not set with the intention of targeting specific sources of $PM_{2.5}$, but rather to ensure that air quality is set at a level to provide requisite public health protection all areas of the U.S. Rather than using the level of the NAAQS to target sources, the regulatory framework supporting NAAQS implementation provides mechanisms for controlling emissions from specific sources. Furthermore, we note that there are a number of non-regulatory programs that can help to reduce emissions from sources that contribute to peak $PM_{2.5}$ concentrations. One such program is the EPA's Burn Wise Program, which is a voluntary partnership program that promotes upgrades to cleaner burning technologies and education on proper use of wood burning appliances.[15]

(11) **Comment:** Commenters suggest that the primary 24-hour $PM_{2.5}$ standard should be lowered to 25 $\mu g/m^3$ to improve health outcomes for people living in communities strained by $PM_{2.5}$

[15] More information regarding the EPA's Burn Wise program is available at: *https://www.epa.gov/burnwise*.

pollution, especially for sensitive individuals. Commenters express concern over the rates of $PM_{2.5}$-attributable respiratory and cardiovascular events for older adults, children, people of color, and people in low-income communities.

Response: Regarding the protection of at-risk populations, the EPA has considered the health effects evidence in the 2019 ISA and ISA Supplement, including numerous epidemiologic studies focusing on at-risk populations such as children, older adults, individuals with preexisting conditions like cardiovascular and respiratory disease, minority populations, and low SES populations. Furthermore, the EPA considered epidemiologic studies in the 2022 PA that have cohorts that include large numbers of individuals in the general population, and often also include those populations identified as at-risk (i.e., children, older adults, minority populations, and individuals with pre-existing cardiovascular and respiratory disease) (U.S. EPA, 2022a, Figures 3-4 to 3-7). These studies evaluated various health outcomes, including morbidity and mortality associations in age-specific populations like Medicare beneficiaries, as well as hospital admissions for cardiovascular effects in populations age 65 and older. The primary $PM_{2.5}$ NAAQS are established at a level that is requisite to protect public health, including the health of sensitive or at-risk groups, with an adequate margin of safety. The EPA expressly considers the available information regarding health effects among at-risk populations in decisions on the primary $PM_{2.5}$ NAAQS. For the reasons stated in section II.B.4 of the preamble, the Administrator concludes that the combination of an annual standard with a level of 9.0 $\mu g/m^3$ and a 24-hour standard of 35 $\mu g/m^3$ will provide the requisite protection for public health with an adequate margin of safety.

(12) **Comment:** Some commenters who recommend revising the level of the primary 24-hour $PM_{2.5}$ standard to 25 $\mu g/m^3$ explicitly point to reducing environmental justice issues related to $PM_{2.5}$ exposure and health risks among minority populations and low SES populations. The commenters cite a number of nationwide epidemiologic studies as support for their position that lowering the 24-hour standard would in particular benefit communities with minority populations and low SES populations who experience disproportionately high exposures to $PM_{2.5}$ and its associated morbidity and mortality risks. Some commenters cite a study by Mullen et al. (2020) that focused on the cognitive impacts of short-term spikes in $PM_{2.5}$ caused by winter stagnation in Salt Lake County, Utah, and contend that concentration of 23 $\mu g/m^3$ was the peak threshold (e.g., the 95^{th} percentile concentrations) that caused children to struggle with test scores countywide. These commenters assert that this study shows disproportionate burdens in specific localities dealing with health effects associated with short-term $PM_{2.5}$ spikes, reaching as low as 23 $\mu g/m^3$.

Some commenters further contend that inequalities in exposure and health risk would not be addressed by revising the primary annual $PM_{2.5}$ standard alone, and that these disparities would be best addressed through a revision of the 24-hour standard to 25 $\mu g/m^3$, coupled with siting permanent regulatory monitors in areas with high pollution. As a part of their rationale, these comments cite to a study by Wang et al. (2022) that investigates various emission-reduction approaches and the ability of those approaches to reduce $PM_{2.5}$ exposures.

Other commenters provide independent analyses of population data from EJScreen to determine which potential combinations of annual and daily standards best offsets current exposure disparities. Their analysis of the projected populations in monitored counties that the EPA projects would be in attainment and nonattainment areas in 2032 at various annual and 24-hour standard levels shows that there would be significantly more people of color living in nonattainment areas if the 24-hour standard is revised to 25 $\mu g/m^3$. A similar trend occurred when commenters carried out analysis using current design values (2019-2021) instead of 2032 projected design values. Altogether, these commenters estimate that millions of people of color would benefit from lowering the primary 24-hour $PM_{2.5}$ standard.

Other commenters performed an analysis of daily air quality data from Chicago Microsoft stationary sensors. Their analysis found that three South Side Chicago stations exceeded 35 $\mu g/m^3$ on 50 days. These commenters express concern over exceedances in the census tract associated with one of the three stations that has a population percentage below the federal poverty level of over 40%. These commenters suggest that it is important to prioritize the most vulnerable communities as the baseline when determining the NAAQS levels and that by doing so other areas will benefit as well. Some commenters further request that if the 24-hour standard is not lowered to 25 $\mu g/m^3$ for all communities, the standard should at least be lowered to 25 $\mu g/m^3$ for environmental justice communities.

Response: The primary $PM_{2.5}$ NAAQS are set together at levels that are requisite to protect public health with an adequate margin of safety. This protection includes the health of sensitive or at-risk groups. To do this, the decisions regarding the NAAQS are grounded in a comprehensive and explicit evaluation of the existing scientific evidence and associated risk analyses. To be more precise, the EPA explicitly takes into account the available information concerning health effects among at-risk populations when making decisions regarding the primary standards. The 2019 ISA and ISA Supplement identified children, older adults, people with pre-existing diseases (cardiovascular disease and respiratory disease), minority populations, and low SES populations as at-risk populations. In cases where populations with disparities in exposure and risk fall within the category of at-risk populations, the determination of the NAAQS is based on providing protection for these and other at-risk populations and lifestages. Thus, the PM NAAQS are set at a level that protects at-risk populations, including minority populations and low SES populations identified by the commenters, and the EPA considers the suggestion to set distinct standards for environmental justice communities as neither necessary nor consistent with the requirements of the CAA for setting *national* ambient air quality standards.

As outlined in the proposal, the EPA explicitly took into account the available information concerning health effects among at-risk populations in the proposed determination that the current suite of primary $PM_{2.5}$ NAAQS is not requisite and should be revised. Thus, in reaching his final decision, the Administrator is establishing primary $PM_{2.5}$ standards which, in his judgment, will provide protection for these at-risk populations, including minority populations, with an adequate margin of safety. Providing the requisite protection for the health of at-risk populations also results in protecting the public health of other populations and reducing risk disparities.

While Mullen et al. (2020) examined short-term $PM_{2.5}$ exposure and nervous system effects in children it was published outside the literature cutoff date for the 2019 ISA (i.e., January 2018). It is important to recognize that one single study on its own would not be sufficient to warrant the changing of a causality determination, as the collective body of evidence is considered in making conclusions regarding causality as detailed in the Preface to the 2019 ISA (U.S. EPA, 2019) and the Preamble to the ISA (U.S. EPA, 2015). Additionally, as noted in the ISA Supplement, short-term $PM_{2.5}$ exposure and nervous system effects was not evaluated as the ISA Supplement focused on those health outcome categories for which the 2020 PA deemed there to be sufficient information to support decisions on potential alternative standards, i.e., health outcome categories for which a "causal relationship" was concluded in the 2019 ISA (U.S. EPA, 2022b, section 1.2.1). With respect to the process of forming causality determinations, the EPA considers the broader body of scientific evidence and not only one line of evidence (e.g., epidemiology). As such, in evaluating a body of evidence the EPA considers the pattern of results across a scientific discipline, such as epidemiology, to assess whether there is consistency, the coherence of results across scientific disciplines including toxicological studies and controlled human exposure studies, and whether there is evidence of biological plausibility for the effects observed.

With regard to the Wang et al. (2022) study, this study used a model to estimate long-term average $PM_{2.5}$ concentrations across the U.S. to evaluate the effectiveness of three approaches for reducing $PM_{2.5}$ concentrations on reducing overall average exposures for the U.S. population and reducing average exposures for minority groups compared to the overall population. As an initial matter, we note that this study is outside of the scope of the 2019 ISA and ISA Supplement because this type of modeling study is not assessed in the ISA when reaching conclusions regarding causality. Furthermore, we note that this study is designed to evaluate approaches for reducing $PM_{2.5}$ emissions. In evaluating the adequacy of the standards, the EPA does not evaluate the various approaches for reducing emissions and/or attaining a NAAQS, but rather considers whether the current or alternative standard levels are protective of public health. Therefore, this study would not be informative for decisions regarding the adequacy or the appropriate level of the primary $PM_{2.5}$ standards.

With regard to the analyses submitted by the commenters that used EJScreen statistics and Chicago Microsoft stationary sensors, we disagree with the commenters that this analysis would support lowering the primary 24-hour $PM_{2.5}$ NAAQS. These analyses simulate implementation of the PM NAAQS. The EPA sets the NAAQS to ensure the requisite protection of human health, including for sensitive sub-populations, but does not base decisions on the standards on projections about the size of populations that will reside in attainment or nonattainment areas, particularly in light of the prohibition on considering the costs or feasibility of attaining the standards. In addition, the EPA risk assessment results suggest that revising the level of the 24-hour standard to 30 $\mu g/m^3$ is estimated to lower risks associated with $PM_{2.5}$ exposure to a much lesser degree than revising the annual standard to 9.0 $\mu g/m^3$. Further, risk reduction predictions associated with a lower primary 24-hour $PM_{2.5}$ standard are predominately confined to areas located in the western U.S., with several of these areas also expected to undergo risk reductions upon meeting a revised annual standard of 9.0 $\mu g/m^3$. With further regard to the comments that report results from analyses that use air quality data from Chicago Microsoft stationary sensors, we note that the data used to determine compliance with the NAAQS are required to be based on FRMs/FEMs, and

sensors such as those used in the commenters' assessment are not FRMs/FEMs. However, if regulatory monitors did find nonattainment with the primary 24-hour $PM_{2.5}$ standard, that may provide a basis for designation of an area and for consideration of control strategies to attain the standard.

(13) **Comment:** Commenters suggest that the 24-hour primary $PM_{2.5}$ standard should be set within a range of 25-30 $\mu g/m^3$ to protect disproportionately impacted communities. These commenters highlight a study by Collins et al. (2022) to note that communities of color, particularly in metropolitan areas, are disproportionately exposed to short-term $PM_{2.5}$.

Response: In considering the available epidemiologic evidence, the 2019 ISA assessed studies concerning short-term $PM_{2.5}$ exposure and disparities for at-risk populations including potential disparities by race and ethnicity (U.S. EPA, 2019, p. 12-34). We note that the study by Collins et al. (2022), which was referenced by the commenters, was published after the literature cutoff date for the ISA Supplement. While this study was provisionally considered, it does not significantly alter the scientific conclusions of the 2019 ISA or ISA Supplement in this reconsideration. The 2019 ISA and ISA Supplement concluded that race, ethnicity, and socioeconomic status were all factors that may contribute to increased risk of $PM_{2.5}$-related health effects. In reaching his final decisions, the Administrator took this evidence into consideration in concluding that the combination of an annual standard of 9 $\mu g/m^3$ and a 24-hour standard of 35 $\mu g/m^3$ provide requisite protection for at-risk populations with an adequate margin of safety, for the reasons explained in section II.B.4 of the preamble.

C. Other Comments Related to the Primary $PM_{2.5}$ Standards

(1) **Comment:** Several commenters recommend revising the PM NAAQS to align with the 2021 World Health Organization (WHO) air quality guidelines for PM to provide increased public health protection, particularly for at-risk populations. The WHO air quality guideline for annual $PM_{2.5}$ is 5 $\mu g/m^3$, for 24-hour $PM_{2.5}$ is 15 $\mu g/m^3$, for annual PM_{10} is 15 $\mu g/m^3$, for 24-hour PM_{10} is 45 $\mu g/m^3$. Commenters provide a number of reasons to support their recommendation, including that the WHO air quality guidelines for PM are more stringent than the PM NAAQS, the development of the WHO air quality guidelines for PM follows a rigorous evaluation of scientific review and the involvement of a number of experts, and comparisons with air quality and air quality standards in other countries. Furthermore, some commenters provide a summary of how the WHO air quality guidelines were set, including the evaluation of health effects evidence associated with PM exposures. Many of the commenters recommend revising the primary $PM_{2.5}$ and PM_{10} standards to be the same as, or close to, the levels of the WHO air quality guidelines.

Response: We disagree with the commenters that the primary PM NAAQS should be set at or close to the WHO air quality guidelines for PM. The EPA sets both primary (health-based) and secondary (welfare-based) NAAQS that include more than a numerical pollutant level, which is what the WHO air quality guidelines for PM are. The EPA's PM NAAQS consist of a level, an averaging time, and a form. As such, they are distinct from the WHO guidelines, which as WHO notes, "are not legally binding standards" (WHO, 2021, p. xv) and also include interim targets that can be found in the complete WHO air quality guidelines document. Direct comparisons of the EPA's PM NAAQS with the WHO air quality

guidelines for PM are difficult and often impractical, given differences in the types, locations, and numbers of monitors, averaging times, units of measure, statistical adjustments, and numbers of allowed exceedances.

Aside from the practical obstacles, the EPA also finds there would be legal obstacles to simply adopting the WHO guidelines. Under the Clean Air Act, the EPA is directed to undertake a review of the air quality criteria and to base decisions on the NAAQS on the air quality criteria. Likewise, the CASAC is required to advise the Administrator on revisions to the criteria and standards as appropriate. Under section 108, the air quality criteria "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on the public health and welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." It would not be consistent with the EPA's obligations under the Clean Air Act to replace its current process of fully assessing the science and consulting with the CASAC with a decision to simply defer to the WHO guidelines. As noted above, direct comparisons between WHO guidelines and NAAQS are difficult, so it is possible that the results of the two approaches may be similar although framed differently, but the Administrator's obligation under the Clean Air Act is to identify the standards that in his judgment provide requisite protection for public health with an adequate margin of safety.

(2) **Comment:** Some commenters suggest that the EPA should follow a similar approach to the one undertaken in the recent regulation for Mercury and Air Toxics Standards (MATS). Commenters state that the findings from the MATS rule found that the resulting human health impacts were disproportionate across populations, and that some of the most exposed populations are minority and/or low-income individuals. They argue that the EPA's risk analysis considered not just the average exposure, but those of sensitive populations. In suggesting that the EPA use a similar approach in this reconsideration of the PM NAAQS, the commenters contend that this approach would properly accounts for specific sensitive populations disproportionately impacted by PM exposure and would protect public health within the necessary margin of safety.

Response: As discussed in section II.B.4 of the notice of final rulemaking, the EPA has carefully evaluated the potential impacts on at-risk populations as a part of this reconsideration, including minority populations and low SES populations as discussed in sections II.A.2, II.A.3, II.B.2, and II.B.4 of the preamble. Furthermore, the 2019 ISA, ISA Supplement, and 2022 PA contain the evaluation of the scientific evidence, quantitative risk analyses and policy considerations that pertain to populations identified as at-risk. Therefore, the EPA disagrees with the commenters assertion that Agency did not appropriately take into consideration health impacts of $PM_{2.5}$ exposure on sensitive populations that are disproportionately affected by exposure to $PM_{2.5}$. The EPA notes the 2022 PA did include an at-risk analysis as a part of the risk assessment that is based on a recent epidemiologic study that is available in this reconsideration that provides mortality risk coefficients for older adults (i.e., 65 years and older) based on $PM_{2.5}$ exposure and stratified by race and ethnicity. Although recognizing that the results of this analysis are even more uncertain than similar estimates from the overall risk assessment due to additional sources of uncertainty specific to the at-risk analysis (as discussed in section II.A.3.b of the notice of final rulemaking). In light of the limitations of the risk assessment, the Administrator places little weight on the

absolute results of the risk assessment, including the at-risk analysis, for purposes of selecting the level of the annual standard, although the EPA notes the stratified population results of the risk assessment suggest that meeting a revised standard would result in higher risk and exposure reductions for minority and low SES populations. As discussed in the preamble and this RTC document, after fully considering all of the evidence and the results of the risk assessment, the Administrator is establishing the revised suite of standards that, in his judgment, will protect the health of at-risk populations, including minority and low SES populations, with an adequate margin of safety.

(3) **Comment:** The EPA also received a number of comments related to the primary $PM_{2.5}$ standards that were not directly related to the adequacy of the current primary $PM_{2.5}$ standards. These comments included recommendations for future research and data collection efforts that could address data gaps and uncertainties to inform future reviews. Some of these areas include additional scientific research to assess $PM_{2.5}$-related health effects in rural areas, minority populations, and Tribes.

Response: The EPA agrees with many of the suggestions from the commenters and notes that the 2022 PA highlighted key uncertainties and data gaps associated with reviewing and establishing secondary PM NAAQS and also areas for future welfare-related research and data gathering (U.S. EPA, 2022a, section 3.7). We encourage research in these areas, although we note that research planning and priority setting are beyond the scope of this action.

(4) **Comment**: Some commenters suggested that the EPA should set both the annual and 24-hour standards with one significant figure, i.e. 8.0 $\mu g/m^3$ not 8 $\mu g/m^3$ and 25.0 $\mu g/m^3$ not 25 $\mu g/m^3$, to ensure that the NAAQS are health protective.

Response: The EPA seeks to have a scientifically robust use of significant figures, taking into consideration the level and form of the standard and the precision of the monitors. This has led us to use one additional figure past the decimal point for the primary annual $PM_{2.5}$ standard where we average several dozen to hundreds of data points in a year. For the primary 24-hour $PM_{2.5}$ standard, we use an integer because we are looking at just one value in a year (i.e., the 98^{th} percentile of each year). The EPA finds that this approach is appropriate for these standards and will ensure the NAAQS provide the intended level of protection for public health with an adequate margin of safety.

V. Responses to Significant Comments on the Primary PM_{10} Standard

The EPA received few comments on the proposed decision to retain the primary PM_{10} standard. Comments related to retaining or revising the primary PM_{10} standard are addressed in section III.B.3 of the preamble to the final rule. In addition to comments on the standard, some commenters provided additional comments on the scientific evidence and information available in this reconsideration. These comments are addressed below.

(1) **Comment:** Some commenters who state their support for retaining the current standard also provide comments on the evidence for $PM_{10-2.5}$ exposures and health effects detailed in the 2019 ISA. These commenters contend that the scientific evidence in the 2019 ISA does not

support changing causality determinations from "inadequate" in the 2009 ISA to "suggestive of, but not sufficient to infer, a causal relationship" in the 2019 ISA for long-term $PM_{10-2.5}$ exposure and cardiovascular effects, cancer, and mortality, or concluding "suggestive of, but not sufficient to infer, a causal relationship" for the initial review of metabolic and nervous system effects. They claim that the EPA should have instead asserted that the available evidence remains insufficient to draw any conclusion on causality. To support their position, they point to a statement from one member of the CASAC's individual comments in their review of the 2019 draft PA that studies reporting positive associations between health effects and $PM_{10-2.5}$ should not be used to assess causality because these findings are not without uncertainties and do not provide evidence for making or strengthening a causal determination, and thus, are not scientifically valid.

Response: The EPA disagrees with the commenter's assertion that the EPA's approach to assessing the available scientific evidence in the 2019 ISA and the application of the causal framework for reaching conclusions regarding causality determinations was inappropriate. We note that, while the causality determinations were changed from "inadequate" in the 2009 ISA to "suggestive of, but not sufficient to infer, a causal relationship" in the 2019 ISA for long-term $PM_{10-2.5}$ exposures for a few of the health outcome categories (i.e., mortality, cardiovascular effects, cancer) and causality determinations were made for the first time for long-term $PM_{10-2.5}$ exposures and new health outcome categories in the 2019 ISA (i.e., nervous system and metabolic effects), the EPA agrees with the commenters that there are still extensive uncertainties in the evidence base. It is important to note that a causality determination of "inadequate to infer the presence or absence of a causal relationship" is concluded when:

> "Evidence is inadequate to determine that a causal relationship exists with relevant pollutant exposures. The available studies are of insufficient quantity, quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an effect" (U.S. EPA, 2015).

Therefore, changing to a causality determination of "suggestive of, but not sufficient to infer, a causal relationship" is possible when evidence "is limited, and chance, confounding, and other biases cannot be ruled out" (U.S. EPA, 2015).

Therefore, as described in the 2019 ISA (U.S. EPA, 2019), the conclusion of a "suggestive of, but not sufficient to infer, a causal relationship" reflects both the studies finding evidence of associations between $PM_{10-2.5}$ concentrations and these health effects as well as the continued uncertainties in the available evidence, which in the case for studies of $PM_{10-2.5}$ includes differences in methods used for estimating $PM_{10-2.5}$ concentrations and uncertainty as to how well correlated the $PM_{10-2.5}$ concentrations are both spatially and temporally between the various methods used. The CASAC in their review of the draft ISA, also recognized that "[t]here is typically more uncertainty for health effects estimates caused by exposure to $PM_{10-2.5}$…than for health effects associated with $PM_{2.5}$ (Cox, 2019a p. 6 of consensus responses). Therefore, as detailed in the 2019 ISA, the available evidence, with its inherent uncertainties and limitations, supports "suggestive of, but not sufficient to infer, a causal relationship" between $PM_{10-2.5}$ exposures and health effects (U.S. EPA, 2019). In their review of the 2019 draft PA, some members of the CASAC agreed with the conclusions of

the 2019 ISA that "new studies since the previous review justify the change in causality determination from 'inadequate' to 'suggestive' for long-term exposure to $PM_{10-2.5}$ and mortality and cardiovascular effects, and that the new data strengthen evidence for effects on cancer, and short-term effects on mortality, cardiovascular disease, and respiratory disease," while other members found the definitions of the causality determinations to be unclear and the change to "suggestive" not clearly justified (Cox, 2019a, p. 3 of letter).

The EPA further notes that the causality determinations for $PM_{10-2.5}$-related health effects did not support revising the primary PM_{10} standard in the 2020 final decision or this reconsideration. The 2020 PA and 2022 PA concluded that the currently available evidence does not call into question the adequacy of the current primary PM_{10} standard. In their reviews of the 2019 draft PA and 2021 draft PA, the CASAC agreed with the EPA's conclusion that the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM_{10} standard and that the evidence supports consideration of retaining the standard (Cox, 2019a, p. 3 of letter; Sheppard, 2022, p. 4 of letter). At the time of the proposal, recognizing the limitations in the available evidence, the EPA recognized that there is considerable uncertainty with regard to the public health implications of a revised primary PM_{10} standard (88 FR 5650, January 27, 2023). In considering the body of available scientific evidence, with its inherent uncertainties and limitations as reflected by the "suggestive of, but not sufficient to infer," causal determinations for $PM_{10-2.5}$ exposures and health effects, the Administrator proposed to conclude that there is not adequate evidence to support to consider revisions to the primary PM_{10} standard in this reconsideration (88 FR 5650, January 27, 2023).

(2) **Comment**: A number of commenters who support retaining the current standard assert that the epidemiologic studies of $PM_{10-2.5}$ related health effects are not applicable to all areas of the U.S. due to differences in sources and composition of coarse PM that are influenced by geographical (i.e., urban versus rural) distribution. Commenters contend that studies in the 2019 ISA linking crustal material to negative health effects are flawed because they combine crustal material with other anthropogenic sources of PM. Specifically, they state that studies in the 2009 ISA and 2019 ISA combine the health effects of crustal material with the health effects of other components of PM, including soil, road dust, and traffic-related particulates. Further, commenters assert that some of the studies rely on dust storms rather than studies that examine ordinary ambient air conditions of $PM_{10-2.5}$.

Response: We appreciate the support for the EPA's decision to retain the current standard, although we disagree with the commenters that the studies evaluated in the 2019 ISA are flawed. We note that in evaluating relationships between individual PM components and health, specific criteria were instituted as noted in the Scope of the 2019 ISA (see Section P.3.1), which states: "studies that focus on a single component, group of components, or source, must also examine a composite measure of PM (e.g., mass of $PM_{2.5}$ and/or $PM_{10–2.5}$, or in the case of ultrafine particles [UFP] mass, particle number, etc.). This requirement helps in comparing effects or associations observed for individual components or alternative metrics to the current mass-based PM indicators" (Section P.3.1.). The EPA's evaluation of PM components as summarized in Section 1.5.4 of the 2019 ISA, with an emphasis on evidence from studies of $PM_{2.5}$. This is because, to date, a limited number of studies have

been identified that attempted to examine relationships between $PM_{10-2.5}$ components and health and how those relationships compare to $PM_{10-2.5}$ mass.

Furthermore, the epidemiologic studies considered in the 2019 ISA that demonstrate associations between $PM_{10-2.5}$ exposure and health effects do not provide support for the suggestion that PM from certain geographic origins (i.e., non-urban areas) is not associated with health effects or is associated with different health effects than other geographic areas (i.e., urban areas). Finally, we note that while there are fewer studies of non-urban coarse PM than urban coarse PM, several studies have reported positive and statistically significant associations between coarse particles of crustal, non-urban origin (i.e., studies of Saharan dust) and morbidity (U.S. EPA, 2019, sections 5.3.5, 6.3.5, and 6.3.7). These studies formed part of the basis for the causality determinations for $PM_{10-2.5}$ exposures in the 2019 ISA.

In further considering these comments, we recognize that similar uncertainties and limitations have persisted since the completion of the 2009 ISA. As noted in the 2012 review, epidemiologic studies have not demonstrated that coarse particles of non-urban origin do not cause health effects, and commenters have not provided additional evidence on this point. While there are fewer studies of non-urban coarse particles than of urban coarse particles, as evaluated and described in previous assessments, several studies have reported positive and statistically significant associations between coarse particles of crustal, non-urban origin and mortality or morbidity (Bell et al., 2008; Ostro et al., 2003; Chan et al., 2008; Middleton et al., 2008; Perez et al., 2008). These studies formed part of the basis for the 2009 ISA conclusion that "recent studies have suggested that PM (both $PM_{2.5}$ and $PM_{10-2.5}$) from crustal, soil or road dust sources or PM tracers linked to these sources are associated with cardiovascular effects" (U.S. EPA, 2009, p. 2-26). Moreover, coarse crustal particles may be contaminated with toxic trace elements and other components from previously deposited fine PM from ubiquitous sources such as mobile source engine exhaust, as well as by toxic metals from smelters or other industrial activities, animal waste, or pesticides (U.S. EPA, 2004a, p. 8-344). Limited evidence evaluated in the 2019 ISA further supports conclusions from the 2009 ISA. For all of these reasons, we disagree with the commenters that the studies of $PM_{10-2.5}$-related health effects were flawed.

(3) **Comment:** Some commenters, while recognizing challenges associated with reliably measuring $PM_{10-2.5}$, assert that using PM_{10} as a substitute for $PM_{10-2.5}$ until more data are available on $PM_{10-2.5}$ leads to inconsistencies and is confusing to the public. Further, these commenters assert that the current level of the primary PM_{10} standard is arbitrary, noting that the level was established more than 30 years ago before there were improved methods of analysis while also noting that the 2022 PA concluded that the available scientific evidence does not call into question the adequacy of the current standard based on recent U.S.-based epidemiologic studies. Additionally, the commenters contend that there are several large epidemiologic studies that specifically examine the health effects of PM_{10} and that these studies offer consistent and statistically strong evidence for the health effects of PM_{10}, including mortality, likely because of the high fraction of $PM_{2.5}$ that comprises PM_{10} (i.e., more than 50% in urban areas). These commenters contend that PM_{10} is not a good stand-in for $PM_{10-2.5}$ because they believe that the majority of PM_{10} is made up of the $PM_{2.5}$ fraction, and because of this, retaining the primary 24-hour PM_{10} standard at a level of 150 $\mu g/m^3$, which is four times greater than the primary 24-hour $PM_{2.5}$ standard level of 35 $\mu g/m^3$,

contradicts the available health effects evidence for PM_{10}. These commenters, citing available epidemiologic studies for PM_{10}, recommend that the level of the primary PM_{10} standard be set close to or less than twice the level of the primary $PM_{2.5}$ standard.

Response: As an initial matter, in considering the appropriate indicator, we note that the primary PM_{10} standard is intended to provide public health protection against health effects associated with exposures to $PM_{10-2.5}$. In the 1997 review, the EPA promulgated revisions to the PM NAAQS whereby it was determined that although the standards should continue to focus on protecting against health effects associated with thoracic particles (PM_{10}), the fine and coarse fractions of PM_{10} should be considered separately (62 FR 38666-38668, 38677-38679, July 18, 1997). In that review, new primary 24-hour and annual standards were promulgated, with $PM_{2.5}$ as the indicator for fine particles. The primary 24-hour and annual PM_{10} standards were retained in order to provide public health protection against health effects associated with a coarse fraction of PM_{10} (referred to as thoracic coarse particles or $PM_{10-2.5}$) (62 FR 38666-38668, 38677-38679, July 18, 1997). Since that time, in the PM NAAQS reviews completed in 2006, 2012, and 2020, the then Administrators concluded that the primary 24-hour PM_{10} standard continues to provide public health protection against exposures to $PM_{10-2.5}$ (62 FR 38652, 38662, July 18, 1997; 71 FR 61141, 61148 -61149, October 17, 2006; 85 FR 82725, December 18, 2020). In reaching conclusions in this reconsideration, the Administrator considered the available scientific evidence for $PM_{10-2.5}$-related health effects, including uncertainties and limitations, and concluded that the available information does not call into question the adequacy of the primary PM_{10} standard, nor does the available evidence provide support for an alternative indicator. Furthermore, the Administrator recognized the CASAC's advice in their review of the 2019 draft PA and the 2021 draft PA that the current indicator continued to be appropriate (Cox, 2019a; Sheppard, 2022). In light of this information, the Administrator proposed to conclude that the current primary PM_{10} standard, with its PM_{10} indicator, remains appropriate (85 FR 5558, January 27, 2023).

The commenters also suggest that there are several epidemiologic studies that provide support for PM_{10}-related health effects. We first note that the commenters did not provide the studies that they reference for PM_{10}-related health effects. Therefore, the EPA is unable to consider these studies in responding to the commenters. Next, we further note that the proposal recognized that the PM_{10} size fraction includes both fine ($PM_{2.5}$) and coarse ($PM_{10-2.5}$) particles, even in locations with the highest concentrations of $PM_{10-2.5}$. Because of the variability in the $PM_{10-2.5}$ and $PM_{2.5}$ contributions to PM_{10} in different areas, the extent to which PM_{10} effect estimates in epidemiologic studies reflect associations with $PM_{10-2.5}$ versus $PM_{2.5}$ can be highly uncertain. Additionally, it is often unclear how PM_{10} health studies should be interpreted when considering a standard meant to protect against exposures to $PM_{10-2.5}$. Studies examining the relationship between exposure to PM_{10} and health effects, generally cannot distinguish between whether the health effects are associated with $PM_{10-2.5}$, $PM_{2.5}$, or the total PM_{10} exposures.

Given the uncertainties associated with studies of PM_{10} (versus $PM_{10-2.5}$ or $PM_{2.5}$) exposures and health effects and the availability of a number of $PM_{10-2.5}$ health studies in this reconsideration, the 2019 ISA considered $PM_{10-2.5}$ studies but not PM_{10} studies when drawing weight-of-evidence conclusions regarding the coarse fraction (U.S. EPA, 2019, section

P.3.2.1). Given the uncertainty in attributing the health effects associated with PM_{10} in such studies to either the coarse or fine fractions, the EPA believes that the best evidence for effects associated with exposures to $PM_{10-2.5}$ comes from studies evaluating $PM_{10-2.5}$ itself rather than studies of PM_{10}. This approach, which draws weight-of-evidence conclusions for $PM_{2.5}$ and $PM_{10-2.5}$ but not for PM_{10}, was adopted in the 2009 ISA (U.S. EPA, 2009) and supported by the CASAC during their review of that document (Samet, 2009).The EPA continues to conclude that it is appropriate to focus on $PM_{10-2.5}$ health studies when considering the degree of public health protection provided by the current primary PM_{10} standard, a standard intended exclusively to provide protection against exposures to $PM_{10-2.5}$.

Finally, we disagree with the commenters that the primary 24-hour PM_{10} standard should be set proportionally to the primary 24-hour $PM_{2.5}$ standard. As described in section III.B.4 of the final rule and noted above, the primary PM_{10} standard is intended to protect against health effects associated with exposure to $PM_{10-2.5}$, whereas the primary $PM_{2.5}$ standard is intended to provide protection against $PM_{2.5}$ exposures. In reaching conclusions on the adequacy of these standards, the Administrator considers the public health protection afforded by the standards against the fraction of PM for which the standard is intended to provide protection from. Therefore, the Administrator's decision to retain the current primary PM_{10} standard – including its level of 150 $\mu g/m^3$ – is based on his consideration of the available scientific evidence for $PM_{10-2.5}$-related health effects and is not based on his conclusions regarding the primary $PM_{2.5}$ standard. The Administrator finds that proportionality is not needed to increase protection from $PM_{10-2.5}$exposures because the primary PM_{10} standards continue to provide requisite protection against $PM_{10-2.5}$exposures.

(4) **Comment:** Some commenters who support revising the primary PM_{10} standard state that the EPA needs to properly consider the most recent scientific evidence in reaching decisions regarding the adequacy of the current standard. In so doing, these commenters note that in determining the scope of the 2022 ISA Supplement to support the reconsideration, the EPA did not include an evaluation of scientific evidence of $PM_{10-2.5}$-related health effects published since the literature cutoff date of the 2019 ISA because the evidence at that time did not support a causal relationship. These commenters also cite the CASAC's advice in their review of the 2019 draft PA that there is a "clear progression" in the strength of the evidence, including for mortality, cardiovascular effects, and cancer. These commenters further cite new studies that they assert have demonstrated links between $PM_{10-2.5}$ and respiratory effects, nervous system effects, and reproductive and developmental effects.

Response: The EPA disagrees with commenters that the most recent scientific evidence was not properly considered in reaching conclusions regarding the adequacy of the current primary PM_{10} standard. Furthermore, the EPA did consider scientific evidence of $PM_{10-2.5}$-related health effects published since the literature cutoff date of the 2019 ISA in determining the scope of the ISA Supplement. However, in determining the scope of the ISA Supplement, the EPA focused on health effects for which the evidence supported a "causal relationship" because those were the health effects that were most useful in informing conclusions in the

2020 PA (U.S. EPA, 2020b, section 1.2.1).[16] In reaching this decision on scope, the EPA concluded that it was not appropriate or necessary to include health effects evidence that were unlikely to provide new information that would materially change the conclusions of the 2019 ISA or that would not be useful for the Administrator's decision making. In the case of studies of $PM_{10-2.5}$ health effects, very little new information has become available since the literature cutoff date of the 2019 ISA. The 2019 ISA concluded that "uncertainties in the evidence regarding biological plausibility for health effects related to $PM_{10–2.5}$ exposure and in the methods used to assign $PM_{10-2.5}$ exposure in epidemiologic studies contributed to causality determinations of "suggestive of, but not sufficient to infer," a causal relationship or inadequate to infer the presence or absence of a causal relationship" for health effect categories for both short- and long-term exposure. Because of the extent of these uncertainties, the EPA judged that the body of science had not expanded enough since the cutoff date of the 2019 ISA to alter the conclusions regarding the causal relationships and that much more research is necessary to reach different conclusions. Therefore, the 2022 ISA Supplement did not include studies related to $PM_{10-2.5}$ exposures published since the literature cutoff date of the 2019 ISA.

Further, we note that in the CASAC's review of the 2019 draft PA, they did recognize that more scientific evidence has become available since the 2009 ISA that has supported the upgrading of some causality determinations in the 2019 ISA (Sheppard, 2022, p. 18 of consensus responses). While we agree with the commenters and the CASAC that the body of evidence related to $PM_{10-2.5}$ exposures and health effects has expanded since the 2009 ISA, there are still inherent limitations and uncertainties in the evidence base, as described above, that contributed to causality determinations of "inadequate to infer the presence or absence of a causal relationship" and "suggestive of, but not sufficient to infer a causal relationship" in the 2019 ISA. EPA has taken these causality determinations into account in determining that the current standards are requisite (i.e., neither more stringent or less stringent than necessary) to protect public health with an adequate of safety. However, the EPA does not consider the "progression" of the evidence in and of itself to warrant a more stringent standard at this time. Finally, the EPA has provisionally considered the studies submitted by the commenters in support of revising the current standard. As an initial matter, we note that the studies conducted by Kollath et al. (2022) and Herrera-Molina et al. (2021) are not considered to be within the scope of the ISA, as they do not directly inform our understanding of $PM_{10-2.5}$-related health effects. These two studies examine the health effects associated with PM_{10}, rather than $PM_{10-2.5}$. The study of low birth weight conducted by Enders et al. (2018) was also provisionally considered, and the EPA concluded that this study does not materially change the broad scientific conclusions of the ISA regarding birth

[16] As described in section 1.2.1 of the ISA Supplement: "In considering the public health protection provided by the current primary $PM_{2.5}$ standards, and the protection that could be provided by alternatives, [the U.S. EPA, within the 2020 PM PA] emphasized health outcomes for which the ISA determined that the evidence supports either a '*causal'* or a '*likely to be causal'* relationship with $PM_{2.5}$ exposures" (U.S. EPA, 2020b). Although the 2020 PA initially focused on this broader set of evidence, the basis of the discussion on potential alternative standards primarily focused on health effect categories where the 2019 PM ISA concluded a '*causal relationship*' (i.e., short- and long-term $PM_{2.5}$ exposure and cardiovascular effects and mortality) as reflected in Figures 3-7 and 3-8 of the 2020 PA (U.S. EPA, 2020b)."

outcomes. The 2019 ISA concluded that the evidence was "inadequate" to support a causal relationship between $PM_{10-2.5}$ exposure and birth outcomes, and the Enders et al. (2018) study is insufficient to alter that conclusion or warrant reopening the criteria or revising the standard.

VI. Response to Significant Comments on the Secondary PM Standards

The EPA received relatively few comments on the proposed decision to retain the secondary PM standards. Comments related to retaining or revising the secondary PM standards are addressed in section V.B.3 of the preamble to the final rule. In addition to comments on the standards, some commenters provided additional comments on the scientific evidence and information available in this reconsideration. These comments are addressed below.

(1) **Comment:** One commenter suggested that in reviewing the secondary PM standards that the EPA should take into consideration the impact of PM on ecosystem functions.

Response: The EPA disagrees that the effects of PM on ecosystem functions are within the scope of this reconsideration. The EPA is separately reviewing the ecological effects associated with PM in conjunction with reviews of other pollutants that, along with PM, contribute jointly to atmospheric deposition. As explained in both the 2016 Integrated Review Plan (IRP) for PM (U.S. EPA, 2016, p. 1-17) and the IRP for review of the secondary NAAQS for oxides of nitrogen and oxides of sulfur (U.S. EPA, 2017, p. 1-1), and discussed in the proposal (88 FR 6543, January 27, 2023), oxides of nitrogen, oxides of sulfur, and PM are being reviewed together because they are interrelated through complex chemical and atmospheric processes and because they all contribute to nitrogen (N) and sulfur (S) deposition, which in turn contributes to well-documented ecological effects including reduction in growth and survival of various species, as well as altering species richness, species composition and biodiversity. Addressing the pollutants together enables the EPA to take a comprehensive approach to considering the nature and interactions of the pollutants, which is important for ensuring that all scientific information relevant to ecological effects is thoroughly evaluated.

This combined review of the ecological criteria for oxides of nitrogen, oxides of sulfur, and particulate matter is ongoing. The EPA initiated the review of the secondary standards for oxides of nitrogen, oxides of sulfur, and PM in August 2013 with a call for information in the Federal Register (78 FR 53452, August 29, 2013). The current review of the secondary standards for oxides of nitrogen, oxides of sulfur and PM considers secondary standards for these three pollutants together with regard to protection against adverse ecological effects on public welfare. This review differs from the review completed in 2012 in that the current review includes consideration of the secondary PM standards, in addition to the secondary standards for oxides of nitrogen and sulfur. Given the contribution of nitrogen compounds to PM, including but not limited to those related to oxides of nitrogen, the current review provides for an expanded and more integrated consideration of nitrogen deposition and the current related air quality information. The EPA finalized the IRP for this review in January 2017 and finalized the ISA in October 2020. The EPA also developed a Risk and Exposure Assessment Planning Document in August 2018. The draft PA, including the quantitative analyses for the review, was released in June 2023 (U.S. EPA, 2023; 88 FR 34852, May 31,

2023). This review is on a court ordered deadline, with a proposed decision no later than February 9, 2024, and a final decision no later than December 10, 2024 (87 FR 39821, July 5, 2022). More information about and documents associated with the review of the secondary standards for oxides of nitrogen, oxides of sulfur, and PM are available at: *https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards*.

(2) **Comment:** Some commenters agree with the majority of the CASAC's recommendation in their review of the 2021 draft PA that the EPA develop a Federal Reference Method (FRM) to directly measure light extinction. These commenters assert that continuous $PM_{2.5}$ measurements can support a sub-daily secondary $PM_{2.5}$ standard to address visibility impairment until the methods for measuring light extinction directly are established.

Response: The EPA disagrees that a FRM to directly measure light extinction is appropriate at this time. The 2019 ISA and ISA Supplement includes consideration of some recent research that confirms and adds to the body of knowledge regarding direct measurement of light extinction, no major new developments have been made with these measurement methods since prior reviews (U.S. EPA, 2019, section 13.2.2.2; U.S. EPA, 2022b, section 4.2). The 2019 ISA and ISA Supplement note that measurements of light extinction can be made with high time resolution, allowing for characterization of subdaily temporal patterns of visibility impairment. A number of measurement methods have been used for visibility impairment (e.g., transmissometers, integrating nephelometers, teleradiometers, telephotometers, and photography and photographic modeling), although each of these methods has its own strengths and limitations (U.S. EPA, 2019, Table 13-1). The EPA recognizes the advice of the majority of the CASAC, who suggested that "[a] more extensive technical evaluation of the alternatives for visibility indicators and practical measurement methods (including the necessity for a visibility FRM) is need for future reviews" and that they "recommend[ed] that an FRM for a directly measured $PM_{2.5}$ light extinction indicator be developed" to inform the consideration of the protection afforded by the secondary PM standards against visibility impairment (Sheppard, 2022, p. 22 of consensus responses). We also recognize that the minority of the CASAC "believe that a light extinction FRM is not necessary to set a secondary standard protective of visibility" (Sheppard, 2022, p. 22 of consensus responses). As such, the EPA included the development and implementation of direct monitoring of PM2.5 light extinction as a key area for future research and data gathering in the 2022 PA (U.S. EPA, 2022a, section 5.6). More research and information related to direct measurement of light extinction will help to characterize visibility and the relationships between PM component concentrations and light extinction and to evaluate and refine light extinction calculation algorithms for use in areas near anthropogenic sources, and would provide measurements for future visibility effects assessments.

With regard to the commenters' assertion that a sub-daily secondary $PM_{2.5}$ standard based on continuous $PM_{2.5}$ measurements is supported until such a time that these methods are more fully developed, and a monitoring network is established, we disagree that the currently available information warrants an alternative averaging time. The EPA has responded to comments related to alternative averaging times for the visibility index and the secondary 24-hour $PM_{2.5}$ standard in section V.B.3 of the notice of final rulemaking.

(3) **Comment:** Some commenters suggest that the appropriateness of the target level of protection for the visibility index (i.e., 25 dv versus 30 dv) is dependent on the frequency with which people could experience visible landscape features at further distances (i.e., greater than 40 km) versus closer distances (i.e., 10 km). These commenters argue that individuals find lower levels of visibility impairment to be unacceptable when the landscape features are at further distances. In so doing, these commenters cite to several studies (Schichtel et al., 2016; Stefani et al., 2012; Malm et al., 2019) that examine sight paths or the influence of including clouds in the scenes.

Response: We agree with the commenters that numerous factors influence public preferences related to visibility impairment, including the frequency of viewing landscape features at various distances and the inclusion of clouds in the images being considered. With regard to the citations provided by the commenters, we note that two of these citations (Schichtel et al., 2016; Stefani et al., 2012) are not peer-reviewed publications and, as such, do not meet the criteria for inclusion in the ISA. The Malm et al. (2019) study was included in the 2022 ISA Supplement. Malm et al. (2019) included an evaluation of the same public preference studies that have informed the EPA's conclusions regarding visibility preferences in the 2012 and 2020 reviews, as well as in this reconsideration (Ely et al., 1991; Pryor, 1996; BBC Research & Consulting, 2003; Abt Associates, 2001; Smith and Howell, 2009). As discussed in the proposal, differences between these studies include the variability in the sight paths and changes in meteorologic conditions (i.e., clouds) and these differences can influence preferences regarding visibility impairment (88 FR 5652, January 27, 2023). However, very little new information regarding public preferences has become available beyond those public preference studies, and as such, significant uncertainties remain regarding the variability in public preferences across the studies.

(4) **Comment:** Commenters who support revising the visibility index and the secondary 24-hour $PM_{2.5}$ standard argue that the EPA illegally and arbitrarily relies on uncertainties in the available information and on concerns over overprotectiveness of a more protective standard in reaching its proposed conclusions. These commenters contend that the EPA's concerns about a secondary standard being "overprotective in some areas" ignores the CAA requirement that a secondary standard must "specify a level of air quality the attainment and maintenance of which…is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air." These commenters state that the word "any" is broad sweeping, and that if the EPA identifies an effect that is known or anticipated to be adverse in portions of the country, that effect remains known or anticipated to be adverse even if it may not constitute a known or anticipated adverse effect in other parts of the country, and therefore, the EPA must set the standard to protect against it. These commenters further assert that the EPA's proposal does not mention or rationally explain how its concern about overprotectiveness is consistent with the CAA or the EPA's approach to the primary standards, and that the EPA irrationally fails to consider an under-protective standard. Further, these commenters assert that the EPA's reliance on uncertainties is arbitrary and inconsistent with the CAA. These commenters state that the CAA supports protection through its "preference for preventative…regulation" *Ctr for Biological Diversity v. EPA*, 749 F.3d 1079, 1090 (D.C. Cir. 2014) and that EPA should act not only when it might have "perfect information" or be able to predict adverse effect certainly, but to protect against "anticipated adverse effects," "suggesting that EPA must act

as soon as it has enough information (even if crude) to 'anticipate[]' such effects." *Am. Trucking Ass'ns*, 283 F.3d at 380 (alteration in original); *see Ctr. for Biological Diversity*, 79 F.3d at 1090 & n.18. These commenters further contend that EPA cannot "merely recite the terms 'substantial uncertainty' as a justification for its actions." *State Farm*, 463 U.S. at 52; *Murray Energy*, 936 F.3d at 619. The commenters note that, in past reviews, the CASAC and public commenters have provided suggestions for reducing uncertainty. Moreover, the commenters contend that the EPA has provided no reason for why it should resolve the uncertainties and limitations in favor of less protection rather than more.

Response: In reaching his final decision regarding the secondary PM standards, the Administrator recognizes that the assessment of when visibility impairment is adverse to public welfare requires a public welfare policy judgment informed by available scientific and quantitative information. In exercising his judgment to reach that decision, the Administrator finds it important to take into consideration the uncertainties in the evidence. With respect to visibility impairment, those uncertainties include significant uncertainties and variability in the scientific evidence and quantitative analyses. With regard to the scientific evidence, the Administrator specifically takes note of the variations in the available public preference studies, not only in terms of the methods and/or images used in conducted those studies, but also in the preferences of visibility impairment themselves. Some studies, such as the Phoenix, AZ, study, presented less noisy public preference results than other studies, but considering how to judge what is considered adverse to public welfare based on all of the public preference studies together is still bound by uncertainties that have not been addressed with additional research in recent years. Moreover, the Administrator recognizes that, while the relationship between PM and light extinction is well established, there is significant variability associated with estimating light extinction in different geographic areas of the U.S. and based on the version of the IMPROVE equation that is used. As detailed in section V.B.3 of the notice of final rulemaking, factors such as PM composition, size fraction, and age of the particles in ambient air, as well as relative humidity, can vary across geographical areas, and differences in these factors can influence the estimates of light extinction in areas differently. Moreover, the Administrator recognizes that these factors, along with the age of the PM in ambient air, can also complicate estimating light extinction because there is not necessarily a clear distinction regarding which IMPROVE equation is most appropriate in certain areas of the U.S. compared to others.

The Administrator finds it appropriate to take these uncertainties into consideration in reaching his decisions, but he also agrees that it is often necessary to set NAAQS on the frontiers of scientific knowledge and without perfect information. The Administrator has provided his rationale for his decision based on the record for this reconsideration and disagrees that his consideration of uncertainties in the evidence as part of his consideration of that evidence is arbitrary or capricious or that the revised secondary standards provide insufficient protection against known or anticipated adverse effects on public welfare.

(5) **Comment:** The EPA also received a number of comments related to the secondary PM standards that were not directly related to the adequacy of the current secondary PM standards. These comments included recommendations for future research and data collection efforts that could address data gaps and uncertainties to inform future reviews.

Response: The EPA agrees with many of the suggestions from the commenters and notes that the 2022 PA highlighted key uncertainties and data gaps associated with reviewing and establishing secondary PM NAAQS and also areas for future welfare-related research and data gathering (U.S. EPA, 2022a, section 5.6). We encourage research in these areas, although we note that research planning and priority setting are beyond the scope of this action.

(6) **Comment**: One commenter asserted that the EPA must consult under Section 7(a)(2) of the Endangered Species Act ("ESA") with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service when reviewing and revising the PM NAAQS.

The commenter claims that without consultation, the EPA cannot ensure that any final standard is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of critical habitat and further states that Section 7 "consultation" is required for "any action [that] may affect listed species or critical habitat." The commenter asserts that agency "action" is broadly defined in the ESA's implementing regulations at 50 CFR 402.02 to include:

> "all activities …of any kind …carried out, in whole or in part, by Federal agencies in the United State[sic] …. Examples include, but are not limited to: … (b) the promulgation of regulations; … or (d) actions directly or indirectly causing modifications to the land, water, or air."

The commenter also notes that ESA regulations at 50 CFR 402.03 provide that section 7 applies to all actions in which there is discretionary Federal involvement or control and asserts that the EPA has discretion to consider impacts to listed species in its review of both the primary and secondary NAAQS. With respect to the secondary NAAQS, the commenter argues that the protection of listed species and critical habitat is required in reviewing the secondary NAAQS designed to protect the "public welfare" which is defined to include effects on soil, water, crops, vegetation, animals, wildlife, weather, visibility, and climate. The commenter claims that that the protection of listed species and critical habitat is required in reviewing the primary NAAQS designed to protect the public health because the health and vigor of human societies and the integrity and wildness of the natural environment are closely linked, and many people suffer significant long-term stress from species going extinct and their critical habitat being adversely modified. These commenters also contend that the EPA failed to discuss listed threatened or endangered species and habitats that would be affected by the PM NAAQS and its relationship to climate change.

The commenter also notes that listed species and their critical habitat may be useful to human health as a source of medicine, and that, following ESA consultation, the EPA can exercise its discretion in reviewing and revising the primary PM NAAQS by considering what standards would save species that could lead to drug developments that would improve human health. They further contend that this argument allows for the primary PM NAAQS to consider impacts to listed species and their critical habitat. The commenter further notes that the 2019 ISA failed to consider the transportation of antibiotics and antibiotic resistant bacteria through the environment via PM, and cite to several studies that provide evidence of effects to a number of bee species.

Moreover, the commenter asserts that in past reviews, the EPA has justified its failure to consult by claiming that a final decision not to revise a NAAQS would mean that it is not an agency action under ESA section 7. They claim that this justification does not apply in this reconsideration, given that the EPA is proposing to revise the primary annual $PM_{2.5}$ NAAQS. Furthermore, the commenter notes that this is a proposed rulemaking, and the EPA has not made a final decision regarding revisions to other PM NAAQS, and any predetermined final decisions prior to reviewing public comments would be illegal. Finally, the commenters argue that the EPA's justification for not engaging in consultation when retaining or not changing a standard "would lead to absurd results," in that revising a standard to a lower level would result in more protection for listed species and critical habitat would require consultation, whereas an unchanged standard would offer less protection but would not require consultation.

The commenter notes animal toxicological studies in the 2019 PM ISA and the 2022 PM ISA Supplement regarding the concept that PM affects lung growth in mice and that the EPA should extrapolate that study to other species in the same family or order, including listed rodent species. Similarly, the commenter further argues that animal toxicological studies in the 2019 PM ISA and the 2022 PM ISA Supplement also provide support for nervous system effects in rodents.

Response: Even assuming that the ESA consultation requirement could apply to a decision to revise the NAAQS, the EPA does not agree that leaving the secondary NAAQS unaltered triggers the requirement to consult under the ESA. Leaving the secondary NAAQS unchanged does not authorize or carry out any "action" under the statutory terms of the ESA.[17] Both the Code of Federal Regulations and the status quo regarding secondary NAAQS are entirely undisturbed. Moreover, leaving the secondary NAAQS unaltered will not require the EPA to make new air quality designations, nor will it require states or authorized tribes to undertake new planning or control efforts or to change air quality for the secondary NAAQS. Similarly, even if the EPA's review decision on the secondary PM NAAQS were found to be an "action" for ESA purposes, the EPA's decision to leave the secondary PM NAAQS unaltered causes no change to the status quo for air quality and regulatory requirements, and thus has no effect on species or their habitat. The EPA disagrees with the commenter that because this decision is contained within a notice that is described as a proposed rule that the decision thereby becomes an action subject to ESA section 7(a)(2) consultation. Likewise, the EPA disagrees that it is absurd that ESA consultation requirements could apply to the process of revising a NAAQS but not to unchanged NAAQS—that simply reflects both the requirements of the ESA and the basic distinction between action and inaction.

Further, even if the ESA consultation requirement could apply, as a general matter, to the EPA's review of a secondary NAAQS, the ESA would not apply to this reconsideration as regards ecological welfare effects because the EPA's review of the secondary PM NAAQS has been bifurcated, and ecological effects of PM deposition, including effects on species and habitats, are not a part of this review, and that EPA is taking no action in this reconsideration

[17] Section 7(a)(2) of the ESA only applies to "action authorized, funded, or carried out" by a federal agency.

regarding such effects. Rather, this review addresses non-ecological welfare effects, including climate. The ecological effects of PM deposition are beyond the scope of this review. As explained in both the PM IRP (U.S. EPA, 2016) and the NO_X/SO_X/PM IRP (U.S. EPA, 2017) and discussed in the preamble to the proposed rule, in recognition of the linkages between oxides of nitrogen, oxides of sulfur, and PM with respect to atmospheric chemistry and deposition, and with respect to ecological effects, the reviews of the ecological effects evidence and the secondary standards for these pollutants are being conducted together. Addressing the pollutants together enables the EPA to take a comprehensive look at the nature and interactions of the pollutants, which is important for ensuring that all scientific information relevant to ecological effects is thoroughly evaluated. Conducting the PM NAAQS review in two separate phases is eminently reasonable and supported by considerations of atmospheric science.

With respect to climate effects, the EPA agrees that potential effects of PM on climate are within the scope of this reconsideration. However, after a comprehensive review of the science, consultation with the CASAC, and consideration of public comment, the EPA concludes that the effects of PM on climate are diverse and uncertain. Depending on the circumstances, the radiative forcing effects of PM in the atmosphere can vary, such that positive forcing could result in warming of the Earth's surface, whereas a negative forcing could result in cooling (U.S. EPA, 2019, section 13.3.2.2). Moreover, there is not an adequate scientific basis to link attainment of any particular PM concentration in ambient air in the U.S. to specific climate effects. As a result, EPA concludes that it is not possible to set a secondary PM NAAQS to address climate effects at this time because there is insufficient scientific information to make a reasoned judgment identifying a standard that is requisite to protect against adverse effects of climate. As noted above and in the preamble, this conclusion was supported by the CASAC and is not contradicted by anything in the public comments.

In light of these limitations in currently available scientific information, the EPA is unable to identify for consideration any secondary PM standard to address climate effects that would be consistent with the requirements of the CAA., In these circumstances, the CAA does not provide the EPA authority to select a secondary PM standard to address climate effects. The EPA was not faced with a question of how to exercise its discretion when choosing from among a range of possible standards. Rather, any standard the Administrator selected to address PM-related climate effects would have been in conflict with the requirements of the Clean Air Act. In these circumstances, any consultation with the Services would have been similarly futile. The EPA also notes that the same scientific limitations make it impossible to assess with reasonable certainty any potential climate-related effects on listed species or critical habitat of a revised secondary PM standard, even if the EPA were able to select such a standard (which it cannot) under the CAA. Accordingly, the EPA had no obligation to consult under the ESA and properly declined to revise the secondary PM NAAQS to address climate effects.

Finally, the EPA does not believe it is necessary or appropriate to consider PM impacts on species and habitats as part of this reconsideration of the primary NAAQS. To the extent the commenter is suggesting the primary standard should be set to protect species and habitats, the EPA believes that would be inconsistent with the text and structure of the Clean Air Act.

Section 109 of the CAA requires the EPA to establish primary standards to protect public health (see section 109(b)(1)) and secondary standards to protect public welfare (see section 109(b)(2)). Under Section 109(b)(1) and *Whitman v. Am. Trucking Associations*, 531 U.S. 457 (2001), the EPA sets primary standards that are requisite to protect public health, allowing an adequate margin of safety. The EPA does not have discretion to set a different primary standard than the one the Administrator judges is required under Section 109(b)(1)) to protect public health in order to protect species and habitats. Rather, even assuming the ESA consultation requirement could apply to a decision to revise the NAAQS, these impacts on species and habitats should be evaluated in reviewing the secondary NAAQS, insofar as such evaluation is needed. As the commenter notes, the definition of effects on welfare in CAA section 302 clearly encompasses effects on animals and vegetation. Thus, any evaluation of these PM effects on species and habitats would be done in the context of setting and reviewing the secondary standard.

Similarly, to the extent the commenter is arguing that effects on species also have effects on people, e.g., because the commenter knows of people who place great value on the continued existence of species, the EPA finds those effects would fall within the scope of the review of the secondary standard. In considering the public welfare protection provided by the secondary NAAQS, the Administrator considers the potential for welfare effects to occur and the associated public welfare implications of those effects. In assessing public welfare implications, the Administrator considers the value placed by the public on the welfare effects that are being evaluated. The commenters' assertion that there are people who place great value on the continued existence of a particular species would, therefore, be most relevant in assessing public interest in such an effect and fall within the scope of the review of the secondary standard. Furthermore, the EPA would be unable to consider how effects on species can affect people without assessing the effects on species, which is done as part of the secondary review. Similarly, the possibility that protecting plants or wildlife would benefit people by reducing the prevalence of disease or supplying future medicines would be considerations in setting a secondary standard to provide requisite protection for plants and wildlife and ecosystem services. Thus, any such indirect effects on people are beyond the scope of this reconsideration. In addition, the EPA finds that, even if such effects were within the scope of this reconsideration, the EPA lacks sufficient information in the air quality criteria to base a standard on these effects. The commenter has not submitted published studies that might support consideration of effects on people, such as long-term stress, attributable to the effects on species, nor has the CASAC provided advice in this area.

VII. Response to Significant Comments Related to Communication of Public Health

The final rule for PM revises 40 CFR 58.50 Appendix G with respect to specific breakpoints for the $PM_{2.5}$ Air Quality Index (AQI) and AQI reporting requirements and recommendations. In addition to responses contained in section IV of the preamble to the final rule, the EPA provides the following responses to specific comments related to the AQI sub-index for $PM_{2.5}$ and AQI reporting requirements and recommendations.

A. Comments on Proposed Revisions to the $PM_{2.5}$ AQI Breakpoints

1. Comments on Proposed Revisions to the $PM_{2.5}$ AQI 50, 100, 150 Breakpoints

(1) **Comment:** Some commenters urged the EPA not to revise the 50 breakpoint of the AQI, even if the annual standard was revised, for programmatic reasons. Some state and local programs and policy decisions may be tied to the daily AQI breakpoint levels, and so the commenters argued that revising the 50 breakpoint of the AQI could create issues for decisions, such as crop residue burning and use of prescribed fire, that use a combination of concentration data and AQI values. Some commenters also argued that the proposed change in the AQI scale could result in more approved burning in the moderate category instead of the good category.

In supporting this, a few commenters noted that their ability to use prescribed fire could be inhibited since their permitting entities use the 50 breakpoint of the AQI to determine their permit eligibility. Therefore, if the annual primary $PM_{2.5}$ standard were lowered the 50 breakpoint of the AQI would also be lowered, reducing the opportunities for prescribed fire. In contrast, other commenters noted that revising the AQI breakpoints would not impact their prescribed fire planning because they use $PM_{2.5}$ concentrations and not AQI values.

Response: While the EPA recognizes that the AQI may be used in a variety of ways by other government agencies, the AQI was developed by the EPA to provide general information to the public about air quality and its relationship to public health. As noted in the August 4, 1999, rulemaking (64 FR 149, 42531) that established the current AQI, and in the proposed reconsideration (88 FR 5558, January 27, 2023), the EPA established the nationally uniform air quality index, called the Pollutant Standards Index (PSI), in 1976 to meet the communication needs of state and local agencies. Such information from the AQI can help the members of public learn when their health may be affected, so they can take actions to avoid or to reduce exposures to ambient pollution at concentrations of concern. The AQI is also used to encourage the public to take actions that will reduce air pollution on days when concentrations are projected to be of concern.

While other government agencies may decide to employ the AQI to make decisions on how to reduce public exposure to air pollution, the use of the AQI in these programs is determined by these agencies and not the EPA. In light of EPA's decision to revise the AQI, these agencies may determine it is appropriate to make changes in how they use the AQI in making certain decisions, such as tracking how the changes in the AQI affect their prescribed fire programs and deciding whether to use concentration-based approaches for purposes of their prescribed fire programs.

(2) **Comment**: A few commenters contended it is inappropriate to propose revisions to the 50 breakpoints of the AQI based on a proposed range for the primary $PM_{2.5}$ annual standard because there is not a discrete concentration to review for comment, but multiple possibilities making it difficult to review them all.

Response: The EPA disagrees with this comment. Proposing a range is common practice in NAAQS proposals to allow the Agency to better identify for the public the options under consideration, and potential associated rationales. EPA proposed a relatively narrow range for the annual standard and solicited comment on a wider range and does not consider that either range was so extensive as to make it difficult, much less impossible, for commenters to provide views on the proper breakpoints for the AQI.

2. Comments on Proposed Revisions to the $PM_{2.5}$ AQI 200 and Above Breakpoints

(1) **Comment**: A few commenters suggested the EPA should eliminate the usage of "beyond the index" when AQI values goes above 500 because it is confusing, and the health messaging does not change. Instead, the EPA should eliminate the ceiling for the Hazardous category or if preferred could add an "extremely hazardous" category. In doing this, the EPA should also adjust the AQI calculator and NowCast to account for this.

Response: The EPA agrees that "beyond the index" can be confusing and has been working outside this rulemaking to adjust AQI materials and public health information to continue the Hazardous category above the AQI breakpoint of 500 and remove the term "beyond the index." The EPA will continue to use the 500 breakpoint of the AQI, as noted in Appendix G, to calculate the AQI values in the hazardous category (AQI values above 300), with AQI values above 500 based on the same linear slope as the AQI values between 301 and 500.

3. Other Comments Related to Proposed Revisions to the $PM_{2.5}$ AQI

(1) **Comment:** Some commenters contended that while revisions to the AQI based on new scientific knowledge may or may not be needed, if the EPA proceeds with revisions to the AQI, it should inform the public that air quality overall is not declining, since it is not. The commenters note that the proposed changes could give the impression to the public that air quality is declining and so the EPA should ensure it communicates that air quality is not declining. One of the commenters suggested the EPA could address this issue is several ways including "identifying additional breakpoints," increasing the concentrations for breakpoints, or adjusting the category language to "more clearly convey the risk."

Response: Since the establishment of the AQI, the EPA and state and local air agencies and organizations have developed experience in educating the public about changes in the standards and, concurrently, related changes to AQI breakpoints and advisories. When the standards change, EPA and state and local agencies have tried to help the public understand that air quality is not getting worse, it's that the health evidence underlying the standards and the AQI has changed. EPA's Air Quality System (AQS), the primary repository for air quality monitoring data, is also adjusted to reflect the revised breakpoints. Specifically, all historical AQI values in AQS are recomputed with the revised breakpoints, so that all data queries and reports downstream of AQS will show appropriate trends in AQI values over time.

(2) **Comment:** A few commenters suggested that more significant changes would make the AQI more useful. Commenters expressed the view that the AQI has been underprioritized, and a separate rulemaking is needed to more fully address the tool and protect public health. In particular, they noted that the EPA should reassess the $PM_{2.5}$ AQI breakpoints given the critical use of the AQI in clinical settings, and recommended the EPA initiate a new and separate rulemaking process to more fully address revisions to the breakpoints and the associated health messaging. Some commenters noted they could only provide initial feedback on the proposed revisions to the 200, 300 and 500 breakpoints without also re-evaluating the accompanying health messaging.

Some commenters suggested the EPA should consider the usefulness of a multipollutant index, which may more clearly communicate air quality and more strongly protect public health than a single pollutant index. These commenters expressed the view that the AQI does not give an "accurate" representation of the overall air quality as a single pollutant index. Some of these commenters also suggested the EPA should consider additional indicators of $PM_{2.5}$ for the $PM_{2.5}$ AQI, such as black carbon, lung deposition and particle number concentration, as well considering health effects from exposure to "local combustion process, such as traffic," which would give a more detailed characterization of air quality to the public. One of these commenters further advised the EPA to include cumulative exposure in all categories and create a seventh category to better account for potential cumulative exposure at lower concentrations. This commenter also suggested updating the AQI category colors to account for people with vision deficiencies as has been piloted in the AirNow Fire and Smoke Map.

Response: The EPA appreciates the recognition of the AQI's importance to the public and the general support for revising the AQI breakpoints. At this time, the EPA is focused on revising the $PM_{2.5}$ AQI breakpoints.

As stated in the proposal (88 FR 5558, January 27, 2023), in 1976, the EPA established a nationally uniform air quality index, then called the Pollutant Standard Index (PSI), for use by State and local agencies per Sec. 319 of the Clean Air Act (CAA, 41 FR 37660, September 7, 1976; 52 FR 24634, July 1,1987). In August 1999, the EPA adopted revisions to this air quality index (64 FR 42530, August 4, 1999) and renamed the index the AQI.

The AQI establishes a nationally uniform system of indexing pollution concentrations for ozone, carbon monoxide, nitrogen dioxide, PM, and sulfur dioxide. Across these pollutants, the AQI index value of 100 typically corresponds to the level of the short-term (e.g., 24-hour, 8-hour, or 1-hour standard) NAAQS for each pollutant. Below an index value of 100, an intermediate value of 50 is defined either as the level of the annual standard if an annual standard has been established (e.g., $PM_{2.5}$, nitrogen dioxide), a concentration equal to one-half the value of the 24-hour standard used to define an index value of 100 (e.g., carbon monoxide), or a concentration based directly on health effects evidence (e.g., ozone). An AQI value greater than 100 means that a pollutant is in one of the unhealthy categories (i.e., unhealthy for sensitive groups, unhealthy, very unhealthy, or hazardous). An AQI value at or below 100 means that a pollutant concentration is in one of the satisfactory categories (i.e., moderate or good). The scientific evidence on pollutant-related health effects for each pollutant is evaluated in the pollutant-specific ISA, which forms the scientific basis of each NAAQS review. Where possible, the information presented in an ISA supports decisions related to pollutant concentrations at which to set the various AQI breakpoints, which delineate the AQI categories for each individual pollutant (i.e., the pollutant concentrations corresponding to index values of 150, 200, 300, and 500). The AQI identifies the pollutant with the highest index value for the day as the pollutant of concern and recommends at least reporting that value as the AQI for the day. However, index values for other pollutants are also calculated. Both ozone and $PM_{2.5}$ index values are commonly reported and easily available to the public, e.g., through EPA's AirNow program. The EPA does not find the available health information and air quality measurements support considering a different approach for reporting air quality, such as a multipollutant index or cumulative risk.

The EPA disagrees with the commenters assertion that a multipollutant index would more clearly communicate air quality conditions to the public. The EPA sets a uniform AQI for ozone, carbon monoxide, nitrogen dioxide, PM, and sulfur dioxide as noted in 42 U.S. Code § 7619 of the CAA. The scientific basis for the NAAQS that also informs the AQI is presented in the ISA. Within each ISA the focus is on assessing the criteria pollutant-health effects relationship. This information is ultimately used in determining the adequacy of the current NAAQS and generally used to set the 50 and 100 breakpoints of the AQI as mentioned above. Additional information in the ISA is then often used to inform the establishment of breakpoints above 100, which indicates when air quality starts to become unhealthy, and to identify those lifestages (e.g., children, older adults) and populations that may be at greater risk of experiencing a health effect in response to a criteria pollutant exposure. The identification of lifestages and populations at increased risk of experiencing health effects helps inform responses to the questions "Am I at risk? Should I take action to reduce my exposure?" The ISA also identifies health effects, including symptoms, that can occur from being exposed to a criteria pollutant. This information allows AQI advisories to provide an accurate list of potential symptoms to help people know when they may be affected by a pollutant and thus when to reduce exposure. Information from studies evaluated in the ISA examining dosimetry as well as studies that characterize criteria pollutant exposures, and specifically the relationship between indoor and outdoor exposures to ambient concentrations, can help inform recommendations on exposure reduction measures for each pollutant in AQI advisories. For these reasons, the EPA considers the individual pollutant format of the AQI the best supported and most effective approach to communicating air quality conditions and risks to the public, and it is consistent with the regulatory language of the CAA.

With respect to the commenter's contention that the EPA should use multiple different indicators for the PM AQI, the EPA disagrees with this assertion as it is not supported by the current scientific evidence detailed in the 2019 ISA (U.S. EPA, 2019). As part of the review of the latest scientific evidence to support the PM NAAQS review, the Agency assessed whether individual PM components or sources were more strongly associated with health effects than $PM_{2.5}$ mass. In that assessment the EPA concluded: "Overall, recent studies continue to demonstrate that many $PM_{2.5}$ components and sources are associated with health effects ranging from subclinical (e.g., changes in heart function, such as HRV, or circulating biomarkers) to the more overt (i.e., ED visits, hospital admissions, and mortality). The results of these studies confirm and further support the conclusion of the 2009 PM ISA that many $PM_{2.5}$ components and sources are associated with many health effects and that the evidence does not indicate that any one source or component is consistently more strongly related with health effects than $PM_{2.5}$ mass. (Section 1.5.4, 2019 ISA)" (U.S. EPA, 2019). The EPA concludes that there is insufficient scientific evidence to support the use of alternative indicators of $PM_{2.5}$ to communicate the AQI.

For similar reasons, the EPA does not agree with the commenters that suggest accounting for cumulative exposure in the AQI categories. The comment points to a single study which suggests that hospital admissions occur even when the AQI is "good." However, the Administrator has judged the current primary standards inadequate to protect public health with an adequate margin of safety and the AQI is being revised accordingly, so this study provides limited, if any, support for the conclusion that the structure of the AQI is

inadequate, nor do the commenters provide any suggestions for how cumulative risk should be represented in the AQI. As stated above, the EPA's judgment is that there is insufficient scientific evidence to support a multiple pollutant exposure index or an index that would account for cumulative exposures.

With regard to the commenter's suggestion to use colors that are more easily discernable by people who have problems seeing colors, the EPA appreciates this suggestion and as noted by the commenter has been piloting this color scale (Color Vision Assist) as a supplemental option on the AirNow Fire and Smoke map. The EPA plans to continue assessing this pilot and to consider if and how it could be used in other AQI products.

B. Comments on Proposed Revisions to AQI Reporting Requirements

(1) **Comment**: Some commenters supported the EPA's proposed revision to recommend, but not require, near real-time reporting of the AQI and hourly air quality data submission. These commenters noted this revision would better inform the public about their air quality. Of these commenters, a few encouraged the EPA to make this proposed revision a requirement given the need for real-time information and "lack of downsides." Other commenters agreed with the EPA that it should be a recommendation and not a requirement.

A few commenters sought clarification on this proposed revision and whether the "future analogous systems" is the EPA's Air Quality System (AQS). If so, these commenters would oppose the recommendation to submit hourly data because of quality assurance and quality control issues.

Response: The EPA agrees with recommending but not requiring real-time AQI reporting and hourly air quality data submission to continue communication of air quality to the public. While some commenters did not see "downsides" with requiring this reporting, the EPA agrees with the many air agencies that preferred this to be a recommendation and not a requirement. The current AirNow system started in 1998 as the Ozone Mapping System. Initially only agencies on the east coast participated, but over time the system has grown to encompass the entire U.S. The program has always been structured as a voluntary, opt-in for state, Tribal and local air agencies, and has been very successful with that approach. Thus, EPA believes it is appropriate to maintain the current structure and its collaborative approach with state, Tribal and local air agencies, as well as to allow flexibility in reporting requirements. Also as discussed in the proposal (88 FR 5558, January 27, 2023), many state, Tribal and local air agencies already take these actions, meaning this recommendation aligns with current practices and there would be little benefit to making it a requirement. In response to the "future analogous system" question, the EPA intentionally used general terminology since this revision is codified and, given rapid technology change, the general term enables flexibility depending on technology needs and availability.

(2) **Comment**: Some commenters encouraged the EPA to work more closely with the Tribal Air Monitoring Support Center (TAMS) steering committee to ensure Tribal data is appropriately used for the AQI while respecting Tribal data sovereignty.

Response: The EPA appreciates this comment and will continue to work with Tribal partners such as the TAMS steering committee to ensure Tribal data sovereignty is respected while utilizing Tribal air quality data for the AQI.

VIII. Response to Significant Comments Related to Proposed Amendments to Ambient Monitoring and Quality Assurance Requirements

The final rule for PM revises several technical areas found in 40 CFR parts 50 (appendix L), 53, and 58 (appendices A, B, C, D, and E). In addition to responses contained in section VII of the preamble to the final rule, the EPA provides the following responses to specific comments related to the ambient monitoring and quality assurance requirements.

A. Comments on proposed Amendments to Ambient Monitoring and Quality Assurance Requirements

The EPA received several comments on the proposed changes to monitoring requirements in the Proposed Changes to 40 CFR part 58, appendix A - Ambient Air Quality Surveillance, and appendix B - Quality Assurance Requirements for Prevention of Significant Deterioration (PSD). The EPA's responses to comments that provide guidance and interpretation to the rule changes for revising appendices A and B are provided in section VII.C.1 and VII.C.2 of the preamble to the final rule. The remaining responses to the comments on the revisions to appendices A and B not addressed there are addressed below.

(1) **Comment:** A commenter stated that it was problematic to keep the same number of eight required audits ($PM_{2.5}$ Performance Evaluation Program) for large primary quality assurance organizations, especially when reaudits are often not possible for cases when the samples are rendered "invalid" due their low levels. The commenter also questioned the justification of the valid sample totals in general.

Response: There was no proposal in this rulemaking to modify the $PM_{2.5}$ Performance Evaluation Program audit frequency. The minimum value required by appendix A, section 3.2.4, to be considered valid sample pairs for the $PM_{2.5}$ Performance Evaluation Program (PEP) was changed from 3 $\mu g/m^3$ to 2 $\mu g/m^3$ in this rulemaking. This change should increase the number of valid samples at the existing required frequency. The EPA appreciates the comment, and notes that updates to the program frequency may be considered at a future time.

(2) **Comment:** A commenter indicated that while they agreed with many of the proposals, they are not applicable to the $PM_{2.5}$ rulemaking. Furthermore, they indicated that the EPA should continue the practice of making more general proposals in each of its proposed rule changes but identify these other changes in future proposals.

Response: The EPA appreciates the commenter supporting the practice of making more general proposals in rulemaking. The EPA did describe in detail the changes and justification for each of these in the preamble to the proposal.

(3) **Comment:** In section VII.C.2 of the preamble describing the proposed changes to Part 58, Appendix B, Quality Assurance Requirements for Prevention of Significant Deterioration

(PSD) Air Monitoring, the EPA erroneously referenced Appendix A in the proposal descriptions that followed.

Response: The EPA agrees that the references in section VII.C.2 should have referenced Appendix B. The EPA believes it is apparent that appendix B should have been referenced in this section given the notice of proposed rulemaking's Table of Contents, the proposed regulatory text, and the introductory language in section VII.C.2. Moreover, the proposed changes to appendix B mirrored those proposed to appendix A, a fact expressly recognized by two of the two commenters who submitted comments on this portion of the proposal, apparently without noticing the inadvertent error in section VII.C.2. Both commenters asked the EPA to apply their comments on the appendix A proposed changes equally to appendix B, with one commenter stating, "comments above related to Appendix A should also apply to Appendix B where U.S. EPA is mirroring the language."

B. Comments on Proposed Revisions to Amendments to PM Ambient Air Quality Methodology

The EPA received comments on the proposed changes to 40 CFR part 58, appendix C – Ambient Air Quality Monitoring Methodology. The EPA's responses to comments that provide guidance and interpretation to the rule changes for revising appendices C is provided in section VII.C.3 of the preamble to the final rule. The remaining responses to the comments on the revisions to appendices C not addressed there are addressed below.

(1) **Comment:** One commenter pointed out that while regulatory-grade FRM data should form the foundation for FEM adjustments, many monitoring sites collect hourly data from various types of collocated FEMs, such as T640x, BAMs, TEOMs, but lack a robust FRM dataset to compare with.

Response: Performance criteria for approval of PM FRMs and FEMs are based on 24-hour data. Because the shortest time-period used in a NAAQS for any PM standard is based on 24 hours of data, the EPA believes that setting the performance criteria of the methods on a 24-hour basis is most appropriate.

(2) **Comment:** EPA received a comment that the proposed changes to the Class III equivalent methods for PM_{10} should include an alternate inlet for the PM_{10} FEM in areas that have not experienced concentrations close to the NAAQS in five years.

Response: The EPA disagrees that an alternative PM_{10} inlet should be allowed at this time in such circumstances. Utilizing the standard EPA-approved PM_{10} inlet head ensures that a consistent fractionation of PM aerosol will occur regardless of the ambient concentration, and independent of ambient wind speed and direction.

(3) **Comment:** A commenter suggested that the EPA should require FEM field comparability tests in the northwest (for example, in EPA Region 10) in areas where particulate derived from biomass predominates to ensure that certified instruments will perform reliably in areas influenced by these sources. A related comment asked that FEM determinations be required to include a representative test location that adequately compares the candidate device to the Federal Reference Method (FRM) in an area with significant levels of biomass particulate.

Response: The EPA notes that it did not propose any new test locations for field testing of candidate $PM_{2.5}$ FEMs. Also, while additional testing of FEMs may have merit—especially with regard to specific aerosols such as biomass (i.e., organic carbon)—any new requirements for testing would presumably only apply to new candidate methods and they would not address the nearly 900 $PM_{2.5}$ FEMs already deployed. Also, there are approved PM FEMs that work very well with high ratios of organic carbon and these methods were approved under the existing test specifications for Class III $PM_{2.5}$ FEMs (§ 53.35). Finally, the EPA is concerned that additional field testing could be considered a barrier for instrument companies to pursue designation when developing and pursuing new PM FEMs.

(4) **Comment:** A regional correction factor potentially could improve instrument accuracy to biomass sources that are a large component of PM in many Alaskan communities.

Response: For the reasons stated in the preamble of the final rule, the EPA is not pursuing local or regional correction factors. Also, as mentioned in the response above, there are already approved PM FEMs that work very well in areas with high ratios of organic carbon, and these methods were approved under the existing test specifications for Class III $PM_{2.5}$ FEMs (§ 53.35).

(5) **Comment:** Several commenters support allowing correction factors established by states using FRM monitor data to be applied to all $PM_{2.5}$ data obtained from co-located continuous FEM monitors, especially any and all data used for attainment demonstration. Related to this, another commenter identified that to ensure higher quality corrections are attained, the EPA must allow agencies the ability to locally correct their own data.

Response: As explained in the preamble of the final rule, the EPA is finalizing its proposal that valid State, local, and Tribal (SLT) air monitoring data from Federal Reference Methods (FRMs) generated in routine networks and submitted to the EPA may be used to improve the PM concentration measurement performance of approved FEMs. The EPA considered the comments recommending local and regional calibration of data, but due to negative comments from agencies not wanting to reinstall PM FRMs due to minimal staff resources and other reasons explained in the preamble, the EPA is not acting on the recommendations to allow regional and / or local calibration of data.

(6) **Comment:** One commenter suggested that it makes sense to keep the data submitted prior to the approval of a factory calibration "as is" unless there would be benefits to adjusting earlier data to either January 1st of the year in which the application was approved or to the beginning of the date range for the new calibration.

Response: In the preamble to the final rule, the EPA addresses reporting of data. Also, in the preamble to the final rule, the EPA identified that prior and future monitoring data and how it will be used in the implementation of this NAAQS, such as for designations, and for air quality regulatory programs is outside the scope of this rulemaking and will therefore be addressed by the EPA in a subsequent relevant action or actions.

(7) **Comment:** Another commenter identified that the EPA must allow for the use of either corrected FEM data or, in the case of collocated FRM and FEMs and the absence of a correction factor, the use of FRM data to make any attainment designation.

Response: In the preamble to the final rule, the EPA addresses reporting of data. Also, in the preamble to the final rule, the EPA identified that prior and future monitoring data and how it will be used in the implementation of this NAAQS, such as for designations, and for air quality regulatory programs is outside the scope of this rulemaking and will therefore be addressed by the EPA in a subsequent relevant action or actions. With regard to only using FRM data if FEM data are not adjusted, the EPA points out that the rules for combining data from FRMs and FEMs which are explained in Appendix N to part 50 would still apply.

(8) **Comment:** One commenter stated that no area should be designated nonattainment for the new $PM_{2.5}$ standard by an FEM if there are data from an FRM at the same site that contradicts that designation.

Response: The EPA provides the following responses to the several points made by this commenter. First, it is the monitoring agency that selects the method to be used in its annual monitoring network plan under 40 CFR § 58.10. Second, the quality of the data is based on the method used across the network of the primary quality assurance organization. Third, each year, the head official in each monitoring agency, or his or her designee, must certify that the previous year of ambient concentration and quality assurance data are completely submitted to AQS and that the ambient concentration data are accurate to the best of her or his knowledge, taking into consideration the quality assurance findings per 48 CFR § 58.15. And fourth, monitoring agencies can consider setting aside $PM_{2.5}$ FEM data in situations where FEMs that are collocated with FRMs do not meet sufficient comparability as described in 40 CFR part 53, subpart C, table C–4, leading the monitoring agency to request that the FEM data should not be used in comparison to the NAAQS per 40 CFR § 58.11. In considering all of these regulatory pieces, agencies can, on a limited basis, set aside $PM_{2.5}$ FEM data; however, for cases where the $PM_{2.5}$ FEM data quality is meeting the criteria cited in 40 CFR § 58.11, such data cannot be set aside.

(9) **Comment:** One commenter had a concern that agencies and tribes may not be able to opt out of the firmware updates if their analyses indicate that their instruments perform better prior to the update.

Response: The EPA addressed a related question in the preamble to the final rule. While the EPA expects in most cases that monitoring agencies will produce data with improved data quality following factory calibration, agencies that demonstrate the original method calibration provides better data quality—especially to meet the bias measurement quality objectives—they may opt out of the method update, so long as the original method designation remains valid.

(10) **Comment:** One commenter supports any action that results in the most accurate data possible for comparison against the NAAQS, ensuring that attainment designations and clean data determinations will be based on sound information.

Response: The EPA is finalizing its proposal that valid State, local, and Tribal (SLT) air monitoring data from Federal Reference Methods (FRMs) generated in routine networks and submitted to the EPA may be used to improve the PM concentration measurement performance of approved FEMs. The EPA believes this is an important step towards ensuring more sites meet the bias MQOs with automated PM FEMs.

(11) **Comment:** One commenter stated that comparing data from various types of collocated FEMs offers a unique opportunity to examine biases during different hours/times of the day and on a continuous basis, which is not possible using FRM datasets.

Response: The EPA concurs that the more PM FEMs operated, the more likely we can examine additional types of data such as diurnal variation not available when only PM FRMs are operated on a daily basis.

(12) **Comment:** One commenter suggests that the EPA should consider provisions that would allow correction factors to be developed in a way that accounts for outside factors such as differences in climate by allowing for the development of correction factors on a site-by-site basis when a FRM is co-located with the FEM and allows for a correction factor from a climatically similar site when there is no collocated FRM.

Response: With regard to the suggestion to allow correction factors to be developed in a way that accounts for outside factors such as differences in climate, entities seeking a correction may pursue such factors so long as any potential change can be demonstrated to work successfully across the full network in which it is used. The issue of an allowance for site-by-site correction factors is addressed in the preamble to the final rule.

(13) **Comment:** One commenter identified that alternative approaches, such as allowing operating agencies to make site-by-site adjustments, could be perceived as subjective and be difficult to manage, calling data quality into question.

Response: The EPA did not propose site-by-site site calibrations of data. However, the EPA did take comment on alternatives that could lead to more sites meeting the bias measurement quality objectives. The EPA is not finalizing any provisions related to site-by-site calibration of data but acknowledges the concern that such adjustments could be perceived as "subjective" and "difficult to manage" which could call data quality into question.

(14) **Comment:** One commenter strongly urges the EPA to allow correction factors to be applied on a site- or region-specific basis and apply the factor retroactively to FEM data for the dates used for the NAAQS design value determination to ensure a representative analysis.

Response: The EPA addresses the comments supporting site- or region-specific basis correction factors in the preamble to the final rule. Also, in the preamble to the final rule, the EPA identified that prior and future monitoring data and how it will be used in the implementation of this NAAQS, such as for designations, and for air quality regulatory programs is outside the scope of this rulemaking and will therefore be addressed by the EPA in a subsequent relevant action or actions.

(15) **Comment:** One commenter stated that further studies are warranted to account for correction factors, topography, regional variability, and manufacturers' standards.

Response: The EPA believes that in finalizing its new approach to calibration of PM FEMs, we will be able to take advantage of the large dataset already provided across the country in routine networks from SLT agencies. Therefore, while new studies are informative, there exists sufficient data from the operating network to support calibration and verification for any new factory calibration of a PM FEM.

(16) **Comment:** One commenter asked the EPA to approve and accept only these calculations (i.e., the data resulting from application of the calibration calculations) as submitted (i.e., by the State).

Response: The EPA does not believe it would be appropriate to have SLT agencies report only the result of the calibration calculations. Therefore, in the preamble to the final rule, the EPA states that monitoring agencies should continue to report PM FEM data as measured (i.e., they shall not correct data before reporting it).

(17) **Comment:** One commenter stated that because the states are required to rely fully on these method designations in choosing which instruments to utilize, and the EPA's designation of a biased instrument could not have been foreseen by states, the burden should not now fall to the states to provide justification on a case-by-case basis for these corrections.

Response: As explained in the preamble to the final rule, the EPA did not propose and is not finalizing any requirement that PM FEMs be calibrated on a site-by-site or regional basis.

(18) **Comment:** One commenter identified that to keep the light scattering in FEM within 10% of the FRM, the EPA should allow for customized linear regression calibrations. The commenter fully supports this proposed change, and encourages EPA to allow regionally specific calibrations, not just a single nationwide calibration from the instrument manufacturer.

Response: The EPA proposed and is finalizing its proposed action to allow valid SLT air monitoring data from PM FRMs and FEMs generated in routine networks and submitted to the EPA to update factory calibrations included as part of approved FEMs on a national basis. The EPA did not propose local or regional calibration of data and is not finalizing any requirement that PM FEMs be calibrated on a site-by-site or regional basis.

(19) **Comment:** One commenter recommends that manufacturers review FEM and FRM data closely on a regional basis, as the chemical composition of $PM_{2.5}$ can vary across regions, and therefore the bias that FEM instruments may introduce could vary as well. It would also be prudent for equipment manufacturers to review collocated FEM/FRM data on a regular basis to ensure whether correction factors should be updated.

Response: As discussed in the preamble to the final rule, the EPA notes that while it does not have the authority to require instrument companies to evaluate the quality of data from operating FEMs under 40 CFR part 58, EPA does routinely participate in conferences and workshops and makes assessments of data quality specific to instrument makes and models

publicly available. EPA also regularly summarizes relevant FRM and FEM data quality in documents such as the 2022 PA (U.S. EPA, 2022a).

(20) **Comment:** One commenter stated that the CASAC recommended that equivalency box criteria used in assessing FEM performance needs to have more stringent standards. The commenter agrees and further adds that until a gold standard FEM is created, much like what was done with FRM years ago, all FEM's will need to align very closely with the FRM.

Response: The CASAC offered multiple options on ways to improve FEM performance in its review of the 2021 draft PA (Sheppard, 2022). One option focused on calibrations, which is what is being finalized in this action on a national basis. The other was on the cited revision of the equivalency box. Revisions to the equivalency criteria won't improve the existing inventory of approximately 900 operating $PM_{2.5}$ FEM, since these methods are already deployed. However, it is also important to note that many of these operating $PM_{2.5}$ FEMs are already meeting measurement quality objectives, and more are expected to do so with the recently available method updated from one of the more prominently used PM FEMs.

(21) **Comment:** One commenter identified that State and local agencies have raised concerns about PM monitoring method comparability, an issue that needs to be evaluated in consideration of this proposal due to potential impacts on attainment recommendations and designations.

Response: With this final rule, the EPA is addressing PM method comparability by finalizing our proposal that valid State, local, and Tribal (SLT) air monitoring data from FRMs generated in routine networks and submitted to the EPA may be used to improve the PM concentration measurement performance of approved FEMs.

C. Comments on Proposed Revisions to $PM_{2.5}$ Monitoring Network Design Criteria to address At-Risk Communities

The EPA received comments on the proposed changes to 40 CFR part 58, appendix D – Network Design Criteria for Ambient Air Quality Monitoring. The EPA's responses to comments that provide guidance and interpretation to the rule changes for revising appendices D are provided in section VII.C.4 of the preamble to the final rule. The remaining responses to the comments on the revisions to appendices D not addressed there are addressed below.

(1) **Comment:** One commenter requested additional time for comment to review network and monitoring requirements.

Response: The EPA believes it has provided sufficient time with respect to notice and comment on the proposal and declines to extend the comment period for this action.

(2) **Comment:** One commenter raised concerns with the Greeley Hospital monitor in Weld County, CO, and local sources.

Response: The comment is outside the scope of the proposal.

(3) **Comment:** One commenter stated that the Environment Justice inclusions need to be applied to all PM standards.

Response: Specific to ambient air monitoring of $PM_{2.5}$, the EPA addressed Environmental Justice in the PM NAAQS proposal (88 FR 5673–76, January 27, 2023). For PM_{10} ambient air monitoring, while the EPA did not propose changes to the PM_{10} standard, monitoring agencies are free to consider environmental justice considerations in their PM_{10} networks in line with this final action. Additionally, as explained in the preamble to the final rule, because many PM_{10} and $PM_{2.5}$ sites are already collocated, the EPA believes that many of the existing $PM_{2.5}$ sites are already in at-risk communities, meaning that many existing PM_{10} sites may also already be in at-risk communities.

(4) **Comment:** One commenter stated that stronger annual and daily limits for $PM_{2.5}$ pollution must be accompanied by robust air quality monitoring techniques and technologies in order for the environmental justice potential of this regulation to be reached. While the proposed standards include various positive steps toward increasing the capacity of the monitoring system—such as incorporating an "environmental justice factor" in its design— there is a lack of concrete actionables to improve this network, which remains inadequate in accounting for environmental justice concerns on the ground. The commenter asked the EPA to expand the EJ factor to ensure the accuracy of monitoring technology in overburdened communities.

Response: The EPA believes that by finalizing its proposal, valid State, local, and Tribal (SLT) air monitoring data from FRMs generated in routine networks and submitted to the EPA may be used to improve the PM concentration measurement performance of approved FEMs, and that this will improve the monitoring methods used across the network, including for use in EJ communities.

(5) **Comment:** One commenter stated that the national system of air quality monitors provides a piecemeal and inaccurate accounting of air quality regulation breaches, allowing for source noncompliance and disproportionately affecting environmental justice communities. In addition to the improvement of the current monitoring network, the EPA should recognize the value of community-led monitoring as an invaluable scientific tool and promote the scientific data brought forth by the impacted communities to the level of regulatory data.

Response: The EPA believes that its long-standing network design criterion that there be at least one monitor in each CBSA required to have monitors in the area of expected maximum concentration ensures that all communities are protected, since if we protect the community with the high concentrations with the NAAQS, we protect all other communities in the same metropolitan statistical area with the NAAQS. With regard to the value of community-led monitoring, the EPA believes that data produced by any method should be utilized with a "fit for purpose" scope, so that the quality of the data produced is appropriate for the use of that data. At this time, the EPA does not agree with the commenter that data collected by non-FEM and -FRM methods, such as sensors, is appropriate for regulatory use.

(6) **Comment:** One commenter brought up a local mining issue that is not being caught on regulatory monitors, but sensors are showing very large concentrations.

Response: The comment is outside the scope of the proposal, although the EPA notes that a mining source-related issue is likely related to coarse particle emissions than rather than fine particle ones, and with this action, EPA is not addressing PM_{10} monitoring requirements.

(7) **Comment:** One commenter believes that there is a lack of adequate monitoring in New Mexico, additional point source monitoring needed there, and there are legislative and funding concerns in the state.

Response: The comment is outside the scope of the proposal. However, the EPA's action requires that any new or moved minimally required $PM_{2.5}$ sites are to represent "area-wide" air quality, since these sites have the most utility in being applicable to both the annual and 24-hour $PM_{2.5}$ NAAQS. This applies to monitoring in New Mexico.

(8) **Comment:** One commenter brought up unmonitored communities near coal mining in Illinois.

Response: The comment is outside the scope of the proposal. Also, it is possible that a mining issue is more directly related to coarse particle considerations than to fine particle ones. The EPA notes it did not propose to make any changes in PM_{10} monitoring requirements which includes coarse particles.

(9) **Comment:** One commenter provided comments that even within areas of similar economic, minority, and ethnic composition, there are large discrepancies in the spatial distribution of pollution, such that people can experience dramatically different levels within the same monitoring district. Severe hot spots of pollution can be completely missed by state monitoring networks. For example, a household downwind of a neighbor burning wood for heat during the winter can experience Beijing, China, levels of pollution, while an upwind neighbor can enjoy clean air. Studies from California show that within a single square kilometer of a residential area, concentrations of wood smoke can vary as much as 2,500 times. The highest measured concentrations were up to 100 times higher than the community average. Similar distribution discrepancies are in play within neighborhoods adjacent to freeways or near industrial facilities.

Response: The EPA has seen no evidence that any part of a community is 100 times higher than the community average of the same community for the time period (24-hours daily or 3-year annual average) of the $PM_{2.5}$ NAAQS. The commenter may be citing examples of very short durations; however, the scientific evidence of exposures is translated into averaging times associated with the $PM_{2.5}$ NAAQS, which in its shortest duration is 24 hours.

(10) **Comment:** One commenter stated they believe the proposal for at-risk community monitoring may conflict with the EPA's 1997 Network Design guidance.

Response: While no specific citations demonstrating the proposal for at-risk community monitoring may conflict with the EPA's 1997 Network Design guidance were provided, the EPA points out that if it did, a regulation would supersede any previously issued guidance.

(11) **Comment:** One commenter stated that the EPA should retain its current population-based analysis for network assessments.

Response: The EPA did not propose, nor is it finalizing any changes to its population-based requirements for monitoring in CBSA's that also factor in the relative design value of the MSA. See Table D-5 of Appendix D to Part 58 – $PM_{2.5}$ Minimum Monitoring Requirements. Therefore, these population-based requirements will remain a part of network assessments.

(12) **Comment:** One commenter stated that if this requirement (in reference to proposal to modify $PM_{2.5}$ monitoring network design criteria to include an environmental justice (EJ) factor) is implemented, the EPA should clarify that the requirement is for MSAs greater than 1 million people.

Response: As explained in the preamble to the final rule, the revised network design criteria apply to any case where at least one additional site is required but not already covered as required to meet another network design criteria. This will most often be for cases over 1 million, but in certain cases may also apply to cases in MSA's with populations between 500,000 and 1,000,000 where the most recent 3-year design value is >=85% of any $PM_{2.5}$ NAAQS. Also, as explained in the preamble, for various reasons the EPA believes that it is in the best interest of the network for sites to remain in existing locations and thus this requirement would only apply to new sites or in cases where a site needs to move.

(13) **Comment:** One commenter stated that they support efforts to monitor in at-risk communities if siting criteria can be met and there is accommodation for adjacent existing sites.

Response: The EPA notes the support for the proposal. With regard to meeting siting criteria and accommodations for adjacent existing sites, any site whether existing or new would need to meet siting criteria or a waiver may be sought according to the rules in Appendix E to 40 CFR Part 58.

(14) **Comment:** One commenter stated that the proposed changes to monitoring requirements should be better supported and that the EPA should fully evaluate the impact of the proposal to locate monitors in at-risk communities (e.g., will the proposal to include monitors in at-risk communities be beneficial).

Response: The EPA believes the proposal provided sufficient support for the proposed changes to the monitoring requirements (88 FR 5673–76, January 27, 2023). The EPA notes the largest share of commenters on the proposal were supportive of the proposed changes to monitoring. With respect to fully evaluating the impact of the proposal to locate monitors in at-risk communities, as explained in the preamble to the final rule, the scientific evidence evaluated in the 2019 ISA (U.S., EPA, 2019) and ISA Supplement (U.S. EPA, 2022) indicates that subpopulations at potentially greater risk from $PM_{2.5}$ exposures include: children, lower socioeconomic status (SES) populations, minority populations (particularly Black populations), and people with certain preexisting diseases (particularly cardiovascular disease and asthma). With much of the $PM_{2.5}$ ambient air data coming from the very sites that are already operational in State, local, and tribal routine networks, the EPA believes that it has sufficient information that these sites are already beneficial.

(15) **Comment:** One commenter stated that there is inadequate network coverage: with most monitors in urban areas, gaps in network in rural areas impacting permit applicants.

Response: The EPA believes that it would be impractical to have a site everywhere; however, as explained in the preamble to the final rule, we do have requirements for $PM_{2.5}$ monitors in rural areas. Specifically, the EPA requires each state to measure regional background and regional transport (40 CFR part 58, appendix D, section 4.7.3). These required sites at the state level are largely located in rural areas and may include use of IMPROVE samplers or continuous $PM_{2.5}$ monitors. While these requirements for monitoring in rural areas are minimums, monitoring agencies have the discretion to operate more monitors than the minimums.

(16) **Comment:** One commenter stated that the agency ought to expand its own air quality monitoring infrastructure to better quantify PM levels in non-attainment zones.

Response: While the comment does not address the proposal, the EPA notes the comment with a goal to better quantify PM levels in non-attainment zones.

(17) **Comment:** All public schools should have public WIFI monitors for PM_{10} and $PM_{2.5}$ and PM, ozone and HCHO.

Response: While the comment does not address the proposal, the EPA notes the comment with a goal to better quantify PM, ozone, and HCHO levels in schools.

(18) **Comment:** One commenter stated that our wood smoke-polluted air is virtually unmonitored and in practice completely unregulated. We also badly need a more robust monitoring network. There is one regulatory $PM_{2.5}$ monitor in our entire geographically large county. One regulatory monitor in a geographically large and diverse county like ours is simply nowhere near adequate and does not protect the public.

Response: The EPA notes that while the comment does not address the proposal and that there are other opportunities to monitor beyond the existing regulatory network, some of these options were discussed in the Next Generation Data portion of the proposal preamble (88 FR 5678–80, January 27, 2023).

(19) **Comment:** One commenter requested to please expand air quality monitoring to better tally the true costs of soot pollution nationwide.

Response: The EPA notes that while the comment does not address the proposal, there are other opportunities to monitor beyond the existing regulatory network. Some of these options were discussed in the Next Generation Data portion of the proposal preamble (88 FR 5678–80, January 27, 2023).

(20) **Comment:** One commenter asked if the EPA could assist interested states in deploying speciation monitors at scale to resolve the difficulty of connecting beneficial fire to exceedances of the $PM_{2.5}$ standard.

Response: The EPA notes that while the comment does not address the proposal, there is an existing network of chemical speciation samplers known as the chemical section network (CSN). The CSN has both long term-sites as well as sites that can be associated with special projects and studies. Interested State, local, or tribal monitoring programs may pursue additional sites for the CSN as needed by contacting their EPA Regional office.

(21) **Comment:** One commenter stated that the EPA should require states to work with impacted communities and other stakeholders in network design evaluation.

Response: The EPA has an existing requirement that monitoring agencies subject to § 58.10 - Annual monitoring network plan and periodic network assessment - are to provide that annual monitoring network plans must be made available for public inspection and comment for at least 30 days prior to submission to the EPA and the final submitted plan shall include and address, as appropriate, any received comments. The EPA did not propose to change this part of the monitoring requirements.

(22) **Comment:** One commenter requested that the U.S. EPA provide additional clarity on the interpretation of footnote 4 in 40 CFR part 58, Appendix D, Table D-5. The footnotes states "These minimum monitoring requirements apply in the absence of a design value" with respect only to column 2 which addresses the number of monitors required in areas with design values <85% of the NAAQS. This would imply that U.S. EPA interprets the lack of meeting data completeness requirements (and therefore having an invalid design value) to presume the design value would be <85% of the NAAQS, regardless of what the available data shows. Therefore, fewer monitors could be required in such an MSA.

Response: Application of the lower required number of monitors per 40 CFR part 58, Appendix D, Table D-5 would only apply in the absence of any $PM_{2.5}$ design value for the history of the CBSA. Should the most current design value be incomplete such that a valid design value cannot be calculated, then apply the most recent valid design value.

(23) **Comment:** One commenter specified that the EPA stated its intent to amend § 58.12 by revising paragraphs (d)(1) and (3). The commenter notes that changes to Section 58.12 paragraph (d)(3) are missing from the proposal (88 FR 5704, January 27, 2023). The commenter recommends that the EPA review the stated intent and add the necessary amendment or remove the intent. The commenter also recommends that the EPA allow agencies an opportunity to review these changes and provide comment prior to finalizing them.

Response: The EPA did not intend to amend the language in paragraph (d)(3) of § 58.12 and is not finalizing any changes to this paragraph.

(24) **Comment:** One commenter stated that the current proposed deadline (for planning and implementing any newly required sites) should incorporate at least two years after adoption to formulate a site selection and plan development through the annual network plan, and then an additional two years after plan approval to deploy, given the timelines to procure sites and instruments.

Response: A discussion of the promulgated timeline for planning and implementing any newly required sites is discussed in the preamble to the final rule.

(25) **Comment:** One commenter offered a clarification that "The plan shall provide for any newly required sites to be operational no later than 24 months from date of approval of a plan or January 1, 2027, whichever comes first. Existing sites that necessitate relocation to meet this requirement shall be relocated at the time circumstances arise that require relocation."

Response: The EPA concurs that sites necessitating movement due to lost leases, construction, or related issues would need to be on their own timeline that would happen "…at the time circumstances arise that require relocation." For example, this would be true for a currently operating site where the lease is lost in 2025 or 2026. While monitoring agencies would need to expediently find a new suitable location, it may be on a timeline that takes more time than the EPA finalized with respect to cases where we know a new site is needed or a site needs to move at the time of the final rule becoming effective.

(26) **Comment:** One commenter stated that they need more monitors, and we need them to be placed in locations where they can record emissions in residential areas. The largest pollution source in many communities does not come from industry or traffic; it comes from wood stoves and fireplaces, but our current monitoring network does not reflect this.

Response: The EPA did not propose to add new sites beyond those required associated with the revised annual $PM_{2.5}$ NAAQS described in section II of the final rule as they pertain to the minimum requirements associated with Table D–5 of Appendix D to Part 58—$PM_{2.5}$ Minimum Monitoring Requirements. As explained in the preamble, the EPA did consider comments on the need to include additional localized sources such as communities with wood stoves.

D. Comments on Proposed Revisions to Probe and Monitoring Path Siting Criteria

The EPA received few comments on the proposed changes to monitoring requirements in Appendix E—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring (88 FR 5676-78). The EPA's responses to comments that are instructive and provide guidance and interpretation to the rule changes for revising Appendix E are provided in section VII.C.5 of the preamble to the final rule. Most of the comments received are addressed in the preamble. The remaining responses to the comments on the revisions to Appendix E are addressed below.

(1) **Comment:** A commenter stated that it can take years to secure a suitable site that meets the rigorous siting criteria in 40 CFR part 58, Appendix E. As such, the proposal's timelines for finding a suitable site, obtaining site approval from the EPA, and having the site fully installed with equipment and operating are problematic.

Response: While the EPA agrees that establishing a new site can be difficult and requires detailed planning, the EPA disagrees with the commenter that the proposed action's timelines are problematic. The intent of EPA's proposed revision to Appendix E was to communicate existing requirements more clearly and to correct a few existing unintended and conflicting regulatory requirements. Very few new requirements were proposed. As such, the EPA does

not anticipate the establishment of many new sites based on this action because a preponderance of the NAAQS sites already meet the regulatory requirements.

(2) **Comment:** A commenter stated that they support the EPA's proposed action to expand the list of acceptable probe materials for sampling reactive gases (88 FR 5678, January 27, 2023). The commenter suggested that the EPA also consider a similar regulatory change to allow additional materials for VOC monitoring.

Response: The EPA appreciates the comment and agrees that additional materials for sampling VOCs would be very advantageous. However, at the time of the proposal and rulemaking, the EPA did not have studies to support the request to expand the list of acceptable probe materials for sampling reactive gases beyond the list of NAAQS pollutants provided in the proposal.

(3) **Comment:** One commenter did not provide any objections to the proposed action but noted that the proposed amendments to 40 CFR part 58, Appendix E, Tables E-1, E-2, and E-3 to require that distance measurements will be rounded to retain at least two significant figures (88 FR 5676, January 27, 2023) also referenced a table that did not exist in the current regulation. The commenter noted that in the current regulations there is no Table E-3.

Response: The EPA acknowledges the commenter is correct and acknowledges the inaccuracy in the proposed action and the inadvertent misnumbering of the tables in the regulation that was current at the time of the proposed revisions. The EPA meant to state that the rounding convention would apply to the proposed tables E-1 – E-6 instead of the current regulation.

IX. Responses to Significant Comments on Implementation

A. Comments on Attainment Planning

(1) **Comment:** The EPA received comments on various topics related to attainment planning for nonattainment areas. For example, commenters suggested that the EPA revise the $PM_{2.5}$ State Implementation Plan (SIP) Requirements Rule (81 FR 58010, August 24, 2016); provide additional implementation guidance; and develop additional federal measures to help reduce emissions, among other comments.

Response: As stated in the NPRM, comments regarding implementation, including attainment planning, are outside the scope of this rulemaking, which is revising the PM NAAQS. The EPA acknowledges that many implementation-related comments were received and emphasizes that interested parties look to the $PM_{2.5}$ SIP Requirements Rule for guidance on implementation planning. In some instances, the comments regarded costs associated with implementation of the NAAQS. The EPA notes that under CAA Section 109(b)(1), the EPA is barred from considering costs in setting the NAAQS level. *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001). The $PM_{2.5}$ SIP Requirements Rule was developed in such a way that it would apply to nonattainment areas for any $PM_{2.5}$ NAAQS that are revised in the future. To assist with implementation of the final revised $PM_{2.5}$ NAAQS, the EPA intends to provide a webinar for state, Tribal, and local air agencies, and other interested parties, following issuance of the final NAAQS, that reviews the

provisions of the $PM_{2.5}$ SIP Requirements Rule. The EPA intends to engage with state, Tribal, and local air agencies throughout the implementation process to assist in their development of approvable attainment plans.

(2) **Comment:** The EPA received a few comments requesting that we allow, in addition to EJ Screen, other EJ-related tools for attainment planning analysis.

Response: The EPA encourages air agencies to take EJ into consideration as they develop SIP submissions for the new $PM_{2.5}$ NAAQS. The EPA recognizes that tools similar to EJ Screen exist and may be beneficial for attainment planning purposes. The EPA recommends that air agencies consider the EJ-related guidance included in the SIP Requirements Rule, Section XI "Environmental Justice Considerations," (81 FR 58010, August 24, 2016), and utilize any appropriate tools to help provide a robust analysis. We note that the recently released Climate & Economic Justice Screening Tool (CEJST) also may be useful when developing an EJ analysis for attainment plans. The CEJST can be found at: *https://screeningtool.geoplatform.gov/en/*

B. Comments on Initial Area Designations

(1) **Comment:** The EPA received comments on various topics related to initial area designations including but not limited to the proposed schedule, monitoring, consideration of background concentrations, international emissions, and emissions from prescribed fires and wildfires in the designations process.

Response: As stated in the NPRM, comments regarding initial area designations following promulgation of a new or revised NAAQS are outside the scope of this rulemaking, which is only revising the primary annual $PM_{2.5}$ standard for the NAAQS. As relevant and appropriate, the EPA expects to consider these comments as we develop the Initial Area Designations for the 2023 Revised Primary Annual Fine Particle National Ambient Air Quality Standard Memorandum (the "Annual $PM_{2.5}$ NAAQS Designations Memorandum"). In particular, the EPA acknowledges specific information on which commenters requested additional information and/or support in the context of designations. The EPA anticipates that the Annual $PM_{2.5}$ NAAQS Designations Memorandum will cover topics identified in the comments including certain aspects of the timing of submission of exceptional events demonstrations. As noted in the proposed rule, the EPA plans to release this memorandum around the time of promulgation of the revised PM NAAQS.

C. Comments related to Exceptional Events

(1) **Comment:** The EPA received multiple comments raising a broad array of issues related to the exceptional events program, including requests for additional guidance or rules to inform the exceptional events process, questions regarding the schedule for submitting exceptional events initial notifications and demonstrations, and suggestions for streamlining the process for air agencies' preparation and the EPA's review of exceptional events demonstrations, in an effort to reduce time and resources spent by air agencies on the exceptional events process.

Response: As stated in the NPRM, comments regarding implementation, which include comments related to exceptional events matters, are outside the scope of this rulemaking. The EPA acknowledges the wide array of comments regarding the exceptional events program, including specific information about how exceptional events issues may impact timing for designations and other implementation considerations.

(2) **Comment:** Some commenters suggested that, given that the frequency and magnitude of wildfires have increased, the EPA streamline the exceptional events process in the following ways: allow a single demonstration for a range of dates regardless of whether those dates are consecutive; allow multi-agency or regional demonstrations; and allow the exclusion of concentrations affecting the annual standard.

Response: As stated in the NPRM, comments regarding implementation, which include comments regarding the Exceptional Events Rule, are outside the scope of this rulemaking. For clarification purposes, exceptional events demonstrations for multiple dates, multi-jurisdictional events, and concentrations affecting the annual standard are all permitted under the Exceptional Events Rule. The EPA will consider any exceptional event demonstration that has regulatory significance for the revised standard during the designations process, so long as the demonstration is submitted in the timeframe consistent with the exceptional events schedule for initial area designations, found at 40 CFR 50.14(c)(2)(vi). Additional resources regarding the Exceptional Events Rule, including best practices for multi-jurisdictional demonstrations, the Exceptional Events Frequently Asked Questions (FAQ) document, and example demonstrations, can be found at *https://www.epa.gov/air-quality-analysis/treatment-air-quality-data-influenced-exceptional-events-homepage-exceptional*.

(3) **Comment:** Some commenters stated that wildfires should no longer be considered exceptional events due to their increased frequency in recent years.

Response: As stated in the NPRM, comments regarding implementation, including comments related to the Exceptional Events Rule, are outside the scope of this rulemaking. For clarification purposes, CAA Section 319(b)(1)(A) defines an 'exceptional' event as an event that "(i) affects air quality; (ii) is not reasonably controllable or preventable; (iii) is an event caused by human activity that is unlikely to recur at a particular location or a natural event; and (iv) is determined by the Administrator through the process established in the regulations promulgated under paragraph (2) to be an exceptional event." The increased frequency of a natural event does not necessarily preclude the event from meeting this definition for the purposes of the Exceptional Events Rule. See *https://www.epa.gov/air-quality-analysis/treatment-air-quality-data-influenced-exceptional-events-homepage-exceptional* for more information on the Exceptional Events Rule.

(4) **Comment:** Several commenters expressed concerns that a revised NAAQS could inhibit prescribed burning. Some commenters expressed concern that state and local air agencies will issue burn bans and limit permitting of prescribed fires because of the potential that a prescribed burn will cause an exceedance or violation of the NAAQS. Further, commenters suggest that the Exceptional Events Rule discourages air agencies from issuing burn permits due to the resources required to prepare and submit an exceptional event demonstration were the burn to cause a regulatorily significant exceedance or violation of a NAAQS.

Commenters recommend the EPA provide additional resources or flexibilities for prescribed fires under the Exceptional Events Rule. Some commenters recommended the EPA consider some form of exemption for prescribed fires, such as removing the need for exceptional event demonstrations for prescribed fires.

Response: The EPA acknowledges the commenters' concerns regarding implementation of the Exceptional Events Rule. As stated in the NPRM, comments regarding the Exceptional Events Rule are outside the scope of this rulemaking.

D. Comments on New Source Review (NSR) Permitting

(1) **Comment:** Several commenters expressed concern that the narrowing difference between an area's baseline ambient concentration and the NAAQS will prevent new project construction and/or plant expansions because companies will be unable to meet NSR preconstruction permitting requirements. These commenters state that the EPA's proposal to reduce the $PM_{2.5}$ NAAQS to a level close to measured ambient backgrounds in many areas is likely to halt new industrial projects and expansions. These commenters state that the required emission offsets are scarce and expensive, likely making it cost prohibitive to site a new facility or expand an existing one in a nonattainment area. Commenters also indicated that obtaining Prevention of Significant Deterioration (PSD) offsets is prohibitively expensive. One commenter added that this may also implicate minor source permitting. These commenters stated that projects that go forward may be forced to obtain expensive emissions offsets or would fail if those offsets are not available. Commenters provided examples of projects, especially power generation projects such as the installation of simple cycle combustion turbine (CT) natural gas units and reciprocating engines, that will be implicated by the revised NAAQS.

Response: As stated in the NPRM, comments regarding implementation are outside the scope of this rulemaking. For clarification purposes regarding permitting obligations that will become requirements upon the effective date of this rule, the EPA is providing the following information. The EPA is cognizant that the revised annual $PM_{2.5}$ NAAQS will result in new permitting analyses for new sources and major modifications of existing sources as of the effective date. As a general matter, these additional analyses and issues have existed for prior NAAQS revisions. The EPA has previously responded to many of the issues raised, indicating that sources can offset emissions increases to allow for expansion in the event that little room exists between an area's baseline ambient concentration and the revised NAAQS. *See, e.g.,* 44 FR 3274, 3278, January 16, 1979; See also *In re Interpower of New York, Inc.,* 5 E.A.D. 130, 141 (EAB 1994) (describing an EPA Region 2 PSD permit that relied in part on offsets to demonstrate the source would not cause or contribute to a violation of the NAAQS). 52 FR 24634, 24684, July 1, 1987; 78 FR 3085, 3261-62, Jan. 15, 2013. The EPA recognizes the ability of sources to obtain offsets in the context of PSD though the PSD provisions of the Act do not expressly reference offsets as the NNSR provisions of the Act do. *See* 80 FR 65292, 65441, October 26, 2015. The EPA is aware that offsets, either in the context of the required air quality impact demonstration under the PSD program or as required under the NNSR program, may be expensive and/or difficult to obtain as commenters note. Additionally, under CAA Section 109(b)(1), the EPA is barred from

considering costs in setting the NAAQS level. *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001).

(2) **Comment:** Several commenters (including industry groups and two states) recommend that, to avoid significant challenges to PSD permitting for $PM_{2.5}$ and to address the 2019 court decision that does not allow grandfathering provisions, the EPA should consider establishing an effective date for a new primary annual $PM_{2.5}$ NAAQS later than the traditional 60 days after Federal Register publication. These commenters suggest that the EPA consider establishing an effective date of either one or two years after the final rule is published in the Federal Register. Another commenter adds that a two-year effective date for any revised NAAQS: (1) would be consistent with the policies underlying Executive Orders, the APA, and the CAA provisions regarding rule effective dates; (2) would conform to recent case law in Murray Energy; (3) would not delay the CAA's schedule for § 107 designations and § 110 SIP preparation, submittal, and approval, which are tied to promulgation date rather than effective date; (4) would promote fairness to pending permit applicants; (5) would avoid disruption to permitting of important projects necessary for modernizing the nation's infrastructure and diversifying our production and energy sources; (6) would advance the public interest by assisting with the implementation of policies recently enacted by this Administration through Congress; and (7) would allow the EPA time to develop new modeling and permitting tools. A state commenter requested that the EPA allow for a grace period for permit applications received prior to the revision of the standards. More specifically, the commenter requests a period of at least six months from when the application was received to give permitting authorities reasonable time to finalize issuance of permits submitted prior to the promulgation of the new standard. Another state commenter recognizes that the EPA can no longer provide for grandfathering of sources, but urges the EPA to find a solution to this issue.

Other commenters stated that the EPA correctly recognized that, after the new standards go into effect, the CAA requires that a preconstruction prevention of significant deterioration permit cannot issue without a demonstration that the new or modified source of $PM_{2.5}$ will not cause or contribute to violations of the new standards, 88 Fed. Reg. at 5685-86. 42 U.S.C. § 7475(a)(3); *see Murray Energy*, 936 F.3d at 625-27. Though the EPA may have included a grandfathering provision in a prior iteration of its PM NAAQS, the legal bar on including one here still applies. *Murray Energy*, 936 F.3d at 626-27; see also 88 FR at 5686 n.200.

Response: The EPA is not extending the effective date for the revised PM NAAQS for a number of reasons. The EPA has the authority to set a 60-day effective date, consistent with the Congressional Review Act (CRA) and the EPA's precedent for significant rules. The timing of the 60-day effective date will ensure that important health benefits associated with the revised NAAQS are not delayed. Finally, the timing of the 60-day effective date is not inconsistent with the D.C. Circuit Decision in *Murray Energy*. A delay of the type requested by commenters would essentially allow for increases in emissions that could cause or contribute to a violation of the revised standard, which conflicts with the PSD provisions of the CAA and could jeopardize attainment of the NAAQS in some areas. While the EPA is aware that the revised NAAQS will immediately take effect for PSD permitting purposes upon the effective date, and that new areas will later be designated nonattainment for the revised standard, there is not a sufficient record to support that the 60-day effective date

would disrupt PSD permitting. Regulated parties have had notice of this matter since at least 2019 when the D.C. Circuit issued the *Murray Energy* decision. Further information was also included in the January 2023 proposed $PM_{2.5}$ NAAQS revision. As described in the preamble to the final rule and elsewhere in this RTC, tools are available under the PSD and NNSR programs to facilitate permitting in most cases. In some limited cases, the air quality in an area and the projected impact of a new or modified source may be such that the source cannot make the required air quality impact demonstration under PSD or obtain required offsets under the NNSR program. The CAA requires that these criteria corresponding to the NAAQS be met before construction on new major stationary sources and major modifications may be authorized. Moreover, the EPA is barred from considering costs in setting the NAAQS level.

(3) **Comment:** A commenter stated that EPA "must clarify the applicability of 'Prevention of Significant Deterioration (PSD)' and 'Nonattainment New Source Review (NNSR)' permitting to ammonia to avoid predictable permitting impasses and resulting lost economic opportunities." The commenter requested confirmation that ammonia is not a NSR regulated pollutant under PSD, and that ammonia is not subject to a NNSR major modification significance level unless and until one is set by a state for its $PM_{2.5}$ nonattainment areas.

Response: The EPA previously addressed this comment in prior actions. With regard to ammonia and the PSD program, the EPA regulations explain that ammonia is not a regulated air pollutant under the PSD program. See 40 CFR 51.166(b)(49); 52.21(b)(50). See also 70 FR 65983, 66036 (November 1, 2005) (proposing not to identify ammonia as a regulated NSR pollutant for purposes of PSD in any attainment or unclassifiable areas); 73 FR 28321, 28330 (July 15, 2008) (reaffirming that ammonia is not a regulated NSR pollutant for PSD). Ammonia, as a precursor to $PM_{2.5}$, is a regulated air pollutant under the NNSR program. See 40 CFR 51.165(a)(1)(xxviii); 40 CFR part 51 Appendix S II.A.4.31. The EPA finalized a rule in 2016 requiring reviewing authorities to regulate ammonia, among other pollutants, as a precursor to $PM_{2.5}$ in all nonattainment areas. The EPA promulgated this rule following a D.C. Circuit Court decision, *NRDC v. EPA*, which required PM2.5 be implemented under subpart 4 of Title I, Part D of the CAA. No. 08-1250 (D.C. Cir. 2013). As subpart 4 includes requirements only pertinent to nonattainment areas, the EPA does not consider the portions of the 2008 $PM_{2.5}$ NSR Rule that address requirements for $PM_{2.5}$ attainment and unclassifiable areas to be affected by the court's opinion in *NRDC* v. *EPA.* Therefore, the EPA did not propose to revise any PSD requirements promulgated in the 2008 $PM_{2.5}$ NSR Rule in order to comply with the court's decision.

Ammonia is presumed to be a precursor to $PM_{2.5}$ in all $PM_{2.5}$ nonattainment areas. With respect to the regulation of ammonia as a precursor to $PM_{2.5}$ under the NNSR program and the requirement that the reviewing authority establish a significant emission rate for ammonia in certain circumstances, the EPA established a phase-in approach for newly designated $PM_{2.5}$ nonattainment areas in the absence of an approved $PM_{2.5}$ NNSR SIP. The phase-in provides a reasonable timeframe for submittal of a NNSR precursor demonstration or the establishment of a SER for ammonia, either area-wide or on a permit-specific basis, in accordance with 40 CFR part 51, Appendix S. 81 FR 58010, 58106 (August 24, 2016).

(4) **Comment:** A commenter stated its perspective that the practice of permitting facilities in areas with $PM_{2.5}$ concentrations at or near the NAAQS means that many permitted facilities are likely already violating the current $PM_{2.5}$ standards that we know are insufficient to protect human health and the environment. The commenters state that because facilities are often permitted at or near the NAAQS, and knowing that facilities will likely not be in continuous compliance, they request that the EPA to adopt the most stringent $PM_{2.5}$ standards recommended by the CASAC expert panel, of 8 $\mu g/m^3$ for the annual standard and 25 $\mu g/m^3$ for the 24-hour standard in order to address reduce the overall amount of $PM_{2.5}$ in these already overburdened airsheds and best protect the health of New Mexico's communities.

Reviewing authorities should not be permitting major modifications and new facilities that cause or contribute to a violation of the NAAQS. 42 USC 7475(d). Reviewing authorities should evaluate every project or new source permit to ensure that the project does not cause or contribute to a NAAQS violation. Id.

Response: The CAA and the EPA's implementing regulations require a PSD permit applicant to demonstrate that emissions from a proposed major stationary source or major modification will not cause or contribute to a violation of any NAAQS or PSD increment and to provide an analysis of the impact of those emissions on ambient air quality based on monitoring data and air quality modeling. *See* CAA § 165(a)(3), CAA § 165(e), 40 CFR 52.21(k) and 40 CFR 52.21(m). Each individual decision to issue a PSD permit must be supported by a record sufficient to demonstrate that the proposed construction and operation of a stationary source will not cause or contribute to a violation of the applicable NAAQS and PSD increments. The EPA agrees that reviewing authorities should ensure that such demonstrations and PSD permit records meet the requirements of the CAA and implementing PSD regulations.

(5) **Comment:** A commenter supports continued refinement of the EPA's regulatory tools to assess more accurately a source's impacts on air quality, including reducing conservatism in modeling and in tools that may overestimate emissions impacts on projected air quality. The EPA should continue to refine and expand data supporting tools, such as its 2019 Guidance on Modeled Emission Rates for Precursors (MERPs).

A state commenter recommends that the EPA's "Guidance for Ozone and Fine Particulate Matter Permit Modeling," is unduly burdensome and may prevent economic development opportunities at existing major sources, for projects with even minimal direct $PM_{2.5}$ emissions. The commenter therefore recommends that the EPA revisit the significant emission rate of 40 tons per year established for precursors to secondary PM2.5 formation, namely NOx and SO_2, established in 40 CFR 51.166(b)(23)(i) and 40 CFR 52.21(b)(23)(i). The commenter states that forty tons per year of either precursor does not equate to the significant emission rate of 10 tons per year of direct $PM_{2.5}$ and is overly conservative.

Response: As stated in the NPRM, comments regarding implementation, including NSR applicability and permit modeling guidance are outside the scope of this rulemaking which is setting the standard for the NAAQS. However, the EPA acknowledges commenter's statements regarding the EPA's guidance on modeling for particulate matter, including the

"Guidance for Ozone and Fine Particulate Matter Permit Modeling" and the significant emission rates for $PM_{2.5}$ precursors in the EPA NSR regulations.

X. Response to Significant Comments on Legal, Administrative, and Procedural Issues and to Miscellaneous Comments

A. Legal Comments

(1) **Comment:** A number of commenters contend that the proposal exceeds the EPA's statutory authority. These commenters argue that there is nothing in section 109 of the CAA that authorizes the Agency to reconsider a decision by the Administrator not to revise a NAAQS in a previous statutorily prescribed NAAQS review, and that the EPA assumes it has some inherent authority to do so without identifying such authority in January 2021. These commenters recognize that section 109(d)(1) of the CAA allows for the review and revision of the air quality criteria or promulgation of new standards more frequently than every five years, but assert that under section 109 "any such revision should be effectuated '*in the same manner*' in which those standards were first 'promulgated'" and that the proposed revision to the primary annual $PM_{2.5}$ standard is not the result of a "thorough review of…the national ambient air quality standards" pursuant to section 109(d)(1) of the CAA. Some commenters suggest that the EPA may not reopen the air quality criteria without undertaking a comprehensive review of the entire criteria. Furthermore, these commenters suggest that promulgation or revision of any NAAQS is governed by section 307(d)(1)(A), and that the only sort of reconsideration proceeding contemplated under section 307(d) is that described in section 307(d)(7), subparagraph (B). They state that subpart (B) "provides that 'the Administrator shall convene a *proceeding for reconsideration* of the rule' in those circumstances where a person who seeks to challenge a final rule on the basis of an objection not raised during the public comment period 'can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule.' CAA § 307(d)(7)(B) (emphasis added)." They further note that while several petitions for reconsideration were filed following the 2020 final decision, the Administrator did not refer to those petitions in announcing the reconsideration of the PM NAAQS. The commenters also contend that reconsideration of the 2020 final decision to retain the PM NAAQS must be considered in light of precedents such as *American Methyl Corp. v. EPA*, 749 F.2d 826 (D.C. Cir. 1984), and *New Jersey v. EPA*, 517 F.3d 574, 583 (D.C. Cir. 2008), noting that the U.S. Court of Appeals for the D.C. Circuit observed that, "when Congress has provided a mechanism capable of rectifying mistaken actions . . . it is not reasonable to infer authority to reconsider agency action." The commenters recognize that the Agency is not considering the 2020 final decision to be "mistaken" but state that Congress provided an express "mechanism" by which the EPA is authorized to review and determine whether or not to revise the NAAQS and that is under the procedures set for expressly under section 109(d)(1) of the CAA. Other commenters contend that the CAA does not give the EPA unlimited authority to address all environmental issues generally, stating that Congress determines the extent of that authority, not the Agency.

A number of commenters assert that, because they believe the reconsideration is a discretionary action, the Administration must justify cost. Some commenters suggest that, in reconsidering the "appropriateness" of the 2020 final decision that revisions to the PM NAAQS were not "appropriate," and in concluding that revisions to the PM NAAQS are "appropriate," the EPA must consider all costs that would result from the implementation of the proposed revisions. The commenters assert that the EPA cannot evade consideration of costs in determining whether or not to revise a NAAQS by invoking an unprecedented procedure (i.e., a reconsideration) to circumvent the requirements of section 109(d)(1) of the CAA. The commenters state that the EPA is obligated to engage in reasoned decision making, which requires the Administrator to account for the full range of costs associated with the decision to reconsider the PM NAAQS and to depart from the 2020 final decision. The commenters suggest that the cost of a more stringent standard is a relevant factor that must be considered and an important aspect of the problem that cannot be ignored, and failure to consider the full range of costs would render any final action arbitrary and capricious. These commenters further contend that the EPA does not indicate that it understands these obligations, suggesting that the EPA's invocation of *Whitman v. American Trucking Associations* is not valid in this context. Furthermore, these commenters argue that the EPA must first determine whether it should proceed to regulate at all at this time (including treating cost as a relevant factor in reaching such a decision) and before addressing how to revise the NAAQS, the EPA must confront whether to revise, and in reaching a decision to proceed, the EPA must take into consideration costs, citing to *Michigan v. EPA*, 576 U.S. 743 (2015). These commenters also suggest that if the EPA revises the PM NAAQS as proposed, the Agency must consider the broader social and economic impacts of a revised NAAQS in determining the acceptable level of risk. In so doing, the commenters note that, in *Whitman*¸ the EPA cannot consider implementation costs, but the EPA is not prohibited from considering other costs (i.e., "disbenefits"), specifically those listed in section 109 of the CAA, including adverse public health, welfare, social, economic, and energy effects. These commenters also point to Justice Breyer's separate opinion in *Whitman* and state that, in the reconsideration, the Administrator must embrace the range of discretion afforded to him to ensure reasoned decision making. These commenters further assert that the EPA should withdraw the reconsideration proposal because it creates regulatory uncertainty and burden in economically challenging times. These commenters note that this would not be the first Administrator to consider the costs and burdens when withdrawing a reconsideration, pointing to the decision to withdraw the reconsideration of the ozone NAAQS in 2011. These commenters state that the U.S. once again faces economically challenging times, and that the costs from any revisions that are finalized would undermine competitiveness of U.S. manufacturing and businesses that support critical infrastructure and electricity needs of the U.S., and businesses would be driven to other countries. These commenters also argue that the standards are unattainable, citing the Regulatory Impact Analysis (RIA) and analyses of the RIA, and should be withdrawn pending development of strategies to attain the proposed standards because Congress could not have anticipated the difficulties that may be associated with attaining the standard.

On the other hand, other commenters state that the EPA's decision on reconsideration must be based solely on health and welfare, and there is no room for consideration of costs. They suggest that the decision to end the previous reconsideration of the ozone standards was

made under different circumstances and the justification for ending the reconsideration was never judicially upheld. They also point to the reconsideration petitions pending before the Agency as supporting reconsideration of the PM NAAQS and supporting the conclusion that more stringent standards are warranted.

Some commenters question how the reconsideration will impact the five-year review cycle, as mandated by the CAA. These commenters ask if, given the reconsideration, the EPA should complete another PM NAAQS review in 2025 or if the next review should be in the 2028 timeframe.

Response: This action is squarely within EPA's authority under section 109 of the CAA and the EPA has always been clear it is acting under section 109 consistent with its statutory mandate from Congress. Congress intended the EPA to periodically revisit and revise, as appropriate, the air quality criteria and the NAAQS, and this action is consistent with both the EPA's implicit and explicit authority to revisit earlier decisions on the NAAQS. It is well-established that agencies generally have implicit, or inherent, authority to reconsider their prior actions and take new action in a different direction, provided the Agency is not precluded from doing so by the statute and has a sufficient rationale for the new action. See, e.g., *FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009); *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co*., 463 U.S. 29, 42 (1983). Certainly nothing in the Clean Air Act precludes the EPA from revisiting earlier decisions on NAAQS, and the language of section 109 indicates that Congress clearly intended the EPA to revisit, reconsider, and revise earlier decisions as appropriate.

The EPA agrees with the commenters that the Agency is required to engage in reasoned decision-making in this action, but maintains that it has done so in both the notice of proposed rulemaking and in this final action. The EPA disagrees with the commenters that the requirement of reasoned decision-making for this action imposes an additional requirement that the Administrator consider costs of implementation of implementing a revised standard, and with the suggestion that the Supreme Court's holding in *Whitman* does not apply to reviews under section 109(d), including this reconsideration. The Supreme Court held in *Whitman v. American Trucking Ass'ns* that "The text of § 109(b), interpreted in its statutory and historical context and with appreciation for its importance to the CAA as a whole, unambiguously bars cost considerations from the NAAQS-setting process…." 531 U.S. 457, 471 (2001). There is no basis for suggesting that this holding is limited to reviews undertaken under section 109(b) but not those undertaken under section 109(d) since every review since 1990 (including the reviews at issue in *Whitman*) has necessarily been undertaken pursuant to both section 109(b) and 109(d) and 109(d) expressly references 109(b). Moreover, the Supreme Court in *Whitman* expressly considered and rejected the argument raised by petitioners that the EPA must consider "disbenefits" from adverse public health, welfare, social, economic or energy effects. The Court noted that Congress "not only anticipated that compliance costs could injure the public health, but provided for that precise exigency." *Id.* at 467. The Court went to note that "Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions – it does not, one might say, hide elephants in mouseholes" and that the statutory text left no room for the argument that the EPA was supposed to incorporate considerations of the effects of implementation into its decision making on the NAAQS. *Id.* at 468. Moreover, for the same

reasons, courts have consistently held that attainability of the standard is also not a relevant criterion in selecting a NAAQS. See *Lead Indus. Ass'n, Inc. v. EPA*, 647 F.2d 1130, 1148 (D.C. Cir. 1980); *Am. Petroleum Inst. v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); *Murray Energy Corp. v. EPA*, 936 F.3d 597, 623 (2019). The EPA also disagrees that the Regulatory Impact Analysis (RIA) demonstrates that the revised standards are unattainable or that Congress did not anticipate the difficulties associated with attainment of a standard based solely on public health without consideration of economic or technological feasibility. The RIA examines illustrative emissions control strategies toward reaching attainment and does not purport to make a judgment whether the standard will be attainable by the attainment dates established in the CAA. As the DC Circuit noted in *Lead Industries*, "[t]he 'technology-forcing' requirements of the Act are expressly designed to force regulated sources to develop pollution control devices that might at the time appear to be economically or technologically infeasible." 647 F.2d at 1149 (internal quotation omitted). Past experience with the NAAQS has demonstrated this to be true, as the City of Houston, which unsuccessfully challenged the 1979 ozone NAAQS in *API* on the grounds that it was unattainable, has since attained that standard (see 85 FR 8411, February 14, 2020). Likewise Congress has been well aware throughout the history of the CAA that attaining the NAAQS may pose severe challenges. The DC Circuit noted in *Lead Industries* that in establishing the NAAQS in the 1970 CAA the Senate drafters considered whether to use "the concept of technical feasibility as the basis for ambient air quality standards" but concluded that "the health of people is more important." 647 F.2d at 1149. However, Congress well understood that this approach could necessitate shutdown of existing sources of pollution, result in significant economic impacts, and might even prove beyond the ability of industry to meet. The court quotes Senator Muskie as saying "I think that we have an obligation to lay down the standards and requirements of this bill. I think that the industry has an obligation to try to meet them. If, in due course, it cannot, then it should come to Congress and share with the Congress the representatives of the people the need to modify the policy." Id. at 1150. Thus, the court finds that Congress has made a policy decision to base the standards on public health regardless of concerns about technical feasibility and if it turns out there is a problem then Congress is "the only institution with the authority to remedy the problem." Id. Of course it is worth noting that in later years Congress did amend the CAA to extend the attainment deadlines for different NAAQS where it found it appropriate to do so in light of the challenges of attaining the standards. For example, the attainment deadline for areas classified as serious nonattainment for the PM NAAQS is ten years, rather than five years, after designation. For all of these reasons, although the EPA does not agree that the standards have been shown to be unattainable, the Administrator has acted consistently with the requirements of the CAA in declining to consider the analyses in the RIA or attainability of the revised standards in revising the standards under section 109.

The EPA in this action is following the direction of *Whitman* and setting the NAAQS that provide the requisite protection for public health and welfare, as required by the CAA section 109. Nonetheless the EPA notes that some comments suggest that the EPA lacks authority to set such a NAAQS under the "major questions doctrine," on the theory that the revised NAAQS could have significant economic impacts. This of course is a perverse inversion of the holding of *Whitman,* which is commonly understood to be part of the "major questions doctrine" line of cases and held that the EPA is *required* to set NAAQS to protect public health and public welfare without consideration of the potential economic impact of the

standards. *See, e.g., Whitman*, 531 U.S. at 471 ("The text of § 109(b) … unambiguously bars cost considerations from the NAAQS-setting process, and thus ends the matter for us as well as the EPA."); *see also*, *West. Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022) (citing *Whitman* for the proposition that "Extraordinary grants of regulatory authority are rarely accomplished through 'modest words,' 'vague terms,' or 'subtle device[s].'").

Similarly, some commenters argue that because under the CAA the Administrator is charged with periodically reviewing and making such revisions to air quality criteria and NAAQS "as may be appropriate" that the scope of "appropriate" in NAAQS reviews must encompass costs, under the Supreme Court's decision in *Michigan v. EPA*, 576 U.S. 743 (2015). Such an argument is also plainly inconsistent with the Supreme Court's decision in both *Whitman* and *Michigan*,[18] as well as the D.C. Circuit's decision in *Murray Energy* (*see* 936 F.3d 597, 621-622 (D.C. Cir. 2019)).

Some commenters further suggest that the EPA is at least required to consider costs because this is a reconsideration completed sooner than the statutory 5-year deadline for periodic NAAQS reviews. The EPA notes that section 109(b) provides that NAAQS "may be revised in the same manner as promulgated." The EPA understands this provision to authorize the Administrator to revise the NAAQS and to require that every NAAQS revision be subject to the same basic requirements under section 109 (and *Whitman*) – the standards must be based on the air quality criteria and must be requisite to protect the public health for primary standards and public welfare for secondary standards. The NAAQS decisions made in this action conform to those requirements for primary and secondary standards, respectively.[19] It would be an absurd result, contrary to both the statute and caselaw, if the Administrator was required to disregard costs of implementation in setting a NAAQS under the 5-year schedule but was free to turn around the following year and revise the NAAQS to a different level based on the costs of implementation.

Similarly, the EPA rejects the suggestion that it is required to consider costs of implementation in deciding whether to revise the NAAQS, or that it is required undertake any particular analysis to justify its decision to reconsider the NAAQS. Some commenters point to statements made by the President and the Administrator of OIRA regarding the completion of interagency review of a draft final decision on a prior reconsideration of a NAAQS. These statements, which were not made by the EPA, do not establish that the EPA Administrator has discretion, much less the obligation, to consider costs of implementation in making any decisions regarding the NAAQS under section 109, particularly where such considerations are prohibited under section 109. As just noted, section 109(b) provides that NAAQS may be revised in the same manner as promulgated, and section 109(d) provides that the Administrator "may review and revise criteria or promulgate new standards earlier or

[18] In *Michigan*, the Court did not over-rule *Whitman*; it simply noted the principles of *Whitman* were irrelevant to the statutory provision at issue in *Michigan*, highlighting textual differences between the statutory provision before it in *Michigan* and the provisions at issue in *Whitman* and repeating that the provision at issue in *Whitman* "does not encompass cost." *Michigan*, 576 U.S. at 755–56.

[19] Although section 109(b) does not specify any particular process that must be followed, this reconsideration followed the same notice and comment rulemaking procedures, as required by section 307(d), as previous reviews.

more frequently than required under this paragraph." Nothing in section 109 suggests that before undertaking a review of the air quality criteria or standards the Administrator is required to assess the potential economic or social impacts of a possible decision that he might reach to revise the NAAQS based on such a review. As noted above, the Supreme Court has held that "Congress does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions -- it does not, one might say, hide elephants in mouseholes." Imposing such a requirement on the Administrator as a precondition to reviewing the NAAQS would fundamentally alter the nature of the NAAQS review process away from its focus on the health of the public. "And because § 109(b)(1) and the NAAQS for which it provides are the engine that drives nearly all of Title I of the CAA, 42 U.S.C. §§ 7401-7515, that textual commitment must be a clear one." *Whitman*, 531 US at 468. There is no such textual commitment in section 109, and the EPA concludes there is no such requirement on the Administrator.

Some commenters also suggest that the EPA lacks authority to undertake this action because Congress has specified the mechanism for the EPA to revise NAAQS in section 109(d)(1) and this proceeding fails to satisfy the requirements of that provision. The EPA disagrees that this action falls outside the scope of section 109(d)(1). As noted above, section 109(d)(1) specifically authorizes the Administrator to "review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph." That is precisely what the Administrator is doing here. This reconsideration is based on the thorough review of the air quality criteria completed in 2020, as supplemented by the additional studies, information, and analyses in the ISA Supplement and 2022 PA. The EPA acknowledges that the ISA Supplement does not itself satisfy the EPA's obligation to periodically complete a thorough review of the air quality criteria. There are a number of areas, such as respiratory effects and reproductive and developmental effects, where commenters have identified new studies that the EPA judged did not warrant reopening the air quality criteria at this time but will warrant closer consideration in a future review. Thus, a "thorough review" of the air quality criteria for PM, along with any revisions to the criteria and NAAQS that may be appropriate, should still be completed within five years of the most recent complete review, which concluded in 2020. However, nothing in the last sentence of section 109(d)(1) indicates that the authority of the Administrator to revise air quality criteria or NAAQS is limited to the context of a new full review of the air quality criteria.

It is true that the first sentence of section 109(d)(1) imposes a duty on the Administrator to "complete a thorough review of the criteria published under section 7408 of this title and the national ambient air quality standards promulgated under this section and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate …." However, a careful reading makes plain that the last sentence of section 109(d)(1) provides additional authority, independent of the requirement to undertake a full review of the air quality criteria and revise the criteria and the NAAQS, as appropriate, every five years. The first sentence of section 109(d)(1) clearly specifies that every five years the Administrator must undertake "a thorough review of the criteria" and then, based on that review make such changes in the air quality criteria and the NAAQS as may be appropriate. By contrast, the last sentence of section 109(d)(1) simply says "may review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph." Thus, while the first sentence of section 109(d)(1) establishes the baseline

requirement that the air quality criteria must undergo a "thorough review" at least every five years (which may necessitate revisions to the NAAQS), the last sentence authorizes the Administrator to review and revise *either* the air quality criteria or the NAAQS on a shorter schedule of the Administrator's choosing. The plain language of the last sentence of section 109(d)(1) authorizes the Administrator to revise the NAAQS *without* revising the air quality criteria. It also authorizes the Administrator to revise the air quality criteria, without undertaking a "thorough review" of the criteria. It follows that the action of the Administrator here, to reopen the air quality criteria to seek CASAC advice on certain studies he considered most useful in informing conclusions on the health effects of PM and revising the NAAQS based the entire air quality criteria (including both the thorough review completed in 2020 as well as additional studies judged most likely to be useful), was entirely consistent with the authority granted by Congress in section 109(d)(1).

Moreover, as explained at length in the final decision on the 2012 PM NAAQS (78 FR 3095-96), "[s]ince the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria." As a consequence, when the EPA believes new science is sufficiently important to be material to decision making on NAAQS, it reopens the air quality criteria to allow the CASAC and the public, as well as the Administrator, to fully consider the evidence. In each review the EPA faces the question of whether "new" studies that become available, or are brought to EPA's attention, at the time of the rulemaking but were not initially presented to the CASAC should be considered for decision making on the NAAQS, and where the EPA has concluded these studies should be considered for decision making, the EPA has reopened the air quality criteria for the review, as it has done here. Thus, the EPA finds that its approach to reopening the air quality criteria in this reconsideration, recognizing that there were additional studies that should be considered for decision making, and deciding to bring to the CASAC a draft ISA Supplement considering those studies most likely to be useful in judging whether the current standards are requisite, is entirely consistent with the CAA and the EPA's longstanding practice.

Finally, because the Administrator is acting within the scope of his authority under section 109 (whether that authority is characterized as implicit or explicit), it is irrelevant that CAA section 307(d)(7)(B) also requires the Administrator to convene a reconsideration proceeding under certain circumstances. Section 307(d)(7)(B) is intended to ensure that any objections to EPA's decisions on the NAAQS are brought before the Agency for consideration before being raised in judicial review. Thus, where a commenter identifies an issue of central relevance to the rule that was impracticable to raise an issue in public comment (or that arose after the public comment period but before judicial review), this provision specifies EPA shall convene a reconsideration proceeding to consider the issue. However, section 307(d)(7)((B) merely specifies certain circumstances when reconsideration is necessary—it does not limit the availability of reconsideration to only those circumstances, and it does not alter the Administrator's authority to revise NAAQS when acting within the scope of his authority under section 109.

(2) **Comment:** Some commenters, in their questioning of the Agency's statutory authority for the reconsideration, suggest that in reaching decisions regarding the adequacy of the NAAQS the CAA requires consideration of science-based criteria, not policy-based criteria.

Therefore, the commenters contend that policy initiatives, such as environmental justice, should not be included because the EPA does not have the authority to include them.

Response: The EPA agrees that the NAAQS must be based on the air quality criteria, although any decision on the appropriate NAAQS necessarily requires the Administrator to exercise his judgment, including with respect to science policy and public health policy judgments on the strength and uncertainties of the scientific evidence. The EPA did not seek to rewrite or expand its authority in this reconsideration but simply set standards requisite to protect the public health and welfare based on the air quality criteria. The Administrator expressly considered the available information regarding health effects among at-risk populations in reaching the proposed decisions that the current primary annual $PM_{2.5}$ standard is not requisite to protect public health with an adequate margin of safety, and should be revised. The 2019 ISA and ISA Supplement identified children, older adults, people with pre-existing diseases (cardiovascular disease and respiratory disease), minority populations, and low SES populations as at-risk populations. Consistent with the EPA's longstanding approach to the NAAQS, which is supported by legislative history and case law as discussed in section I of the preamble, the EPA set the NAAQS to protect the at-risk populations identified for this review, including minority and low SES populations.

(3) **Comment:** Several commenters contend that the EPA's reconsideration of the 2020 final decision is a discretionary action. Commenters assert that the EPA's proposed decision to reconsider the PM NAAQS is premature, and that the EPA should withdraw its reconsideration and defer further action to a future required review. Commenters also suggest that the reconsideration is based more on a change in administration rather than the NAAQS process as described in the CAA, that the proposed decision is based on politics rather than science, and that the reconsideration should be suspended.

Some commenters note that the CAA requires review of the NAAQS no more than five years after its previous review, and assert that the EPA should wait the mandatory timeframe before embarking on a new standard. Other commenters express concerns about proposing revisions to the standards in the reconsideration three years ahead of the schedule of the CAA statutorily-mandated review, suggesting that predictability helps state and local officials engage in long-term planning for NAAQS implementation and other environmental requirements.

Response: As discussed in responding to the earlier comment in this section, the CAA authorizes the Administrator to revise the air quality criteria or the NAAQS more frequently than every five years. The Administrator initiated the reconsideration because he concluded that the available scientific evidence and technical information indicated that the current standards may not be adequate to protect public health and welfare, which is a sufficient and appropriate basis for reconsidering the NAAQS. When such questions arise, the CAA does not require the Administrator to wait until the next statutory review deadline before addressing them. Moreover, the PM NAAQS was most recently revised in 2012 and Congress clearly anticipated that the NAAQS could – and, where appropriate based on a review of the science and the standards, should – be revised more often than every 10 years. To the extent that the comments related to implementation of the NAAQS implicate consideration of the costs of implementation or consideration of attainability and

technological feasibility, those are not relevant considerations in making decisions about whether to revise the NAAQS. *See, e.g., Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); *accord Murray Energy Corporation v. EPA,* 936 F.3d 597, 623-24 (D.C. Cir. 2019). Even assuming the concerns raised in these comments were appropriate for consideration in this action, there are no implementation activities that were triggered by the 2020 final decision to retain the PM NAAQS that could be disrupted by revising the NAAQS in this action.

As discussed in the preamble to the final rule, the decision to revise the NAAQS was based on additional scientific evidence that was not part of the criteria considered by the prior Administrator, and additional advice from the CASAC and public comment taking that additional evidence into account, as well as on the current Administrator's judgments about the evidence, including an approach to the epidemiologic evidence that is more in line with the EPA's approach to considering such evidence in past PM NAAQS reviews compared with the approach in the 2020 final decision. Thus, the EPA rejects the suggestion of some commenters that the reconsideration is not based on science or is not fully consistent with the requirements of the CAA.

(4) **Comment:** Other comments argue that, while the EPA may not consider the cost of implementing the standard, it may consider the relative proximity of the standard to background concentrations. These commenters assert that the proposal fails to meet this legal standard and revisions to the NAAQS will result in a $PM_{2.5}$ standard that is at or near existing background concentrations in the Western U.S., noting for example, increases in wildfires, and calculation of "background" $PM_{2.5}$ on a permit application. Some commenters acknowledge EPA's estimates of background as 0.5-3 $\mu g/m^3$ but suggest that estimate is not representative of the entire country, with one commenter citing an estimate of 6 $\mu g/m^3$ of "background" $PM_{2.5}$ which was modeled as part of an application to modify a state air pollution permit.

Response: The EPA agrees that, in the context of considering standard levels within the range of reasonable values supported by the air quality criteria and judgments of the Administrator, the EPA may consider proximity to background concentrations as a factor in the decision on whether and how to revise the NAAQS.[20] However, the EPA disagrees that the revised primary annual $PM_{2.5}$ NAAQS will be at or near existing background levels. The EPA presented two estimates for background $PM_{2.5}$ in the proposed rule, one based on zero-out modeling which produced a range of 0.5-3 $\mu g/m^3$ and one using speciated monitoring

[20] The EPA generally understands prior court decisions addressing consideration of background concentrations of a pollutant in NAAQS reviews to hold that while the Agency may not establish a NAAQS that is outside the range of reasonable values supported by the air quality criteria and the judgments of the Administrator because of proximity to background concentrations, it is not precluded from considering relative proximity to background concentrations as one factor in selecting among standards that are within that range. *See American Trucking Ass'ns v. EPA*, 283 F.3d 355, 379 (D.C. Cir. 2002); *Murray Energy v. EPA*, 936 F.3d 597, 622–624 (D.C. Cir. 2019); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1982).

data from IMPROVE sites which suggests background concentrations are in the range of 1-3 $\mu g/m^3$. It is important to note that, as explained in the 2022 PA, the EPA defines U.S. background PM for this reconsideration as any PM formed from emissions other than U.S. anthropogenic (i.e., manmade) emissions. The EPA considers IMPROVE sites, which are generally located away from major sources of anthropogenic PM, to be suitable sites to examine background PM, but also notes that its estimate for background PM was supported by the zero-out modeling which looked at U.S. regions in addition to IMPROVE monitoring sites. By contrast, one commenter cites an estimate of 6 $\mu g/m^3$ of "background" which was modeled as part of an application to modify a state air pollution permit. Although neither the permit application nor the modeling itself was submitted and thus the EPA is unable to fully assess the validity of the modeling for these purposes, generally "background" in this context refers to emissions other than from the source, and would include anthropogenic emissions from other sources, thus explaining the higher value. Furthermore, as some commenters recognize, emissions attributable to wildfires may be eligible for exclusion from design value calculation under the Exceptional Event Rule. Thus, the EPA finds no reason to conclude that the revised primary annual $PM_{2.5}$ NAAQS will approach background levels. Even assuming background levels could be somewhat higher than 1-3 $\mu g/m^3$ they still wouldn't be at or near the level of the revised primary annual $PM_{2.5}$ NAAQS, and the Administrator set the standards based on his assessment of what is requisite to protect public health, consistent with the requirements of the CAA.

(5) **Comment:** A number of commenters contend that revising the PM NAAQS will impose harm, including economic impacts, employment impacts, exacerbating poverty, threatening electric grid reliability, national security risk, impacts on clean energy transition, and timing concerns, among others.

Response: The EPA notes that several commenters provide analyses in support of their claims that are of questionable or no relevance (e.g., analyzing impacts of a carbon dioxide tax of $300/ton, or of Clean Air Act regulations other than a PM NAAQS), and which ignore the health and economic benefits of reduced pollution and illness. Without conceding or agreeing with any of these commenters' predictions, such concerns would not be valid considerations for this action. As discussed in the preamble to the proposed and final rules and in response to other comments, the Clean Air Act, as the Supreme Court held in *Whitman*, "unambiguously bars cost considerations from the NAAQS-setting process," 531 U.S. at 471, including these various concerns raised by commenters. [21]

(6) **Comment:** Some commenters suggest that it was inappropriate to propose a range of levels for consideration in revising the primary annual $PM_{2.5}$ standards. These commenters suggest that the EPA should propose a recommended specific level in order to help define exactly what the EPA intends and to assist the public in providing more focused and specific comments regarding the proposal. Some commenters state that the range is too broad and is

[21] The EPA notes that in *Am. Petroleum Inst. v. Costle*, 665 F.2d 1176 (D.C. Cir. 1981), the City of Houston claimed that the then-recently adopted 1-hour ozone standard had been set below natural concentrations of ozone and was unattainable. The DC Circuit rejected the argument that "attainability" is a relevant criterion for the NAAQS, *id.* at 1185, and the EPA has since determined that air quality in the area including Houston has attained the 1979 1-hour ozone standard. See 85 FR 8411 (Feb. 14, 2020).

impossible to fully evaluate, and therefore, the EPA should withdraw the proposal and repropose specific standards for meaningful comment from the public. Some commenters also assert that proposing a range of options would be more appropriate in an Advanced Notice of Proposed Rulemaking (ANPRM) rather than in a reconsideration request and that the reconsideration request should not be to take comments on options for new standards.

Response: The EPA disagrees that it was inappropriate to propose a range, and to solicit comment on potential values above and below the range. The EPA recognizes that the NAAQS are of great significance to a wide variety of stakeholders and that often there is a range of reasonable values that could be supported by the air quality criteria and judgments of the Administrator. Accordingly, the EPA has in the past, as in this reconsideration, found it helpful to identify for public comment the range of values under closest consideration for the final decision, along with the rationale for identifying that range, while also soliciting comment on a wider range in order to benefit from stakeholder input before reaching a final decision. The proposed range for the level of the primary annual $PM_{2.5}$ standard was 9-10 $\mu g/m^3$, which is a fairly narrow range.

Had the EPA proposed a single level rather than proposing a range of levels, the Agency still would have solicited comment on a range of 8-11 $\mu g/m^3$ for the level of the primary annual $PM_{2.5}$ standard, which would have been entirely appropriate under the Clean Air Act and general principles of administrative law but would have provided even less guidance to public commenters.

Further, the EPA disagrees that it would be more appropriate to proceed by ANPRM instead of reconsideration, particularly given the scope of the record and the nature of the considerations that informed the initiation of the reconsideration. As explained in responding to other comments, considering revisions to the PM NAAQS through this reconsideration is consistent with the EPA's authority under the CAA.

(7) **Comment:** Some commenters state that having multiple significant regulatory actions proposed simultaneously interferes with the ability for states to provide meaningful participation and comment to the EPA, especially with overlapping public comment periods for proposed actions.

Response: The EPA recognizes that it has in a number of significant regulatory actions ongoing at various stages and appreciates the contributions of stakeholders through public comments to each of them. In the case of this action, the proposed decision was announced on January 6, 2023, and the pre-publication version of the notice of proposed rulemaking was posted to the EPA's website. The notice was published in the Federal Register on January 27, 2023, and the public comment period was open until March 28, 2023. In addition to the written public comment period, the EPA offered a multi-day virtual public hearing for the public to provide oral comments to the Agency on the proposed rule in February 2023. The EPA considers this a fully adequate amount of time for states and other commenters to provide comments to the Agency regarding the proposed decisions for the PM NAAQS Furthermore, we note that for this reconsideration, the public also had opportunities to provide written comments on the 2021 draft ISA Supplement and the 2021 draft PA, as well

as to offer oral comments at the public CASAC meetings during which these documents were reviewed.

B. Process Comments

(1) **Comment:** Several commenters who support retaining the current PM standards contend that the proposal does not discuss the 2020 decision or clearly distinguish between the facts from the 2020 review and this reconsideration. These commenters state that it is unclear what differentiates the Administrator's proposed conclusions in this reconsideration from the decisions made in the 2020 final action. They further assert that the EPA must provide a full justification for reversing the 2020 final decision and must distinguish and explain its new policy without ignoring the previous Administrator's decision to retain the PM NAAQS. In so doing, the commenters note that the EPA is bound to the docket for the reconsideration proposal, which includes all of the information since its establishment in 2015. These commenters contend that the information available in the reconsideration, based on which the Administrator proposed to conclude that the current primary annual $PM_{2.5}$ standard is not adequate, is largely the same as the information considered by the Administrator in reaching his final decision in 2020 to retain the PM NAAQS. They state that the EPA must explain why the evidence is certain enough to revise the PM NAAQS in this reconsideration and why it is reasonable to conclude that the previous Administrator placed too much weight on the uncertainties in the 2020 final action.

Commenters state that a reconsideration must reconsider, not simply replace, a previous agency decision, otherwise it is arbitrary and capricious. These commenters assert that the EPA must provide a "reasoned explanation" for "disregarding facts and circumstances that underlay…the previous policy" and provide a "more detailed justification" than it would for a new policy, citing to *FCC v. Fox*, 566 U.S. at 515 (2009). These commenters also point to *California v. Bernhardt*, 472 F. Supp.3d 573, 600-601 (N.D. Cal. 2020) and *Physicians for Soc. Resp. v. Wheeler*, 956 F. 3d 634, 644 (D.C. Cir. 2020), arguing that "agency cannot flip-flop regulations on the whims of each new administration" and reasoned decision making requires the Agency to "offer a reason to distinguish them or explain its apparent rejection of their approach." Some industry commenters suggest there is a reliance interest at stake because state planning efforts and regulated industries likely assumed that the PM NAAQS would be retained for five years.

Response: The EPA agrees that the Administrator must provide a full explanation for his decisions in this reconsideration of the PM NAAQS, but notes that it has done so in this action. The EPA disagrees that it must provide a "more detailed justification" for the Administrator's decisions in this action than was provided for the 2020 decision, or that he has not offered "good reasons" for his decision. The Administrator has provided a very detailed explanation of the basis for his decision, carefully evaluating the scientific evidence and considering CASAC advice and public comments, and he has noted reasons why his decision differs from the decision of the prior Administrator. As explained in the preamble to the final rule, the decision to revise the NAAQS was based on the thorough review of the air quality criteria completed in 2020, as well as additional studies, information, and analyses that were not part of the criteria considered by the prior Administrator, and additional advice from the CASAC and public comments taking that additional evidence and information into

account. After considering the entire updated record, for the reasons explained in the preamble, the Administrator reached a different judgment than the prior Administrator reached based on the record that was before him. Moreover, the Administrator has explained how he has considered the uncertainties in the evidence before him in the record, recognizing his obligation to set standards that protect public health with an adequate margin of safety in the face of scientific uncertainties, but also selecting standards which are requisite for that purpose, and not more stringent than necessary. The EPA disagrees that the Clean Air Act or general principles of administrative law require more.

In particular, the EPA notes that the Supreme Court in *FCC v. Fox* held that an agency changing policy "need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates." 556 U.S. 502, 515 (2002).[22] It is true that the Court noted that in some circumstances an agency may have a higher burden of justification, such as when "its new policy rests upon factual findings that contradict those which underlay its prior policy" or when the former policy "engendered serious reliance interests" but neither of those is applicable here. For example, while the scientific record for this reconsideration is broader than what was available in the 2020 decision, it strengthens (by reducing uncertainties), rather than contradicts, the conclusions of the 2019 ISA. Nor does the EPA consider that reliance interests provide a basis for not revising the standards.

The EPA does not consider potential reliance interests a sufficient reason to alter the Administrator's judgment as to the requisite degree of protection of the NAAQS for multiple reasons. First, the statutory structure of the NAAQS is built on frequent review, and potential revisions of the air quality criteria and the standards. As such, it is very different from circumstances where a regulated entity takes action it believed was lawful based on a "longstanding, official administrative construction" of a statute,[23] or compensation practices for an entire industry have been structured for decades around a particular interpretation of a statute.[24] The central principle of the NAAQS is that they are based on the science – which is not static (as might be appropriate for a statutory interpretation), but instead subject to ongoing revision and development as the scientific community engages in ongoing research – and must be reviewed and revised as appropriate no later than every 5 years but possibly sooner. Thus, it is very doubtful that there could ever be "legitimate reliance on prior interpretation" of what NAAQS is requisite the protect the public health and welfare, or the anticipated schedule for NAAQS reviews. *Smiley v. Citibank (S. Dakota), N.A.*, 517 U.S. 735, 742 (1996).

[22] The EPA does not view the cases cited in the comments as inconsistent with *Fox,* nor, as lower court decisions, could they be. These decisions appear to turn on the agency's lack of explanation, but as noted in this final action the Administrator has provided a fulsome explanation of his decision, including identifying reasons why his judgment differed from that of the prior Administrator.
[23] *United States v. Pennsylvania Indus. Chem. Corp.*, 411 U.S. 655, 670 (1973)
[24] *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016)

However, further considering the potential for reliance, the EPA notes that the prior decision was to retain the standard. Thus, no state was required to undertake any planning obligation in response. At most, as a commenter suggests (but does not substantiate), it is possible that a state did not plan to undertake planning for the PM NAAQS and may incur planning obligations sooner than it expected. Likewise, no private entity was required to do anything as a result of the 2020 decision, and at most the reconsideration somewhat accelerates the timing of potential applicability of control strategies to a source. However, the decision to reconsider it was undertaken promptly thus making it even more unlikely that any actions were taken in reliance on the prior decision.

Furthermore, even if some entity for whatever reason made plans based on the assumption that the PM NAAQS would not change until the next review, due in 2025, the EPA would still not find this a sufficient basis for altering the Administrator's judgment about the appropriate PM NAAQS or for retaining NAAQS that in the Administrator's judgment did not provide the requisite protection. Such potential reliance interests can be viewed as another aspect of the costs of implementing the standard. Given that the costs of implementation are not a relevant consideration for the EPA in setting the NAAQS, as discussed in the preamble to the final rule and in responding to other comments on the proposal, it would not be consistent with the statute, or with Congressional intent, to delay or reduce the health and welfare benefits which Congress intended to achieve through the NAAQS in order to protect such potential reliance interests, particularly under the circumstances presented here, including the fact that the prior decision did not change the standards at all.

However, even there was some sort of specific, additional obligation on the Administrator to explain his decision, the Administrator's detailed rationale would satisfy the requirements of the Clean Air Act and relevant principles of administrative law. The Administrator has clearly identified the additional science that was before the CASAC and the Agency, as well his evaluation of the entire scientific record (which as noted differs in some ways from that of the prior Administrator). As the DC Circuit held in *Mississippi v. EPA*,

> Every time EPA reviews a NAAQS, it (presumably) does so against contemporary policy judgments and the existing corpus of scientific knowledge. See 42 U.S.C. §§ 7408–09. It would therefore make no sense to give prior NAAQS the sort of presumptive validity Mississippi insists upon. The statutory framework requires us to ask only whether EPA's proposed NAAQS is "requisite"; we need not ask why the prior NAAQS once was "requisite" but is no longer up to the task.

744 F.3d 1334, 1343 (2013). Here the Administrator has plainly met his burden to "reasonably explain [his] actions." Id.

(2) **Comment:** In addition to their comments on differing conclusions by different Administrators, several commenters who support retaining the current PM standards contend that the EPA must also take into consideration the advice of the CASAC during their review of the 2019 draft PA as a part of the 2020 rulemaking in addition to the CASAC's advice during their review of the 2021 draft PA as a part of this reconsideration. These commenters state that the CAA does not allow the EPA to pick advice of one CASAC over another and

that the EPA must discuss the viewpoints of the previous CASAC and the current CASAC and explain how the EPA weighs their advice and recommendations in reaching decisions in this reconsideration. Some commenters assert that the EPA has failed to do this in a meaningful way in the proposal.

Some commenters state that, in their review of the 2021 draft PA, the CASAC did not reach a unanimous recommendation on the level of the primary annual $PM_{2.5}$ standard, noting that the majority of the CASAC recommended revision to within the range of 8-10 $\mu g/m^3$, while the minority of the CASAC recommended revision to within the range of 10-11 $\mu g/m^3$. These commenters assert that the EPA does not fully evaluate the significance of the lack of consensus by the CASAC.

Response: In reaching his conclusions regarding the PM NAAQS, the Administrator considered all of the CASAC advice that was provided during the review and reconsideration. This includes the majority CASAC advice and minority CASAC advice for their review of both the 2019 draft PA and the 2021 draft PA (as well advice by the CASAC on the 2018 draft ISA and the 2021 draft ISA Supplement). The EPA noted the advice of the CASAC where it was pertinent to his consideration of the evidence and his decision on whether to retain or revise a standard. Furthermore, the Administrator noted that the 2021 draft PA included scientific evidence and quantitative risk information that was not available in the 2019 draft PA, and therefore, the advice and recommendations of the CASAC in their review of the 2021 draft PA are based on consideration of newly available information in this reconsideration that expands upon the information previously available. However, the EPA disagrees that it is required to further explain how it evaluates the significance of the lack of consensus within the CASAC or to attempt to characterize or reconcile the different advice provided by the CASAC on the 2019 draft PA and the 2021 draft PA. The CASAC provides advice on scientific and policy considerations which in part reflect the exercise of the individual members' expertise and judgment and the collective deliberation of the committee, and where there are differences in the views of CASAC members, those differences may also be informative. The Administrator recognizes that he received a range of advice from CASAC in the course of this review (and reconsideration). He has considered all of the advice of the CASAC and has explained his consideration of the CASAC's advice including by providing an explanation of why there are important differences between some of the CASAC's recommendations and his final decision. Particularly in light of the nature and range of CASAC advice in this review, this is appropriate and sufficient under the CAA.

(3) **Comment:** A number of commenters assert that the EPA's failure to reconsider the full record means that the proposal is flawed. The commenters contend that the flaws cannot be addressed in the final rule because it would deny the public due process because the EPA would be justifying its action on analysis that was not presented in the proposal. These commenters state that every part of the final rule must be a logical outgrowth of the proposal, and the public has no way of anticipating the Administrator's justifications for deviating from the prior Administrator's reasoning. Therefore, the commenters recommend a supplemental proposal to allow for meaningful public comment before finalization of the PM NAAQS, which must include (1) justifications for the Administrator reaching different conclusions in this reconsideration than the Administrator in the 2020 final decision; (2) explanations of differences from any pertinent findings, recommendations, and comments of

the CASAC; and (3) distinguishing or explaining any apparent rejection of a position taken in the 2020 RTC.

Response: The EPA disagrees that it has not considered the full record in this reconsideration, or that the notice of proposed rulemaking did not provide an adequate basis for commenters to comment on the Administrator's proposed decision. The EPA provided a very detailed explanation of its view of the science and the rationales that could support revision of the primary annual $PM_{2.5}$ standard to a level between 9 and 10 $\mu g/m^3$, as well as the Administrator's proposed rationale for concluding that the current PM NAAQS are not requisite to protect public health with an adequate margin of safety. Those detailed rationales were the proposed justifications for reaching different decisions in this action than the decision of the prior Administrator, for explaining differences from pertinent findings, recommendations and comments of the CASAC, and for explaining any differences with the 2020 RTC. The notice of proposed rulemaking made it very clear that the EPA was proposing, and soliciting comment on a proposal, to revise, rather than retain, the primary annual $PM_{2.5}$ NAAQS, as well as the reasons why the EPA was proposing that change. After consideration of public comments, these same considerations inform the Administrator's final decisions on the PM NAAQS, and to the extent there are differences between the proposed and final decision, the EPA views these as a logical outgrowth of the proposal. Thus, even if the commenters would have preferred the EPA to present its proposal with different phrasing, the central issues of the rule were the subject of thorough public comment and a supplemental proposal is unnecessary.

(4) **Comment:** Commenters who supported revising the current PM standards reiterate their concerns with the process and the CASAC from their comments on the 2020 proposal. In light of these comments, the commenters suggest that the conclusions reached in the 2020 decision, as well as the majority of the CASAC's advice at that time, merit no deference in this reconsideration.

Response: The EPA has considered commenters' concerns with the process and the CASAC for the 2020 decision. The EPA acknowledges that in reviewing the 2018 draft ISA, the CASAC indicated that it required additional expertise to provide a thorough review because the "breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members, or indeed of any seven individuals" (Cox, 2019b, p. 1 of consensus letter). However, in response to this request, the EPA did make additional subject matter experts available to the CASAC as part of their review of the 2019 draft PA. The Administrator has considered the advice of the CASAC on all of the documents on which it has provided advice, including the 2018 draft ISA and the 2019 draft PA in reaching his judgments about the appropriate PM NAAQS. Furthermore, he considers the expanded body of evidence available in this reconsideration and the CASAC's advice on the assessment of this evidence in the 2021 draft ISA Supplement. He recognizes that the 2021 draft PA included scientific evidence and quantitative risk information that was not available in the 2019 draft PA, and therefore, the advice and recommendations of the CASAC in their review of the 2021 draft PA are based on consideration of newly available information in this reconsideration that expands upon the information previously available to the CASAC at the time of their review of the 2019 draft PA.

(5) **Comment:** Commenters who support retaining the current PM standards assert that the decision to reconstitute the CASAC was undertaken prior to announcing the reconsideration of the 2020 final decision to set the stage for reconsideration with CASAC support. These commenters assert that the Agency selected scientists predisposed to supporting its desired policy outcomes, and then only used science that would support these outcomes while ignoring science that would undermine them. Some commenters similarly suggest that revisions to the air quality criteria and risk assessment were targeted to support revision of the NAAQS. Some of these commenters state that because the process informing the proposal was arbitrary and capricious, the proposal and entire rule are arbitrary and capricious.

Response: The decision to reconstitute the CASAC was made months before the decision to reconsider the PM NAAQS and the two decisions were made separately for their own independent reasons.[25] Moreover, no member of the CASAC was selected based on a purported predisposition to support any particular policy outcome. Indeed, the EPA notes that it reappointed two of the prior seven members of the chartered CASAC, and one of those members changed his advice on whether revisions to the primary annual $PM_{2.5}$ standard were required after considering the additional information available in the reconsideration. Likewise, while the EPA did seek to focus consideration of newly available scientific evidence on areas that would be most relevant to judging *whether* the standards are requisite to protect public health and welfare, including addressing certain uncertainties and gaps that had been identified in the 2020 final decision (and to update the quantitative risk assessment to reflect the newly available information in this reconsideration) that is because it is the Administrator's responsibility to determine *whether* the standards are requisite, not because the Administrator was seeking to determine *that* the standards are not requisite. The Administrator did not prejudge any aspect of the reconsideration of the PM NAAQS. The EPA further notes that Administrator's final decisions accord with some but not all recommendations of the majority of the CASAC from their review of the 2019 draft PA and some but not all of the recommendations of the majority of the CASAC from their review of the 2021 draft PA. Thus, the EPA disagrees that there was anything arbitrary or capricious about the process for this reconsideration, much less that any purported procedural issues were of such central relevance that they cause the resulting proposed and final rules to be arbitrary or capricious.

(6) **Comment:** Commenters contend that the CASAC failed to fulfill its statutory duties under sections 109(d)(2)(C)(iii) and (iv) of the CAA, in that they did not advice on the relative contribution of $PM_{2.5}$ concentrations of natural versus anthropogenic activities, nor did they

[25] See h*ttps://www.epa.gov/newsreleases/administrator-regan-directs-epa-reset-critical-science-focused-federal-advisory* (March 31, 2021, news release noting several "process irregularities" that were being corrected in the SAB and the CASAC); *https://www.epa.gov/newsreleases/epa-reexamine-health-standards-harmful-soot-previous-administration-left-unchanged* (June 10, 2021, news release noting reconsideration of PM NAAQS because "available scientific evidence and technical information indicate that the current standards may not be adequate to protect public health and welfare, as required by the Clean Air Act").

advise on "adverse public health, welfare, social, economic, or energy effects resulting from compliance" with a revised NAAQS.

Response: The CASAC did provide advice on the relative contribution of natural as well as anthropogenic activity to ambient concentrations of $PM_{2.5}$. Chapter 2 of each draft PA describes sources of PM emissions, specifically including anthropogenic sources (see, e.g., U.S. EPA, 2021b, section 2.1.1) as well as natural sources (see, e.g., U.S. EPA, 2021b, section 2.4.1). The CASAC provided some advice on chapter 2 in its review of the 2019 draft PA and additional, detailed comments on chapter 2 were provided in the CASAC's review of the 2021 draft PA. A request to "advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS" was included in the EPA's charge memorandum seeking the CASAC's review of the 2019 draft PA (Sasser, 2019). However, the EPA is not aware of, and the CASAC did not identify, potential adverse public health or welfare effects (as that term was interpreted in *Whitman*) which may result from various strategies to meet potential alternative NAAQS under consideration. The commenters' criticism of the CASAC for failing to provide advice on potential adverse social, economic, or energy effects from strategies to comply with the NAAQS is misplaced. Even if the CASAC had provided advice on potential adverse social, economic, or energy effects that may result from such strategies, the EPA could not have considered that advice in its decision making on the standards because consideration of such advice in decision making on the NAAQS would be grounds for vacating the NAAQS under *Whitman*.

(7) **Comment:** Some commenters assert that the EPA has not provided evidence that a reconsideration of the 2020 decision is necessary, as the reconsideration should include new evidence and the necessity of reaching a different conclusion from the 2020 review, and that the EPA failed to provide justification for reversing its 2020 final decision.

Response: As discussed above in response to comments, the EPA disagrees that it must establish that it is "necessary" to reconsider the 2020 review in order to reopen the air quality criteria and review the NAAQS. The Clean Air Act provides the EPA with authority to review and revise the criteria and the NAAQS, and the Administrator has provided sufficient rationale for his final decisions on the PM NAAQS, including his decision to revise the primary annual $PM_{2.5}$ NAAQS.

(8) **Comment:** Some commenters contend that the proposal violates the Unfunded Mandates Reform Act (UMRA) and suggest that, if the EPA moves forward with the final rule, it should explain why it finds that the federal mandates included in the proposal would not result in the expenditure by the private sector of $100 million in any one year. These commenters state that the proposal does not detail how the EPA has satisfied the procedural requirements of the UMRA, nor does it indicate that the EPA has undertaken analyses of the impacts of compliance on states, local governments, and Tribes.

Response: As the EPA explained in the notice of proposed rulemaking as well as in the final rule, the proposed (and final) rule does not contain an unfunded mandate within the meaning of the Unfunded Mandates Reform Act. First, the EPA notes that the adoption of a NAAQS does not itself impose any obligation on private industry, and this rule is not imposing

additional information collection burdens or other enforceable duties on state, local, or Tribal governments. While future designations under section 107 of the CAA could result in certain planning obligations for state or tribal governments, those designations triggering such planning obligations would be promulgated through a separate rulemaking and therefore that would be the relevant vehicle for EPA to evaluate any applicability of UMRA. The ultimate costs associated with attaining the NAAQS are a function of the control strategies adopted by state governments according to their air planning needs and policy choices. *Am. Trucking Associations, Inc. v. EPA,* 175 F.3d 1027, 1044 (D.C. Cir.), *opinion modified on reh'g*, 195 F.3d 4 (D.C. Cir. 1999), *aff'd in part, rev'd in part, Whitman v. Am. Trucking Associations,* 531 U.S. 457 (2001) ("the NAAQS themselves impose no regulations upon small entities"). Moreover, the EPA did prepare a Regulatory Impact Analysis, which provides an example of illustrative control strategies and the potential costs of applying these control strategies toward reaching the standards. However, as discussed in the preamble and elsewhere in this RTC document, it is well-established that the EPA may not consider the costs of implementation in decision making about revisions to the NAAQS, and thus the results of the RIA have not been, and could not be, considered in issuing this final rule.

(9) **Comment:** Some commenters assert that the reconsideration is connected to "the Biden Administration's climate agenda" because the reconsideration acknowledged that Executive Order 13990 ("Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis") directed the EPA to review the 2020 decision for possible reconsideration. Other commenters also contend that if the motivation for the reconsideration (by following Executive Order 13990) is to reduce greenhouse gases, the rulemaking violates the Administrative Procedure Act's (APA) requirement for reasoned decision making. On the other hand, certain commenters asserted that the EPA needed to use its statutory authority to address the climate crisis and to protect the constitutional rights of the nation's children.

Response: Although President Biden did ask the heads of all agencies to review agency actions taken between January 20, 2017, and January 20, 2021, for possible inconsistency with the policy of his Administration to, inter alia, "listen to the science; to improve public health and protect our environment; [and] to ensure access to clean air," this simply directed Administrator to review the 2020 final action. The decision whether to proceed to reconsider the PM NAAQS rested with the EPA. Indeed, in February 2021, the EPA requested a temporary abeyance in litigation over the 2020 final decision[26] to allow Administrator Regan to review the decision and determine whether to pursue further administrative action. The EPA completed its review of the 2020 final decision in June 2021, and at that time, the Administrator concluded it was appropriate to engage in a limited reopening of the air quality criteria and a reconsideration of the PM NAAQS based on the additional available information, as well as advice from the CASAC and public comment. Furthermore, it is worth noting that Executive Order 13990 covers a number of topics beyond the review of past actions, such as the Keystone XL pipeline, certain national monuments, and the Arctic Wildlife Refuge. Those topics have no relevance for this reconsideration. In particular, the

[26] *California v. EPA*, (D.C. Cir., No. 21-1014).

EPA has no intention or goal to reduce greenhouse gases through this rulemaking.[27] To the extent commenters were suggesting that EPA should take steps to address the climate crisis in this rulemaking, EPA reiterates that the scope of this rulemaking is limited to review of the PM NAAQS and, for the reasons stated in the preamble, it would not be appropriate to establish or revise a secondary standard for PM based on the air quality criteria for this review to address climate effects.

C. Miscellaneous Comments

(1) **Comment:** Some commenters contend that in issuing another response to comments document as a part of the reconsideration, the EPA must distinguish or explain any apparent rejection of a position taken in responding to comments in the 2020 RTC and where the EPA does not address a contrary position, then the EPA retains it.

Response: The Agency has prepared an RTC to accompany the final action in this reconsideration. In some cases, commenters submitted the same comments for the reconsideration as they did for the 2020 proposal and the EPA's responses are largely the same in this document as in the prior RTC document because neither the decision nor the evidence has changed much. In other instances, changes in the evidence or the Administrator's decision, as well as changes in public comments, have resulted in changes in responses. While the prior response to comments remains in the record for this action, the EPA cautions commenters that the more recent preamble and RTC document reflects the EPA's latest views, and there may be issues where the prior RTC is outdated even if an issue has not been squarely raised and addressed in this document or the preamble. The EPA recognizes that the evidence before the Administrator differs from the evidence that was before the prior Administrator, and this Administrator has judged the evidence before him (particularly the epidemiologic evidence) differently in some respects than the prior Administrator judged the evidence before him, and has in some areas reached a different conclusion on whether to revise the NAAQS. The EPA has thoroughly explained the basis for the Administrator's conclusions and has responded to all significant comments on the Administrator's proposed decision in the preamble and this RTC document, and disagrees that more is required.

(2) **Comment:** Some commenters assert that the EPA's confidence in the scientific studies upon which the proposal is based should be undermined not only by limitations and uncertainties but also by the lack of available supporting data and "troubling calls by researchers conducting public health investigations to shield this data from review." These commenters further assert that the proposal relies heavily on research that is not publicly available and has not been independently replicated. In particular, these commenters note that many studies upon which the proposed decision are based are only U.S.-based studies, funded by NIH and EPA, from Harvard's T.H. Chan School of Public Health, suggesting that these studies are

[27] Generally, when the EPA refers to "greenhouse gases" it is referring to the six long-lived, well-mixed gases which were the subject of Endangerment Findings under CAA 202 and 231. It is worth nothing that, as discussed in the preamble to the final rule, PM has been found causally related to climate effects, but the EPA has concluded it would not be appropriate to establish or revise a secondary standard for PM to address climate effects.

not transparent, nor can they be easily reviewed or reproduced by independent researchers, which commenters claim raises concerns about the soundness of the science, specifically citing to the Federal Register notice for the January 6, 2021, "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information." The commenters further claim that the lack of transparency and potential conflict of interest undermines the credibility of the scientific evidence considered in reaching the proposed decisions on the primary $PM_{2.5}$ standards and contend that a thorough and unbiased examination of the available data is necessary prior to any revisions to the standards. In so doing, these commenters point to documents obtained from a FOIA request that included emails from Joel Schwartz to the EPA, apparently supporting the withdrawal of the January 6 Federal Register notice.

Response: The EPA disagrees that the fact that some studies may not be capable of easily being reproduced or reviewed by independent researchers should undermine the EPA's confidence in those studies, particularly when the studies are U.S.-based studies, which the EPA and the CASAC have generally considered the most relevant studies because of reduced concerns over comparability of air quality. The EPA notes that the commenters do not identify a specific study or a specific concern that would raise reasonable concerns about scientific credibility. The EPA notes that similar vague concerns have been raised in the past and the D.C. Circuit expressly upheld the EPA's view that it is reasonable to "rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them." *Am. Trucking Associations, Inc. v. EPA,* 283 F.3d 355, 372 (D.C. Cir. 2002). Moreover, when a reanalysis was eventually undertaken of prior research from the Harvard School of Public Health that has been significant for the PM NAAQS, the results of the reanalysis "assured the quality of the original data, replicated the original results, and tested those results against alternative risk models and analytic approaches without substantively altering the original findings of an association between indicators of particulate matter air pollution and mortality" (Krewski et al., 2000, p. iii-iv). As noted in section 11.2.2.1 of the 2019 ISA, this Harvard (Six Cities) study, and the ACS study, each "have undergone extensive independent replication and extended reanalysis." Thus, the EPA rejects the view that the simple allegation of a lack of transparency or potential conflict of interest is sufficient to undermine the credibility of scientific evidence which has been peer-reviewed before publication as well as considered closely by the CASAC and found to be highly relevant for the review. The EPA notes that the Federal Register notice for the January 6, 2021, "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" was vacated by U.S. District Court for the District of Montana[28] as well as by a subsequent Federal Register notice (86 FR 29515, Junee 2, 2021) and thus does not represent current EPA policy. Although the email from Dr. Schwartz is not included in the comment, since the Federal Register notice has now been vacated by both a court and the EPA, the EPA fails to see any relevance for the scientific credibility of key studies, particularly U.S.-based studies, in the fact that Dr. Schwartz may have supported its withdrawal.

(3) **Comment:** Commenters noted that the NAAQS should be based on science indicating that the current standards and the margins of safety are inadequate. However, the goal of the

[28] *EDF v. EPA* (D. Mont., No, 4:21-cv-00003-BMM)

NAAQS is not to achieve attainment with a NAAQS, then revise the NAAQS upon attainment to set a new goal. These commenters point to the advice of the CASAC related to uncertainties in the scientific evidence and the additional areas for future research that the CASAC identified. In so doing, these commenters urge the EPA to take the opportunity and investment of public and private funds to more appropriately develop, review, and refine the ongoing assessment of the need to revise the PM NAAQS, rather than finalizing revisions to the primary annual $PM_{2.5}$ standard as a part of this reconsideration.

Response: The EPA agrees with the commenters that the NAAQS should be based on the science and revised when the science indicates that, in the judgment of the Administrator, the current standards are inadequate to protect public health with an adequate margin of safety. The EPA agrees that the degree of attainment with existing standards is generally not relevant to consideration of whether standards should be revised. The EPA has explained above and in the preamble why it believes it is appropriate to revise the primary annual $PM_{2.5}$ standard at this time,

(4) **Comment:** Commenters contend that there are incentives for the EPA to inflate the risks of $PM_{2.5}$, arguing that the proposal is politically driven because of alleged co-benefits of reducing PM in other Agency rulemakings and incentives to fund PM-related research.

Response: The EPA rejects the suggestion that it is revising the standards for any purpose other than achieving the public health and welfare goals of the Clean Air Act pursuant to statutory authority and direction from Congress. The EPA recognizes that revisions to the NAAQS are often significant and consequential to a large range of citizens and stakeholders and takes its responsibility seriously to identify primary standards that are neither more stringent nor less stringent than necessary to protect public health with an adequate margin of safety.

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Appendix A: Studies cited in public comments related to the PM standards that were not included in the 2019 ISA or 2022 ISA Supplement and are provisionally considered in responding to comments

This appendix includes those studies cited in public comments or otherwise identified by the EPA while responding to comments related ot the PM standards that were not included in the 2019 ISA or the 2022 ISA Supplement (i.e., published after the literature cutoff date for the 2019 ISA or ISA Supplement but would have been considered within scope of the 2019 ISA or ISA Supplement) (U.S. EPA, 2015; U.S. EPA, 2019; U.S. EPA, 2022b). These studies were provisionally considered by the EPA, as discussed in section I.D of the preamble to the final rule and in this RTC.

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