

Review of the Primary National Ambient Air Quality Standards (NAAQS) for Nitrogen Dioxide (NO₂)

Background, Schedule, and Draft Integrated Review Plan

CASAC Review Meeting
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Overview

- Statutory requirements
- NAAQS review process
- Scope of current review
- Current schedule
- History of Primary NO₂ NAAQS Reviews
- Summary of last review: focus on key policy-relevant issues
- Draft Integrated Review Plan (IRP) for current review
- Primary NO₂ NAAQS team and additional information

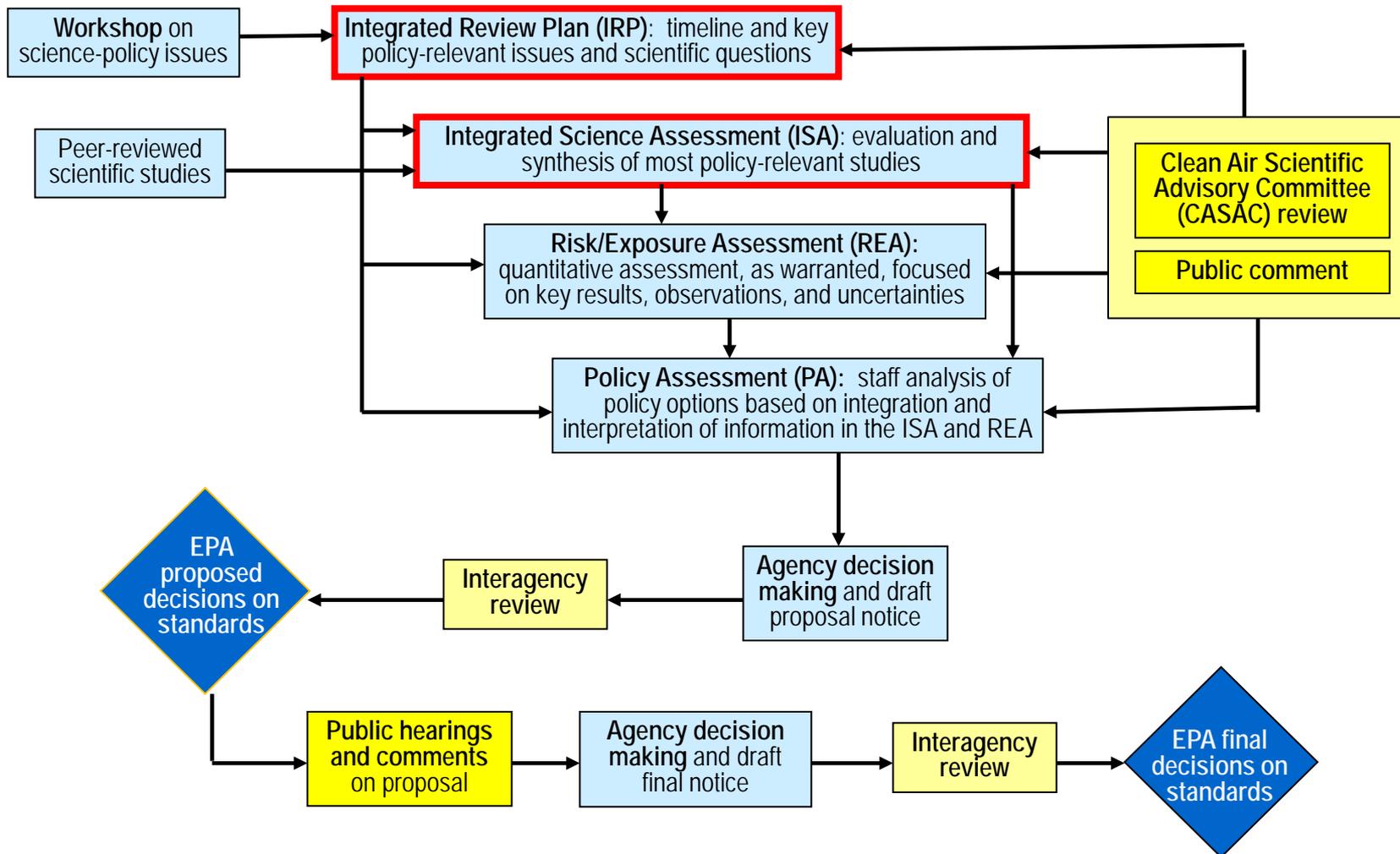


Statutory Requirements

- Sections 108 and 109 of the Clean Air Act govern the establishment, review, and revision (as appropriate) of NAAQS, including:
 - **Primary (health-based) standards** which in the “judgment of the Administrator” are “requisite” to protect public health, including at-risk populations and lifestages, with an “adequate margin of safety”
 - “Requisite” means sufficient but not more than necessary
 - “Adequate margin of safety” – intended to address uncertainties associated with inconclusive evidence, and to provide a reasonable degree of protection against hazards that research has not yet identified
 - **Secondary (welfare-based) standards** which in the “judgment of the Administrator” are “requisite to protect the public welfare from any known or anticipated adverse effects”
 - Welfare effects include “effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate . . .”
- The law requires EPA to review the scientific information and NAAQS for each criteria pollutant every five years, and to obtain advice from the Clean Air Scientific Advisory Committee (CASAC) on each review
 - EPA is required to engage in “reasoned decision making” to translate scientific evidence into standards
 - EPA may not consider cost in setting standards (this has been upheld by the Supreme Court); however, cost is considered in developing control strategies to meet the standards (implementation phase)



NAAQS Review Process





Scope of Current Review

- Considers **gaseous** species of oxides of nitrogen only
 - Particulate species (e.g., nitrates) are considered in review of particulate matter (PM) NAAQS
- Focuses on **primary NAAQS** only; considers relevant scientific information related to health effects associated with exposure to oxides of nitrogen
 - Secondary NO₂ NAAQS are being reviewed separately, in conjunction with review of secondary SO₂ NAAQS
 - Current secondary annual NO₂ standard is identical in all respects to primary annual NO₂ standard

Anticipated Schedule for the Primary NO₂ NAAQS Review

Stage of Review	Major Milestone	Target Date for Completion	Target Date for CASAC Review/Consultation
Integrated Review Plan (IRP)	Literature Search	Ongoing	
	Call for Information	Feb 10, 2012	
	Workshop on Science/Policy Issues	Feb 29 - Mar 1, 2012	
	Draft plan for ISA development	May 2013	Jun 5, 2013
	Draft IRP	Feb 2014	Mar 12-13, 2014
	Final IRP	Jun 2014	
Integrated Science Assessment (ISA)	First draft ISA	Nov 2013	Mar 12-13, 2014
	Second draft ISA	Aug 2014	Oct 2014
	Final ISA	Feb 2015	
Risk/Exposure Assessment (REA)	REA Planning Document	Sept 2014	Oct 2014
	If warranted:		
	First draft REA		
	Second draft REA	TBD	TBD
	Final REA		
Policy Assessment (PA) and Rulemaking	First draft PA	Jan 2015	Feb 2015
	Second draft PA	Oct 2015	Nov 2015
	Final PA	Apr 2016	
	Notice of proposed rulemaking	Sept 2016	
	Notice of final rulemaking	Jun 2017	



History of Primary NO₂ NAAQS

- **1971:** NO₂ NAAQS (both primary and secondary) set as annual standards with a level of 100 µg/m³ (equivalent to 0.053 ppm or 53 ppb)
 - Calculated as mean of all 1-hour concentrations in a year
- **1985 and 1996:** Annual NO₂ NAAQS retained, without revision
- **2010:** Revised primary NO₂ NAAQS by establishing a new 1-hour standard, with a level of 100 ppb and 98th percentile form, averaged over 3 years
 - Existing annual standard was retained, without revision
 - In conjunction with revision, required addition of NO₂ monitors in most populous metropolitan areas near major roadways in order to capture peak concentrations representative of heavily trafficked roads in urban areas



Last Review: Integrated Science Assessment

- Completed in Jul 2008
- Strongest evidence was for **respiratory morbidity following short-term NO₂ exposures** (minutes to weeks); judged *sufficient to infer a likely causal relationship*
 - Greatly expanded number of epidemiological studies reporting associations between respiratory morbidity and short-term (1-hour, 24-hour) NO₂
 - Distribution of 1-hour daily maximum NO₂ concentrations measured at area-wide monitors ranged from 85 to 94 ppb in key epidemiological studies
 - Controlled human exposure studies reported increases in airway responsiveness following short-term (30-minute to 2-hour) exposures to NO₂ concentrations at or above 100 ppb
 - Supporting evidence from animal toxicological studies, generally evaluated higher exposure concentrations (e.g., 500 ppb or higher)
- Greater uncertainty in evidence for other health endpoints
 - *Suggestive but not sufficient to infer a causal relationship* between short-term NO₂ exposures and mortality and between long-term (months to years) NO₂ exposures and respiratory morbidity
 - *Inadequate to infer the presence or absence of a causal relationship* between short-term NO₂ exposures and cardiovascular morbidity and between long-term NO₂ exposures and mortality, cancer, cardiovascular effects, and reproductive/developmental effects



Last Review: Risk and Exposure Assessment

- Completed in Nov 2008
- Characterized NO₂ air quality, exposures, and health risks for recent air quality and air quality adjusted to simulate just meeting potential alternative standards
- Compared ambient NO₂ concentrations (measured, modeled) across U.S., including around roadways, to 1-hour health benchmarks ranging from 100 to 300 ppb
 - Health benchmarks based on controlled human exposure evidence for airway hyperresponsiveness
- Population-based NO₂ daily maximum 1-hour exposure concentrations (modeled) in one urban area (Atlanta) were compared to these same health benchmarks
- Estimated risk of NO₂-associated emergency department visits in one urban area (Atlanta) based on concentration-response relationships from epidemiological study
- **Policy Assessment** included as final chapter of REA, not as stand-alone document
 - Presented staff considerations and conclusions regarding the range of policy options that were supported by scientific evidence and exposure/risk information



Last Review: Final Decision on Adequacy of Existing Annual Standard

- **Overall Conclusion:** Annual standard alone was judged not requisite to protect public health with an adequate margin of safety
 - **Evidence:** NO₂ epidemiological studies reported associations with respiratory emergency department visits or hospital admissions in locations that met the existing annual standard
 - **Air Quality, Exposure, and Risk:** Important NO₂-associated health risks were estimated for areas just meeting the existing annual standard
 - U.S. cities could experience near-road NO₂ concentrations above health benchmarks on most days of the year
 - Most asthmatics in Atlanta could be exposed on multiple days per year to NO₂ concentrations above health benchmarks
 - Large percentage (8 to 9%) of respiratory-related emergency department visits in Atlanta could be associated with short-term NO₂ exposures
- **Next Step:** Considered appropriate revisions in terms of basic elements of NAAQS: indicator, averaging time, form, and level



Last Review: Final Decisions on Elements of NAAQS ⁽¹⁾

- **Indicator:** Retained NO₂ as indicator for oxides of nitrogen
 - Available scientific information regarding health effects related to exposure to oxides of nitrogen was largely indexed by NO₂
 - Emissions that lead to formation of NO₂ can also lead to formation of other oxides of nitrogen, therefore, measures leading to reductions in population exposures to NO₂ can generally be expected to also reduce population exposures to other gaseous oxides of nitrogen
 - NO₂ remained the most appropriate indicator for NAAQS intended to address health effects associated with exposure to NO₂, alone or in combination with other gaseous oxides of nitrogen
- **Averaging Time:** Established new standard with 1-hour averaging time
 - Weight of evidence most directly supported an averaging time that focused protection on short-term exposures to NO₂
 - A standard with a 1-hour averaging time would effectively control short-term (1-hour to 24-hour) NO₂ concentrations



Last Review: Final Decisions on Elements of NAAQS (2)

- **Form and level:** Level of 1-hour standard set at 100 ppb, with a 98th percentile form (averaged over 3 years)
 - EPA and CASAC considered whether the standard should be linked to existing “area-wide” monitors (used in epidemiological studies), or based on maximum concentrations, including near roads
 - In final decision, revisions to standard and monitoring network reflected an emphasis on protecting against exposures to peak NO₂ concentrations, such as those that can occur around major roadways
 - New 1-hour standard is expected to...
 - Limit short-term exposures to NO₂ concentrations that have been reported to increase airway responsiveness in asthmatics (i.e., 100 ppb and above)
 - Maintain area-wide NO₂ concentrations (i.e., those that can occur broadly across communities) below those measured in locations where U.S. epidemiological studies have reported associations with respiratory-related hospital admissions and emergency department visits (i.e., below 85 to 94 ppb, 98th percentile concentrations)
- Also retained all aspects of existing annual standard to continue to provide protection for effects potentially associated with long-term exposures



Last Review: Monitoring Network

In conjunction with the revised NO₂ NAAQS...

- Required changes to NO₂ monitoring network in order to measure short-term NO₂ concentrations near important sources of oxides of nitrogen, such as major roadways
- At least one near-road monitor required for urban areas with populations greater than or equal to 500,000
 - Additional near-road monitors required for larger urban areas and/or urban areas with the busiest roads
 - Near-road monitors began coming online in Jan 2014
- Approximately 52 "area-wide" monitors are required in areas with populations at or above 1 million
 - Characterizing areas with highest expected NO₂ concentrations at the neighborhood or larger spatial scales
- About 40 monitors will be sited to focus specifically on at-risk populations
 - Monitoring to characterize NO₂ concentrations in locations with susceptible or vulnerable populations



Current Review: Overarching Questions

- Does the currently available scientific evidence and exposure/risk information support or call into question the **adequacy of the protection afforded by the current primary standards**?
 - NAAQS protect public health, including the health of at-risk populations and lifestages, with an adequate margin of safety
- What **alternative standards**, if any, are supported by currently available scientific evidence and exposure/risk-based information, and are appropriate for consideration?
 - In terms of basic elements of NAAQS: indicator, averaging time, level, and form



Current Review: Expanded Role of IRP

- Provide more context related to previous review to improve orientation of CASAC Panel members
 - Discuss decisions made in previous review, including rationales for those decisions
 - Include background on key scientific issues and uncertainties from previous review
- Discuss more fully planned scopes of ISA, REA, and PA
 - Include discussion of the considerations that will influence whether new air quality, exposure, and risk analyses are conducted, and whether a new REA is warranted
- Conduct CASAC review of draft IRP rather than CASAC consultation
 - Request specific and focused CASAC advice earlier in review process in order to facilitate a clear understanding of, and agreement on, the rest of the process



Current Review: Key Issues (1)

- Many key issues to be addressed in current review are based upon uncertainties in evidence and exposure/risk information identified in last review
- These key issues have guided the development of the key policy-relevant questions presented in draft IRP
- Specific issues to be considered with regard to the **evidence** include...
 - Extent to which new evidence reinforces or calls into question the evidence presented and evaluated in the last review
 - Evidence of health effects not previously identified or stronger evidence than previously considered?
 - Evidence of effects at lower concentrations than previously observed or in areas that would likely meet current standards?
 - Expanded understanding of at-risk populations and lifestages?
 - Extent to which uncertainties in scientific evidence from last review have been reduced and/or whether new uncertainties have emerged
 - Extent to which NO₂ itself, as opposed to one or more co-occurring pollutants (e.g., PM_{2.5}, O₃, traffic-related pollutants), contributes to health effects reported in epidemiological studies?



Current Review: Key Issues (2)

- Specific issues to be considered with regard to **exposure and risk analyses** include...
 - Extent to which newly available scientific evidence and tools/methodologies provide support for conducting quantitative risk and exposure assessments, beyond those conducted in the last review
 - Information on NO₂ concentration gradients around important sources, such as major roads and point sources, and relating those gradients to broader ambient concentrations?
 - Information to inform an improved characterization of NO₂ exposures and risks?
 - Information and/or approaches that would inform simulations of current or potential alternative NO₂ standards?
 - Extent to which uncertainties in scientific evidence from last review have been reduced and/or whether new uncertainties have emerged
 - Can important uncertainties identified in 2008 REA be addressed by newly available information or tools/methodologies to improve our understanding of exposures and risks associated with oxides of nitrogen?
 - What specific new analyses, if any, would be most informative?



Current Review: Organization of Draft IRP

1. Introduction (including regulatory history)
2. Status and Schedule
3. Key Policy-Relevant Issues
4. Science Assessment (reflects consideration of Jun 2013 CASAC consultation and public comment on draft ISA plan)
5. Quantitative Risk and Exposure Assessment
6. Ambient Air Monitoring
7. Policy Assessment and Rulemaking
8. References



Primary NO₂ NAAQS Review Team

Office of Air Quality Planning and Standards

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- Dr. Molini Patel, ISA Team Lead
 - See complete ISA team list in ISA presentation materials
- Dr. Steven Dutton, Branch Chief (Acting)
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- Mr. David Orlin



Additional Information

- Documents from the current and previous primary NO₂ NAAQS reviews are available at: http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_index.html
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