

U.S. National Ambient Air Quality Standards (NAAQS) Program

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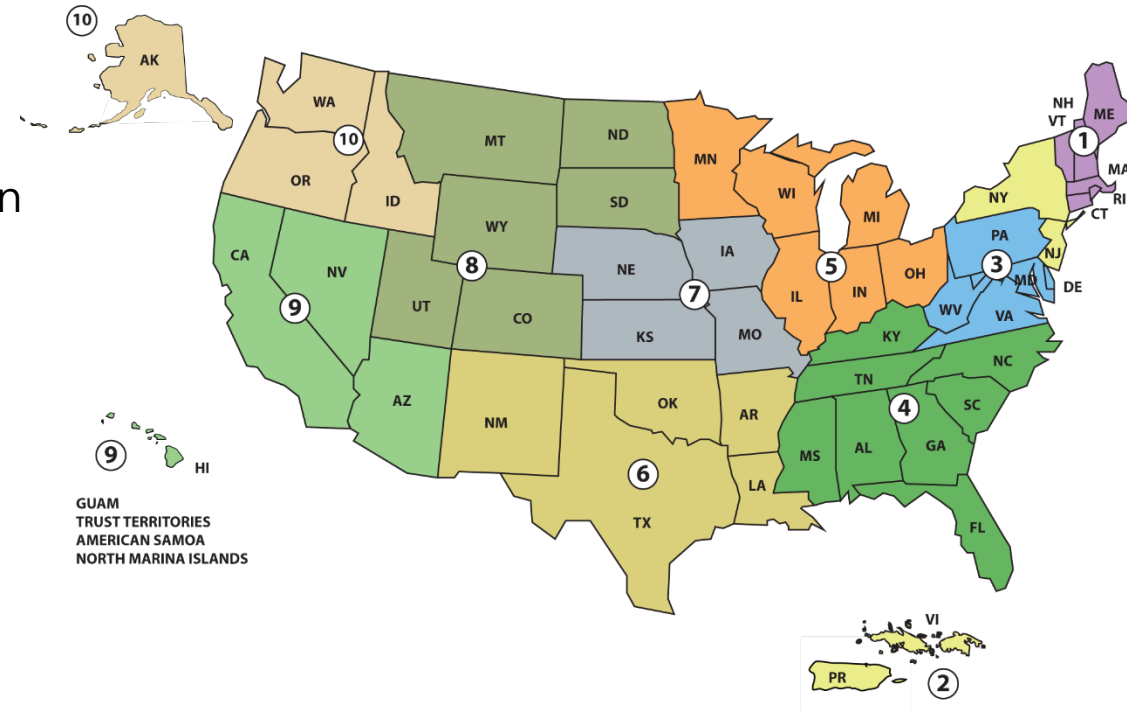
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Outline

- Strengths of U.S. Air Quality Standards System
- NAAQS Statutory Requirements
- Current NAAQS Standards
- NAAQS Review Process
 - Integrated Science Assessment
 - Risk and Exposure
 - Policy Assessment
 - Rulemaking
- NAAQS Designation and Implementation Process
- Air Quality Trends

Strengths of U.S. Air Quality Standards System

- Clear legislation on air quality standard setting
 - Based on extensive scientific review in order to protect public health and welfare
 - Mechanisms to address interstate transport of pollution
 - Non-attainment areas classified by severity of air pollution problem
 - EPA required to review NAAQS every 5 years
- Robust implementation and enforcement process of NAAQS
 - EPA "designates" an area based on whether or not it is meeting the standard
 - EPA approves and enforces State Implementation Plans
 - EPA develops detailed guidance to interpret NAAQS requirements to assist States
 - Stringency of requirements for attaining NAAQS based on severity of air pollution problem



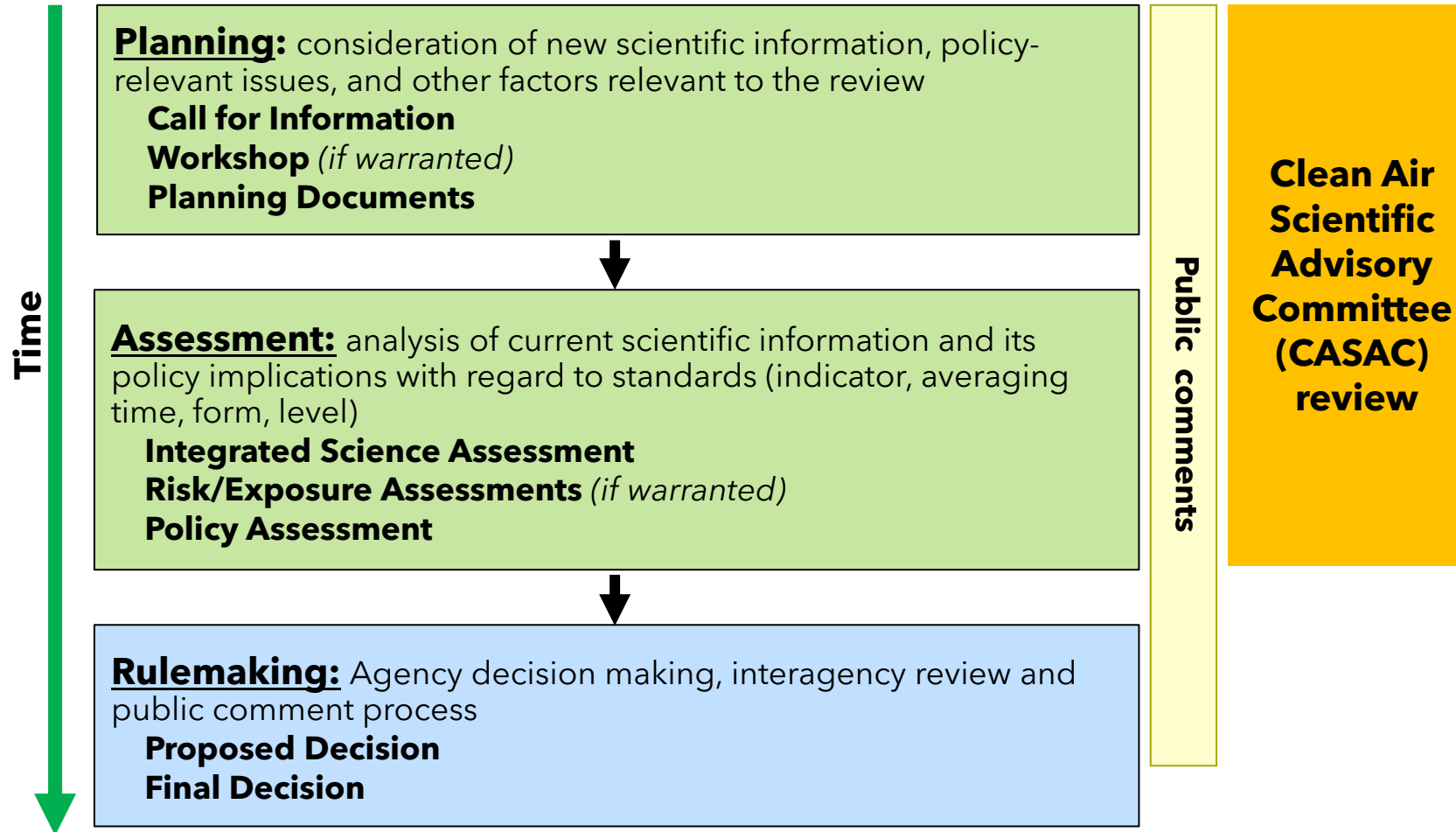
Background and Statutory Requirements

- EPA sets National Ambient Air Quality Standards (NAAQS) for six criteria pollutants; the Clean Air Act requires EPA to **review the standards every 5 years**
 - Ground-level ozone
 - Carbon monoxide
 - Oxides of Nitrogen
 - Particulate matter
 - Lead
 - Oxides of Sulfur
- **Primary (health-based) standards:** in the “judgment of the Administrator” must be “requisite” to protect public health with an “adequate margin of safety”
 - The term requisite means “sufficient, but not more than necessary” [a zero-risk standard is neither possible nor required]
 - By requiring an “adequate margin of safety”, Congress was directing EPA to build a buffer to protect against uncertain and unknown dangers to human health
- **Secondary (welfare-based) standards:** “...specify a level of air quality the attainment and maintenance of 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 . . .”
- In setting NAAQS, EPA is **barred from considering the cost of implementing the standards** or adjusting a protective standard solely on the basis of attainability in light of background concentrations of the pollutant

Summary of Current U.S. Standards

Pollutant		Type	Averaging Time	Level	Form
Carbon Monoxide (CO)		primary	8 hours	9 ppm	Not to be exceeded more than once per year
			1 hour	35 ppm	
Lead (Pb)		primary & secondary	Rolling 3-month average	0.15 µg/m ³	Not to be exceeded
Nitrogen Dioxide (NO ₂)		primary	1 hour	100 ppb	98 th percentile of 1-hour daily maximum concentrations, averaged over 3 years
		primary & secondary	1 year	53 ppb	Annual mean
Ozone (O ₃)		primary & secondary	8 hours	0.070 ppm	Annual fourth highest daily maximum 8-hour concentration, averaged over 3 years
Particle Pollution (PM)	PM _{2.5}	primary	1 year	12.0 µg/m ³	annual mean averaged over 3 years
		secondary	1 year	15.0 µg/m ³	
		primary & secondary	24 hours	35 µg/m ³	98 th percentile, averaged over 3 years
	PM ₁₀	primary & secondary	24 hours	150 µg/m ³	Not to be exceeded more than once per year on average over 3 years
Sulfur Dioxide (SO ₂)		primary	1 hour	75 ppb	99 th percentile of 1-hour daily maximum concentration, averaged over 3 years
		secondary	3 hours	0.5 ppm	Not to be exceeded more than once per year

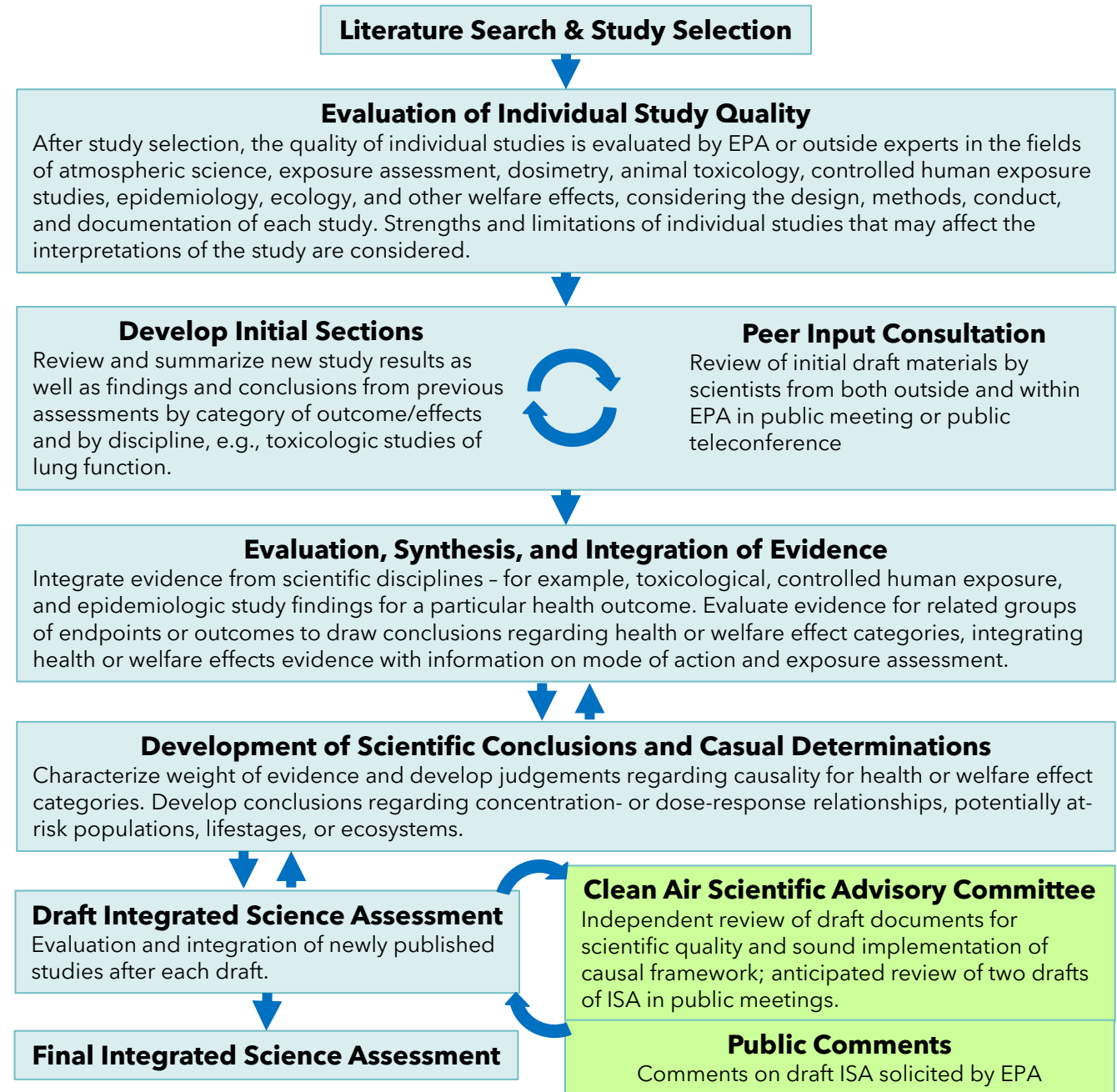
NAAQS Review Process: Overview



Integrated Science Assessment (ISA)

- Comprehensive evaluation and synthesis of the policy-relevant scientific information that is the foundation for the review
 - Characterization of the strengths and uncertainties of the evidence
 - Conclusions on causality for health and welfare effects
 - Characterization of evidence for at-risk populations
 - Assessment of evidence for dose/concentration-response relationships

<http://www.epa.gov/isa>

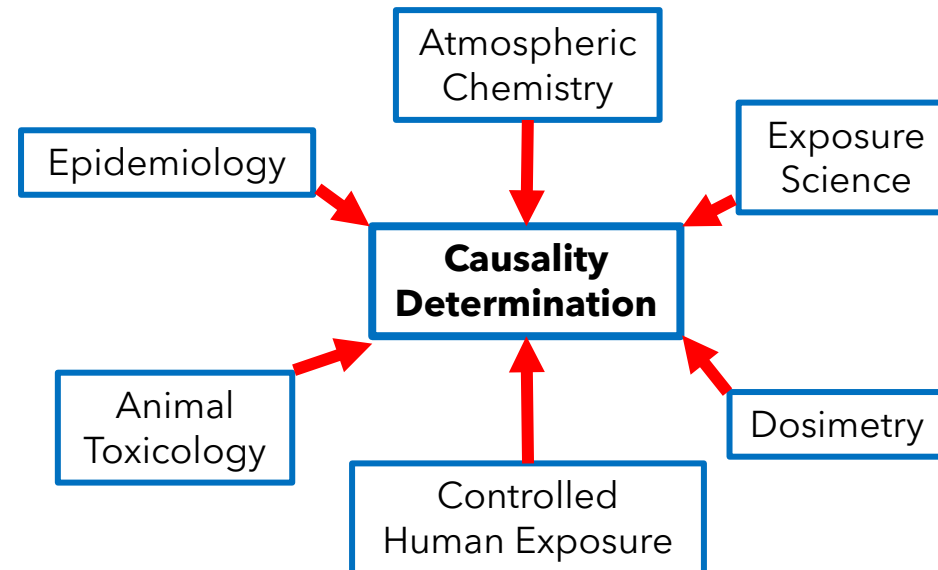


ISA Causality Determinations

- Organize relevant literature for broad health and welfare effect categories
- Evaluate studies, characterize results, extract relevant data
- Integrate evidence across disciplines for health and welfare outcome categories
- Develop causality determinations using established framework
- Evaluate evidence for populations potentially at increased risk
- Consideration of evidence spans many scientific disciplines from source to effect

Example: Health Effects Integration

- Atmospheric chemistry
- Exposure
- Controlled human exposure studies
- Epidemiologic studies
- Animal toxicologic studies
- At-risk populations/lifestages



****Informs Hazard Identification step of Risk Assessment Process****

Weight-of-Evidence Approach for Causality Determinations for Health and Welfare Effects

- Provides transparency through structured framework
- Developed and applied in ISAs for all criteria pollutants
- Emphasizes synthesis of evidence across scientific disciplines
- **Five categories** based on overall weight-of-evidence:
 - Causal relationship
 - Likely to be a causal relationship
 - Suggestive of, but not sufficient to infer, a causal relationship
 - Inadequate to infer the presence or absence of a causal relationship
 - Not likely to be a causal relationship

Ex: PM ISA Health Effects Causality Determinations

Human Health Impacts		PM _{2.5}	PM ₁₀
Respiratory	Short-term	Likely Casual	Suggestive
	Long-term	Likely Casual	Inadequate
Cardiovascular	Short-term	Casual	Suggestive
	Long-term	Casual	Suggestive
Metabolic	Short-term	Suggestive	Inadequate
	Long-term	Suggestive	Suggestive
Nervous System	Short-term	Suggestive	Inadequate
	Long-term	Likely Casual	Suggestive
Reproduction and Fertility	Long-term	Suggestive	Inadequate
Pregnancy and Birth Outcomes	Long-term	Suggestive	Inadequate
Cancer	Long-term	Likely Casual	Suggestive
Mortality	Short-term	Casual	Suggestive
	Long-term	Casual	Suggestive

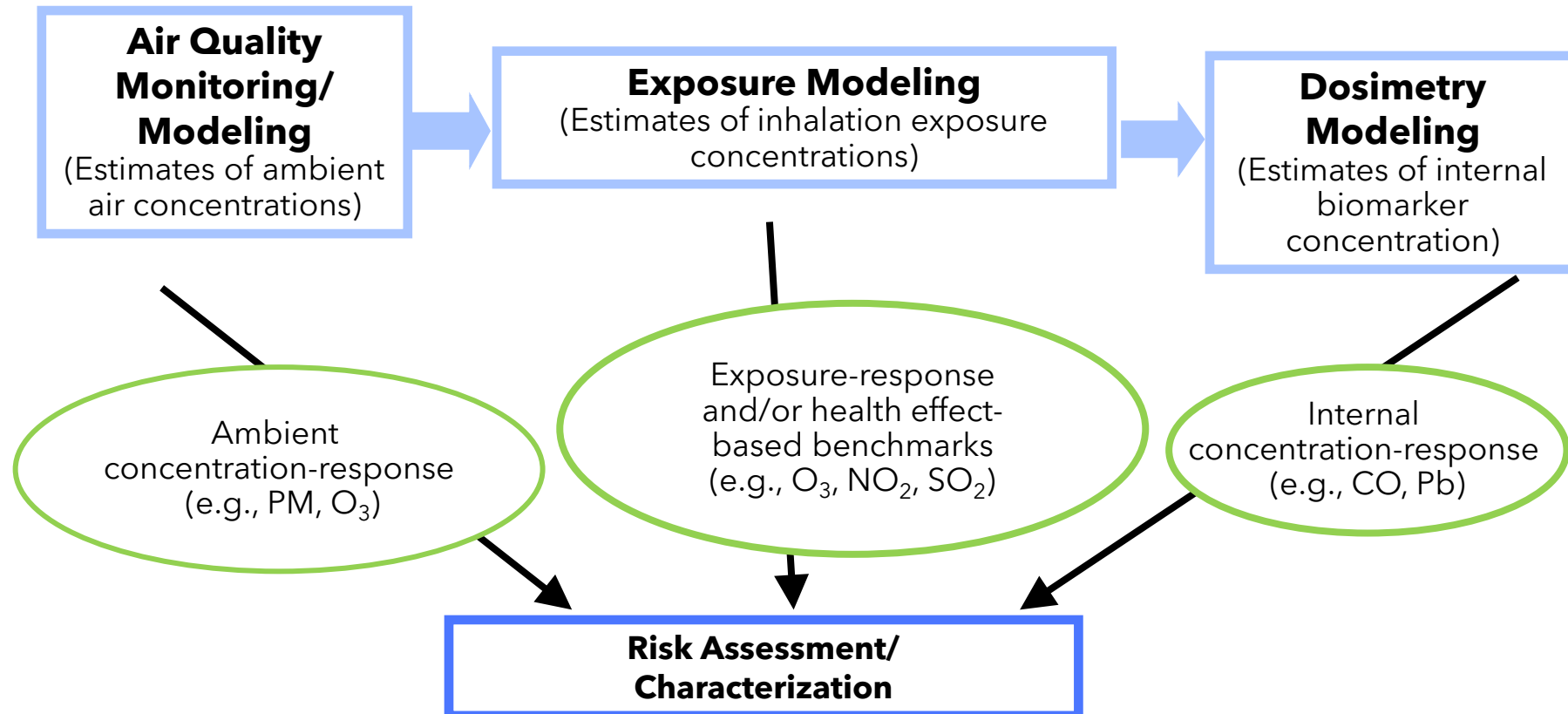
Assessing Causality from a Multidisciplinary Evidence Base for National Ambient Air Quality Standards

- A committee of the National Academies of Sciences, Engineering, and Medicine will consider frameworks to assess causality of health and welfare effects of air pollutants in EPA's Integrated Science Assessments (ISAs) conducted as part of EPA reviews of National Ambient Air Quality Standards (NAAQS).
- Advances for integrating scientific evidence will be assessed, and issues concerning confounders, the most useful types of evidence for causal determinations, and whether a single framework for assessing causality is applicable to both health and welfare effects will be considered.
- Recommendations regarding the development and use of future ISA frameworks and priority research will be described.

<https://www.nationalacademies.org/our-work/assessing-causality-from-a-multidisciplinary-evidence-base-for-national-ambient-air-quality-standards>

Risk and Exposure Analyses

The nature and strength of evidence influences selection of appropriate quantitative risk characterization model.

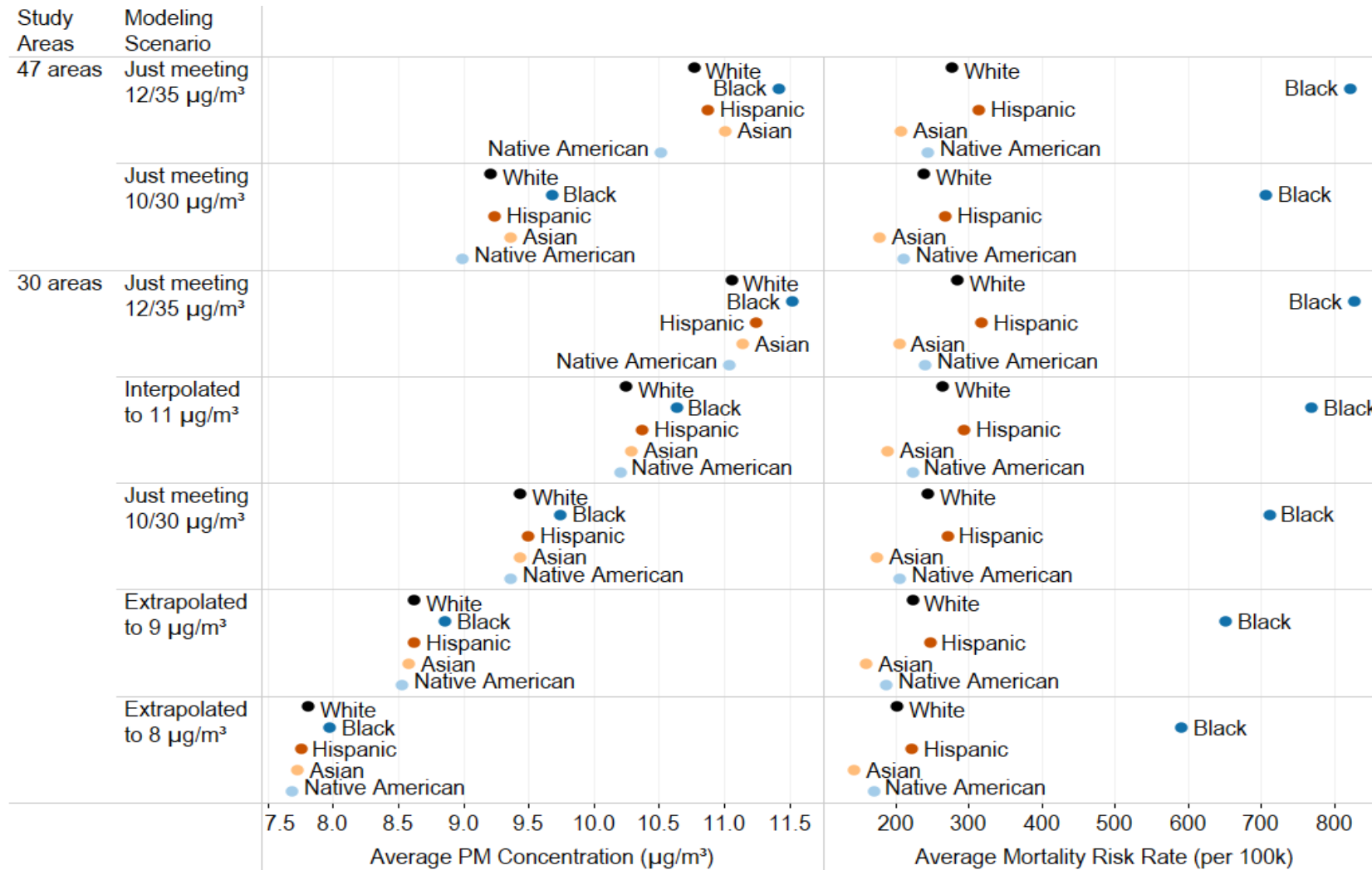


Evaluating At-Risk Populations

- Quantitative risk and exposure analyses attempt to characterize impacts to U.S. populations, including at-risk groups (children, older adults, people with preexisting disease, etc.)
- Informs the Administrator's judgement regarding what standard provides an adequate margin of safety
- Example: **PM_{2.5} At-Risk Analysis**
 - 2019 PM ISA and 2022 PM ISA Supplement provide strong evidence for racial and ethnic disparities in PM_{2.5} exposures and PM_{2.5}-related health risk
 - EPA used CR functions stratified by race/ethnicity from the Di et al. (2017) Medicare analysis to evaluate how mortality risk changes under alternative standards (evaluated those > 64 years old in U.S.)

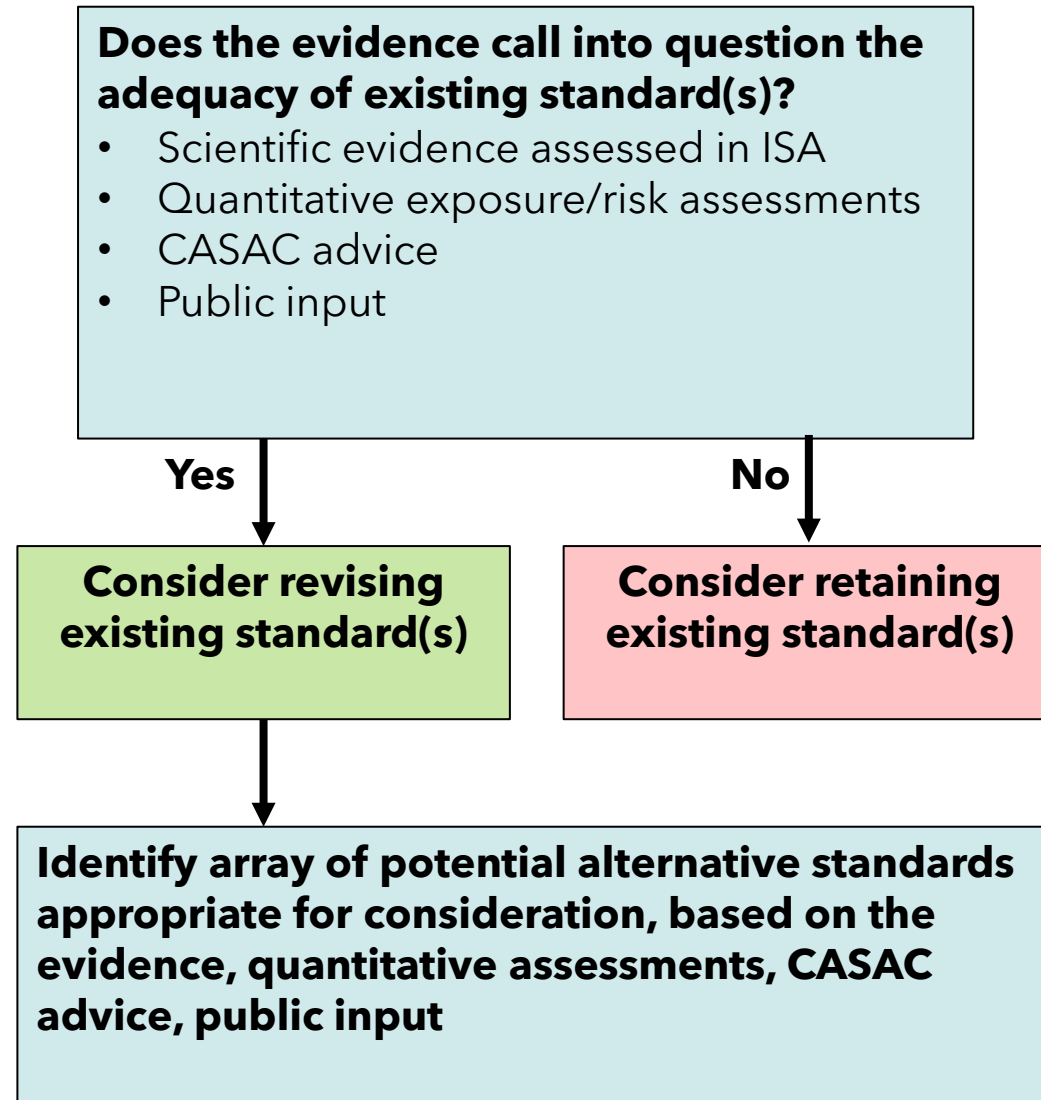
PM_{2.5} At-Risk Analysis

Average reduction in PM_{2.5} exposure concentrations and PM_{2.5}-attributable risk estimates by demographic population when moving from the current to alternative PM_{2.5} standards



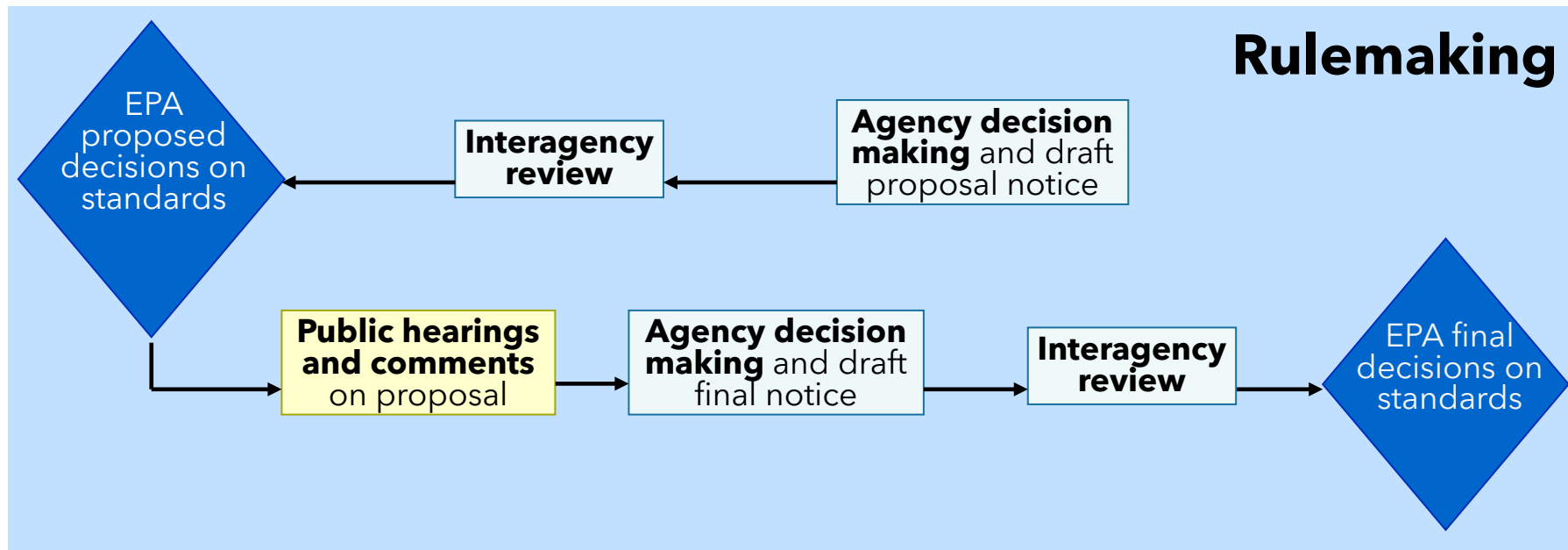
Policy Assessment

- Presents conclusions regarding the policy options supported by the current scientific evidence and quantitative assessments
- Considers all elements of the standard: indicator, averaging time, form, level

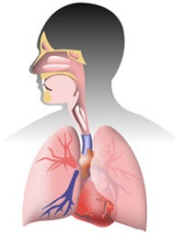


NAAQS Process: Regulatory Steps

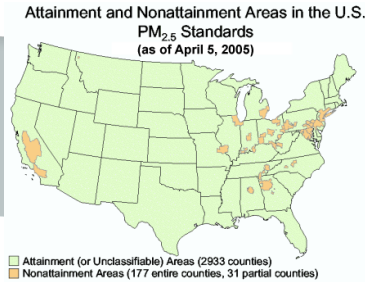
- The Agency decision-making process for the proposed and final rulemaking decisions includes internal EPA deliberation of key issues and decisions, development of proposed and final decision notices and review of draft notices by other federal agencies
 - Interagency review is coordinated through the Office of Management and Budget
- Final decisions are informed by scientific evidence, any quantitative analyses conducted, staff conclusions in the PA, CASAC advice, and public comments on the proposal



NAAQS Designations & Implementation



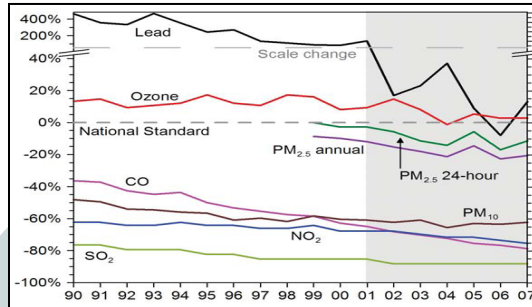
EPA revises National Ambient Air Quality Standards, Monitoring Requirements



EPA Designates Nonattainment Areas



Air Agency Assesses Expected Improvement From Federal Measures, and Develops Additional Control Strategies to Attain Standards



Ongoing Evaluation by EPA and Air Agency: Air Quality Monitoring, Tracking Emissions and Implementation of Control Programs

Scientific Research



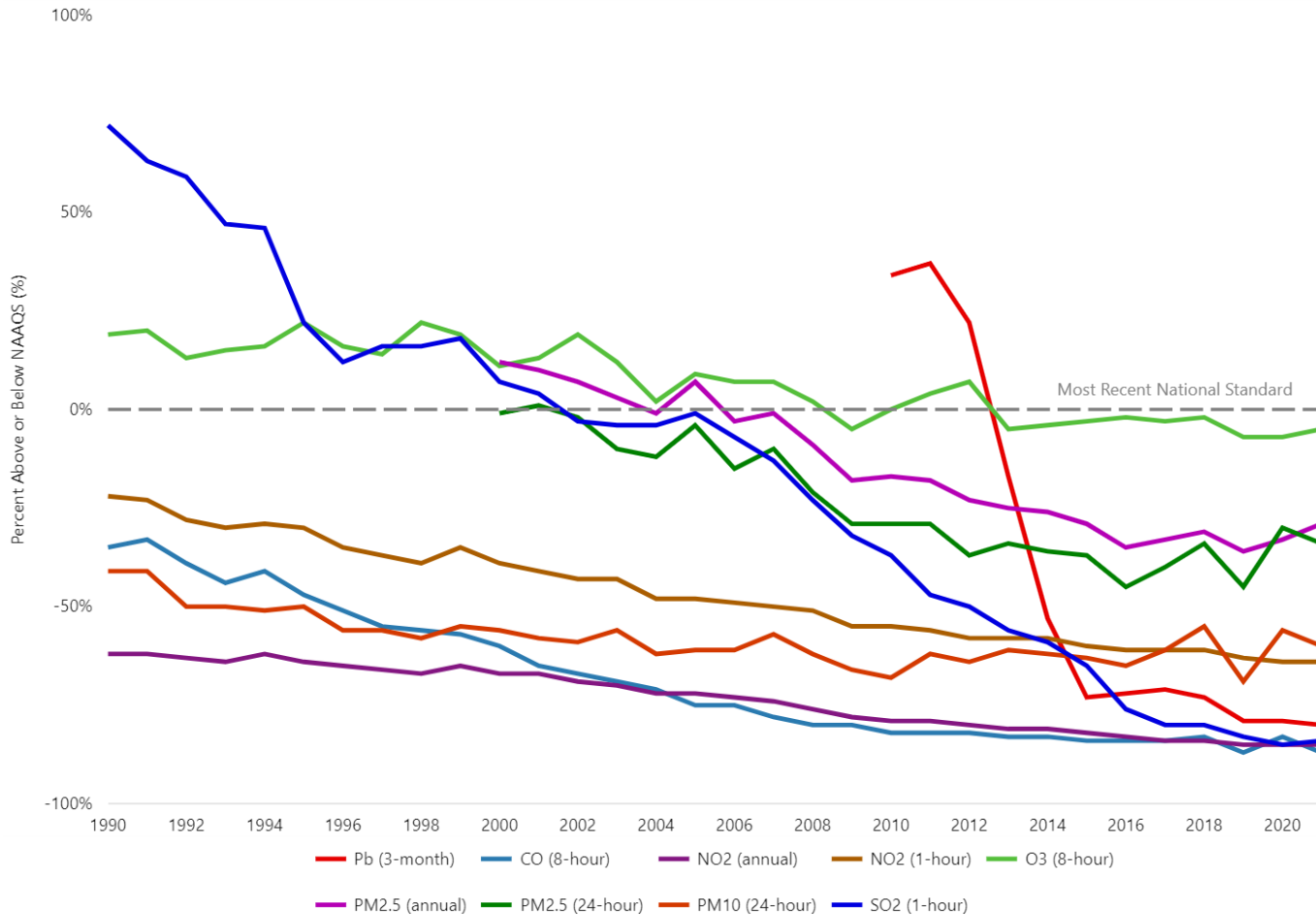
Air Agency Submits Plan to EPA and Implements Control Strategies Through Regulatory and Non-regulatory Approaches

NAAQS Designations & Implementation

- Once EPA revises a NAAQS, states provide recommendations on **nonattainment areas** within 1 year, and EPA is obligated to designate nonattainment areas within 2-3 years based on air quality data, state recommendations, and other factors
 - “**Nonattainment area**” is an area with air quality that violates the standard, plus the nearby area with sources that contribute to air quality levels that exceed the standard
- States must submit an attainment plan (**state implementation plan, SIP**) within 18-36 months after nonattainment area designation (depends on the pollutant)
 - Must demonstrate attainment “as expeditiously as practicable”, and no later than defined deadlines tied to the severity of nonattainment
 - Considers **expected reductions** from existing federal and state programs, as well as **additional emission reduction measures** from sources in the nonattainment area
 - Includes **contingency measures** to apply in the event the area fails to attain by its attainment date
 - Plan must be adopted by the state after public notice and comment and must be submitted to EPA for review and approval
- To be redesignated to attainment, state must submit a clean data record

Air Quality Trends Show Clean Air Progress

Declining National Air Pollutant Concentration Averages



Nationally, concentrations of air pollutants have dropped significantly since 1990:

- Carbon Monoxide (CO) 8-Hour, ↓ 79%
- Lead (Pb) 3-Month Average, ↓ 85% (from 2010)
- Nitrogen Dioxide (NO₂) Annual, ↓ 61%
- Nitrogen Dioxide (NO₂) 1-Hour, ↓ 54%
- Ozone (O₃) 8-Hour, ↓ 21%
- Particulate Matter 10 microns (PM₁₀) 24-Hour, ↓ 32%
- Particulate Matter 2.5 microns (PM_{2.5}) Annual, ↓ 37% (from 2000)
- Particulate Matter 2.5 microns (PM_{2.5}) 24-Hour, ↓ 33% (from 2000)
- Sulfur Dioxide (SO₂) 1-Hour, ↓ 91%
- Numerous air toxics have declined with percentages varying by pollutant

Thank you

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