United States Environmental Protection Agency

Office of Air Quality Planning and Standards

# Key Health Effects Information in Recent NAAQS Reviews


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# Overview

- Type of health effects data considered in reviews of primary National Ambient Air Quality Standards (NAAQS)

- Recent/ongoing NAAQS reviews
  - Particulate matter (PM)
  - Nitrogen Dioxide ($NO_2$)
  - Lead (Pb)

# Types of Health Effects Evidence

- Epidemiological studies
  - Health outcomes associated with normal exposures to ambient mix of air pollutants (e.g., PM)
  - Health outcomes associated with levels of internal marker (e.g., Pb)
- Controlled human exposure studies
  - Human responses to known exposures
- Toxicological studies
  - Animal studies, short- and long-term exposures
- *In vitro* studies

# NAAQS Assessments . . .

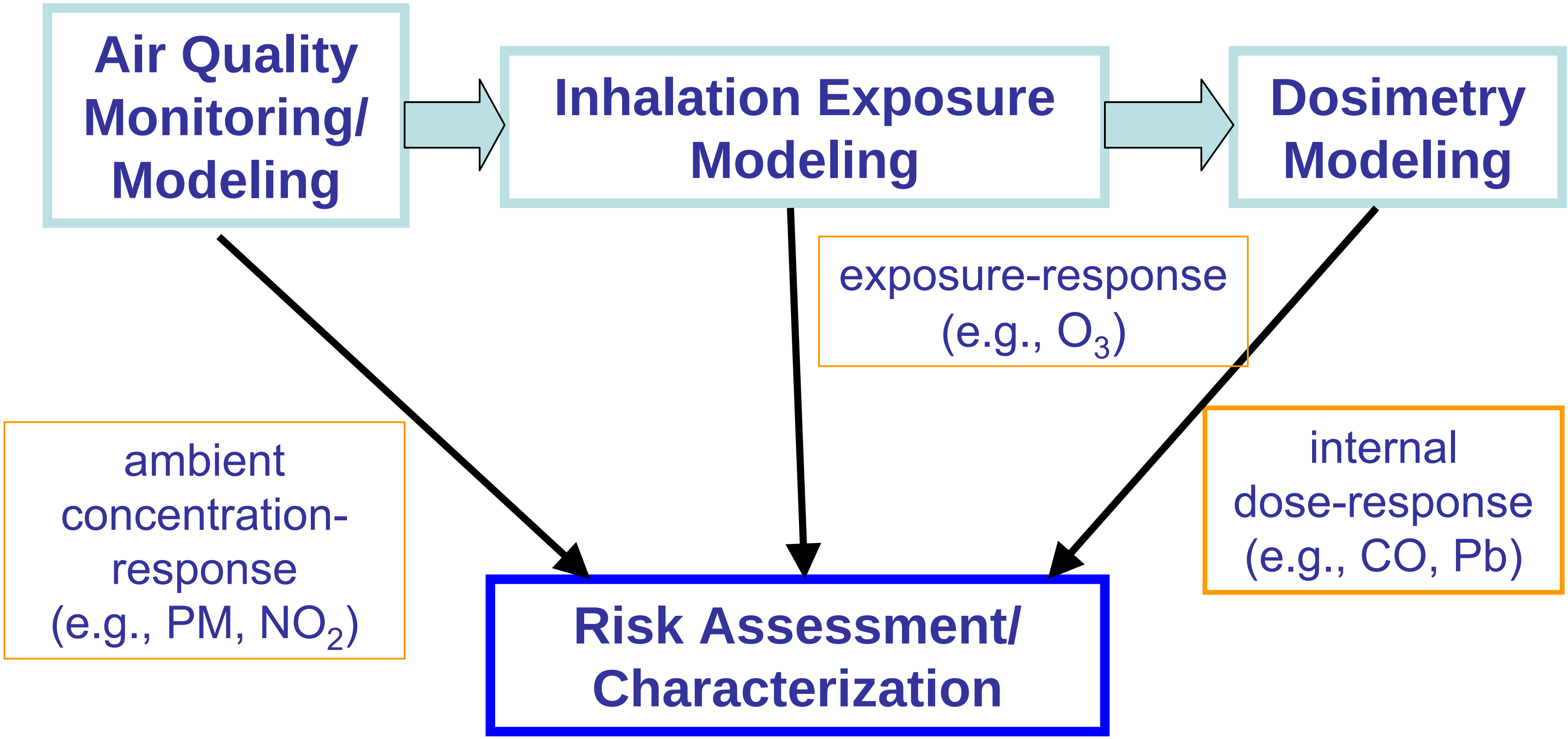
## *Hazard and "Dose"*

- Hazard characterization – weight-of-evidence approach, using all relevant information
  - Patterns of exposure
  - Nature and severity of effects
  - Nature and size of at-risk populations
  - Kind and degree of uncertainties
  - Consistency/coherence across all types of available evidence
- "Dose"-response evaluations – based on nature of available evidence from human studies, generally with no discernable thresholds (effects observed at current ambient concentrations)

# Causality Determinations

- Integrated Science Assessment (ISA) employs a 5-level hierarchy to characterize causality judgments
  - Sufficient to infer a causal relationship
  - Sufficient to infer a likely causal relationship
  - Suggestive, but not sufficient to infer a causal relationship
  - Inadequate to infer the presence or absence of a causal relationship
  - Suggestive of no causal relationship

# Type of Health Effects Evidence Affects How Characterize Risk



# NAAQS Assessments . . .
## *Exposure*

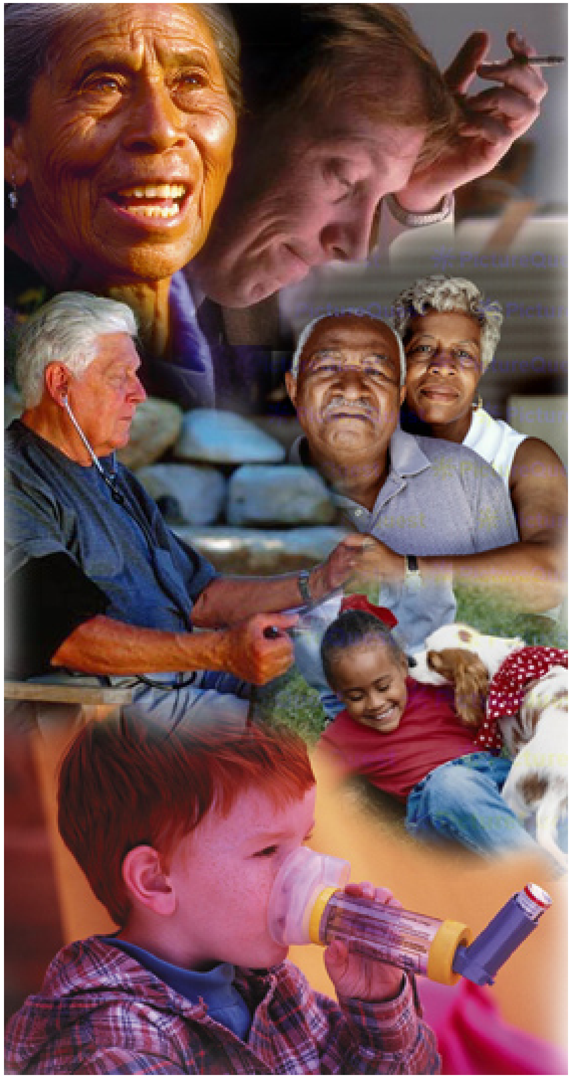
- Inhalation exposure assessment
  - Air quality monitoring/modeling and simulations of "just attaining" alternative standards
  - Pollutant concentrations within relevant microenvironments (home, yard, car, office)
  - Amount of time in different microenvironments and level of exertion (time-activity and breathing rate data)
  - Population demographics (census data, commuting patterns)
  - Probabilistic assessment (including uncertainty, variability, sensitivity analyses)
- Provides ability to identify and characterize exposure distributions for at-risk groups

# NAAQS Assessments . . .

## *Risk Characterization*

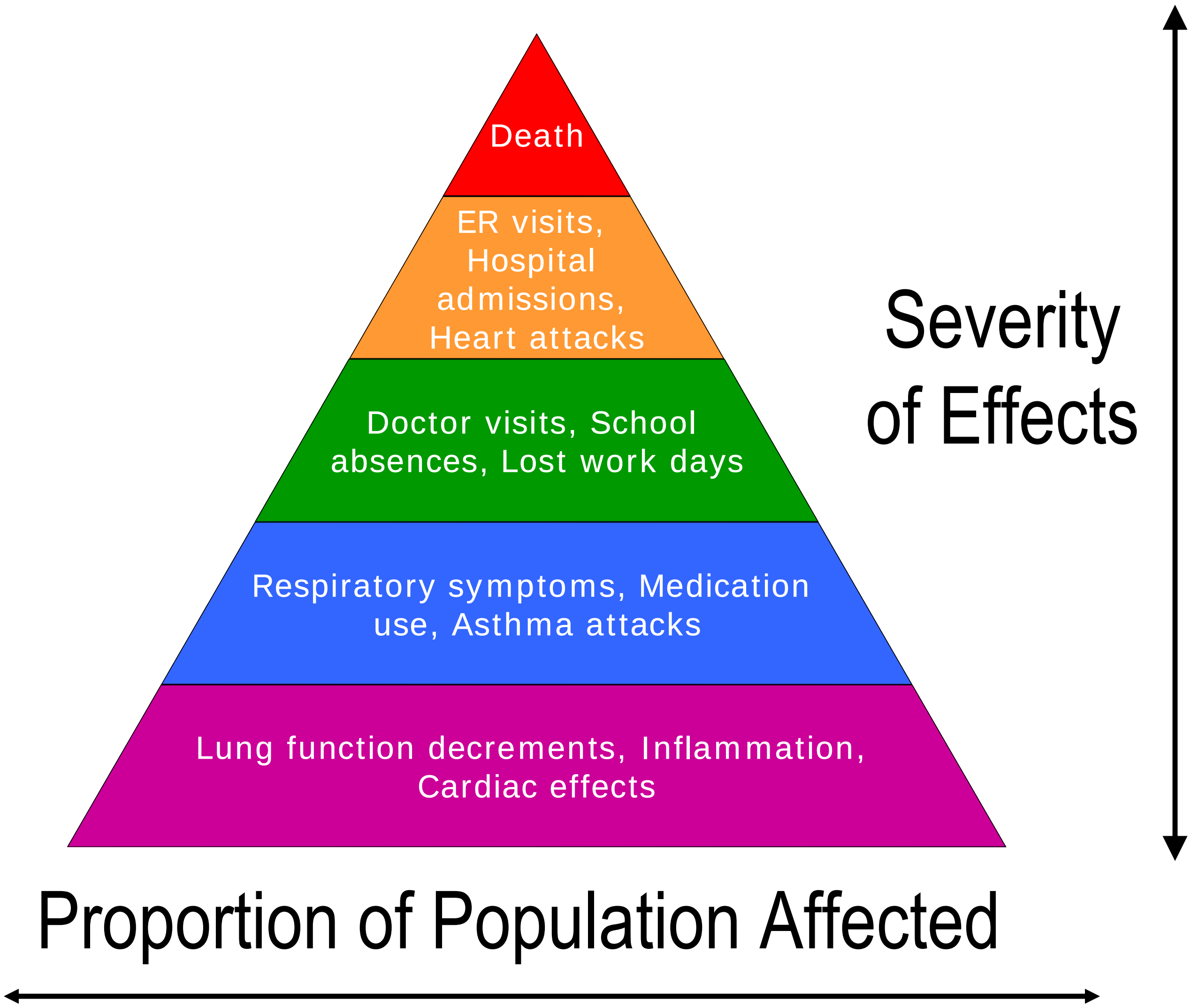
- Risk characterization – qualitative and quantitative approaches
  - Integration of evidence on health effects associated with short- or long-term exposures (strengths, weaknesses, uncertainties)
    - Identification of and focus on at-risk groups
  - Expert judgments on adversity of effects (severity, duration, frequency)
  - Qualitative and quantitative assessments of population exposures of concern and/or risks to public health
- Risk communication – put risk characterization into public health policy context

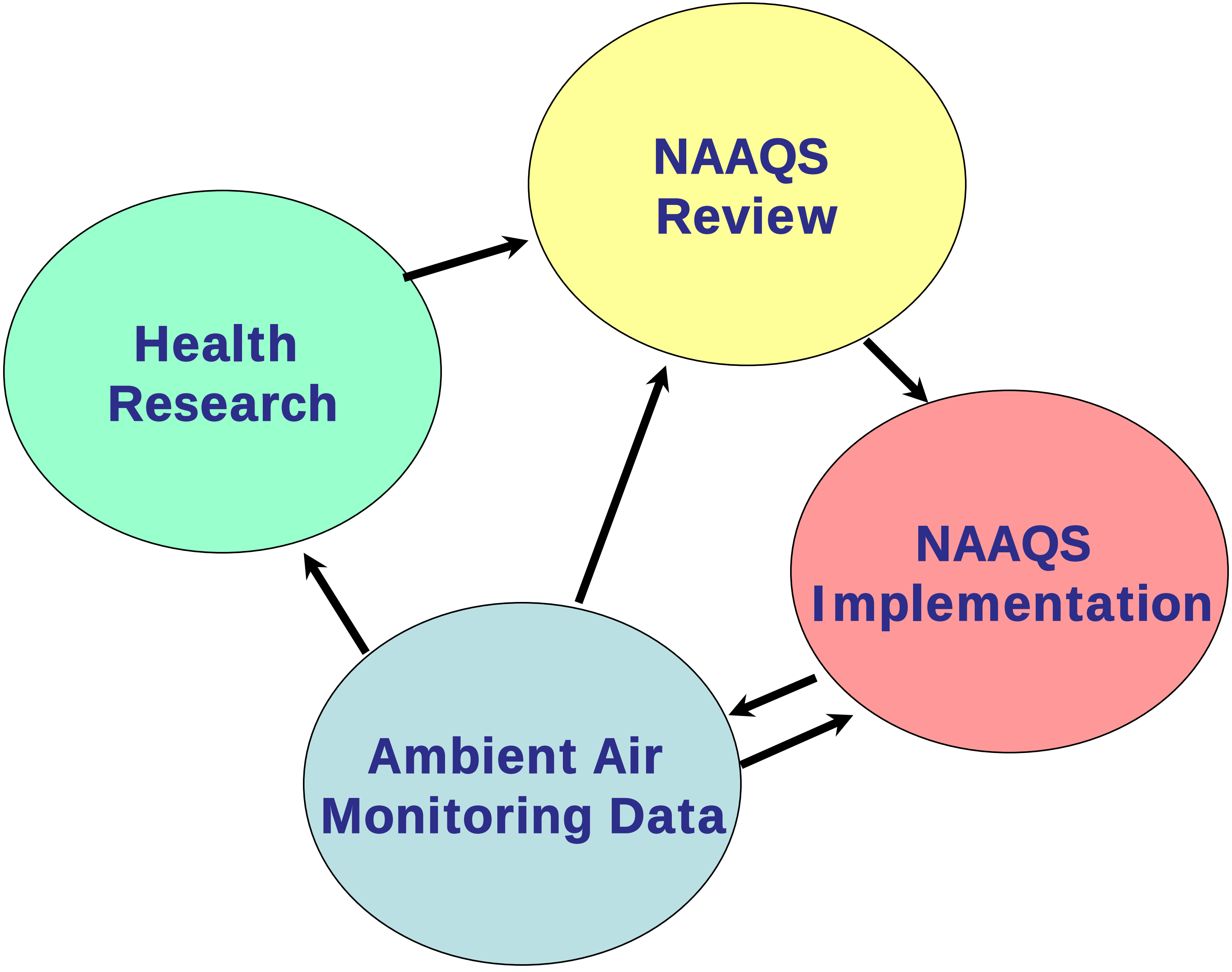
# Some populations are at increased risk . . .



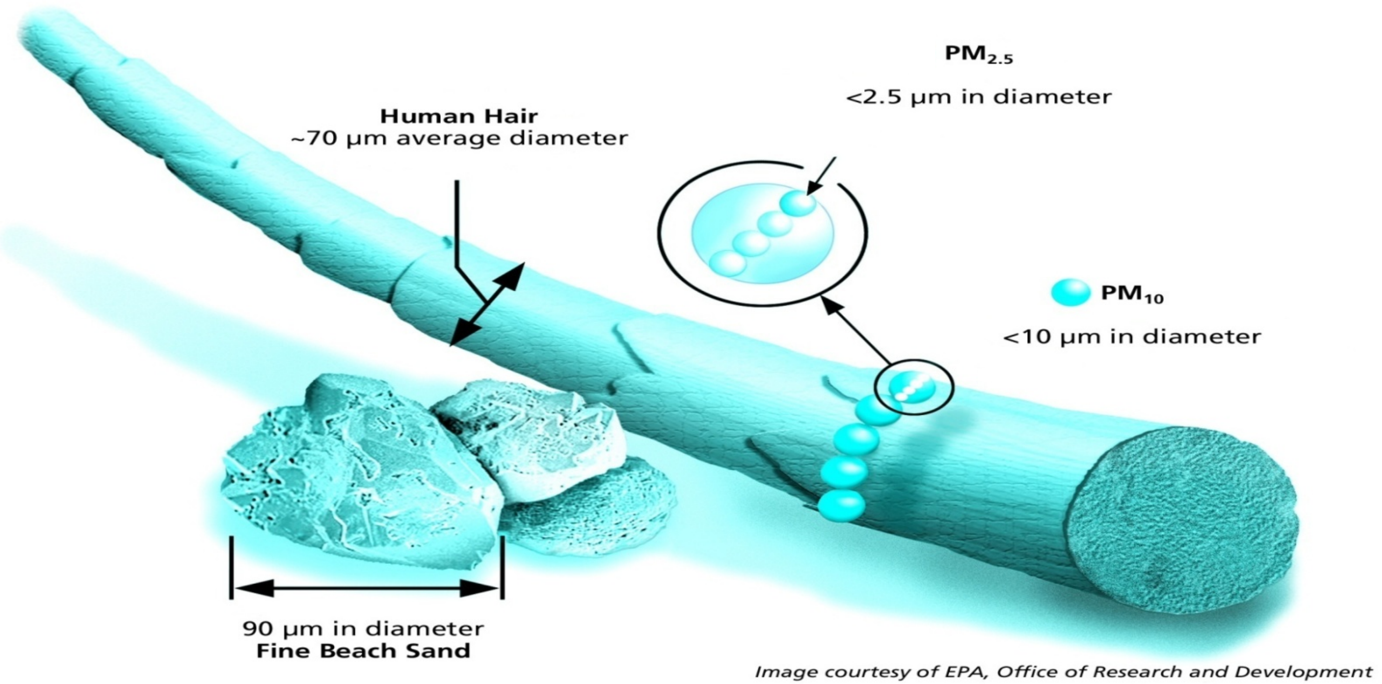
- People with heart or lung disease
- Older adults
  - Greater prevalence of heart and lung disease
- Children
  - More likely to be active
  - Breathe more air per pound
  - Bodies still developing
  - Conditions making some populations more vulnerable
  - Low SES (e.g., less access to health care)
  - Residence near roadways
- Others?

# Risk Characterization: Understanding Broader Public Health Impacts



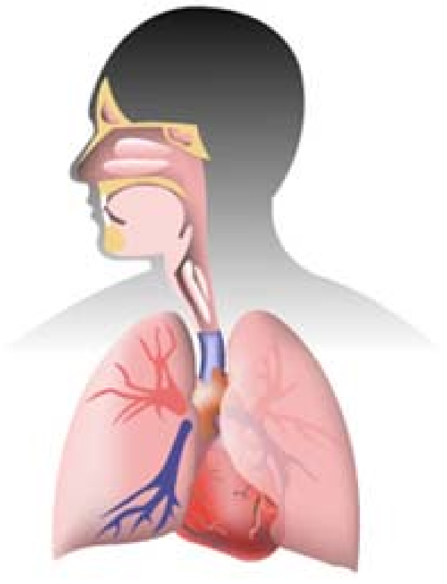

NAAQS
Review
Health
Research
NAAQS
Implementation
Ambient Air
Monitoring Data

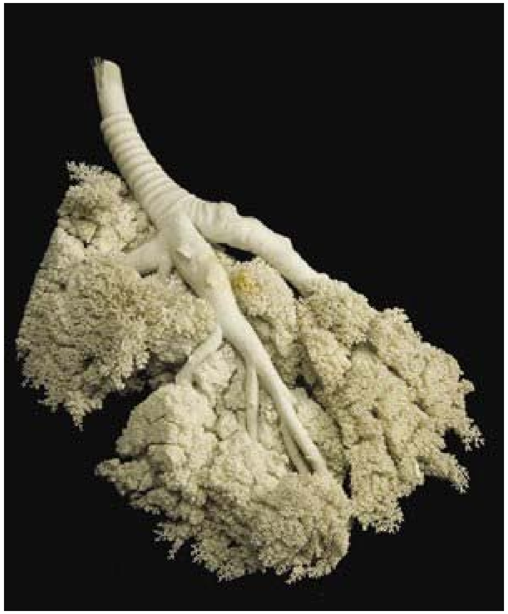
# Particulate Matter (PM)



# Particulate Matter

- Larger particles (> $PM_{10}$) deposit in the upper respiratory tract
- Smaller, inhalable particles (≤ $PM_{10}$) penetrate deep into the lungs





- Both coarse particulate matter and fine particulate matter can penetrate to lower regions of the lung
- Deposited particles may accumulate, react, be cleared or absorbed

| Final Rule | Indicator | Ave. Time | Level | Form |
|---|---|---|---|---|
| 1971 | TSP - Total Suspended Particles ( ≤ 25-45 µm) | 24-hour | 260 µg/m$^3$ (primary) 150 µg/m$^3$ (secondary) | Not to be exceeded more than once per year |
| | | Annual | 75 µg/m$^3$ (primary) | Annual average |
| 1987 | $PM_{10}$ | 24-hour | 150 µg/m$^{3*}$ | Not to be exceeded more than once per year |
| | | Annual | 50 µg/m$^3$ | Annual average |
| 1997 | $PM_{2.5}$ | 24-hour | 65 µg/m$^3$ | 98$^{th}$ percentile |
| | | Annual | 15 µg/m$^3$ | Annual arithmetic mean, ave. over 3 years |
| | $PM_{10}$ | 24-hour | 150 µg/m$^3$ | Initially promulgated 99$^{th}$ percentile form; when 1997 standards were vacated, form of 1987 standards remained in place (not to be exceeded more than once per year on ave. over a three year period) |
| | | Annual | 50 µg/m$^3$ | Annual arithmetic mean, ave. over 3 years |
| 2006 | $PM_{2.5}$ | 24-hour | 35 µg/m$^3$ | 98$^{th}$ percentile, ave. over 3 years |
| | | Annual | 15 µg/m$^3$ | Annual arithmetic mean, ave. over 3 years |
| | $PM_{10}$ | 24-hour | 150 µg/m$^3$ | Not to be exceeded more than once per year on ave. over a 3 year period |

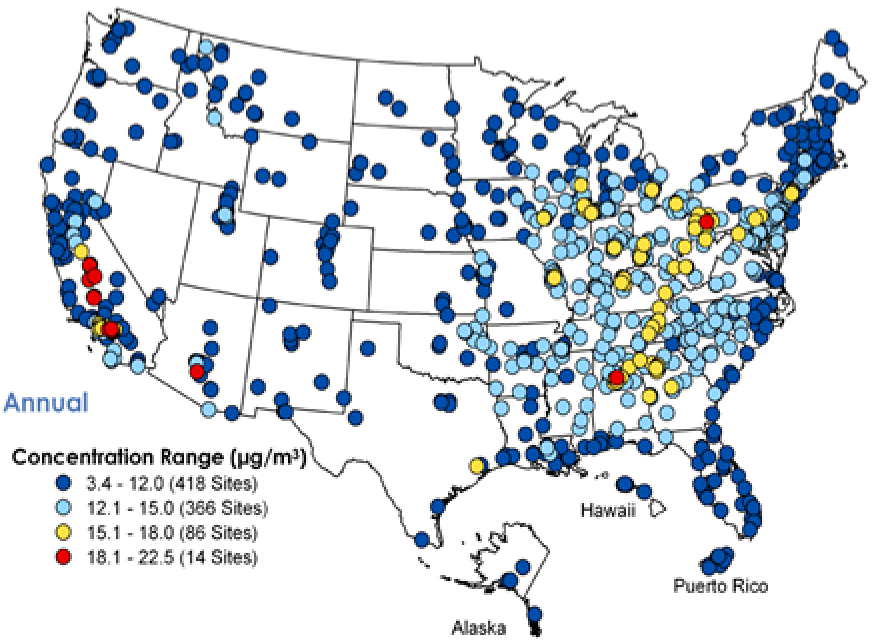
# Remand of 2006 PM NAAQS: *Overview*

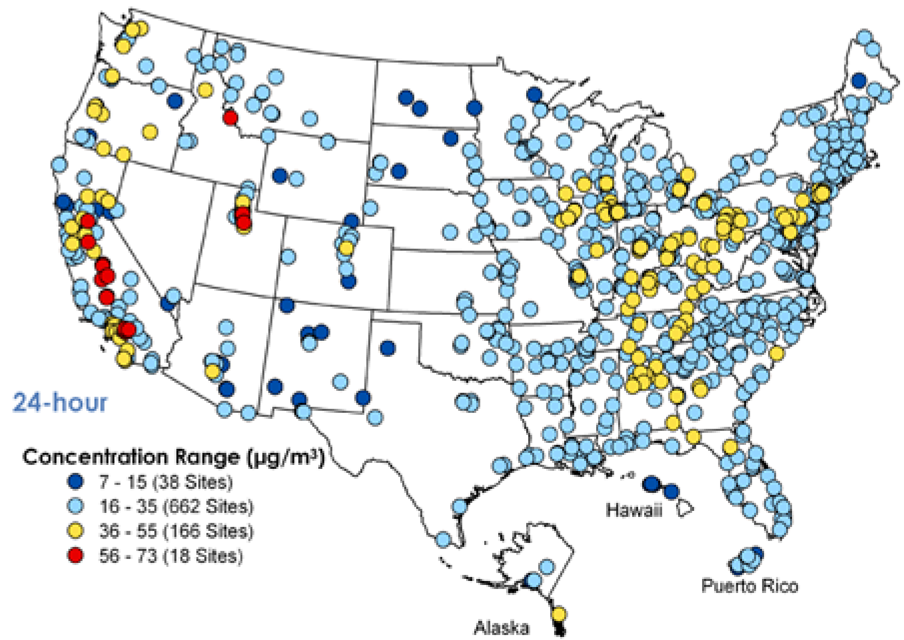
- D.C. Circuit Court issued decision on February 24, 2009
- $PM_{2.5}$ standards:
  - Remanded primary annual $PM_{2.5}$ standard (retained at 15 µg/$m^3$) and secondary $PM_{2.5}$ standards (set identical to primary standards)
  - Primary 24-hour $PM_{2.5}$ standard (revised to 35 µg/$m^3$) not challenged
- $PM_{10}$ standards:
  - Upheld decisions to retain 24-hour $PM_{10}$ standard and revoke annual $PM_{10}$ standard
  - Based on finding EPA reasonably explained decision to regulate all coarse PM (including nonurban PM) and use of $PM_{10}$ as indicator for coarse PM

# Remand: *Primary Annual $PM_{2.5}$ Standard*

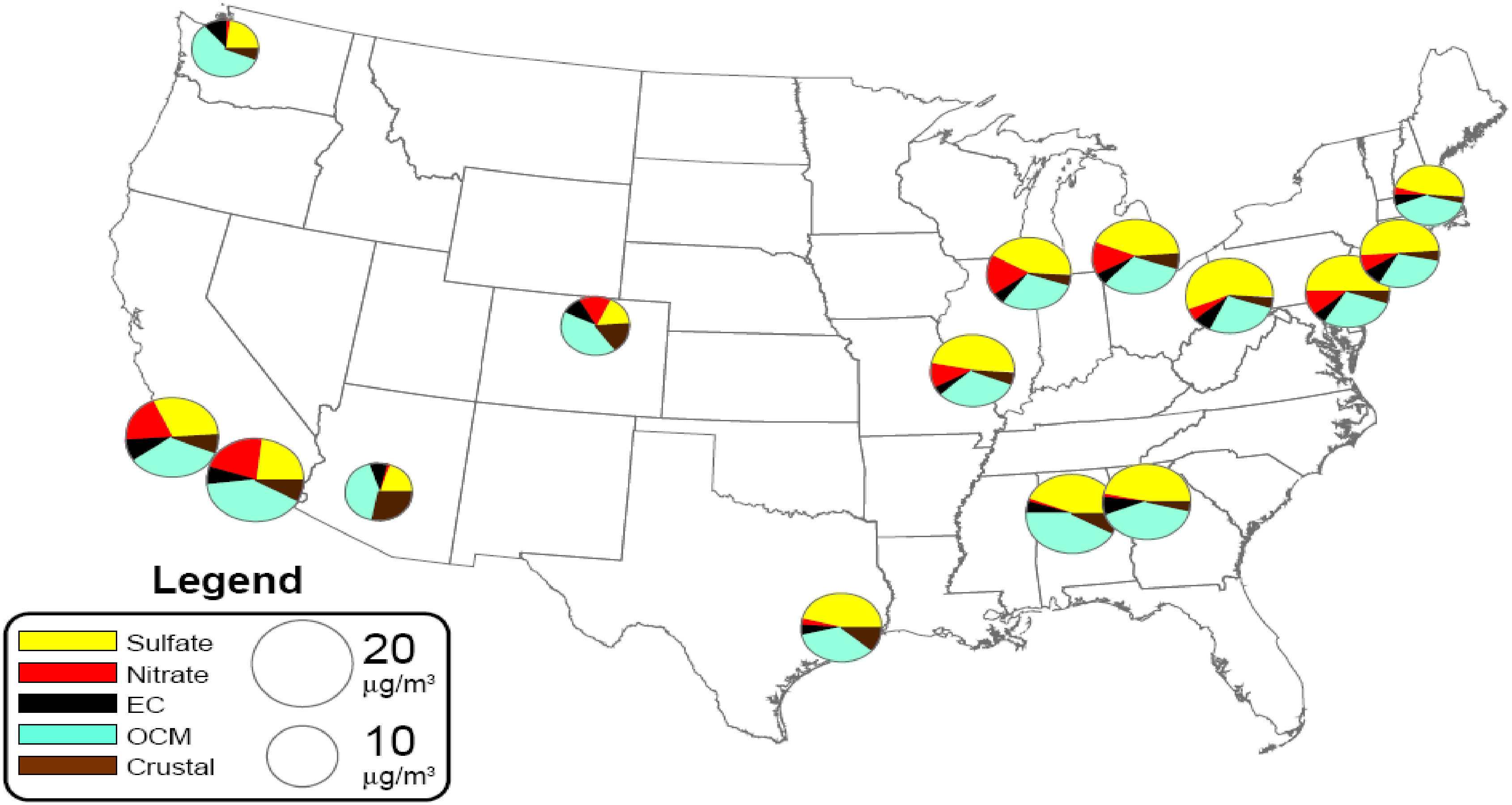
- Court concluded EPA failed adequately to explain why annual $PM_{2.5}$ standard is sufficient to protect public health with an adequate margin of safety
- Remanded annual standard for further consideration of:
  - Whether it provides an adequate margin of safety from the risk of *short-term* exposure to $PM_{2.5}$
  - Whether it provides an adequate margin of safety against *morbidity in children and other vulnerable subpopulations*

# PM$_{2.5}$ National Air Quality – 2007



# $PM_{2.5}$ Speciation Select Urban Areas 2005-2007



# Evidence-based Considerations

- Evidence-based considerations play central role in reviewing the PM NAAQS
  - Primary emphasis given to epidemiological evidence
  - Controlled human exposure and toxicological studies provide coherence and biological plausibility; support a number of potential biologic mechanisms or pathways for PM-related effects
  - Associations and related uncertainties generally characterized with regard to different size fractions, components, sources, and environments
  - Look for trend in ambient levels where adverse health effects are seen across epidemiology studies
  - Decision is complicated by lack of clear threshold, or lowest observable effects level

# Effects Associated with Short-term Exposures to $PM_{2.5}$

- New multi-city U.S. studies
  - Use uniform methodologies to investigate the effects of $PM_{2.5}$ on health with data from multiple locations representing varying regions and seasons representative of different climate and air pollution mixes
- Premature mortality
  - All-cause
  - Cause-specific (cardiovascular- and respiratory-related)
- Morbidity effects as indexed by emergency department (ED) visits and hospitalizations including new Medicare cohort studies
  - Respiratory disease-related
  - Cardiovascular disease-related
- Focusing on effects observed in areas that would meet the current $PM_{2.5}$ NAAQS

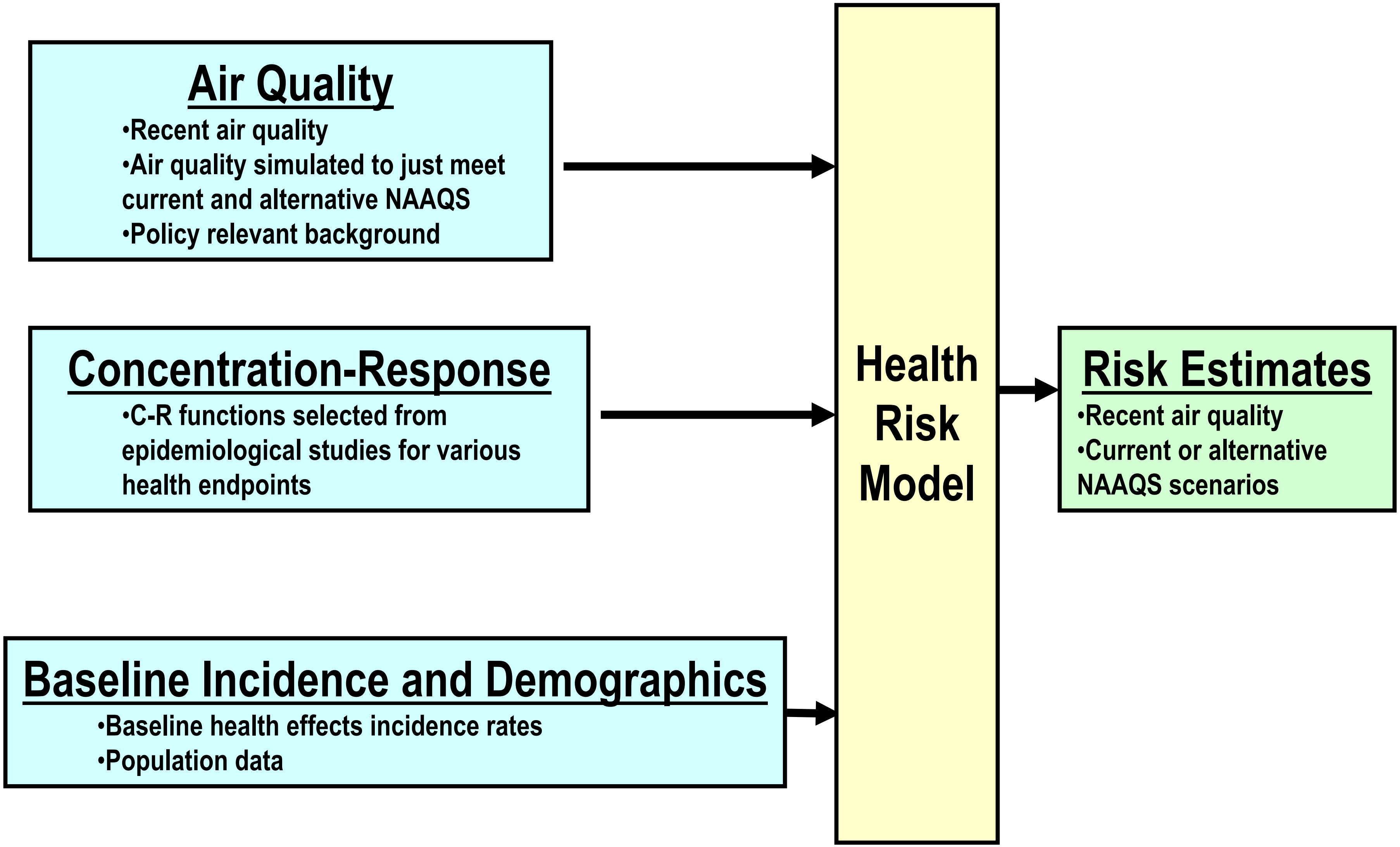
# Effects Associated with Long-Term Exposures to $PM_{2.5}$

- Extended analyses of large multi-city studies largely consistent with previous reports of premature mortality; strongest evidence for cardiovascular-related effects
- New study showing decrease in $PM_{2.5}$ concentrations associated with increased life expectancy
- New evidence of premature mortality and cardiovascular effects in post-menopausal women with no pre-existing cardiovascular effects
- New evidence of effects in at-risk populations
  - Extended analyses of So. California Children's Health Study provide further evidence of respiratory symptoms and reduced lung function growth
  - New study of cystic fibrosis cohort
  - Emerging evidence for developmental effects
- Focusing on effects observed in areas that would meet the current $PM_{2.5}$ NAAQS

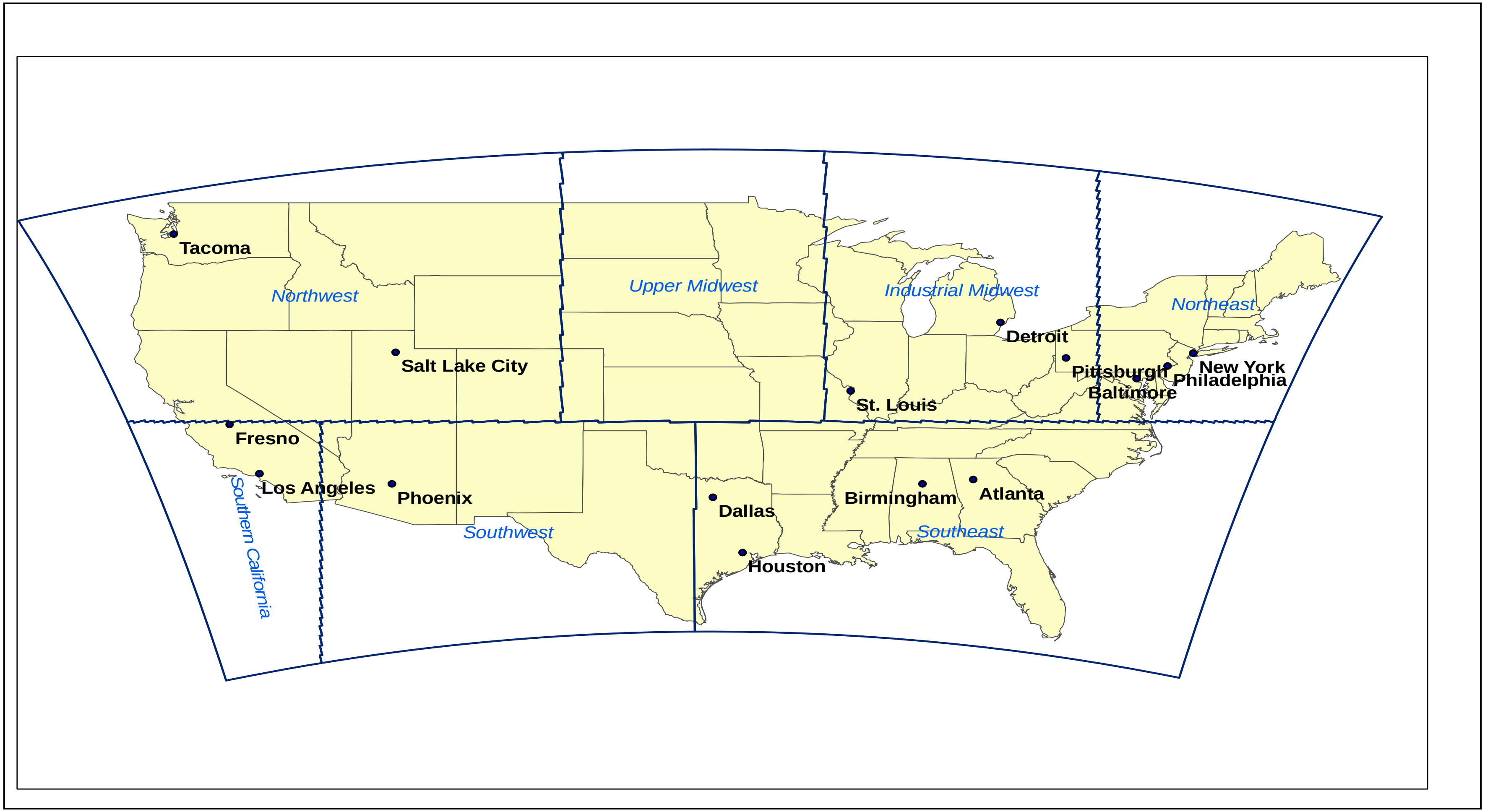
# Effects Associated with Short-Term Exposure to $PM_{10-2.5}$

- More limited air quality data to consider in evaluating health evidence; measurement errors larger than for $PM_{2.5}$
- New multi-city US studies provide evidence of premature mortality
  - Different methods used for estimating ambient concentrations
  - Co-pollutant confounding
- Morbidity
  - Most consistent evidence is for asthma-related outcomes among children
  - Less consistent evidence among adults

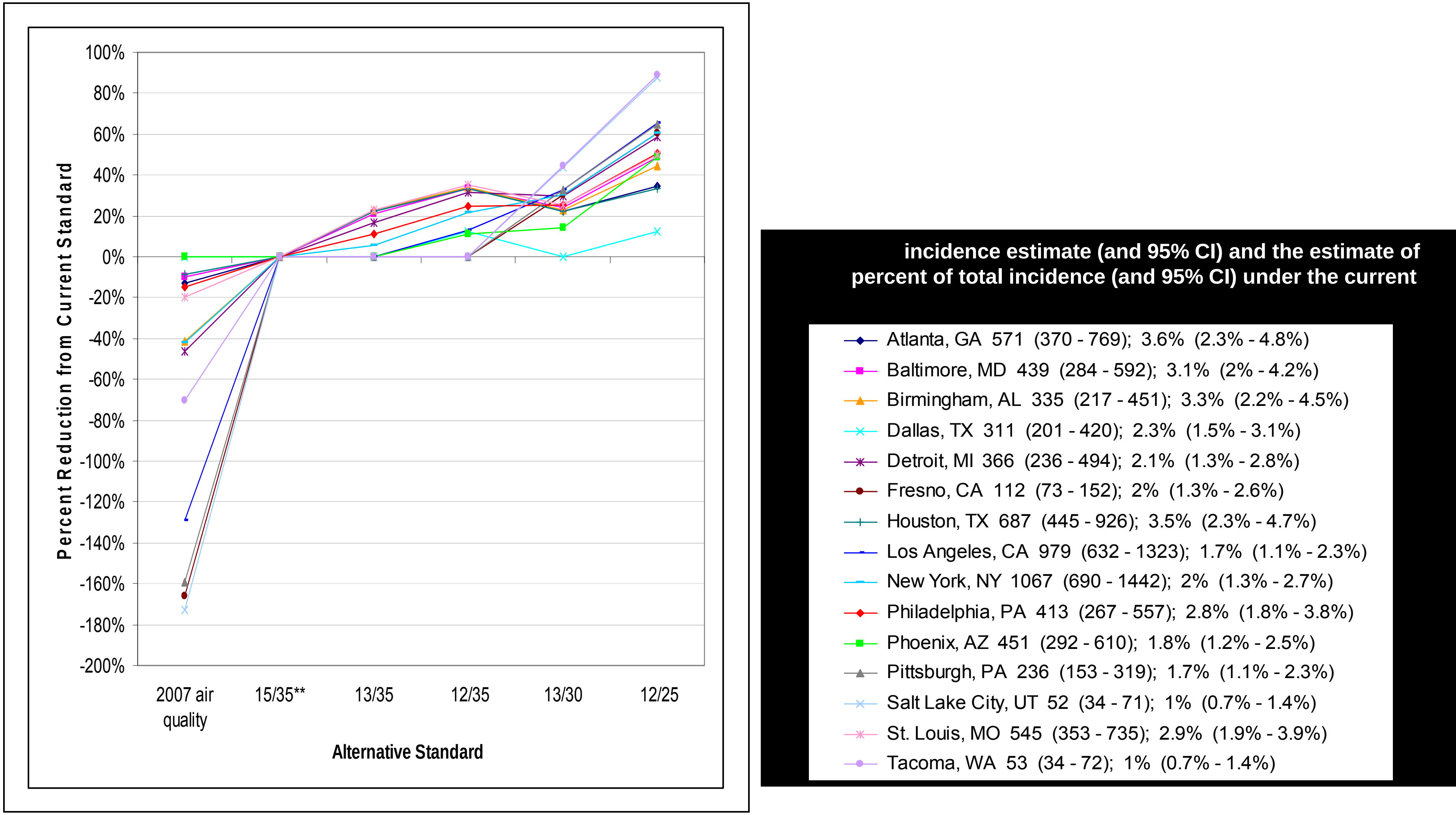
# Overview of PM Risk Assessment Model



# Quantitative Risk Assessment
## 15 urban study areas and 7 regions



# Figure 4-1. Estimated Percent Reductions From the Current Standards to Alternative Set of Standards in All Cause Mortality Associated with Long-Term Exposure to PM2.5 (source: US EPA, 2009)



# Next Steps in Current PM NAAQS Review

- Finalize assessment documents – Dec 2009
  - Integrated Science Assessment
  - Quantitative Risk Assessment
  - Urban-focused Visibility Assessment
- Develop external review draft Policy Assessment for CASAC review and public comment – Feb 2010

# Nitrogen Dioxide ($NO_2$)

# Background: History of the $NO_2$ NAAQS

- 1971: Primary NAAQS set at 0.053 parts per million (ppm) (equivalent to 53 ppb), annual average
  - Based on epidemiologic studies that reported associations of long-term exposure to $NO_2$ with respiratory illness and lung function in children
  - Quantitative basis for the annual standard level was later called into question
- 1985 and 1996: Existing standard retained
  - Standard would maintain annual $NO_2$ concentrations considerably below long-term levels for which serious chronic effects have been observed in animals
  - Areas that met an annual standard of 53 ppb unlikely to experience 1-hour $NO_2$ concentrations that had been associated with respiratory effects in controlled human exposure studies
- September 2005: Deadline suit filed by Center for Biological Diversity (and others)
- Current Review scheduled to be completed on or before Jan 22, 2009

# Background: $NO_2$ Air Quality

- All areas of the U.S. are currently in attainment
- Annual average ambient $NO_2$ levels, as measured at fixed-site monitors, decreased 41% between 1980 and 2006
  - National average now about 10-20 ppb
- However, because mobile sources are important sources of $NO_2$, concentrations on/near roadways can be appreciably higher than concentrations measured at fixed-site ambient monitors
  - Can be 30 to 100% higher near roads and 2- to 3-fold higher in vehicles
- Therefore, short-term $NO_2$ exposures would be considerably higher than indicated at ambient monitors in individuals who spend time near roadways and/or in vehicles on major roadways

# Evidence for $NO_2$-Related Health Effects

- For purposes of characterizing health risks, focused on endpoints for which the evidence was judged sufficient to infer a *causal* or *likely causal* relationship
  - Adverse respiratory morbidity (e.g., respiratory symptoms, ED visits, hospital admissions, physiological endpoints)
  - Support comes from epidemiologic, controlled human exposure, and animal toxicological studies
- Evidence-based considerations including additional endpoints with *suggestive* evidence of a causal relationship
  - Cardiopulmonary and non-accidental mortality with short-term exposure
  - Respiratory morbidity with long-term exposure

# $NO_2$: Overview of Epidemiologic Evidence

- Epidemiologic studies provide the strongest evidence supporting a link between $NO_2$ and adverse respiratory effects
  - A large number (50+) of studies of respiratory morbidity effects (i.e., symptoms, ED visits, hospital admissions) and short-term $NO_2$ exposure published since previous $NO_2$ NAAQS review
  - Look for trend in ambient levels where adverse health effects are seen across studies
    - Ambient, indoor, and personal $NO_2$ concentrations evaluated
    - Consistent results reported in studies of ambient concentrations conducted in multiple U.S. cities (e.g., Atlanta, LA, NYC) as well as cities in Canada, Asia, and Europe
      - In the locations where a number of these studies were conducted, $NO_2$ concentrations were below levels allowed by the current $NO_2$ NAAQS

# Health Effects of $NO_2$: Overview of Controlled Human Exposure Evidence

- EPA conducted a meta-analysis that combined individual data from 19 separate studies on airway responsiveness in asthmatics

- Meta-analysis reported that most asthmatics experienced an increase in airway responsiveness following exposure to $NO_2$ concentrations at or above 100 ppb
  - Approximately 70% of asthmatics experienced an increase

# Rulemaking

- Proposed rule – July 15, 2009 - (74 FR 34404)
  - Scientific evidence
    - Calls into question the adequacy of the current standard to protect public health
    - Supports consideration of a short-term standard to provide increased health protection for at-risk populations
  - Exposure- and risk-based assessments reinforce need to revise current standard so as to provide increased public health protection
  - Proposed to strengthen the primary NAAQS by:
    - Adding a 1-hour $NO_2$ standard at a level between 80-100 ppb to focus on peak short-term exposures
    - Retaining annual $NO_2$ standard at a level of 53 ppb
  - EPA also proposed changes to the $NO_2$ air quality monitoring network
- Final rule – January 22, 2010

# Revision to NAAQS for Lead
# October 2008

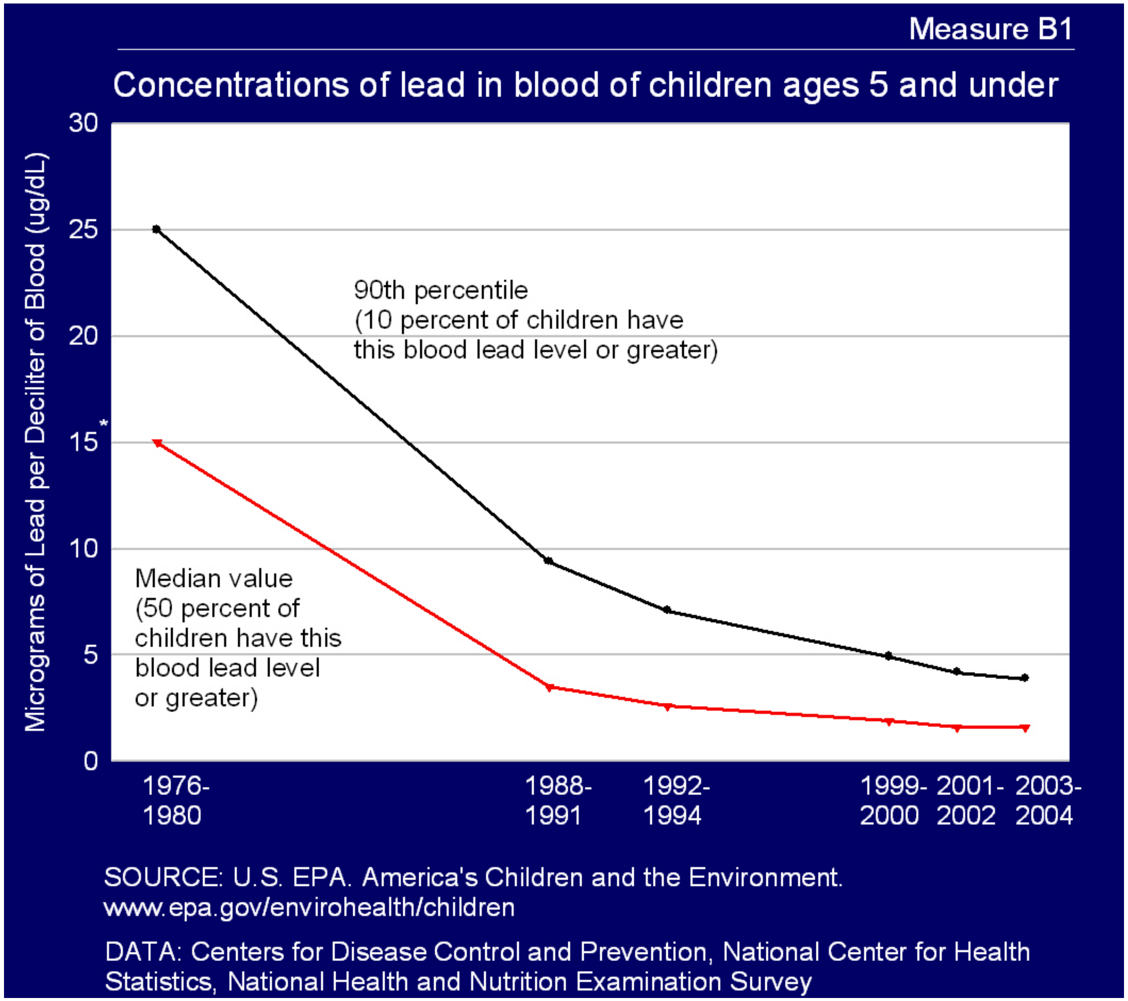
# Background - Lead (Pb) Air Pollution

- Pb occurs naturally and is emitted by many anthropogenic sources
  - Highest levels are generally found near lead smelters
- Pb is generally emitted into the air in the form of particles
  - Can end up in water, soil and dust on surfaces
- People are exposed by inhaling Pb in air or ingesting Pb that has settled onto surfaces or soils
  - Ingestion is the main route of human exposure to air Pb
  - Children are more likely to be exposed to Pb because they exhibit greater “hand-to-mouth” activity
  - Once in the body, Pb is rapidly absorbed into the bloodstream
- Pb is persistent
  - People can be exposed to Pb emitted just yesterday or years ago

# Impacts of Lead on Public Health

- Broad range of health effects
  - Damage to the central nervous system, cardiovascular system, kidneys, immune system and red blood cells
- Effects in children include:
  - Effects on developing nervous system, which can cause impacts into adulthood include
    - IQ loss
    - Poor academic achievement, permanent learning disabilities, increased risk of delinquent behavior
  - Weakened immune system
- Effects in adults include:
  - Increased blood pressure
  - Cardiovascular disease
  - Decreased kidney function

# Changes in Children's Blood Lead Levels Since 1978




http://epa.gov/envirohealth/children/body_burdens/b1-graph.htm

- Significant reduction
  - From a median of 15 µg/dL in late 1970s to 1.6 µg/dL in 2003-04

# New Health Evidence in Recent Review

- Many new studies published since standard set in 1978
  - >6,000 published since 1990
- Serious health effects shown to occur at much lower blood Pb levels than those recognized as harmful in late 70s
  - Strong evidence of adverse effects at blood Pb levels well below 10 micrograms per deciliter (µg/dL)
  - No threshold or “safe” level for lead in blood has been identified
- Epidemiological studies in children demonstrate associations of blood Pb levels with loss of IQ and other neurocognitive effects
  - Results are remarkably consistent across numerous studies with varying designs and study populations
  - Associations have continued to be observed in most recent studies involving populations with lower blood Pb levels
  - The evidence indicates that the effect of Pb on IQ on incremental basis (per µg/dL) is greater at lower blood lead levels

# Revisions to the Lead Standards: Level

- 1978 standard of 1.5 µg/m$^3$ not requisite to protect public health with an adequate margin of safety
  - Health effects demonstrated at much lower exposures that we understood in the past
- Primary standard strengthened to a level of 0.15 µg/m$^3$
  - Provides increased protection for public health
    - Especially the health of children and particularly for children near sources, where air levels are highest
  - In combination with decisions on indicator, averaging time and form - provides requisite protection of public health, including health of sensitive groups, with an adequate margin of safety

# Revisions to the Lead Standards: Level (continued)

- **Primary standard strengthened to a level of 0.15 µg/m$^3$**
  - Decision guided by framework that integrates evidence for relationships between …
    - Pb in air and Pb in children's blood
      - Studies of children whose Pb exposures differ mainly with regard to air Pb levels
    - Pb in children's blood and IQ loss
      - Studies of children's IQ and blood Pb, with control for major IQ-influencing factors
  - Level of 0.15 µg/m$^3$ estimated to protect against air Pb-related IQ loss in most exposed children
    - Based on weight of scientific evidence
  - Quantitative risk assessment results supportive of framework estimates

# Revisions to the Lead Standards: Averaging Time and Form

- New standard is in terms of a maximum (not-to-be-exceeded) rolling three-month average evaluated over a three-year period.
- As compared to previous averaging time of calendar quarter, new standard is:
  - More scientifically appropriate
    - Rolling average gives equal weight to all three-month periods, and
    - New calculation method gives equal weight to each month within each three-month period
  - More health protective
    - Rolling average yields 12 three-month averages each year to be compared to the NAAQS (*versus* four averages in each year for block calendar quarters)

# Revisions to the Lead Standards: Indicator

- Pb in total suspended particles (Pb-TSP) retained as indicator
  - Reflects evidence that Pb particles of all sizes pose health risks
- Use of Pb-$PM_{10}$ monitoring allowed in place of Pb-TSP monitoring in certain limited circumstances

# More Information on All NAAQS Reviews

http://www.epa.gov/ttn/naaqs/