Integrated Review Plan for the Primary National Ambient Air Quality Standards for Oxides of Nitrogen.

Volume 1: Background Document

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Integrated Review Plan for the Primary National Ambient Air Quality Standards for Oxides of Nitrogen.

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U.S. Environmental Protection Agency

Office of Air Quality Planning and Standards
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DISCLAIMER

This document serves as a public information document and as a management tool for the U.S. Environmental Protection Agency's (EPA's) Center for Public Health and Environmental Assessment and the Office of Air Quality Planning and Standards in conducting the review of the health-based air quality criteria and the primary national ambient air quality standards for oxides of nitrogen. It does not represent and should not be construed to represent an Agency determination or policy. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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PREFACE

The planning phase of the U.S. Environmental Protection Agency's (EPA's) reviews of the air quality criteria and national ambient air quality standards (NAAQS) includes the development of an integrated review plan (IRP) which is made available for public comment and provided to the Clean Air Scientific Advisory Committee (CASAC) for consultation. As a result of recent efforts to improve the efficiency and timeliness of planning materials and receipt of input from the CASAC and the public, the IRP for the current review of the primary NAAQS for oxides of nitrogen is comprised of three volumes. Volume 1 (this document) provides background information on the health-based air quality criteria and primary standards for NO_X and may serve as a reference for the public and the CASAC in their consideration of the subsequent two volumes. Volume 2 addresses the general approach for the review of the primary NAAQS for oxides of nitrogen and planning for the integrated science assessment (ISA), and will be the subject of a consultation with the CASAC. Volume 2 identifies policy-relevant issues in the review and describes key considerations in the EPA's development of the ISA. Volume 3 is the planning document for quantitative analyses to be considered in the policy assessment (PA), including exposure and risk analyses as warranted. It will describe key considerations in the EPA's planning with regard to any quantitative exposure/risk analyses to inform the review. Given that the availability of new scientific evidence in the review can inform the plans for any quantitative exposure/risk analyses, the development and public availability of Volume 3 will generally coincide with the availability of the draft ISA, and it will be the subject of a consultation with the CASAC at that time.

1 LEGISLATIVE REQUIREMENTS

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the national ambient air quality standards (NAAQS). Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then issue air quality criteria for those pollutants. The Administrator is to list those pollutants "emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare"; "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources"; and for which he "plans to issue air quality criteria…." (42 U.S.C. 7408(a)(1)). Air quality criteria are intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air…." (42 U.S.C. 7408(a)(2)).

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS[1] for pollutants for which air quality criteria are issued (42 U.S.C. 7409(a)). Section 109(b)(1) defines primary standards as ones "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."[2]

In setting primary standards that are "requisite" to protect public health, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary. In so doing, the EPA may not consider the costs of implementing the standards. See, *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 465–472, 475–76 (2001). Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards." See *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); accord *Murray Energy Corp. v. EPA*, 936 F.3d 597, 623–24 (D.C. Cir. 2019). At the same time, courts have clarified that the EPA may consider "relative proximity to peak background … concentrations" as a factor in deciding how to revise the NAAQS in the context of considering standard levels within the range of reasonable values supported by the air

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[1] This document focuses on health effects associated with gaseous oxides of nitrogen and the protection afforded by the primary NO_2 standards. The EPA is separately reviewing the ecological welfare effects associated with and the secondary standards for oxides of nitrogen, oxides of sulfur, and PM. Additional information on the currently ongoing and prior reviews of the secondary NAAQS for oxides of nitrogen, oxides of sulfur, and PM is available at: *https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards*.

[2] The legislative history of section 109 indicates that a primary standard is to be set at "the maximum permissible ambient air level … which will protect the health of any [sensitive] group of the population," and that for this purpose "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group." S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

quality criteria and judgments of the Administrator. See *American Trucking Ass'ns, v. EPA*, 283 F.3d 355, 379 (D.C. Cir. 2002), hereafter referred to as "*ATA III*."

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research still needs to identify. See *Lead Industries Ass'n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980); *American Petroleum Institute v. Costle*, 665 F.2d at 1186; *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 617–18 (D.C. Cir. 2010); *Mississippi v. EPA*, 744 F.3d 1334, 1353 (D.C. Cir. 2013). Both uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels (see *Lead Industries Ass'n v. EPA*, 647 F.2d at 1156 n.51, *Mississippi v. EPA*, 744 F.3d at 1351), but rather at a level that reduces risk sufficiently to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s),[3] and the kind and degree of uncertainties. Selecting any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Ass'n v. EPA*, 647 F.2d at 1161–62; *Mississippi v. EPA*, 744 F.3d at 1353.

Section 109(d)(1) of the Act requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge concerning the effects of the pollutant on public health and welfare. Under the same provision, the EPA is also to periodically review and, if appropriate, revise the NAAQS based on the revised air quality criteria.[4]

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[3] As used here and similarly throughout this document, the term population (or group) refers to persons having a quality or characteristic in common, such as a specific pre-existing illness or a specific age or life stage. Identification of such sensitive groups (called at-risk groups or at-risk populations) involves consideration of susceptibility and vulnerability.

[4] This section of the Act requires the Administrator to complete these reviews and make any revisions that may be appropriate "at five-year intervals" and also provides that the Administrator "may review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph."

Section 109(d)(2) addresses the appointment and advisory functions of an independent scientific review committee. Section 109(d)(2)(A) requires the Administrator to appoint this committee, which is to be composed of "seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies." Section 109(d)(2)(B) provides that the independent scientific review committee "shall complete a review of the criteria...and the national primary and secondary ambient air quality standards…and shall recommend to the Administrator any new…standards and revisions of existing criteria and standards as may be appropriate …" Since the early 1980s, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of the EPA's Science Advisory Board. Several other advisory functions are also identified for the committee by section 109(d)(2)(C), which reads:

> Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) 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 national ambient air quality standards.

As previously noted, the Supreme Court has held that section 109(b) "unambiguously bars cost considerations from the NAAQS-setting process" in *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 471 (2001). Accordingly, while some of the issues listed in section 109(d)(2)(C), such as those on which Congress has directed the CASAC to advise the Administrator, are relevant to the standard-setting process, others are not. Issues that are not relevant to standard setting may be relevant to implementing the NAAQS once they are established.[5]

[5] Because some of these issues are not relevant to standard setting, some aspects of CASAC advice may not be relevant to EPA's process of setting primary and secondary standards that are requisite to protect public health and welfare. Indeed, were the EPA to consider costs of implementation when reviewing and revising the standards "it would be grounds for vacating the NAAQS." *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 471 n.4 (2001). At the same time, the CAA directs CASAC to provide advice on "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance" of the NAAQS to the Administrator under section 109(d)(2)(C)(iv). In *Whitman*, the Court clarified that most of that advice would be relevant to implementation but not standard setting, as it "enable[s] the Administrator to assist the States in carrying out their statutory role as primary *implementers* of the NAAQS" (id. at 470 [emphasis in original]). However, the Court also noted that CASAC's "advice concerning certain aspects of 'adverse public health…effects' from various attainment strategies is unquestionably pertinent" to the NAAQS rulemaking record and relevant to the standard setting process (id. at 470 n.2).

2 NAAQS REVIEW PROCESS AND DOCUMENTS

This section provides general information about how the NAAQS review process typically proceeds and documents that are typically prepared over the course of the review. Each review of ambient air quality criteria and standards begins with a Call for Information for the Agency to consider in the review. This Call for Information, published in the *Federal Register*, generally is focused on scientific information pertinent to the criteria review but may also solicit comments from the public on policy-relevant issues important to address in the criteria and/or standards reviews. The Call for Information kicks off the first of the three types of phases in NAAQS reviews, the planning phase. The other two types of phases are assessment and regulatory decision making (Figure 2-1). The documents prepared in these three phases, summarized below, are available to the public on an Agency website maintained for this purpose (*https://www.epa.gov/naaqs*).

The Agency's plans for the review are presented to the public in an Integrated Review Plan (IRP).[6] The IRP is prepared jointly by the EPA's Center for Public Health and Environmental Assessment (CPHEA) within the Office of Research and Development (ORD) and the EPA's Office of Air Quality Planning and Standards (OAQPS) within the Office of Air and Radiation (OAR). In general, the IRP contains background material, including information that is generic across reviews (e.g., presentation of legislative requirements) and specific to the pollutant for the review (e.g., history of existing criteria and standards, monitoring methods and network, and review timeline), as well as key scientific, technical or policy aspects of plans for the new review. The IRP also presents the current plan and specifies the intended schedule and process for conducting the review and the key policy-relevant science issues that will guide the review. The IRP is made available to the public, and the critical aspects of plans for the new review are the subject of consultation with the CASAC.

As a result of recent efforts to improve the efficiency of the planning phase and to facilitate the receipt of timely input from the CASAC and the public on key aspects of the review, the IRP for the current review of the primary NAAQS for oxides of nitrogen is comprised of three volumes. Volume 1 (this document) provides background information and may serve as a reference for the public and the CASAC in their consideration of the subsequent two volumes. Volume 1 includes introductory or background information on the legislative requirements for reviews of the NAAQS, an overview of the review process, background information on prior reviews of the health-based air quality criteria and primary standards for

[6] Development of the IRP for some NAAQS reviews may be informed by a science policy workshop to help the Agency identify issues and questions to frame the review.

oxides of nitrogen and a summary of key aspects of the basis for the existing primary NO_2 NAAQS, and a summary of the status and anticipated milestones for the current review. Volume 1 also includes an appendix that aspects of the ambient air monitoring program for oxides of nitrogen, which includes NO_2, the indicator for the primary NO_2 NAAQS. Volume 2 addresses the general approach for the review, identifying policy-relevant issues in the review, and also addresses planning for the integrated science assessment (ISA), including key considerations in its development. Volume 2 will be the subject of a consultation with the CASAC. Volume 3 is the planning document for quantitative analyses to be considered in the policy assessment (PA), including exposure and risk analyses as warranted. It will describe key considerations in the EPA's planning with regard to any quantitative exposure/risk analyses to inform the review. Given that the availability of new scientific evidence in the review can inform the plans for any quantitative exposure/risk analyses, the development and public availability of Volume 3 will generally coincide with the availability of the draft ISA, and it will be the subject of a consultation with the CASAC at that time.

In the assessment phase, the EPA prepares an Integrated Science Assessment (ISA)[7] and any supplementary materials; quantitative air quality, exposure, and risk analyses, as warranted; and a Policy Assessment (PA). The ISA, prepared by the CPHEA, provides a concise review, synthesis, and evaluation of the most policy-relevant science, including key science judgments that are important to the design and scope of air quality, exposure, and risk analyses, as well as other aspects of the NAAQS review. The ISA and its supplementary materials provide a comprehensive assessment of the current scientific literature about known and anticipated effects on public health and welfare associated with the presence of the criteria pollutant in the ambient air, emphasizing information that has become available since the last air quality criteria review to reflect the current state of knowledge. In this way, the ISA forms the scientific foundation for each NAAQS review. Section 2.1 summarizes key aspects of the ISA.

Based on the updated scientific information available in the review and considered in the ISA, along with ISA conclusions, OAQPS staff considers the support provided for the development of quantitative assessments of air quality, exposures, and/or risks of health and/or welfare effects. As warranted in a given review, the EPA develops relevant quantitative analyses, the details of which, in recent reviews, are presented in appendices to the PA. These appendices concisely present methods, key results, observations, and related uncertainties.

The PA, like the OAQPS Staff Paper in earlier reviews, is a document that provides a transparent OAQPS staff analysis and conclusions regarding the adequacy of the current

[7] The ISA and its associated materials function in the NAAQS review process today, as the Air Quality Criteria Document (AQCD) did in reviews of the past.

standards and potential alternatives that are appropriate to consider before the issuance of proposed and final decisions. This evaluation of policy implications is intended to help ''bridge the gap'' between (1) the Agency's scientific and technical assessments (as presented in the ISA and the quantitative exposure and risk analyses) and (2) the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS. In this way, the PA integrates and interprets the information from the ISA and quantitative exposure and risk analyses to frame policy options for consideration by the Administrator. Development of the PA is also intended to facilitate CASAC's advice to the Agency and recommendations to the Administrator on the adequacy of the existing standards or revisions that may be appropriate to consider, as provided for in the CAA. Section 2.2 summarizes key aspects of the PA.

In the last phase of the review process, which generally follows the issuance of the final PA and consideration of conclusions presented therein, the Agency develops and publishes a notice of proposed decision to communicate the Administrator's proposed decisions regarding the standards review. To the extent the proposed decision is to revise the existing NAAQS or establish a new NAAQS, the notice presents the proposed regulatory changes. Before publishing a notice of proposed decision, it generally undergoes interagency review involving other federal agencies coordinated by the Office of Management and Budget (OMB) per Executive Orders 12866 and 14094.[8] Materials upon which the proposed decision is based, including the documents described above, are available to the public in the docket for the review. A public comment period, during which one or more public hearings are generally held, follows the publication of the proposed decision. Considering comments received on the proposed decision, the Agency develops a notice of final decision, including any regulatory revision, which generally undergoes interagency review before publication to complete the regulatory decision-making process. Section 2.3 summarizes the regulatory decision-making steps.

[8] Where implementation of the proposed decision would necessitate implementing emissions controls to reduce emissions to meet a revised standard, that may result in an estimated annual effect on the economy of $200 million or more, the EPA develops and releases a draft regulatory impact analysis (RIA) concurrent with the notice of proposed rulemaking. The RIA is prepared in accordance with Executive Orders 12866 and 14094 and is independent of and, by statute, is not considered in decisions regarding the review of the NAAQS.

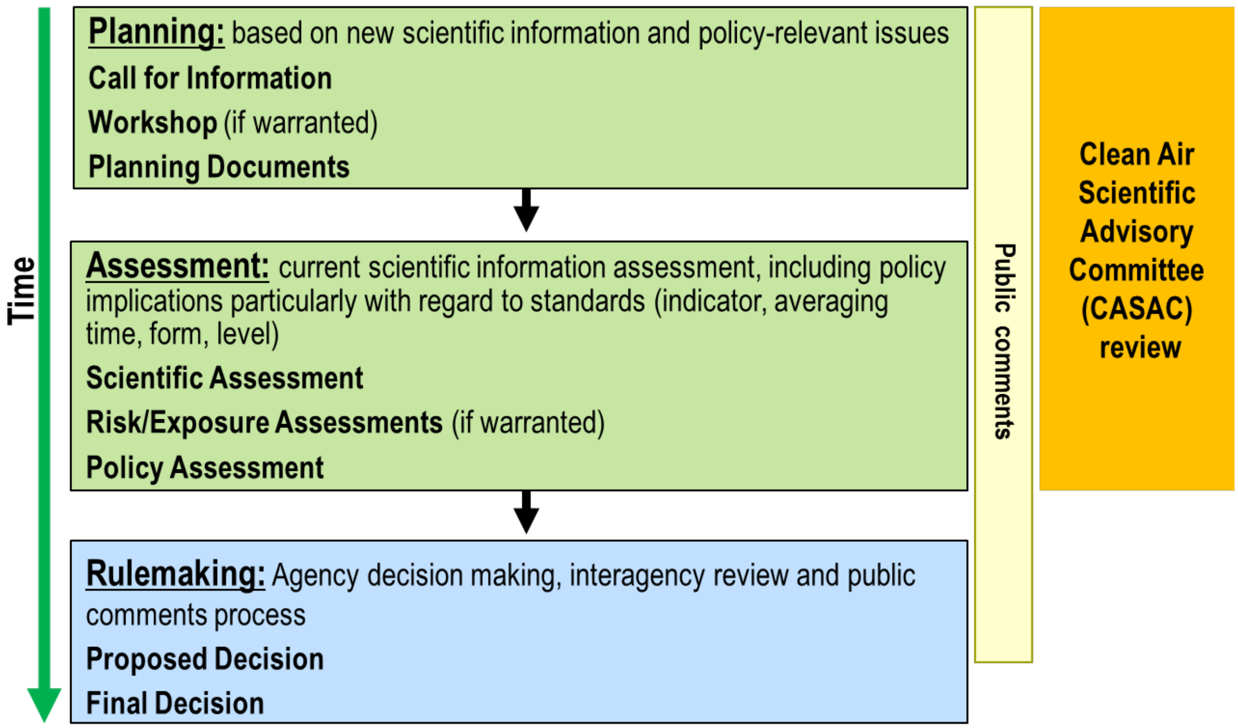

Figure 2-1. Overview of the NAAQS review process.

2.1 INTEGRATED SCIENCE ASSESSMENT

The purpose of the ISA is to draw upon the existing body of evidence to synthesize and provide a critical evaluation of the current state of scientific knowledge on the most relevant issues pertinent to the review of the NAAQS, identify changes in the scientific evidence bases since the previous review, and describe remaining or newly identified uncertainties. The ISA identifies, critically evaluates, and synthesizes the most policy-relevant current scientific literature (e.g., epidemiology, controlled human exposure, animal toxicology, atmospheric science, exposure science, environmental science, and ecology). In doing so, it presents a concise policy-relevant evaluation of the current scientific information along with the EPA's conclusions on the health and welfare effects of the criteria pollutant and associated key science findings that are important to inform the development of risk and exposure analyses (as warranted) and the PA, as well as other aspects of the NAAQS review process.

The ISA provides a focused assessment of the scientific evidence to address specific scientific questions and inform the consideration of overall policy-relevant questions for the PA. Through periodic reviews of the available scientific evidence, ISAs build on the data and conclusions of previous assessments. The ISA for a NAAQS review identifies and evaluates studies published since the cutoff date for studies in the prior ISA, synthesizing and integrating the new evidence in the context of the conclusions from the previous review. Important older studies may be discussed to reinforce key concepts and conclusions. Older studies may also be the primary focus in some subject areas or scientific disciplines where research efforts have subsided and/or where these older studies remain the definitive works available in the literature. More detail on the general ISA development process, as well as additional information on the scientific and public review aspects addressed in the ISA for oxides of nitrogen for the current review, is presented in Volume 2 of the IRP.

2.2 POLICY ASSESSMENT

The PA is a document that evaluates the currently available information regarding the adequacy of the current standards and potential alternatives if any are appropriate to consider in the current review. In so doing, the PA integrates and interprets the current scientific evidence from the ISA and available information from quantitative exposure/risk analysis, together with related limitations and uncertainties, to frame policy options for consideration by the Administrator. This evaluation of policy implications is intended to "bridge the gap" between the Agency's scientific assessments and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS.

Quantitative risk and exposure assessments (REAs), a term used in several past NAAQS reviews, have generally referred to assessments presented in a stand-alone REA document. More recently, we have also used this term or the phrase "REA analyses" to refer to the air quality, exposure, and/or risk analyses that we intend to present in appendices or as supplemental materials to the PA. These quantitative REAs are generally designed to assess human exposure and health risks, as well as ecological exposures and risks to public welfare, for air quality conditions associated with the existing standards and, as appropriate, for conditions associated with potential alternative standards. The objective for such assessments is to provide quantitative estimates of impacts that can inform the Administrator's judgments on the public health and public welfare significance of exposures likely to occur under air quality conditions reflective of the current NAAQS and, as appropriate, any alternative standards under consideration. Accordingly, the assessments also provide a basis for judgments regarding the extent of public health and public welfare protection afforded by such standards. The development of REAs in each NAAQS review draws upon the currently available evidence characterized by the ISA and current methods and tools. In considering whether new analyses are warranted for particular types of assessments in each review, we evaluate the availability of new scientific evidence and technical information, as well as improved methods and tools, that may provide support for conducting updates to address key limitations or uncertainties in analyses from the last review or to provide additional insight beyond those provided by the prior REA. Thus, we focus on identifying new analyses that are warranted in consideration of factors such as those raised here, while also bearing in mind practical and logistical considerations, such as available resources and timeline for the review. The details of any new analyses are documented within the PA (e.g., in appendices or associated volumes), and the findings are presented and discussed within the main body of the PA.

The PA includes pertinent background information, such as information on current air quality and the decisions in the last NAAQS review, as well as a discussion of the currently available health and welfare effects evidence and exposure/risk information. These discussions focus on policy-relevant aspects important for the Agency to consider in reviewing the existing standards. The policy evaluation in the PA of the current scientific evidence from the ISA and the current exposure/risk information is generally framed by a consideration of a series of policy-relevant questions, including the fundamental overarching questions associated with the adequacy of the current standards and, as appropriate, consideration of alternative standards that involve revision to any of the specific elements of the standards: indicator, averaging time, level, and form.[9] To the extent it is concluded to be appropriate to consider alternative standards, the PA will also describe policy options for such revisions supported by the available information. Key considerations in the development of the exposure/risk information will be discussed in Volume 3 of the IRP.

The draft PA, including the current air quality, exposure, and risk information, whether newly developed in this review or drawn from previously developed assessments, is distributed to the CASAC for its consideration and released to the public for review and comment. Review of the draft PA by the CASAC also facilitates CASAC's advice to the Agency and recommendations to the Administrator on the adequacy of the existing standards or revisions that may be appropriate to consider, as provided for in the CAA. The CASAC discusses its review of the draft PA at public meetings that are announced in the *Federal Register*. Based on past practice by the CASAC, the EPA expects that key advice and recommendations for revision would be summarized by the CASAC in a letter to the EPA Administrator. In revising the draft PA document, any such advice and recommendations are taken into account, and comments received from the public are also considered. The final document is made available on an EPA website, with its public availability announced in the *Federal Register*.

[9] The indicator defines the chemical species or mixture to be measured in the ambient air for the purpose of determining whether an area attains the standard. The averaging time defines the period over which air quality measurements are to be averaged or otherwise analyzed. The form of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard. For example, the form of the annual NAAQS for fine particulate matter is the average of annual mean concentrations for three consecutive years, while the form of the 8-hour NAAQS for carbon monoxide is the second-highest 8-hour average in a year. The level of the standard defines the air quality concentration used for that purpose.

2.3 REGULATORY DECISION MAKING

Following the issuance of the final PA, consideration of analyses and conclusions presented therein, and taking into consideration CASAC advice and recommendations, the Agency develops a notice of proposed decision. This notice conveys the Administrator's proposed conclusions, reached in consideration of the analyses and conclusions in the documents developed in the review (e.g., as described in the preceding sections) and advice and recommendations from the CASAC regarding the adequacy of the current standards and any revision(s) that may be appropriate. As appropriate, a draft notice of the proposed decision is submitted to the Office of Management and Budget (OMB) for review and comment. In this interagency review step, the OMB also provides other federal agencies the opportunity to review and comment. After completing the interagency review, the notice of proposed decision is published in the *Federal Register*.

At the time of publication of the notice of the proposed decision, all materials on which the proposal is based are made available in the public docket for the review.[10] Publication of the proposal notice is followed by a public comment period, generally lasting 45 to 90 days, during which the public is invited to submit comments on the proposal to the docket, and one or more public hearings may be held. Taking into account comments received on the proposed decision, the Agency then develops a notice of final decision, which communicates the Administrator's decisions regarding this review and which may again undergo OMB-coordinated interagency review before issuance by the EPA. At the time of the final decision, the Agency responds to all significant comments on the proposal.[11] Publication of the notice of the final decision in the *Federal Register* will complete the review process.

The final decisions on the primary and secondary standards are largely public health or welfare policy judgments by the Administrator. Final decisions must draw upon scientific information and analyses about health or welfare effects and risks, as well as judgments about how to deal with uncertainties inherent in scientific evidence and analyses. Consistent with the Agency's approach across all NAAQS reviews, the approach of the PA to inform these judgments is based on a recognition that the available evidence generally reflects continuums that include ambient air exposures for which scientists generally agree that effects are likely to

[10]The docket for the current review of the primary NO_2 standards is identified as EPA-HQ-OAR-2023-0317. This docket has incorporated the ISA docket (EPA-HQ-ORD-2022-0831) by reference. Both dockets are publicly accessible at *www.regulations.gov*.

[11] For example, Agency responses to all substantive comments on the 2017 proposed decision notice in the last review were provided in the final decision notice (83 FR 17226, April 18, 20218). In some reviews, responses are additionally provided in a separate document (e.g., Responses to Significant Comments on the 2009 Proposed Rule on the Primary National Ambient Air Quality Standards for Nitrogen Dioxide (July 15, 2009; 74 FR 34404)).

occur through lower levels at which the likelihood and magnitude of response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the Act and how the EPA and the courts have historically interpreted the Act.

With regard to primary standards, these provisions require the Administrator to establish standards that are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The provisions do not require that standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of sensitive groups.[12]

[12] More than one population group may be identified as sensitive or at-risk in a NAAQS review. The decision in the review will reflect consideration of the degree to which protection is provided for these sensitive population groups. To the extent that any particular population group is not among the identified sensitive groups, a decision that provides protection for the sensitive groups would be expected to also provide protection for other population groups.

3 BACKGROUND ON THE PRIMARY NAAQS FOR OXIDES OF NITROGEN

3.1 HISTORY OF THE HEALTH-BASED AIR QUALITY CRITERIA AND STANDARDS FOR OXIDES OF NITROGEN

In 1971, the EPA added oxides of nitrogen to the list of criteria pollutants under section 108(a)(1) of the CAA and issued the initial air quality criteria (36 FR 1515, January 30, 1971; U.S. EPA, 1971). Based on these air quality criteria, the EPA promulgated NAAQS for oxides of nitrogen using NO_2 as the indicator (36 FR 8186, April 30, 1971). Both primary and secondary standards were set at 100 micrograms per cubic meter ($\mu g/m^3$) (equal to 0.053 parts per million [ppm]), as an annual average.

The EPA retained the primary and secondary NO_2 standards, without revision, in subsequent reviews completed in 1985 and 1996 (50 FR 25532, June 19, 1985; 61 FR 52852, October 8, 1996). In the latter of the two decisions, the EPA concluded that “the existing annual primary standard appears to be both adequate and necessary to protect human health against both long- and short-term NO_2 exposures” and that “retaining the existing annual standard is consistent with the scientific data assessed in the Criteria Document (U.S. EPA, 1993) and the Staff Paper (U.S. EPA, 1995) and with the advice and recommendations of the CASAC” (61 FR 52854, October 8, 1996).

In 2005, the EPA again initiated the review of the health-based air quality criteria for oxides of nitrogen and the primary NAAQS for oxides of nitrogen (70 FR 73236, December 9, 2005). The Agency’s plan for conducting the review was contained in the *Integrated Review Plan for the Primary National Ambient Air Quality Standard for Nitrogen Dioxide* (2007 IRP; U.S. EPA, 2007), which included consideration of comments received from CASAC consultation as well as the public on a draft IRP. The scientific assessment for the review was described in the 2008 *Integrated Science Assessment for Oxides of Nitrogen – Health Criteria* (U.S. EPA, 2008b), multiple drafts of which received review by the CASAC and the public. After consultation with the CASAC and public comment on a draft analysis plan, the EPA also conducted quantitative human risk and exposure assessments. These technical analyses were presented in the *Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard* (2008 REA; U.S. EPA, 2008a), multiple drafts of which received CASAC and public review.

During the review initiated in 2005, the EPA was engaged in considering changes to the NAAQS review process. An important change that was implemented was the discontinuation of the Staff Paper (the prior term for PAs). To address this discontinuation, prior to the implementation of an alternative to serve its purpose of consideration of policy-relevant aspects of the assessments and discussing policy options for the Administrator to consider, a policy assessment chapter that considered the scientific evidence in the 2008 ISA and the exposure and risk characterization results presented in other chapters of the 2008 REA as they related to the adequacy of the then-current primary annual NO_2 standard and potential alternative standards for consideration was included in the final REA (U.S. EPA, 2008a, chapter 10). The CASAC discussed the final REA, emphasizing the policy assessment chapter during a public teleconference on December 5, 2008 (73 FR 66895, November 12, 2008). Following that teleconference, the CASAC offered comments and advice on the primary NO_2 standard in a letter to the Administrator (Samet, 2008).

After considering the body of evidence on human health effects associated with NO_2 exposures in the ISA and the exposure and risk information in the REA, the Administrator determined that the existing annual average primary NO_2 NAAQS was not sufficient to protect the public health from the array of effects that could occur following short-term exposures to NO_2 in ambient air. In so doing, the Administrator noted the potential for adverse health effects to occur following exposures to elevated NO_2 concentrations that can occur around major roads (75 FR 6482, February 9, 2010). In a notice published in the *Federal Register* on July 15, 2009, the EPA proposed to supplement the existing primary annual NO_2 standard by establishing a new short-term standard (74 FR 34404, July 15, 2009). In a notice published in the *Federal Register* on February 9, 2010, the EPA finalized a new short-term NO_2 standard with a level of 100 parts per billion (ppb), based on the 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations. The EPA also retained the existing primary annual NO_2 standard of 53 ppb as an average annual average (75 FR 6474, February 9, 2010). The Agency's final decision included consideration of the CASAC's advice and recommendations during the review, as well as public comments on the proposed rule. The EPA's final rule was upheld against challenges in a decision issued by the U.S. Court of Appeals for the District of Columbia Circuit. *API v. EPA*, 684 F.3d 1342 (D.C. Cir. 2012).

In addition to revisions to the NAAQS, revisions were also finalized related to the data handling procedures, to the ambient air monitoring and reporting requirements and to the Air Quality Index (AQI). The EPA also included new monitoring network requirements for States to locate monitors near heavily trafficked roadways in large urban areas and in other locations where maximum NO_2 concentrations can occur. Subsequent to the 2010 rulemaking, the EPA revised the deadlines by which the near-road monitors were to be operational to implement a phased deployment approach (78 FR 16184, March 14, 2013). The bulk of the initial set of required near-road NO_2 monitors became operational between January 1, 2014, and January 1, 2017.

In February 2012, the EPA again initiated a review of the health-based air quality criteria and of the primary NAAQS for oxides of nitrogen and issued a Call for Information in the *Federal Register* (77 FR 7149, February 10, 2012), with the review focused on health effects associated with the gaseous species only. The gaseous oxides of nitrogen include NO_2 and nitric oxide (NO), as well as their gaseous reaction products. Total oxides of nitrogen include these gaseous species and particulate species (e.g., nitrates).[13, 14]

A wide range of external experts, as well as EPA staff representing a variety of areas of expertise (e.g., epidemiology, human and animal toxicology, statistics, risk/exposure analysis, atmospheric science, and biology), participated in a workshop held by the EPA on February 29 to March 1, 2012, in Research Triangle Park, NC. The workshop provided an opportunity for a public discussion of the key policy-relevant issues associated with the review of the primary NO_2 NAAQS and the most meaningful new science that would be available to inform our understanding of these issues.

Based in part on the workshop discussions, the EPA developed a draft plan for the ISA and a draft IRP outlining the schedule, process, and key policy-relevant questions that would guide the evaluation of the health-based air quality criteria and the review of the primary NAAQS for oxides of nitrogen. The draft plan for the ISA was released in May 2013 (U.S. EPA, 2013; 78 FR 26026, May 3, 2013) and was the subject of a consultation with the CASAC in June 2013 (78 FR 27234, May 9, 2013). Comments received from that consultation were considered in preparing the first draft ISA, and subject matter experts reviewed preliminary drafts of key ISA chapters at a public workshop hosted by the EPA's National Center for Environmental Assessment (NCEA) in May 2013 (78 FR 27374, May 10, 2013). The first draft of ISA was released in November 2013 (U.S. EPA, 2013; 78 FR 70040, November 22, 2013). During this time, the draft IRP was also in preparation and was released in February 2014 (U.S. EPA, 2014; 79 FR 7184, February 06, 2014). The CASAC reviewed both the draft IRP and first draft ISA at a public meeting held in March 2014 (79 FR 8701, February 13, 2014), and the first draft ISA was further discussed at an additional teleconference held in May 2014 (79 FR 17538, March 28, 2014). The CASAC finalized its recommendations on the first draft ISA in a letter to the Administrator in June 2014 (Frey, 2014).

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[13] Health effects associated with particulate oxides of nitrogen are addressed in the review of the PM NAAQS. Additional information on the PM NAAQS reviews is available at: *https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards*.

[14] The EPA is separately reviewing the ecological welfare effects associated with and the secondary standards for oxides of nitrogen, oxides of sulfur, and PM. Additional information on the ongoing and previous review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur, and PM is available at: *https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards*.

The EPA released a second draft ISA in January 2015 (U.S. EPA, 2015a; 80 FR 5110, January 30, 2015) and the REA Planning Document in May 2015 (U.S. EPA, 2015b; 80 FR 27304, May 13, 2015). The CASAC reviewed these documents at a public meeting held in June 2015 (80 FR 22993, April 24, 2015). A follow-up teleconference with the CASAC was held in August 2015 (80 FR 43085, July 21, 2015) to finalize recommendations on the second draft ISA. The CASAC's advice and recommendations on the second draft ISA were provided in a letter to the Administrator in September 2015 (Diez Roux and Frey, 2015a). The final ISA was released in January 2016 (U.S. EPA, 2016; 81 FR 4910, January 28, 2016). The CASAC's recommendations on the draft REA Planning Document were included in a letter provided to the EPA in September 2015 (Diez Roux and Frey, 2015b). The EPA considered the CASAC's advice and public comments on the draft REA Planning Document in developing and performing the quantitative analyses for the review, which were included as a part of the draft PA.

The EPA prepared a draft PA, which was released in September 2016 (U.S. EPA, 2016b; 81 FR 65353, September 22, 2016). The CASAC reviewed the draft PA at a public meeting held on November 9-10, 2016 (81 FR 68414, October 4, 2016), and a follow-up teleconference was held on January 24, 2017 (81 FR 95137, December 27, 2016). The CASAC's recommendations, based on its review of the draft PA, were provided in a letter to the Administrator dated March 7, 2017 (Diez Roux and Sheppard, 2017). The EPA staff considered these recommendations and public comments on the draft PA when developing the final PA, which was released in April 2017 (U.S. EPA, 2017; 82 FR 17947, April 14, 2017).

In July 2017, the Administrator proposed to retain the existing primary NO_2 standards without revision (82 FR 34792, July 2017). The Administrator solicited comments on his proposed conclusion regarding the public health protection provided by the primary NO_2 standards and on his proposal to retain the standard. In May 2018, after considering the available scientific evidence, the results of quantitative analyses, the CASAC advice, and public comments, the Administrator concluded that the current 1-hour and annual NO_2 primary standards, together, were requisite to protect public health with an adequate margin of safety. Therefore, the EPA retained the 1-hour and annual NO_2 primary standards, without revision (83FR17226, May 2018). The rationale for the final decision is described in more detail in section 3.2 below.

3.2 THE PRIMARY STANDARDS

Ambient air concentrations of NO_2 are influenced by both direct NO_2 emissions and by emissions of nitric oxides (NO), with the subsequent conversation of NO to NO_2 primarily through reaction with ozone (O_3). A large number of oxidized nitrogen species in the atmosphere are formed from the oxidation of NO and NO_2. These include nitrate radicals (NO_3), nitrous acid

(HONO), nitric acid (HNO_3), dinitrogen pentoxide (N_2O_5), nitryl chloride ($ClNO_2$), peroxynitric acid (HNO_4), peroxyacetyl nitrate and its homologues (PANs), other organic nitrates, such as alkyl nitrates (including isoprene nitrates), and particulate nitrate (pNO_3). The sum of these reactive oxidation products and NO plus NO_2 comprise the oxides of nitrogen.[15, 16]

There are currently two primary standards for oxides of nitrogen. NO_2 is the component of oxides of nitrogen of greatest health concern and is the indicator for the primary NAAQS. The two primary NO_2 standards are: a 1-hour standard established in 2010 (75 FR 6502, February 9, 2010) at a level of 100 ppb and based on the 98th percentile of the annual distribution of daily maximum 1-hour NO_2 concentrations, averaged over 3 years; and an annual standard, originally set in 1971, at a level of 53 ppb and based on annual average NO_2 concentrations (36 FR 8186, April 30, 1971).

Consistent with the review completed in 2010, the 2018 review focused on health effects associated with gaseous oxides of nitrogen[17] and the protection afforded by the primary NO_2 standards. The gaseous oxides of nitrogen include NO_2 and NO, as well as their gaseous reaction products. Total oxides of nitrogen include these gaseous species as well as particulate species (e.g., nitrates). Health effects and non-ecological welfare effects associated with the particulate species are addressed in the review of the NAAQS for particulate matter (PM).[18] The EPA is separately reviewing the ecological welfare effects associated with and the secondary standards for oxides of nitrogen, oxides of sulfur, and PM.[19]The 2018 review evaluated whether it was appropriate to consider retaining or revising both of these primary NO_2 standards (83 FR 17226, April 18, 2018). The Administrator's review of these standards in 2018 concluded that they provided the requisite protection of public health, with an adequate margin of safety, and should be retained without revision. These conclusions were informed by careful consideration of the full body of evidence available in the 2018 review, giving particular weight to the assessment of

[15] The focus is on NO_2 in this document, as this is in the indicator for the current standards and is most relevant to the evaluation of health evidence.

[16] Section 108(c) of the CAA specifies that: "Such criteria [for oxides of nitrogen] shall include a discussion of nitric and nitrous acids, nitrites, nitrates, nitrosamines, and other carcinogenic and potentially carcinogenic derivatives of oxides of nitrogen." By contrast, within air pollution research and control communities, the terms "nitrogen oxides" and NO_X are often restricted to refer to only to the sum of NO and NO_2.

[17] These gaseous oxides of nitrogen can also be referred to as "nitrogen oxides" and include a broad category of gaseous oxides of nitrogen (i.e., oxidized nitrogen compounds), including NO_2, NO, and their various reaction products.

[18] Additional information on the PM NAAQS is available at: *https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards*.

[19] Additional information on the ongoing and previous review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur, and PM is available at: *https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards*.

the scientific evidence in the 2016 ISA, analyses in the 2017 PA comparing NO_2 air quality with health-based benchmarks, consideration of the evidence and analyses in the 2017 PA, and the advice and recommendations from the CASAC (83 FR 17226, April 18, 2018).

With regard to the short-term NO_2 exposures, in the last review, the most robust evidence came from studies examining respiratory effects. The strongest support for this relationship came from controlled human exposure studies demonstrating NO_2-induced increases in airway responsiveness in individuals with asthma. Most of the controlled human exposure studies assessed in the 2016 ISA were available in the 2010 review, with the addition in the 2018 review of an updated meta-analysis that synthesized data from these studies. These studies provided an important part of the body of evidence supporting the decision in the 2010 review to establish the 1-hour NO_2 standard with its level of 100 ppb. Beyond the controlled human exposure studies, additional supporting evidence came from epidemiologic studies reporting associations with a range of asthma-related respiratory effects, including effects serious enough to result in emergency room visits or hospital admissions. While there was some new evidence in the 2018 review from such epidemiologic studies of short-term NO_2 exposures, the results of these newer studies were generally consistent with the epidemiologic studies that were available in the 2010 review.

With regard to long-term NO_2 exposures, the Administrator noted that although the evidence supporting associations with asthma development in children was stronger in the 2018 review than it was in the 2010 review, uncertainties remained regarding the degree to which estimates of long-term NO_2 concentrations in these studies were serving primarily as surrogates for exposures to the broader mixture of traffic-related pollutants. Supporting evidence also included studies indicating a potential role for repeated short-term NO_2 exposures in the development of asthma (U.S. EPA, 2016a, p. 6-64 and p. 6-65).

In addition, the Administrator acknowledged that the evidence for some non-respiratory effects had strengthened since the 2010 review. In particular, based on the assessment of the evidence in the 2016 ISA, he noted stronger evidence for NO_2-associated cardiovascular effects (short- and long-term exposures), premature mortality (long-term exposures), and certain reproductive effects (long-term exposures). As detailed in the 2016 ISA, while this evidence was generally strengthened since the 2010 review, it remained subject to greater uncertainty than the evidence of asthma-related respiratory effects (U.S. EPA, 2016a).

In the 2018 review, the Administrator's consideration of potential at-risk populations drew from the assessment of the evidence in the 2016 ISA (U.S. EPA, 2016a, Chapter 7). Based on the systematic approach to evaluating factors that may increase risks in a particular population or during a particular life stage in the 2016 ISA, the Administrator was most concerned about the potential effects of NO_2 exposures in people with asthma, children, and older adults (U.S. EPA, 2016a, Table 7-27). Support for potentially higher risks in these populations was based primarily on evidence for asthma exacerbation or asthma development. Evidence for other health effects was subject to greater uncertainty (U.S. EPA, 2017, Section 3.4).

The Administrator further used the scientific evidence, described in detail in the 2016 ISA (U.S. EPA, 2016a), to directly inform his consideration of the adequacy of the public health protection provided by the primary NO_2 standards. Consistent with the approach in the 2017 PA (U.S. EPA, 2017), and with the CASAC's advice (Diez Roux and Sheppard, 2017), the Administrator specifically considered the evidence within the context of the degree of public health protection provided by the current 1-hour and annual standards together, including the combination of all elements of these standards (i.e., indicator, averaging times, forms, levels).

In doing so, the Administrator focused on the results of controlled human exposure studies of airway responsiveness in people with asthma and on the results of U.S. and Canadian epidemiologic studies of asthma-related hospital admissions, asthma-related emergency department visits, and asthma development in children. He particularly emphasized the results of controlled human exposure studies, which were identified in the 2016 ISA as providing "[t]he key evidence that NO_2 exposure can independently exacerbate asthma" (U.S. EPA, 2016a , p. 1-18). The Administrator's decision to focus on these studies was consistent with the CASAC's advice that the strongest evidence was for an increase in airway responsiveness based on controlled human exposure studies, with supporting evidence from epidemiologic studies.

In considering the controlled human exposure studies of airway responsiveness, the Administrator focused on the results of an updated meta-analysis of data from these studies and the consistency of findings across individual studies. As discussed above, and consistent with the evidence in the 2010 review, the meta-analysis indicated that most study volunteers, generally with mild asthma, experienced increased airway responsiveness following 30-minute to 1-hour resting exposures to NO_2 concentrations from 100 to 530 ppb. Based on these results, the Administrator noted the potential for people with asthma to experience NO_2-induced respiratory effects following exposures in this range and that people with more severe asthma could experience more serious effects. The Administrator further noted that individual studies consistently reported statistically significant increases in airway responsiveness following exposures to NO_2 concentrations at or above 250 ppb, with less consistent results across studies conducted at lower exposure concentrations, particularly 100 ppb.

Therefore, the Administrator judged that it was appropriate to consider the degree of protection provided against exposures to NO_2 concentrations at and above 100 ppb, though his concern was greater for exposures to higher concentrations. In particular, based on the results of the meta-analysis and on the consistent results across individual studies, the Administrator was most concerned about the potential for people with asthma to experience adverse respiratory effects following NO_2 exposures at or above 250 ppb. Because results were less consistent across individual studies that evaluated lower exposure concentrations, the Administrator was increasingly concerned about uncertainties in the evidence as he considered the potential implications of such exposures. While taking these uncertainties into consideration, the Administrator remained concerned about the potential for respiratory effects following exposures to NO_2 concentrations as low as 100 ppb, particularly in people with more severe cases of asthma than have generally been evaluated in the available NO_2-controlled human exposure studies. Thus, when the evidence and uncertainties were considered together, the Administrator judged that it was appropriate to consider the degree of protection provided against potential exposures to NO_2 concentrations at or above 100 ppb, with the most emphasis on the potential for exposures at or above 250 ppb.

In further considering the potential public health implications of the controlled human exposure studies, the Administrator considered the results of quantitative comparisons between NO_2 air quality and health-based benchmarks. As discussed in the 2017 PA, these comparisons helped to place the results of the controlled human exposure studies, which provided the basis for the benchmark concentrations, into a broader public health context. In considering the results of the analyses comparing NO_2 air quality to specific health-based benchmarks, the Administrator first recognized that all areas of the U.S. met the current primary NO_2 standards. When based on the unadjusted NO_2 air quality, these analyses estimated almost no days with the potential for 1-hour exposures to NO_2 concentrations at or above health-based benchmarks, including the lowest benchmark examined (i.e., 100 ppb).

The Administrator additionally recognized that, even when ambient NO_2 concentrations are adjusted upward just to meet the existing 1-hour standard, the analyses estimated no days with the potential for exposures to the NO_2 concentrations that have been shown most consistently to increase airway responsiveness in people with asthma (i.e., above 250 ppb). Such NO_2 concentrations were not estimated to occur, even under worst-case conditions across various study areas with among the highest NO_X emissions in the U.S. and at monitoring sites adjacent to some of the most heavily trafficked roadways in the U.S. In addition, analyses with adjusted air quality indicated a limited number of days with the potential for exposures to 1-hour NO_2 concentrations at or above 100 ppb, an exposure concentration with the potential to exacerbate asthma-related respiratory effects, but where uncertainties in the evidence became increasingly important.

As such, the Administrator concluded that evidence from controlled human exposure studies of airway responsiveness and analyses comparing ambient air NO_2 concentrations to health-based benchmarks supported the degree of the public health protection provided by the current primary NO_2 NAAQS. In particular, he was concerned about exposures to NO_2

concentrations at and above 250 ppb, where the potential for NO_2-induced respiratory effects was supported by results of the meta-analysis and by consistent results reported across individual studies. Regarding this, the Administrator noted that meeting the current standards was estimated to allow no potential for exposure to 1-hour NO_2 concentrations at or above 250 ppb. Additionally, the Administrator was concerned about exposures to lower NO_2 concentrations, including concentrations as low as 100 ppb, though, as described above, he was also concerned about the uncertainties in the evidence at such low exposure concentrations. In considering the degree of protection provided against exposures to 100 ppb NO_2, in light of uncertainties, the Administrator judged that limiting such exposures was appropriate but that it was not necessary to eliminate them. He noted that the current standard is estimated to allow limited potential for exposures to NO_2 concentrations at or above 100 ppb. Thus, given the substantial protection provided against exposures to NO_2 concentrations at and above 250 ppb and the protection provided against exposures to concentrations as low as 100 ppb, the Administrator reached the conclusion that the evidence, when considered in light of its uncertainties, supported the degree of public health protection provided by the current primary NO_2 NAAQS.

Although the epidemiologic evidence for NO_2 is subject to greater uncertainty than the controlled human exposure studies of NO_2-induced changes in airway responsiveness, the Administrator also considered what the available epidemiologic studies indicated with regard to the adequacy of the public health protection provided by the current standards. In particular, he considered analyses of NO_2 air quality in the locations and during the time periods of available U.S. and Canadian epidemiologic studies. These studies did not report associations in locations meeting the current NO_2 standards (i.e., associations were reported for NO_2 concentrations that exceeded the current standards). There was greater uncertainty regarding the potential for reported effects to occur following the NO_2 exposures that are associated with air quality meeting those standards.

With regard to studies of short-term NO_2 exposures, the Administrator noted that epidemiologic studies provided consistent evidence for asthma-related emergency department visits and hospital admissions associated with exposure to NO_2 in locations likely to have exceeded the current standards over at least parts of study periods (based on the presence of relatively precise and generally statistically significant associations across several studies). These studies have not consistently shown such NO_2-associated outcomes in areas that would have clearly met the current standards. In this regard, the Administrator recognized that the NO_2 concentrations identified in these epidemiologic studies are based on a NO_2 monitoring network that, during the study periods, did not include monitors meeting the current near-road monitoring requirements. This was particularly important given that NO_2 concentrations near the most heavily trafficked roadways were likely to have been higher than those reflected by the NO_2

concentrations measured at monitors in operation during study years. As such, the estimated design values associated with the areas during the studies could have been higher had a near-road monitoring network been in place. Thus, while these epidemiologic studies provide consistent evidence for associations with asthma-related effects, the Administrator noted that studies conducted in the U.S. and Canada did not support associations with asthma-related hospital admissions or emergency department visits in locations that would have clearly met the current standards.

With regard to studies of long-term NO_2 exposures, the Administrator noted that the preponderance of evidence for respiratory health effects comes from epidemiologic studies evaluating asthma development in children. These studies report associations with long-term average NO_2 concentrations, while the broader body of evidence indicates the potential for repeated short-term NO_2 exposures to contribute to the development of asthma. Because of this, and because air quality analyses indicate that meeting the current 1-hour standard can also limit annual NO_2 concentrations, when considering these studies of asthma development, the Administrator considered the protection provided by the combination of both the annual and 1-hour standards together. While available epidemiologic studies conducted in the U.S. and Canada consistently report associations between long-term NO_2 exposures and asthma development in children in locations likely to have violated the current standards over at least parts of study periods, those studies did not indicate such associations in locations that would have clearly met the current annual and 1-hour standards. This was particularly the case given that NO_2 concentrations near the most heavily trafficked roadways were not likely reflected by monitors operating during study years. Therefore, while recognizing the public health significance of asthma development in children and recognizing that NO_2 concentrations exceeding the current standards was associated with asthma development, the Administrator placed weight on the 2017 PA conclusion that the evidence did not provide support for NO_2-attributable asthma development in children in locations with NO_2 concentrations that would have clearly met both the annual and 1-hour standards.

Taking all of these considerations into account, the Administrator reached the conclusion that the scientific evidence evaluated, in combination with the results of quantitative analyses comparing NO_2 air quality with health-based benchmarks, supported the degree of public health protection provided by the current 1-hour and annual primary NO_2 standards and did not call into question any of the elements of those standards. He further concluded that the current 1-hour and annual NO_2 primary standards, together, were requisite to protect public health with an adequate margin of safety.

In particular, with regard to short-term exposures and the current 1-hour standard, the Administrator took note of the well-established body of scientific evidence supporting the occurrence of respiratory effects following short-term NO_2 exposures. In reaching the conclusion that the current standards provide requisite protection against these effects, the Administrator noted that meeting the 1-hour NO_2 standard provided a substantial margin of safety against exposures to NO_2 concentrations that have been shown most consistently to increase airway responsiveness in people with asthma, even under worst-case conditions across a variety of study areas with among the highest NO_X emissions in the U.S. Such NO_2 concentrations were not estimated to occur, even at monitoring sites adjacent to some of the most heavily trafficked roadways. Furthermore, the 1-hour standard limited exposure potential to 1-hour concentrations at or above 100 ppb. Thus, the standard provided protection against NO_2 exposures with the potential to exacerbate symptoms in some people with asthma, but uncertainties in the evidence became increasingly important, as discussed in more detail in the 2017 PA. Finally, the Administrator noted that the 1-hour standard was expected to maintain ambient NO_2 concentrations below those present in locations where key U.S. and Canadian epidemiologic studies reported relatively precise and statistically significant associations between short-term NO_2 and asthma-related hospitalizations.

In addition, with regard to long-term NO_2 exposures, the Administrator noted that the evidence supporting associations with asthma development in children was strengthened since the 2010 review, though important uncertainties remained. As discussed above, meeting the current annual and 1-hour standards was expected to maintain ambient NO_2 concentrations below those present in locations where key U.S. and Canadian epidemiologic studies reported such associations between long-term NO_2 and asthma development. In considering the protection provided against exposures that could contribute to asthma development, the Administrator recognized the air quality relationship between the 1-hour standard and annual standard and that analyses of historical ambient NO_2 concentrations in the 2017 PA (U.S. EPA, 2017, Figure B3-1) suggested that meeting the 1-hour standard with its level of 100 ppb would be expected to maintain annual average NO_2 concentrations well below the 53 ppb level of the annual standard, and generally below 35 ppb . The Administrator judged that, as additional years of data become available from the near-road NO_2 monitors, it would be important in future reviews to evaluate the degree to which this relationship is also observed in the near-road environment and the degree to which the annual standard provides additional protection, beyond that provided by the 1-hour standard. Such an evaluation could inform future reviews of the primary NO_2 NAAQS, consistent with the CASAC advice that in the next review cycle for oxides of nitrogen, the EPA should review the annual standard to determine if there is a need for revision or revocation (83 FR 17226, April 18, 2018).

Therefore, in the 2018 review, the Administrator retained the current primary NO_2 standards without revision. The Administrator noted that his judgment to retain the current primary NO_2 standards was consistent with CASAC advice provided in its review of the 2016 draft PA. In their advice to retain the standard, the CASAC specifically focused its conclusions on the degree of protection provided by combining the 1-hour and annual standards against short- and long-term NO_2 exposures. The CASAC stated that the suite of the current 1-hour and annual standards, together, provide protection against adverse effects from exposure to NO_2 (83 FR 17226, April 18, 2018)

Inherent in the Administrator's conclusions were public health policy judgments on the public health implications of the available scientific evidence and analyses, including how to weigh associated uncertainties. These public health policy judgments included those related to the appropriate degree of public health protection that should be afforded against the risk of respiratory morbidity in at-risk populations, such as the potential for worsened respiratory effects in people with asthma, as well as judgments related to the appropriate weight to be given to various aspects of the evidence and quantitative analyses, including how to consider their associated uncertainties. Based on these considerations and the judgments identified here, the Administrator concluded that the current standards provide the requisite protection of public health with an adequate margin of safety, including protection of at-risk populations, such as people with asthma.

The Administrator additionally recognized that the uncertainties and limitations associated with the many aspects of the estimated relationships between respiratory morbidity and NO_2 exposures were amplified when considering progressively lower ambient NO_2 concentrations. In his view, and consistent with the conclusions in the 2017 PA, there was appreciable uncertainty in the extent to which reductions in asthma exacerbations or asthma development would result from revising the primary NO_2 NAAQS to be more stringent than the current standards. Therefore, the Administrator also did not believe standards that are more stringent than the current standards would be appropriate. With regard to this, the CASAC advised that there was no scientific basis for a standard lower than the current 1-hour NO_2 standard (83 FR 17226, April 18, 2018). The CASAC also did not advise setting the annual standard level lower than the current level of 53 ppb, noting that the 1-hour standard can generally maintain long-term NO_2 concentrations below the annual standard (83 FR 17226, April 18, 2018). Thus, the Administrator concluded, based on the evidence, the public health policy judgments summarized above, including weight given to uncertainties in the evidence, and advice from the CASAC, that the 1-hour and annual standards were requisite and should be retained, without revision (83 FR 17226, April 18, 2018).

4 THE CURRENT PRIMARY NO_2 NAAQS REVIEW

In December 2022, the EPA announced the initiation of the current periodic review of the health-based air quality criteria for oxides of nitrogen and the primary NO_2 NAAQS and issued a Call for Information in the *Federal Register* (87 FR 75625, December 9, 2022). The current review of the primary NO_2 standards builds on the substantial body of work completed during prior reviews, represented in comprehensive science assessments (e.g., 2005 ISA and 2016 ISA) and past quantitative exposure and risk analyses. These different types of information, evaluated in policy assessments, provided the basis for decisions on the existing primary NO_2 NAAQS.

The anticipated milestones for the current review are presented in Table 4-1. Concurrent with the release of this background document (Volume 1 of the IRP), the EPA is releasing the planning document for the review and the ISA, as Volume 2 of the IRP. Volume 2 identifies policy-relevant science issues important to guiding the evaluation of the health-based air quality criteria and review of the primary NAAQS for oxides of nitrogen. It will be the subject of a consultation with the CASAC. Based on consideration of input received during this consultation, the EPA will develop a draft ISA for external review by the CASAC and for public comment.

With consideration of the newly available evidence identified in the draft ISA, the EPA will develop Volume 3 of the IRP, which is the planning document for the quantitative analyses, including exposure/risk analyses, that might be warranted to inform decisions in the current review. With consideration of the CASAC review of the draft ISA and consultation discussion on Volume 3 of the IRP, the EPA will develop a draft of the PA (with associated policy evaluations and quantitative analyses) for public and CASAC review.

In September 2023, the Center for Biological Diversity, Sierra Club, and Center for Environmental Health filed a deadline suit regarding completion of the review of the health-based air quality criteria and the primary NAAQS for oxides of nitrogen. That citizen suit has not yet been resolved, and the EPA anticipates that resolution of those claims would inform the schedule for completion of the review.

Table 4-1. Milestones in the review of the health-based air quality criteria and primary NAAQS for oxides of nitrogen.

Stage of Review	Major Milestone
Planning	Federal Register Call for Information
	Integrated Review Plan (IRP), Volumes 1 and 2
	CASAC consultation on IRP, Volume 2
	IRP, Volume 3
	CASAC consultation on IRP, Volume 3
Science Assessment	External review draft of ISA
	CASAC public meeting for review of draft ISA
	Final ISA
Quantitative Exposure/Risk Analyses and Policy Assessment	External draft of PA (including quantitative air quality, exposure and/or risk analyses, as warranted)
	CASAC public meeting for review of draft PA
	Final PA
Regulatory Process	Notice of proposed decision
	Notice of final decision

5 REFERENCES

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APPENDIX A AMBIENT AIR MONITORING AND DATA HANDLING

In the course of NAAQS reviews, aspects of the methods for sampling and analysis of the NAAQS pollutant and the current network of monitors, including their physical locations and monitoring objectives, are reviewed. The methods for sampling and analysis of each NAAQS pollutant are generally reviewed in conjunction with consideration of the indicator element[20] for that NAAQS. Consideration of the ambient air monitoring network generally informs the interpretation of current data on ambient air concentrations and helps identify if the monitoring network is adequate to determine compliance with the existing or, as appropriate, a potentially revised NAAQS. This Appendix describes aspects of the ambient air monitoring program for oxides of nitrogen, which includes NO_2, the indicator for the primary NO_2 NAAQS.

A.1 AMBIENT AIR MONITORING REQUIREMENTS AND NETWORK REQUIREMENTS

Ambient NO_2 concentrations used to determine compliance with the NAAQS are primarily measured by monitors operated by state, local, and Tribal air agencies (SLTs), typically funded in part by the EPA. The EPA provides minimum monitoring requirements for NO_2 and other pollutants in 40 CFR Part 58; additionally, SLTs have the ability to conduct monitoring above the minimum requirements to satisfy additional data needs. From 2022 to 2023, approximately 460 monitoring sites reported hourly NO_2 concentration data to EPA's Air Quality System (AQS). Approximately 96% of these sites are State/Local Air Monitoring Stations (SLAMS), fewer than 2% are operated by industrial sources, and the remaining 2% are sites operated by other federal agencies such as the National Park Service. The monitors used to measure NO_2 for NAAQS compliance are comprised of a chemiluminescent Federal Reference Method (FRM) and Federal Equivalent Methods (FEM) that use either chemiluminescence or direct measurement methods of NO_2. Data produced by chemiluminescence method-based analyzers include NO, NO_2, and NO_X (NO + NO_2) concentrations, while direct methods typically only report NO_2, all of which are routinely logged by SLTs.

The NO_2 monitoring network reflects the minimum monitoring requirements established at 40 CFR Part 58, Appendix D, Section 4.3, plus any additional monitoring conducted by SLTs. The first component of the network is monitors placed near major and highly trafficked roadways in urban areas, that is called the near-road network. The near-road network was

[20] The indicator defines the chemical species or mixture to be measured in the ambient air for the purpose of determining whether an area attains the standard.

introduced and promulgated as part of the 2010 NO_2 NAAQS review in response to the fact that on-road mobile exposures are a primary concern in the setting of the NAAQS. Near-road sites are required in each Core Based Statistical Area (CBSA) with a population of 1 million or more persons, with a second near-road site required in each CBSA with a population of 2.5 million or more persons. Additionally, any CBSA with over 1 million persons that has one or more roadway segments with an average daily traffic volume of 250,000 or more vehicles per day also is required to have a second near-road site. As of the end of 2023, there are 75 near-road sites with NO_2 monitors in operation.

The second component of the NO_2 monitoring network is monitors required at sites with neighborhood or larger spatial scales of representation where maximum concentrations of NO_2 may occur in CBSAs with more than 1 million persons. Notably, there are many more of these types of sites in both urban and rural locations across the country, operated by SLTs for a variety of data needs. Some of these required monitors may also be fulling requirements for the Photochemical Assessment Monitoring Stations (PAMS) program. PAMS monitoring is required within a multipollutant monitoring site network called the National Core multipollutant monitoring station (NCore) network. PAMS monitoring operations are to be conducted at those NCore sites in CBSAs with more than 1 million persons. PAMS measurement include NO, NO_2, NO_Y (total oxides of nitrogen), and other O_3 precursors during the months of June, July and August, although some precursor monitoring may be required for longer periods of time.[21]

A third component of the NO_2 network includes the monitors required for inclusion or identification of any type of NO_2 monitoring site (whether within or above the minimum monitoring requirements) that focuses on making measurements in areas with susceptible and vulnerable populations (40 CFR Part 58, Appendix D, Section 4.3.4(a)). This requirement can be satisfied by any type of NO_2 monitor, so long as it is characterizing air quality in an area with susceptible and vulnerable populations.

Finally, there can also be NO_2 monitors that are installed and operated in a temporary manner (at least initially) known as Special Purpose Monitors (SPMs). While SPMs are to be operated just like routine SLAMS site monitors, SPMs do not count towards minimum monitoring requirements and generally are not initially intended for use for regulatory purposes. The purpose for operating SPMs can include collecting data for human health and welfare studies, industry or facility air quality impact characterization, prevention of significant deterioration information, and other purposes. If an SPM operates for more than 24 months, its data can be eligible for comparison to the relevant NAAQS if it has met all applicable

[21] The requirements for PAMS, which were most recently updated in 2015, is fully described in section 5 of Appendix D to 40 CFR Part 58.

operational requirements and quality assurance criteria established by 40 CFR Part 58, Appendix D, 58.20.

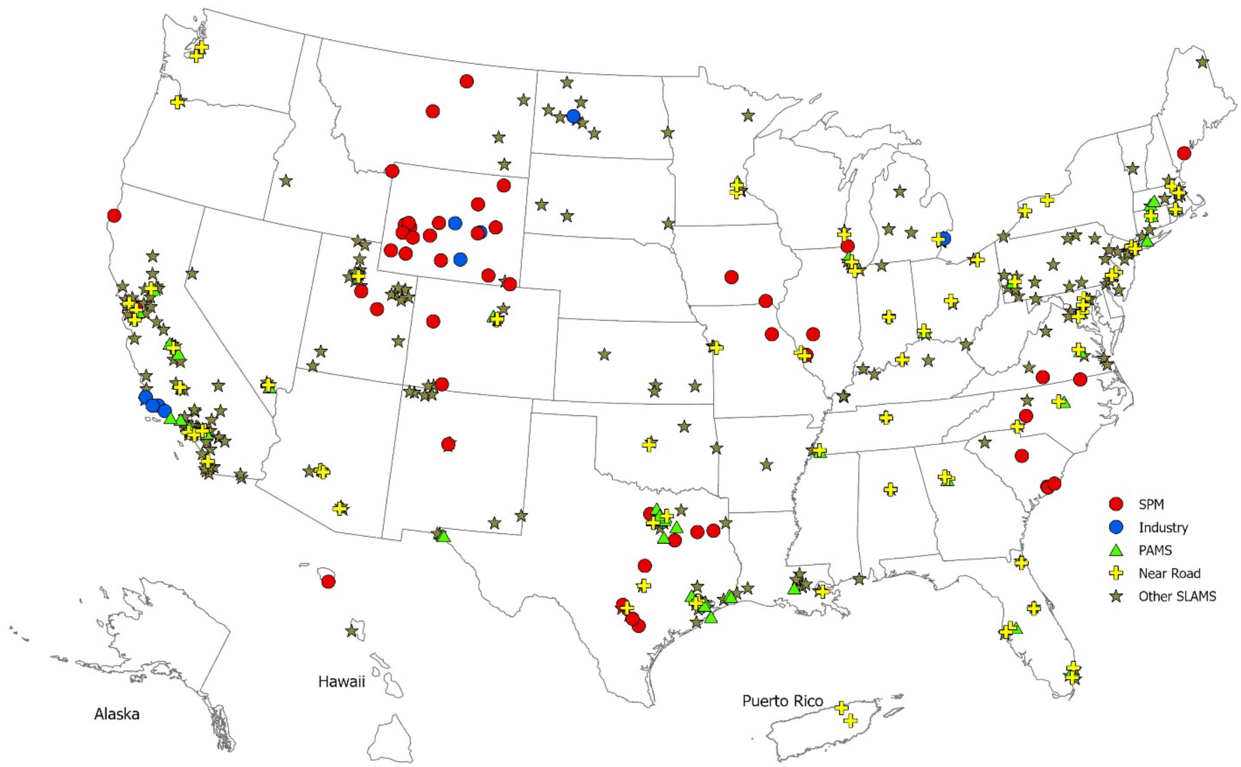

Figure A-1. Map of U.S. NO_2 monitoring sites reporting data to the EPA during the 2022-2023 period. (Source: *https://www.epa.gov/aqs*)

To improve certainty in monitoring data and support assessment of data quality, monitoring agencies must operate with a quality system, which requires the development and adherence to Quality Assurance Project Plans (QAPPs), the use of Standard Operating Procedures (SOPs), and the conduction of quality assurance (QA) activities. For example, for NO_2, SLTs are required to perform QA checks at least once every two weeks to derive estimates of precision and bias for NO_2 and the other gaseous criteria pollutant measurements. The data quality goal for precision and bias is 15 percent or lower for NO_2 monitors. Further, SLTs are also subject to routine audits under the National Performance Audit Program managed by the EPA.

Ambient air quality data and associated QA data are reported to the EPA via AQS.[22] Data are reported quarterly and must be submitted to AQS within 90 days after the end of each calendar quarter (i.e., Jan/Feb/Mar, Apr/May/Jun, Jul/Aug/Sep, Oct/Nov/Dec). Additionally, each monitoring agency is required to certify all FRM/FEM data that is submitted to AQS annually, taking into consideration any QA findings, and a data certification letter must be sent to the EPA Regional Administrator by May 1st of the following year.

A.2 DATA HANDLING CONVENTIONS AND COMPUTATIONS FOR DETERMINING WHETHER THE STANDARDS ARE MET

To assess whether a monitoring site or geographic area (usually a county or urban area) meets or exceeds a NAAQS, the monitoring data are analyzed consistent with the established regulatory requirements for the handling of monitoring data for the purposes of deriving a design value. A design value summarizes ambient air concentrations for an area in terms of the indicator, averaging time and form for a given standard such that its comparison to the level of the standard indicates whether the area meets or exceeds the standard. There are currently two primary NO_2 NAAQS in effect: the annual NAAQS (established in 1971) and the 1-hour NAAQS (established in 2010). See 40 CFR 50.11. Under 40 CFR 50.11(e) and (f), the procedures for calculating design values for both primary NO_2 NAAQS are detailed in Appendix S to 40 CFR Part 50 and are summarized below. For a more detailed description of these requirements, Appendix S should be consulted.

Hourly NO_2 measurement data collected at an ambient air monitoring site using FRMs or FEMs, meeting all applicable requirements in 40 CFR Part 58 and reported to AQS in parts per billion (ppb) with decimal digits after the first decimal place truncated are used in design value calculations. If multiple monitors collect measurements at the same site, one monitor is designated as the primary monitor. Measurement data collected with the primary monitor are used to calculate the design value and may be supplemented with data from collocated monitors only if (a) the primary monitor did not collect sufficient data to determine a valid design value, or (b) the primary monitor has been discontinued and replaced by another monitor.

The design value for the primary annual NO_2 NAAQS is simply the mean of all hourly concentration values reported for a single year, rounded to the nearest integer in ppb. The annual design value is considered valid when hourly concentrations are reported for at least 75% of the hours in the year, or if the design value is greater than 53 ppb, the level of the NAAQS. The

[22] Quality assurance requirements for monitors used in evaluations of the NAAQS are provided in Appendix A to 40 CFR Part 58. Annual summary reports of precision and bias can be obtained for each monitoring site at the EPA's Air Data website.

primary annual NO_2 NAAQS is met at a site when the valid annual primary standard design value is less than or equal to 53 ppb.

For the 1-hour NO_2 NAAQS, the maximum hourly concentration is determined for each day (i.e., the "daily maximum value") in a given 3-year period. For each year, the 98th percentile of the daily maximum values is determined, as described in Appendix S, and the design value is the average of the three consecutive annual 98th percentile values, rounded to the nearest integer in ppb. The 1-hour NO_2 NAAQS is met when the valid 1-hour primary standard design value is less than or equal to 100 ppb, the level of the NAAQS.

In addition, the 1-hour design value must meet data completeness requirements in order to be considered valid. Specifically, a sampling day is considered complete when at least 75% (i.e., 18) hourly measurements are reported. For each calendar quarter, the quarter is considered complete if at least 75% of the sampling days in the quarter have complete data. The 1-hour NO_2 design value is considered complete when all 12 calendar quarters in the 3-year period have complete data. In addition, there are two data substitution tests specified in Appendix S to 40 CFR Part 50 which may be used to yield a valid design value above or below the NAAQS, respectively, in the event that a site falls short of the minimum data completeness requirement.

A.3 NO_2 CONCENTRATIONS MEASURED AT AMBIENT AIR MONITORING SITES ACROSS THE U.S.

Table A-1 below presents summary statistics based on the two daily NO_2 NAAQS metrics: the daily maximum 1-hour (MDA1) metric and the daily 24-hour average (DA24) metric. These statistics are presented for year-round and each season (winter=Dec/Jan/Feb, spring=Mar/Apr/May, summer=Jun/Jul/Aug, autumn=Sep/Oct/Nov) based on data reported to AQS for 2020-2022. Table A-2 presents the same summary statistics for the MDA1 and DA24 metrics for each NOAA Climate Region.[23] Finally, Table A-3 presents the same set of summary statistics for the two daily NO_2 metrics based on three types of sites: near-road sites, urban NCore and PAMS sites, and rural sites.

[23] A map of the NOAA climate regions is available at: *https://www.cpc.ncep.noaa.gov/products/analysis_monitoring/regional_monitoring/regions.shtml*. For Table A-2, monitoring sites in Alaska were assigned to the Northwest Region, monitoring sites in Hawaii were assigned to the West region, and monitoring sites in Puerto Rico were assigned to the Southeast region.

Table A-1. National distribution of NO_2 concentrations in ppb by season for 2020-2022.[24] (Source: *https://www.epa.gov/aqs*)

metric	season	N.sites	N.obs	mean	SD	min	p1	p5	p10	p25	p50	p75	p90	p95	p98	p99	max	max.site
MDA1	all	404	419482	16.5	12.3	-3.4	0.6	1.7	2.9	6.5	14.0	24.3	34.3	39.9	45.9	50.1	315.3	201950001
MDA1	winter	394	101627	20.3	13.3	-1.0	0.7	2.0	3.8	9.1	19.0	29.9	38.5	43.2	49.0	53.6	109.2	295100094
MDA1	spring	391	103552	15.2	11.8	-3.0	0.5	1.3	2.3	5.5	12.2	22.6	32.7	38.2	44.0	48.0	107.4	191770006
MDA1	summer	392	103040	12.9	9.8	-3.0	0.7	1.6	2.5	5.3	10.5	18.3	26.9	32.4	38.7	43.0	84.0	340390004
MDA1	autumn	393	102607	17.8	12.7	-3.4	0.7	1.8	3.0	7.5	15.7	25.8	35.5	41.2	47.8	52.6	315.3	201950001
DA24	all	404	419482	7.8	7.0	-4.5	0.1	0.7	1.2	2.7	5.8	11.0	17.4	22.0	27.5	31.4	64.1	060374008
DA24	winter	394	101627	10.4	8.3	-1.8	0.1	0.8	1.6	4.0	8.5	14.9	22.0	26.6	32.2	36.1	64.1	060374008
DA24	spring	391	103552	6.6	5.9	-3.9	0.0	0.5	1.0	2.3	4.8	9.1	14.7	18.4	23.3	26.5	57.7	060374008
DA24	summer	392	103040	5.9	5.1	-4.1	0.0	0.6	1.1	2.3	4.4	8.0	12.7	16.0	20.4	23.6	53.6	530330030
DA24	autumn	393	102607	8.6	7.3	-4.5	0.1	0.7	1.3	3.1	6.7	12.1	18.6	23.1	28.4	32.2	62.0	060374008

N.sites = number of sites; N.obs = number of observations; SD = standard deviation; min = minimum; p1, p5, p10, p25, p50, p90, p95, p98, p99 = 1st, 5th, 10th, 25th, 50th, 90th, 95th, 98th, 99th percentiles; max = maximum; max.site = AQS ID number for the monitoring site corresponding to the observation in the max column. winter = December/January/February; spring = March/April/May; summer = June/July/August; autumn = September/October/November.

[24] Negative concentration values may appear in AQS datasets down to the negative of the lower detection limit (LDL) to allow for normal instrument variability at very low concentrations. Data that exceed the negative of the LDL are typically indicative of a malfunction or another issue that affects the data defensibility.

According to Table A-1, NO_2 concentrations are generally higher during the autumn and winter months and lower during the spring and summer months. This is at least partially due to NO_X budgeting programs such as CSAPR which are designed to reduce NO_X emissions from stationary sources during the spring and summer months when these emissions are most likely to contribute to elevated ozone concentrations. Table A-2 shows that measured NO_2 concentrations are comparable across most regions of the U.S., except for the West North Central region, which includes more rural states in the northern Rocky Mountains and Great Plains, where NO_2 concentrations are significantly lower. Finally, Table A-3 shows that near-road NO_2 monitoring sites tend to measure slightly higher concentrations than typical urban NO_2 sites, while NO_2 concentrations measured at rural sites are typically much lower than those measured in urban areas. The high maximum MDA1 concentration measured at a rural site in Kansas appears to be an isolated occurrence whose cause is unknown.

Table A-2. National distribution of NO_2 concentrations in ppb by climate region for 2020-2022.[25] (Source: *https://www.epa.gov/aqs*)

metric	region	season	N.sites	N.obs	mean	SD	min	p1	p5	p10	p25	p50	p75	p90	p95	p98	p99	max	max.site
MDA1	all	all	404	419482	16.5	12.3	-3.4	0.6	1.7	2.9	6.5	14.0	24.3	34.3	39.9	45.9	50.1	315.3	201950001
MDA1	C	all	32	33617	18.7	11.2	-0.6	1.6	3.5	5.1	9.7	17.0	26.3	34.2	39.0	44.6	48.0	109.2	295100094
MDA1	E-N-C	all	16	16554	16.5	10.8	0.1	0.9	1.7	2.8	7.9	15.3	23.7	31.3	36.0	41.3	44.2	107.4	191770006
MDA1	NE	all	62	63993	18.4	11.6	-3.0	1.0	3.0	4.2	9.0	17.0	26.1	34.5	39.3	44.9	48.8	97.1	230050029
MDA1	NW	all	6	6420	21.3	9.7	1.6	3.9	6.6	9.3	14.2	20.7	27.5	33.7	38.1	43.5	47.7	78.0	530330030
MDA1	S	all	67	67833	14.1	10.9	-1.8	0.7	2.0	3.0	5.7	11.1	20.0	30.1	35.8	41.8	46.2	315.3	201950001
MDA1	SE	all	37	38279	16.1	10.3	-1.0	0.9	2.2	3.9	7.8	14.7	23.0	30.5	35.0	40.0	43.5	94.8	120110035
MDA1	SW	all	54	56427	17.5	13.7	-3.4	0.6	1.5	2.8	6.3	13.8	26.6	38.5	43.7	49.5	53.9	86.5	080310002
MDA1	W	all	97	102331	19.4	13.2	-2.0	1.0	2.4	4.1	8.6	16.9	28.2	38.2	43.4	49.7	54.6	101.6	060710027
MDA1	W-N-C	all	33	34028	5.2	5.7	-1.8	0.0	0.6	0.9	1.5	3.1	6.6	12.6	17.4	23.1	27.6	79.9	300310017
DA24	all	all	404	419482	7.8	7.0	-4.5	0.1	0.7	1.2	2.7	5.8	11.0	17.4	22.0	27.5	31.4	64.1	060374008
DA24	C	all	32	33617	8.9	6.2	-1.3	0.8	1.5	2.3	4.2	7.5	12.2	17.6	21.2	25.1	27.9	44.0	170310076
DA24	E-N-C	all	16	16554	8.1	5.7	-0.1	0.4	0.9	1.5	3.6	7.0	11.6	16.0	19.0	22.4	24.5	44.6	261630100
DA24	NE	all	62	63993	8.9	6.7	-4.1	0.4	1.3	2.0	3.8	7.3	12.5	18.1	22.1	26.8	30.5	55.8	340130003
DA24	NW	all	6	6420	10.8	5.6	1.0	2.0	3.0	4.1	6.5	10.1	14.3	18.1	20.6	23.8	26.3	53.6	530330030
DA24	S	all	67	67833	6.1	5.2	-2.3	-0.2	0.7	1.2	2.4	4.5	8.2	13.2	16.8	21.1	23.9	47.5	482011052
DA24	SE	all	37	38279	7.6	5.6	-1.6	0.5	1.0	1.7	3.2	6.2	10.6	15.5	18.7	22.5	25.2	39.7	510130020
DA24	SW	all	54	56427	8.1	8.1	-4.5	0.1	0.6	1.1	2.4	5.3	11.1	19.9	25.7	32.0	36.3	60.5	080310028
DA24	W	all	97	102331	9.7	8.0	-2.0	0.1	1.0	1.9	3.7	7.3	13.5	21.2	26.0	31.5	35.4	64.1	060374008
DA24	W-N-C	all	33	34028	1.9	2.0	-2.2	-0.1	0.1	0.3	0.7	1.3	2.4	4.2	5.6	7.9	10.0	26.4	560070009

N.sites = number of sites; N.obs = number of observations; SD = standard deviation; min = minimum; p1, p5, p10, p25, p50, p90, p95, p98, p99 = 1st, 5th, 10th, 25th, 50th, 90th, 95th, 98th, 99th percentiles; max = maximum; max.site = AQS ID number for the monitoring site corresponding to the observation in the max column. Central (C) = Illinois, Indiana, Kentucky, Missouri, Ohio, Tennessee, West Virginia; East North Central (E-N-C) = Iowa, Minnesota, Michigan, Wisconsin; Northeast (NE) = Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont; Northwest (NW) =

[25] Negative concentration values may appear in AQS datasets down to the negative of the lower detection limit (LDL) to allow for normal instrument variability at very low concentrations. Data that exceed the negative of the LDL are typically indicative of a malfunction or another issue that affects the data defensibility.

Alaska, Idaho, Oregon, Washington; South (S) = Arkansas, Kansas, Louisiana, Mississippi, Oklahoma, Texas; Southeast (SE) = Alabama, Florida, Georgia, North Carolina, South Carolina, Virginia; Southwest (SW) = Arizona, Colorado, New Mexico, Utah; West (W) = California, Hawaii, Nevada; West North Central (W-N-C) = Montana, Nebraska, North Dakota, South Dakota, Wyoming.

Table A-3. National distribution of NO_2 concentrations in ppb by site type for 2020-2022.[26] (Source: *https://www.epa.gov/aqs*)

metric	site.type	season	N.sites	N.obs	mean	SD	Min	p1	p5	p10	p25	p50	p75	p90	p95	p98	p99	max	max.site
MDA1	All Sites	all	404	419482	16.5	12.3	-3.4	0.6	1.7	2.9	6.5	14.0	24.3	34.3	39.9	45.9	50.1	315.3	201950001
MDA1	Near Road	all	64	66554	24.9	12.0	-0.3	4.1	8.0	10.6	16.0	23.4	32.2	41.0	46.3	53.1	58.2	109.2	295100094
MDA1	NCore/PAMS	all	57	59041	16.8	11.2	-3.0	1.0	3.0	4.5	8.0	14.1	23.5	33.2	38.5	44.2	48.4	92.3	481410044
MDA1	Rural Sites	all	39	39999	4.9	6.2	-0.9	0.0	0.7	1.0	1.5	2.9	5.7	11.2	17.0	25.0	30.0	315.3	201950001
DA24	All Sites	all	404	419482	7.8	7.0	-4.5	0.1	0.7	1.2	2.7	5.8	11.0	17.4	22.0	27.5	31.4	64.1	060374008
DA24	Near Road	all	64	66554	13.7	8.0	-1.2	1.8	3.7	5.0	7.9	12.1	17.8	24.5	29.2	35.1	39.2	64.1	060374008
DA24	NCore/PAMS	all	57	59041	7.4	5.7	-4.1	0.1	1.2	1.9	3.4	5.9	9.8	15.0	18.7	23.9	27.1	55.8	340130003
DA24	Rural Sites	all	39	39999	2.0	2.4	-1.1	0.0	0.2	0.3	0.7	1.3	2.3	4.4	6.5	9.9	12.7	35.2	081230013

N.sites = number of sites; N.obs = number of observations; SD = standard deviation; min = minimum; p1, p5, p10, p25, p50, p90, p95, p98, p99 = 1st, 5th, 10th, 25th, 50th, 90th, 95th, 98th, 99th percentiles; max = maximum; max.site = AQS ID number for the monitoring site corresponding to the observation in the max column.

[26] Negative concentration values may appear in AQS datasets down to the negative of the lower detection limit (LDL) to allow for normal instrument variability at very low concentrations. Data that exceed the negative of the LDL are typically indicative of a malfunction or another issue that affects the data defensibility.

Figure A-2 below shows a map of the annual NO_2 design values at U.S. ambient air monitoring sites based on data from 2022 and Figure A-3 shows a map of the 1-hour NO_2 design values based on data from the 2020-2022 period. There were no sites with design values exceeding either NAAQS. The maximum annual design value was 29 ppb, while the maximum 1-hour design value was 79 ppb. Both of these maximum design values occurred at near-road sites in the Los Angeles, CA metropolitan area.

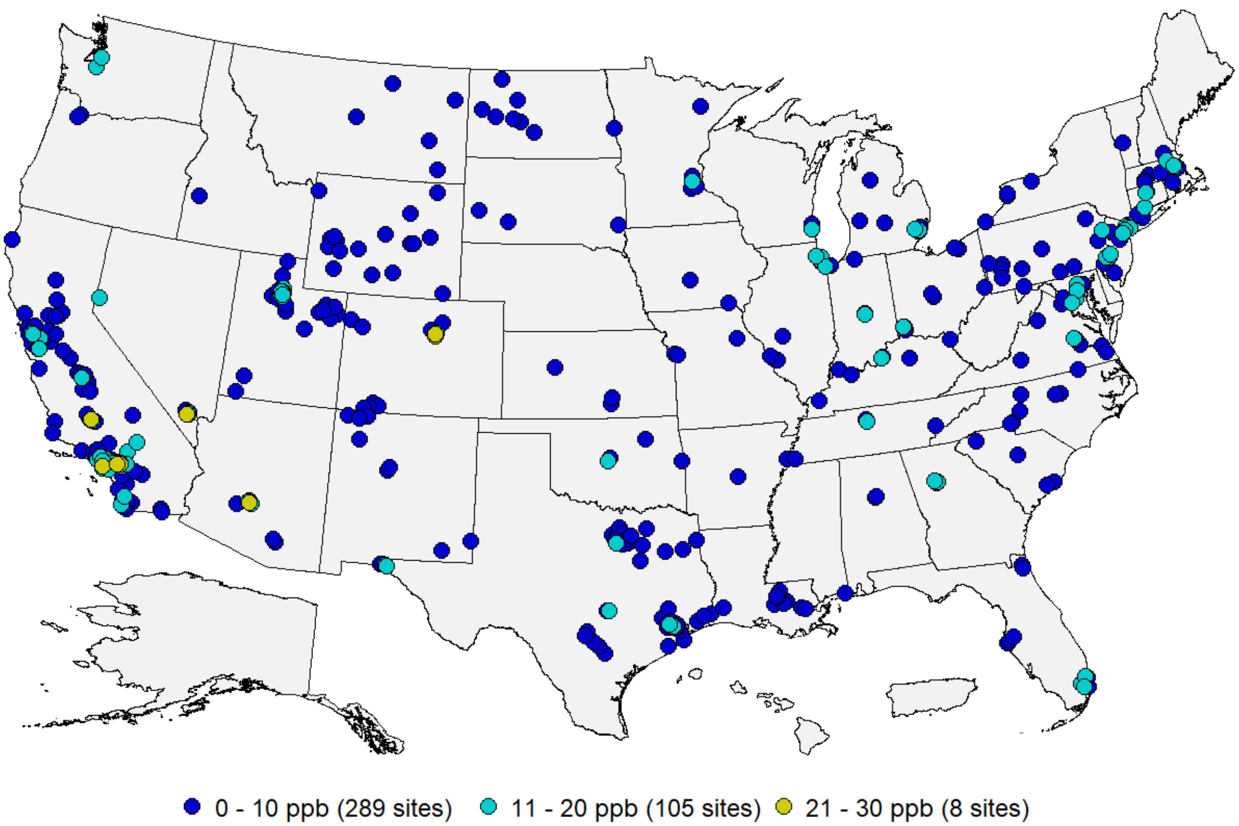

Figure A-2. Annual NO_2 design values in ppb based on data from 2022. (Source: *https://www.epa.gov/aqs*)

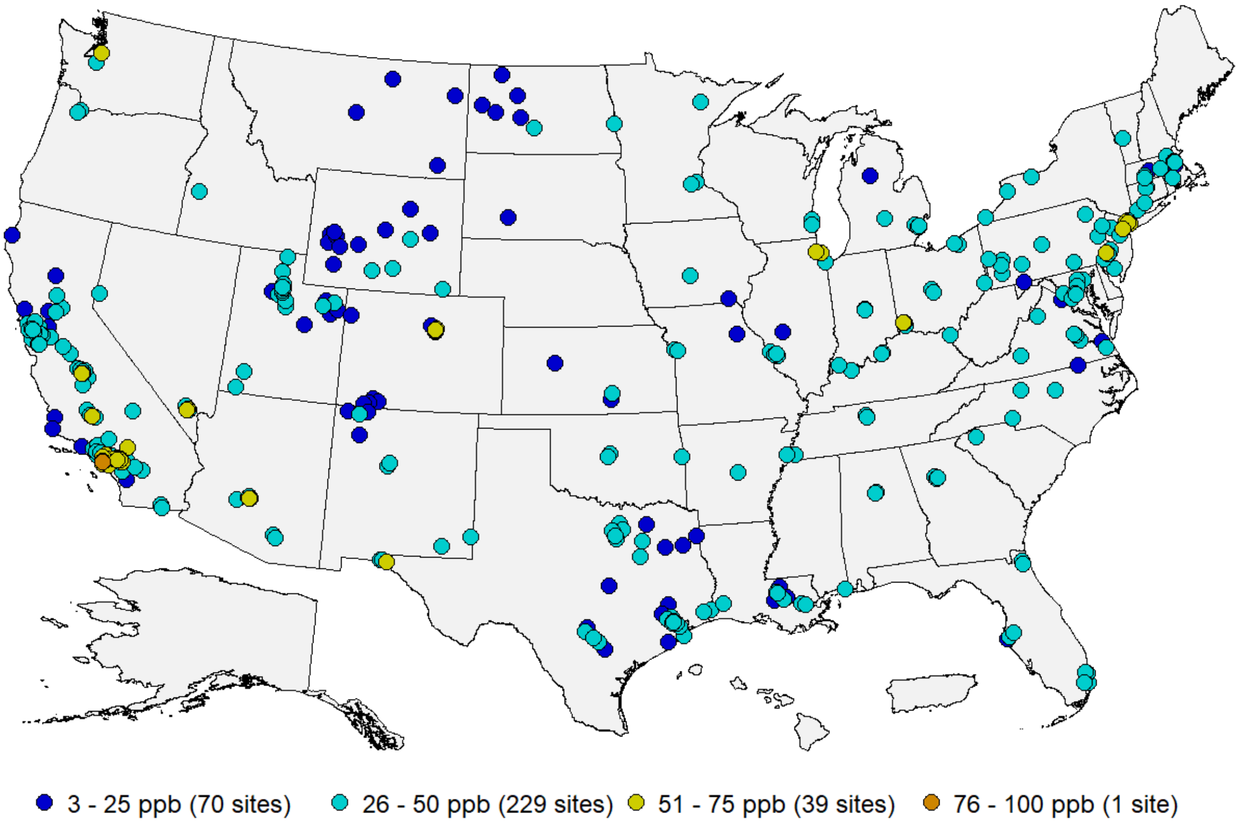

Figure A-3. 1-hour NO_2 design values in ppb for the 2020-2022 period. (Source: *https://www.epa.gov/aqs*)

Figure A-4 below shows a map of the site-level trends in the annual NO_2 design values at U.S. monitoring sites having valid design values in at least 18 years from 2000 through 2022. Figure A-5 shows a map of the site-level trends in the 1-hour NO_2 design values at U.S. monitoring sites having valid design values in at least 16 of the 21 3-year periods from 2000 through 2022. The trends were computed using the Thiel-Sen estimator, and tests for significance ($p\text{-value} < 0.05$) were computed using the Mann-Kendall test. From these figures it is apparent that NO_2 concentrations have been decreasing at nearly all sites in the U.S., which is in part due to federal and state programs designed to reduce NO_X emissions from electricity generation, industrial and mobile sources. Two sites in North Dakota showed an increasing trend in the annual design value (one of these sites also had an increasing trend in the 1-hour design value), which is likely due to an increase in NO_X emissions from oil and gas extraction activity in the region.

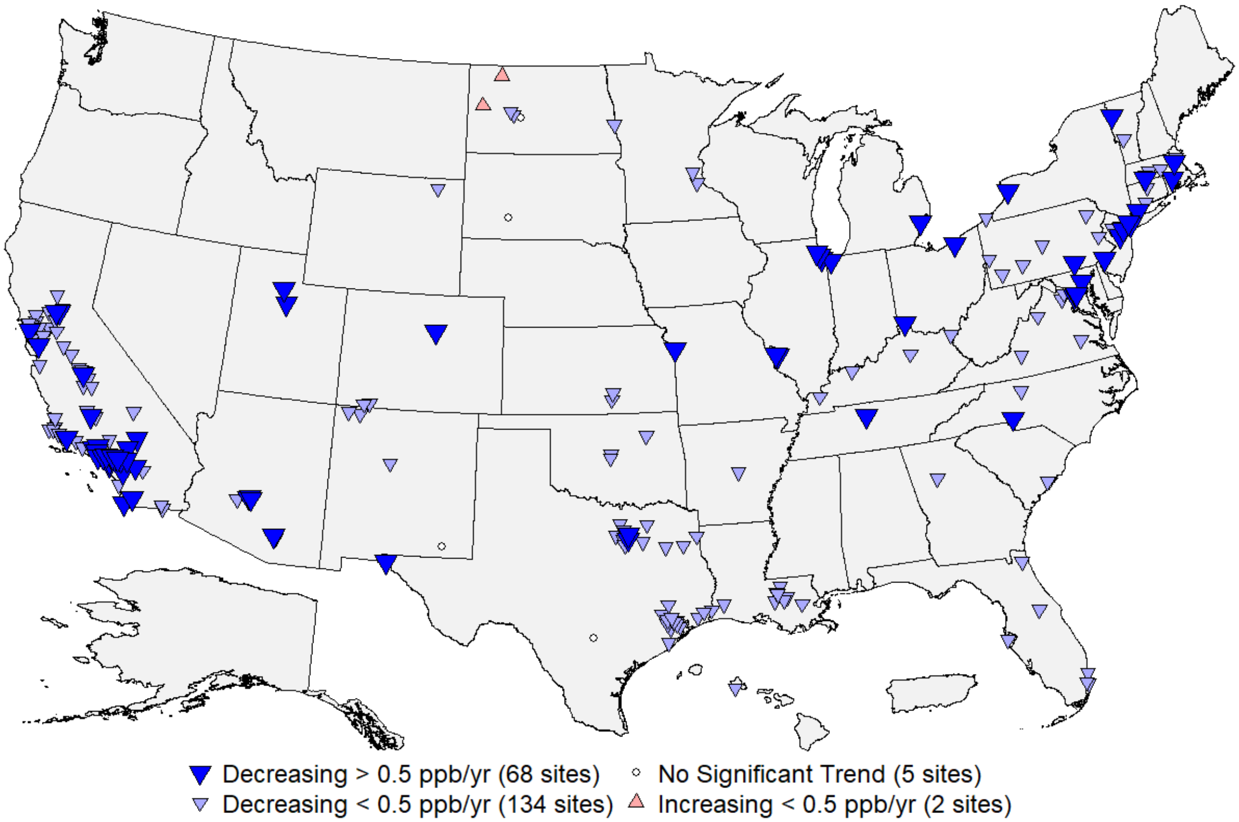

Figure A-4. Site-level trends in annual NO_2 design values based on data from 2000 through 2022. (Source: *https://www.epa.gov/aqs*, trends computed using R statistical software)

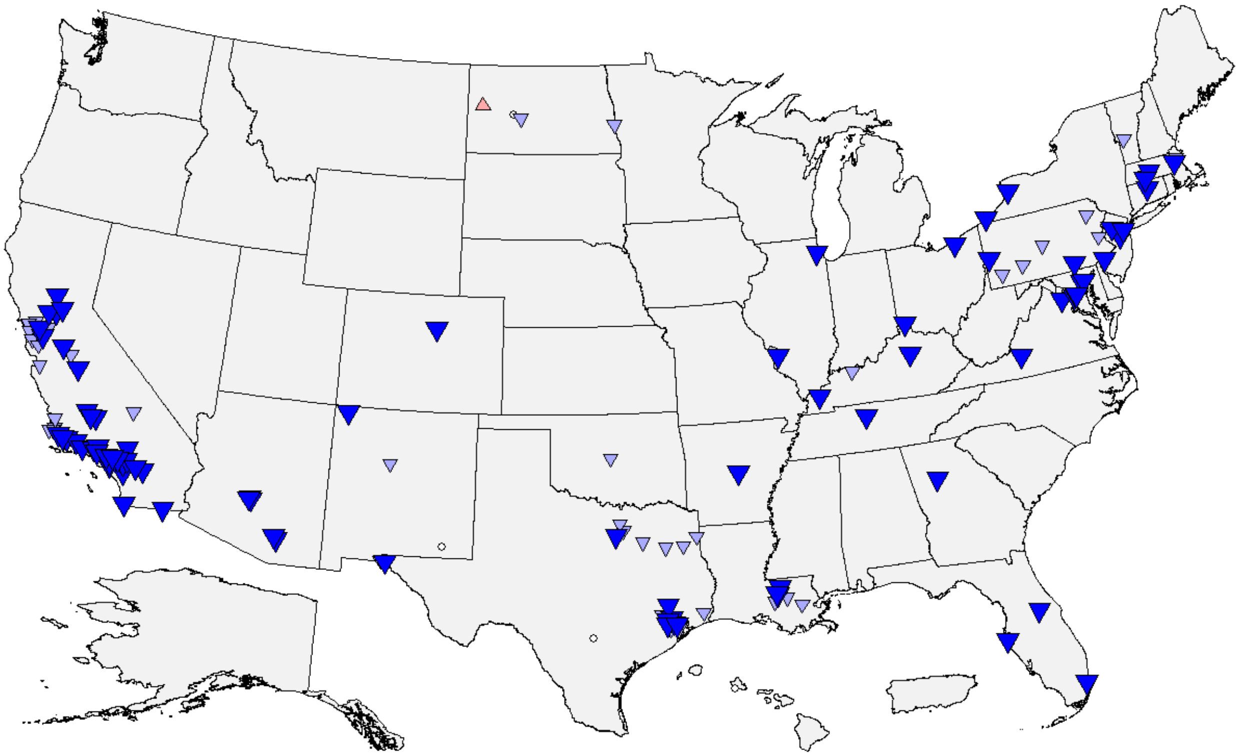

Figure A-5. Site-level trends in 1-hour NO_2 design values based on data from 2000 through 2022. (Source: *https://www.epa.gov/aqs*, trends computed using R statistical software)

Figure A-6 below shows the national trends in the annual and 1-hour NO_2 design values based on the 209 sites shown in Figure A-4 and the 135 sites shown in Figure A-5, respectively. The national median of the annual design values has decreased by 54% from about 15.7 ppb in 2000 to about 7.3 ppb in 2022. The national median of the 1-hour design values has decreased by 38% from 60 ppb in 2000 to 37 ppb in 2022.

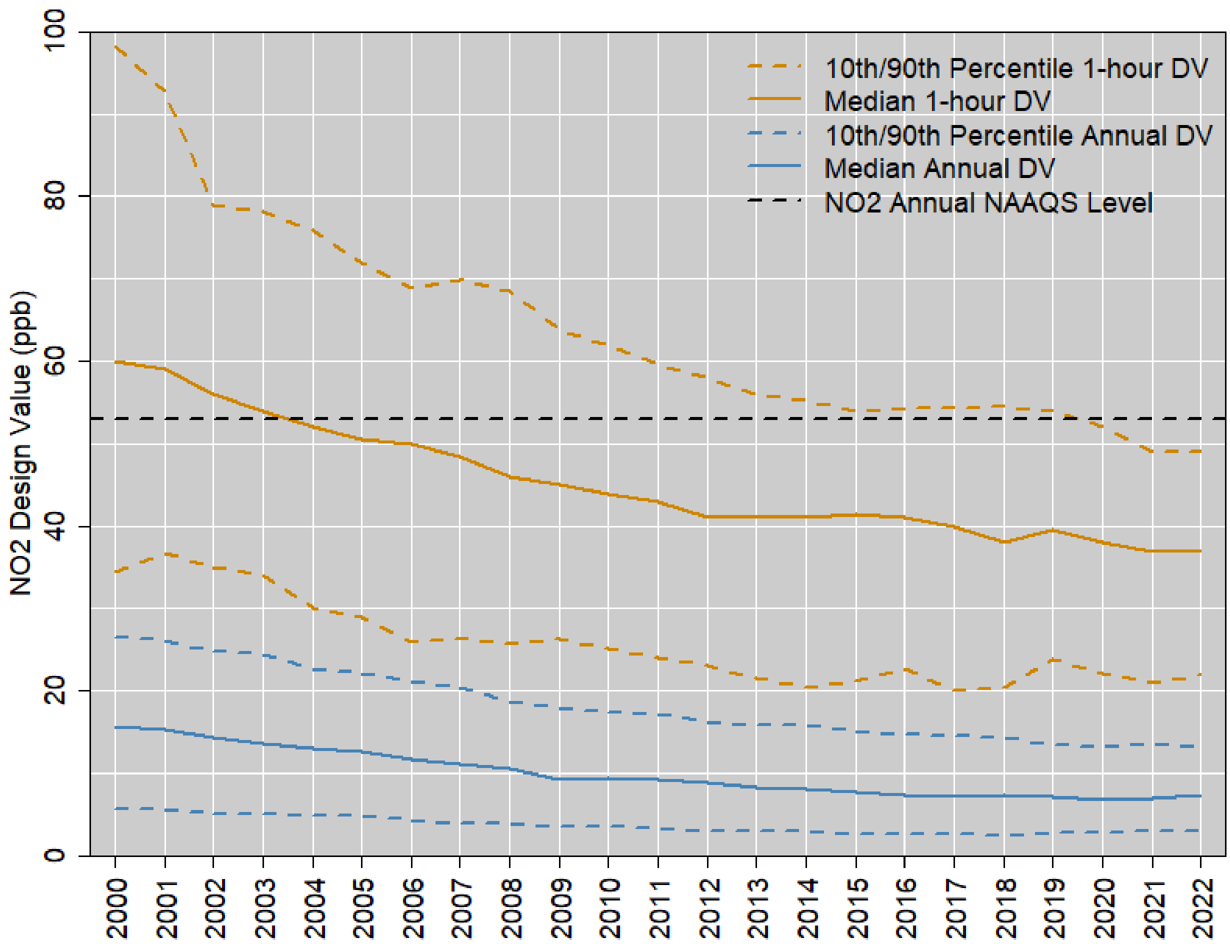

Figure A-6. National trends in NO_2 design values in ppb, 2000 to 2022. (Source: *https://www.epa.gov/aqs*)

Figure A-7 below shows the national distribution of the annual 98th percentile MDA1 NO_2 concentrations reported in each year from 1980 to 2022, while Figure A-8 shows the national distribution of the annual mean NO_2 concentrations reported to the EPA during the same period.[27] The red line shows the number of sites included in the boxplot for each year. These figures show that NO_2 concentrations have decreased steadily over the past 40 years as older cars were replaced with newer models with lower NO_X emissions, and power plants and other industrial sources have added emissions controls and transitioned to cleaner burning fuels. The median 98th percentile MDA1 NO_2 concentration decreased by 59%, from 93.5 ppb in 1980 to 38 ppb in 2022. Similarly, the median annual mean NO_2 concentration decreased by 68%, from 23.2 ppb in 1980 to 7.4 ppb in 2022. No sites have reported 98th percentile MDA1 values that would have exceeded the level of the 1-hour NO_2 NAAQS since 2008, and no sites have reported mean

[27] For this analysis, the annual mean and 98th percentile MDA1 NO_2 concentrations were retrieved from AQS for all U.S. sites for years that had at least 75% annual data completeness.

concentrations that exceeded the level of the annual NO_2 NAAQS since 1991. The size of the NO_2 monitoring network increased from 1980 through the early 2000s, decreased slightly between 2002 and 2011, then increased again over the next few years as the near-road network was implemented. Over the past decade, annual mean and 98th percentile MDA1 NO_2 concentrations have been relatively constant at levels well below the NAAQS. This is likely due to higher concentrations measured at near-road sites offsetting continued reductions in NO_2 concentrations associated with reductions in NO_X emissions.

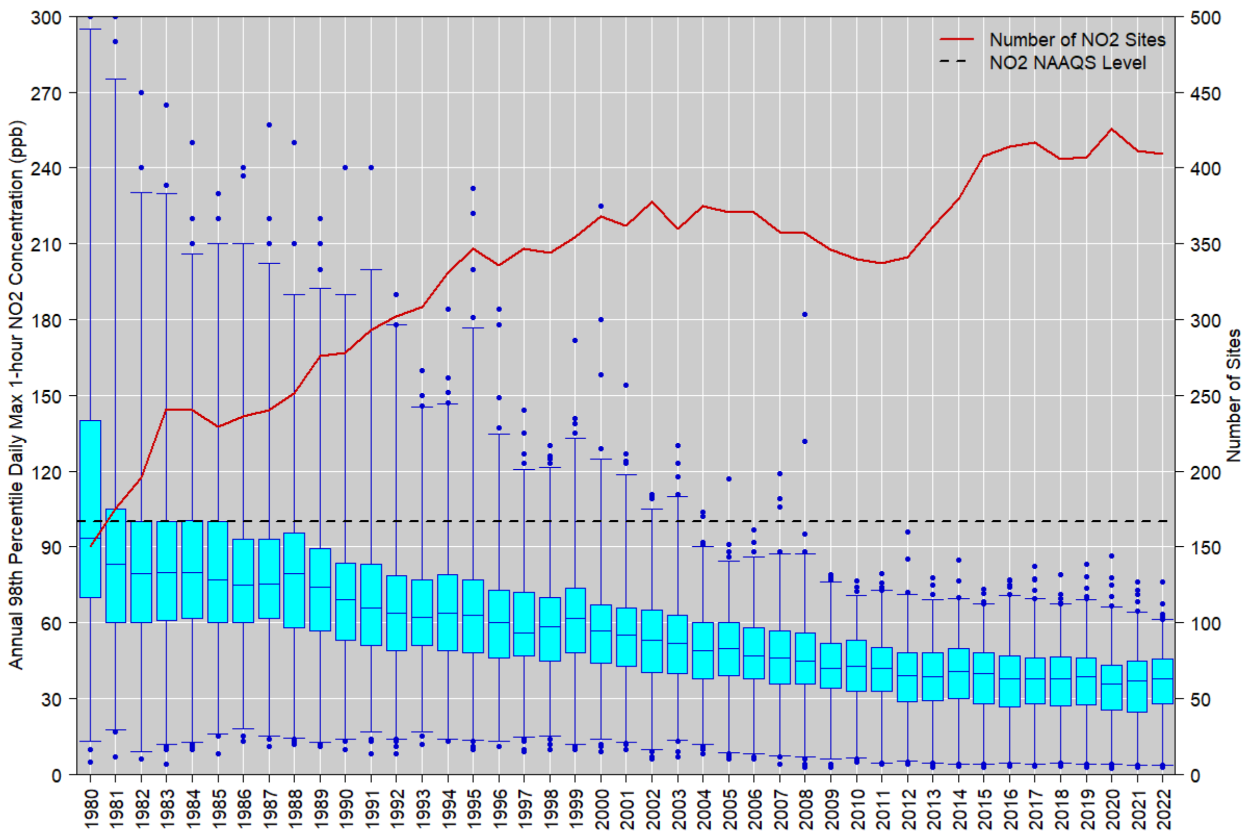

Figure A-7. Distribution of annual 98th percentile MDA1 NO_2 concentrations measured at U.S. monitoring sites, 1980 to 2022. Boxes represent the median and interquartile range, whiskers extend to the 1st and 99th percentiles, and values outside this range are shown as circles. The red line shows the number of NO_2 monitoring sites reporting data to the EPA in each year. (Source: *https://www.epa.gov/aqs*)

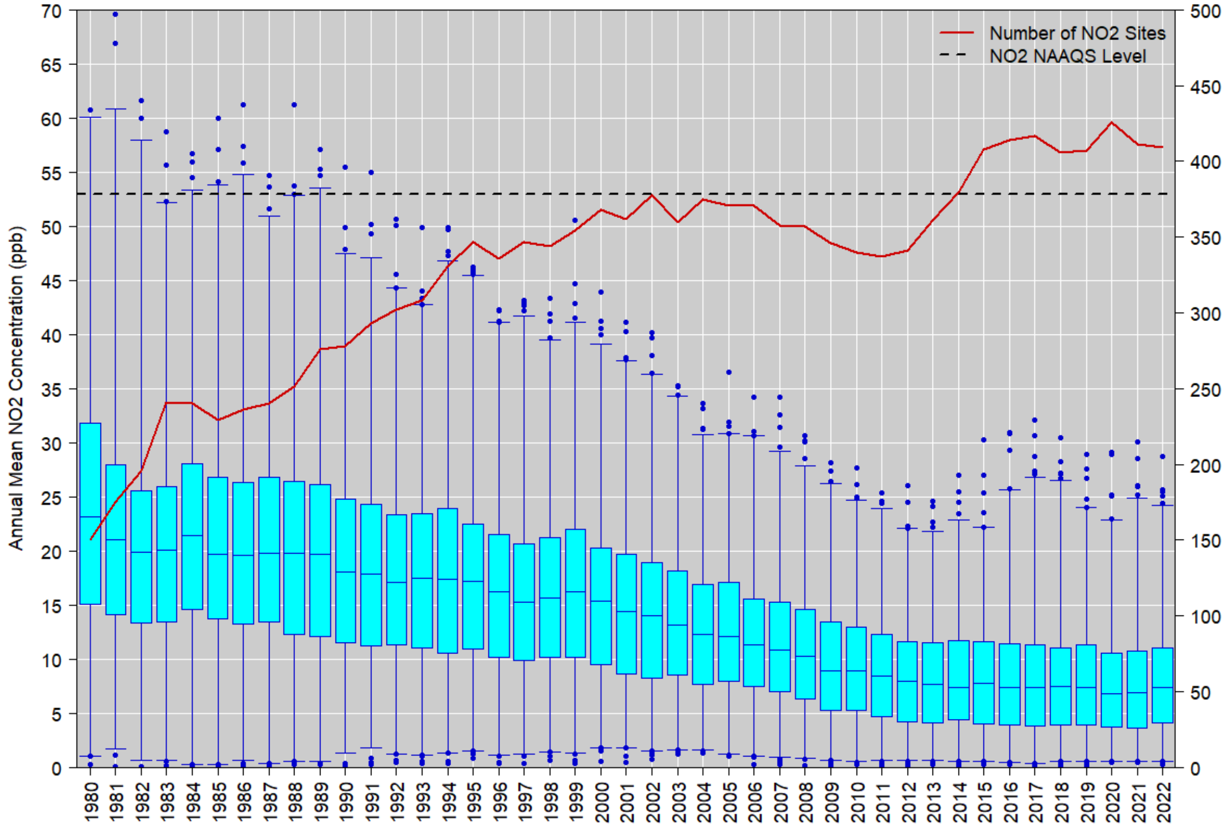

Figure A-8. Distribution of annual mean NO_2 concentrations measured at U.S. monitoring sites, 1980 to 2022. Boxes represent the median and interquartile range, whiskers extend to the 1st and 99th percentiles, and values outside this range are shown as circles. The red line shows the number of NO_2 monitoring sites reporting data to the EPA in each year. (Source: *https://www.epa.gov/aqs*)

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