PM Centers' Research in EPA's NAAQS Program

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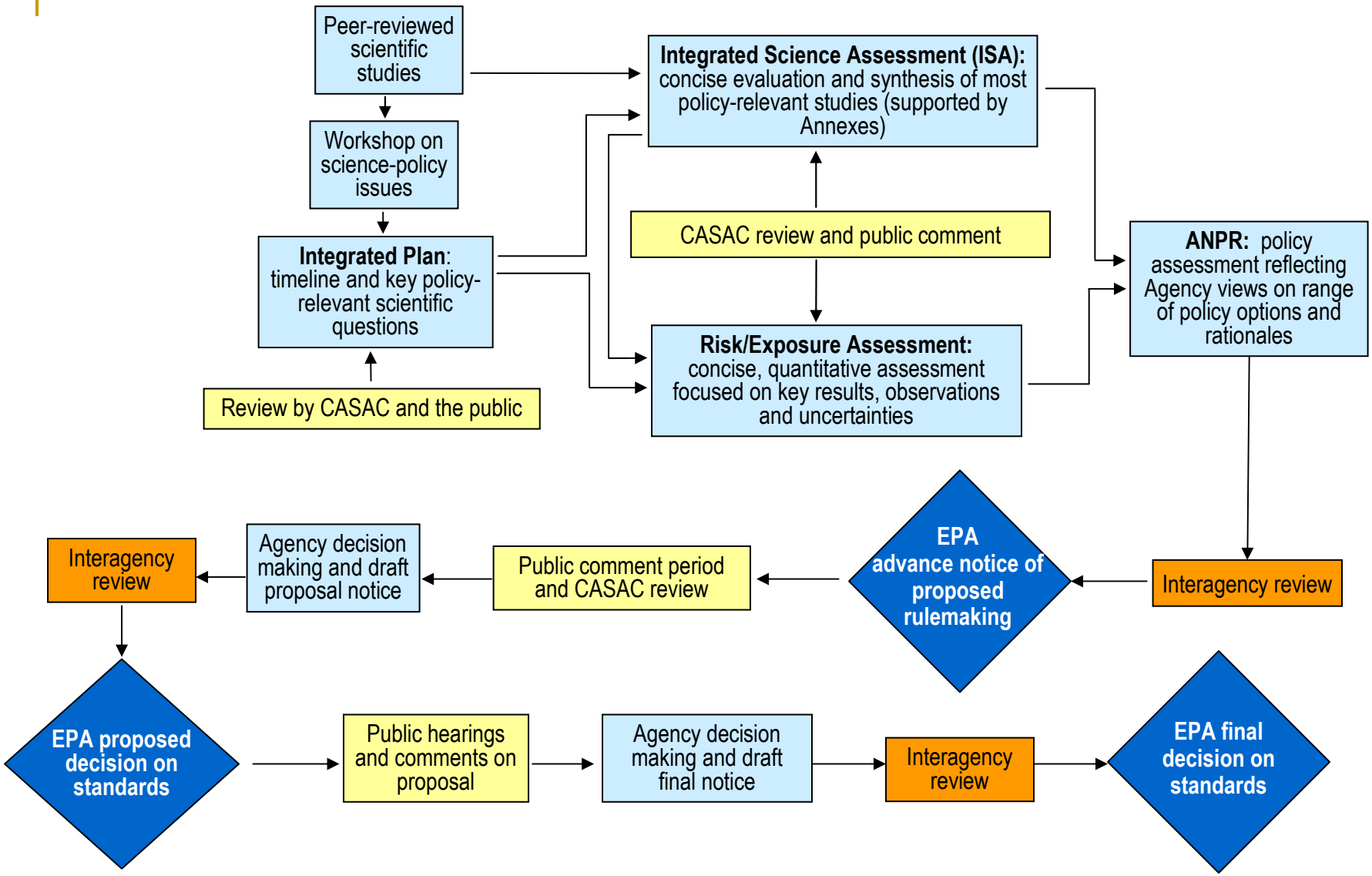
High Quality Research is the Backbone of Credible and Defensible Program Office Decision-Making

- ORD Air research is used in virtually every facet of the review process of the NAAQS as well as in support of standard implementation

- The integration of the intramural and extramural programs ensures the strongest database and science quality needed to move policy decisions forward

Overview of NAAQS Standard-Setting Process



Scientific Research in the NAAQS Review Process

- **Integrated Science Assessment (ISA)**
  - Concise evaluation and synthesis of the most policy-relevant science
- **Risk/Exposure Assessment (REA)**
  - Scientific evidence contained in the ISA provides the foundation to inform the analyses in the REA including…
    - Critical health/welfare endpoints
    - Concentration-response functions
    - Study populations including consideration of sensitive subpopulations
    - Study areas on which to focus
    - Evidence-based identification of potential alternative standards for consideration
- **Sources of scientific research relevant for NAAQS standard-setting include…**
  - PM Research Centers
  - EPA STAR grants program
  - EPA intramural research program
  - National Institute of Environmental Health Sciences (NIEHS) grants programs
  - Health Effects Institute (HEI)
  - California Air Resources Board (CARB)
  - Electric Power Research Institute (EPRI)

PM Centers Research in Recent NAAQS Reviews

- **Notable studies cited in the 2004 Criteria Document and/or 2005 Staff Paper**
  - ACS Study – extended analyses (Pope et al, 2002)
  - Reanalyses of time-series studies due to GAM (HEI special report) (Ito 2003; Mar et al, 2003; Schwartz 2003; Sheppard 2003)
  - Association of PM components with daily mortality as published in an HEI report (Lippmann et al, 2000)
  - Evidence of myocardial infarction (Peters et al, 2001)
  - Evaluation of the relationship between ambient and personal exposure levels (Sarnat et al, 2000/2001)

PM Centers Research in Recent NAAQS Reviews (cont.)

- **2006 Provisional Science Assessment**
  - Completed between proposal & final rule
  - Reviewed significant "new" studies not included in the CD
  - 34% (71 of 211) of studies cited were from PM Centers
- **Notable studies that were cited in the Provisional Science Assessment include:**
  - Follow-up to the Six Cities study (Laden et al, 2006)
    - Reductions in $PM_{2.5}$ resulted in reduced long-term mortality risk
  - Subchronic animal study (Lippmann et al. 2005 and related articles)
    - $PM_{2.5}$ caused cardiovascular effects in mice susceptible to atherosclerosis
  - Source apportionment / health (Hopke et al 2006; Ito et al, 2006; Mar et al 2006)
    - Contribution of sources to total/CV mortality was estimated in Wash. DC and Phoenix
  - Controlled human exposure study of coarse PM (Gong et al, 2004)
    - Increased heart rate & decreased HRV following exposure to coarse CAPS
  - National Medicare cohort (Dominici et al, 2006)
    - Acute exposure to $PM_{2.5}$ was associated with hospitalization for cardiovascular and respiratory diseases
    - Suggests differential cardiovascular effects in eastern v. western U.S. locations
  - Cystic Fibrosis cohort (Goss et al, 2004)
    - Significant association between long-term $PM_{2.5}$ exposure & pulmonary exacerbations

PM Centers Research in Current NAAQS Reviews

- PM Center publications are expected to be influential in current review of the PM NAAQS
  - Almost 200 PM Centers' papers (from the original Centers) are cited in the current version of the 1st draft ISA
    - Citations from current PM Centers have not yet been analyzed
  - PM Centers' publications span a variety of policy-relevant topics including…
    - Cardiovascular effects associated with long-term PM exposure
    - Evidence for PM-associated health effects in susceptible subpopulations
    - Understanding the linkages between PM sources, ambient levels, exposures, and health effects

- PM Centers' papers are also cited in the current ISAs for NO_x and SO_x

Broader Impacts of PM Center Research

- PM Center publications cited in documents from State, local, and international agencies, including:
  - Numerous Regional, State, and local air agencies, for example:
    - South Coast Air Quality Management District
    - California Air Resources Board
  - World Health Organization
  - United Nations Environmental Programme

- Examples of State and local impacts
  - Southern California PM Center research influential in the development of a new California state law prohibiting the construction of new schools within 500 feet of freeways
  - NYU PM Center characterized exposures and health risks resulting from the collapse of the World Trade Center Buildings on September 11, 2001
  - Rochester PM Center working with NY Dept. of Environmental Conservation on ultrafine particle monitoring

Additional Contributions of PM Centers from the Program Office Perspective

- Centers support a large number of extremely high-caliber investigators and serve to focus those investigators on the scientific issues that are of greatest importance to NAAQS decision-making

- Centers provide a source of authoritative input to the Agency at critical steps in the NAAQS review process
  - Investigators participate in Agency-sponsored workshops and advisory activities (e.g., CASAC)
  - Serve as authors for some sections of the Integrated Science Assessments (ISAs)

Important Science-Policy Issues for Future NAAQS that PM Centers Research Can Help Inform Program

- **Particulate Matter**
  - Defining PM - evaluating components, sources, environments
    - Current NAAQS and implementation approach is based on particle mass; however, it is theoretically possible that regulatory efforts could focus on the sources that make the largest contribution to PM-associated health effects by considering linkages between PM sources, PM composition, and health effects
    - Existing scientific evidence is not sufficient to support such an approach
    - Key Issue: To what extent does the newly available information support consideration of alternative indicators for fine and thoracic coarse particles?
  - Improving our understanding of the health impacts of long-term PM exposures, including impacts in sensitive subpopulations

Important Science Policy Issues for Future NAAQS that PM Centers Research Can Help Inform Program (cont.)

- **Multi-pollutant**
  - Agency science advisory bodies (i.e., CASAC) advocate consideration of entire ambient mix of pollutants in our standard-setting and implementation efforts
  - Existing scientific evidence is not sufficient to support a comprehensive, multi-pollutant approach to standard setting and implementation
- **Improving ability to estimate/model exposure**
  - Epidemiology studies, which form an important part of the evidence base that is considered in setting standards, often rely on ambient monitoring data to provide estimates of exposure
  - Research is needed to address uncertainties (particularly important for PM components, sources, and PM size fractions and other pollutants that have received less attention from researchers) and also to improve our ability to estimate exposures for purposes of informing the standard-setting process