The Risk Assessment/Risk Management Nexus: How Each Discipline Informs the Other

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NIEHS Superfund Research Program Meeting

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Overview

- Evolution of the RA/RM Relationship
- The Path Forward for RA/RM
- Case Studies
    - Risk assessment driving remedial options
    - Risk management informing the risk assessment process

Risk Assessment/Risk Management

Superfund Paradigm - RA part of RI; RM part of the FS

Why? Concern with RM unduly influencing RA

RA/RM - Never the twain shall meet (Kipling, 1892)

The Path Forward

SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT

National Research Council

Committee on Improving Risk Analysis Approaches Used by EPA

Board on Environmental Studies and Toxicology

EVALUATION

Two broad elements:

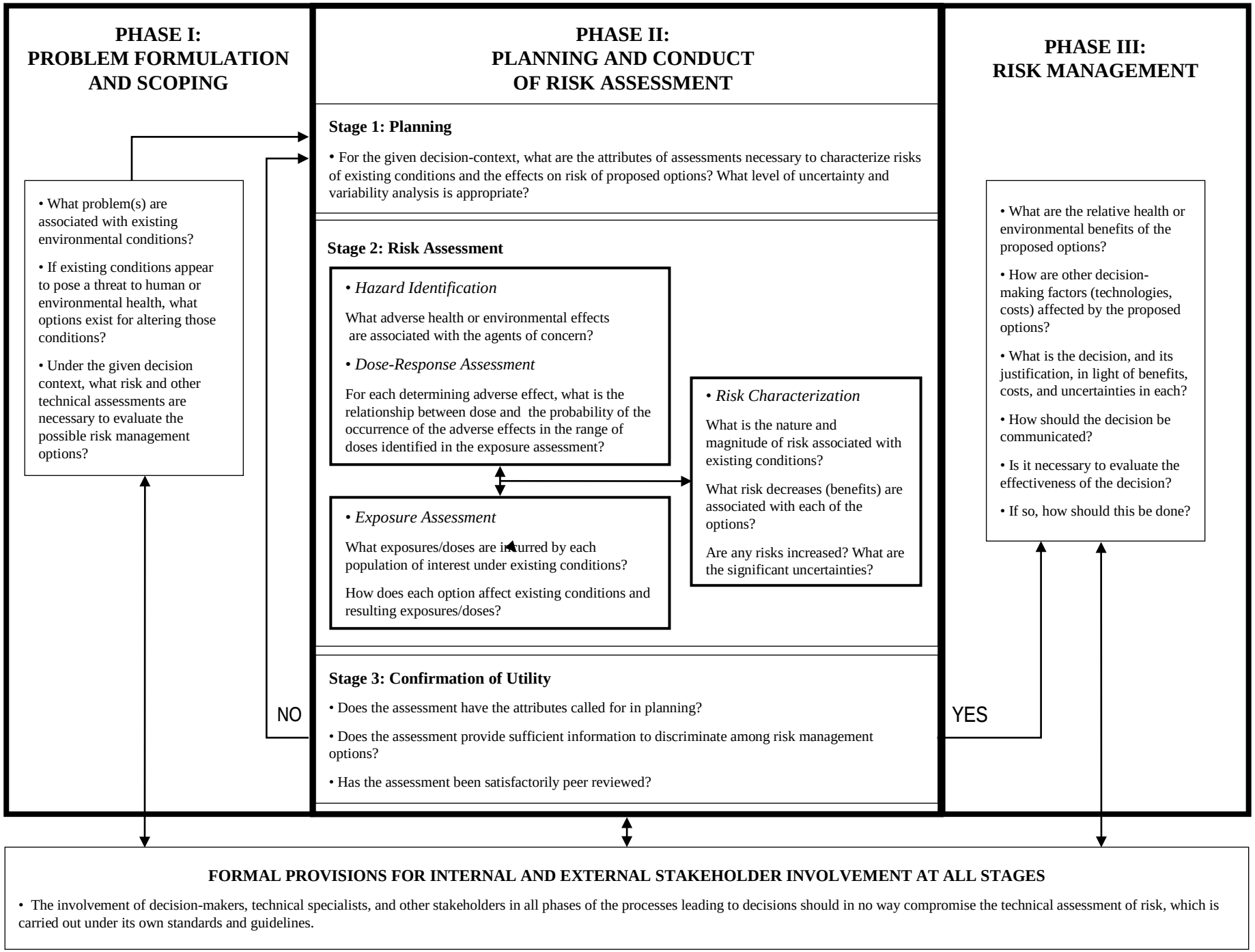
- Improving ***technical analysis*** entails the development and use of scientific knowledge and information to promote more accurate characterizations of risk.

- Improving ***utility*** entails making risk assessment more relevant to and useful for risk-management decisions.

DESIGN OF RISK ASSESSMENT

- “Design” - The process of planning a risk assessment and ensuring that its level and complexity are consistent with the needs to inform decision-making (i.e., fit for purpose).

Recommendation: Increased attention to the design of risk assessment in its formative stages is needed. The committee recommends that planning and scoping and problem formulation, as articulated in EPA guidance documents (EPA 1998, 2003), should be formalized and implemented in EPA risk assessments.


PHASE I:
PROBLEM FORMULATION
AND SCOPING
PHASE II:
PLANNING AND CONDUCT
OF RISK ASSESSMENT
PHASE III:
RISK MANAGEMENT
Stage 1: Planning
• For the given decision-context, what are the attributes of assessments necessary to characterize risks of existing conditions and the effects on risk of proposed options? What level of uncertainty and variability analysis is appropriate?
• What problem(s) are associated with existing environmental conditions?
• If existing conditions appear to pose a threat to human or environmental health, what options exist for altering those conditions?
• Under the given decision context, what risk and other technical assessments are necessary to evaluate the possible risk management options?
Stage 2: Risk Assessment
• Hazard Identification
What adverse health or environmental effects are associated with the agents of concern?
• Dose-Response Assessment
For each determining adverse effect, what is the relationship between dose and the probability of the occurrence of the adverse effects in the range of doses identified in the exposure assessment?
• Exposure Assessment
What exposures/doses are incurred by each population of interest under existing conditions?
How does each option affect existing conditions and resulting exposures/doses?
• Risk Characterization
What is the nature and magnitude of risk associated with existing conditions?
What risk decreases (benefits) are associated with each of the options?
Are any risks increased? What are the significant uncertainties?
• What are the relative health or environmental benefits of the proposed options?
• How are other decision-making factors (technologies, costs) affected by the proposed options?
• What is the decision, and its justification, in light of benefits, costs, and uncertainties in each?
• How should the decision be communicated?
• Is it necessary to evaluate the effectiveness of the decision?
• If so, how should this be done?
Stage 3: Confirmation of Utility
• Does the assessment have the attributes called for in planning?
• Does the assessment provide sufficient information to discriminate among risk management options?
• Has the assessment been satisfactorily peer reviewed?
NO
YES
FORMAL PROVISIONS FOR INTERNAL AND EXTERNAL STAKEHOLDER INVOLVEMENT AT ALL STAGES
• The involvement of decision-makers, technical specialists, and other stakeholders in all phases of the processes leading to decisions should in no way compromise the technical assessment of risk, which is carried out under its own standards and guidelines.

Putting Policy into Practice

- Scoping and Problem Formulation Workshop to Inform Development of EPA's Integrated Risk Information System (IRIS) Toxicological Review of Inorganic Arsenic (Non-cancer and Cancer Effects of Oral Exposures) Location: Potomac Yards, Arlington, VA, September 27-September 28, 2012
  - This workshop is designed to inform the planning and development of EPA's human health risk assessment of chronic oral exposure to iAs (cancer and non-cancer effects of oral exposures)

SCOPING QUESTIONNAIRE FOR AGENCY PARTNERS

Instructions: Please fill in the columns corresponding to your respective program / office / region. Please add more defined descriptions of your specific office or program (Row 4), if there are multiple regulatory standards or approaches. Responses to the questions will be collated into a master spreadsheet including all programs and regions. Information provided in this table will only be utilized for the internal EPA workshop.	
Scoping Questions Relevant to the IRIS iAs assessment	**(Office or Region Designation)**
1) Under what legislation does / would your office regulate exposures to or make decisions about iAs?	
2) Please describe your current regulatory or decision-making requirements and practices as it relates to iAs.	
3) What are your programmatic needs or specific risk-related issues that could be addressed in a new IRIS assessment of iAs ?	
4) Does your office have recommendations for key components, approaches, or analyses that would facilitate future decisions regarding arsenic risk?	
5) How would your office use the IRIS assessment of iAs?	
6) Regarding your program, are there plausible risk management alternatives that may inform approaches for risk estimation in the new IRIS assessment of iAs?	
7) Are there specific time constraints or deadlines within your program for which a new iAs IRIS assessment would impact risk assessment or management decisions?	
8) Which of your external stakeholders are potentially impacted by the iAs assessment?	
9) What are your external stakeholders' principal concerns based upon current and potential future regulatory standards which may be impacted by a new iAs assessment?	
10) Who are the principal contacts regarding iAs within your office?	
11) How would you like to stay informed of developments on the iAs assessment?	

Highlight current regulatory standards, risk assessment and management practices, and pending regulatory actions related to iAs;

Some additional discussion points: inhalation pathway, impact of valence state, role of bioavailability, EJ issues, background exposure.

Next steps: External stakeholder outreach

RA/RM Case studies

- CDC Recommendations for lowering childhood BLLs ⇒ impact soil remediation options at hazardous waste sites

- PCBs in Schools – How the exposure scenario and remedial alternatives inform the design of the risk assessment

CDC 2012 - Scientific Rationale for Eliminating the 10 ug/dL Blood Lead Level of Concern

- Replaced with a "Reference Value" i.e., the 97.5% of NHANES distribution childhood BLLs ⟹ presently 5 ug/dl
- Recent studies reporting decrements in school age IQ among children whose peak BLLs had never exceeded 10 ug/dL
- Builds upon risk assessments carried out by other regulatory and policy bodies (e.g., EPA's 2008 Pb NAAQS review)
- Collectively, these new studies and re-interpretation of past studies have demonstrated that it is not possible to determine a threshold below which BLL is not inversely related to IQ.

Environmental Implications of CDC Recommendation (5 ug/dl Reference Value)

- Soil Pb clean-up goal for Superfund sites with residential land use drops from 400 ppm to 150 ppm (may need to revisit existing RODs)
- Could impact recommendations on gardening in Pb contaminated soil

even the chickens are suspect
(NY Times, Oct 12, 2012)

- The HUD/EPA standard for Pb dust on floors (40 ug/ft^2) will likely require revision (ACCLPP report states: floor Pb of 12 ug/ft^2 equates to a GM BLL of 3.9 ug/dl)
- Drinking water Action Level (15 ug/l) may warrant review based on
  - IEUBK Pb Model output: 0.2 ug/dl increase in blood lead for every 1ug/l increase in drinking water Pb
- NAAAQS of 0.15 ug/m^3 (recently lowered from 1.5 ug/m^3) is probably safe

10 ug/dl ➡ 5 ug/dl - RM Implications

- Soil Pb clean-up goal for Superfund sites with residential land use drops from 400 ppm to 150 ppm
  - Could be below background in many urban areas
  - Excessive excavation costs at large area Pb sites
  - Community acceptance concerns

- Promising Remedial Alternative
  - Use of soil amending agents to reduce Pb bioavailability
    - Phosphates, biosolids, compost
    - Need more research on magnitude and durability of effect and potential mobilization of co-contaminants (e.g., As)

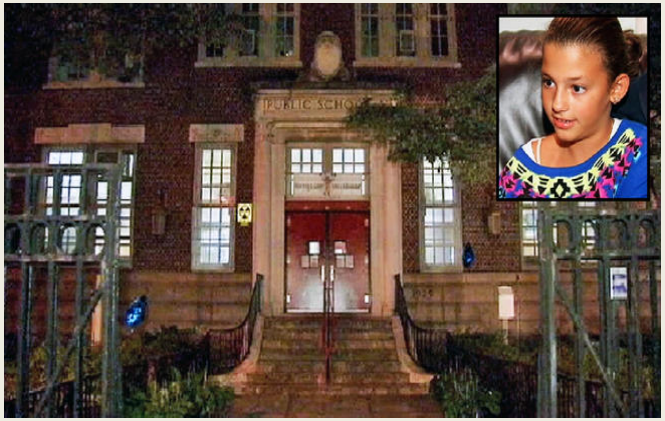
PCBs in NYC Schools

- PCBs used in caulking and lighting ballasts

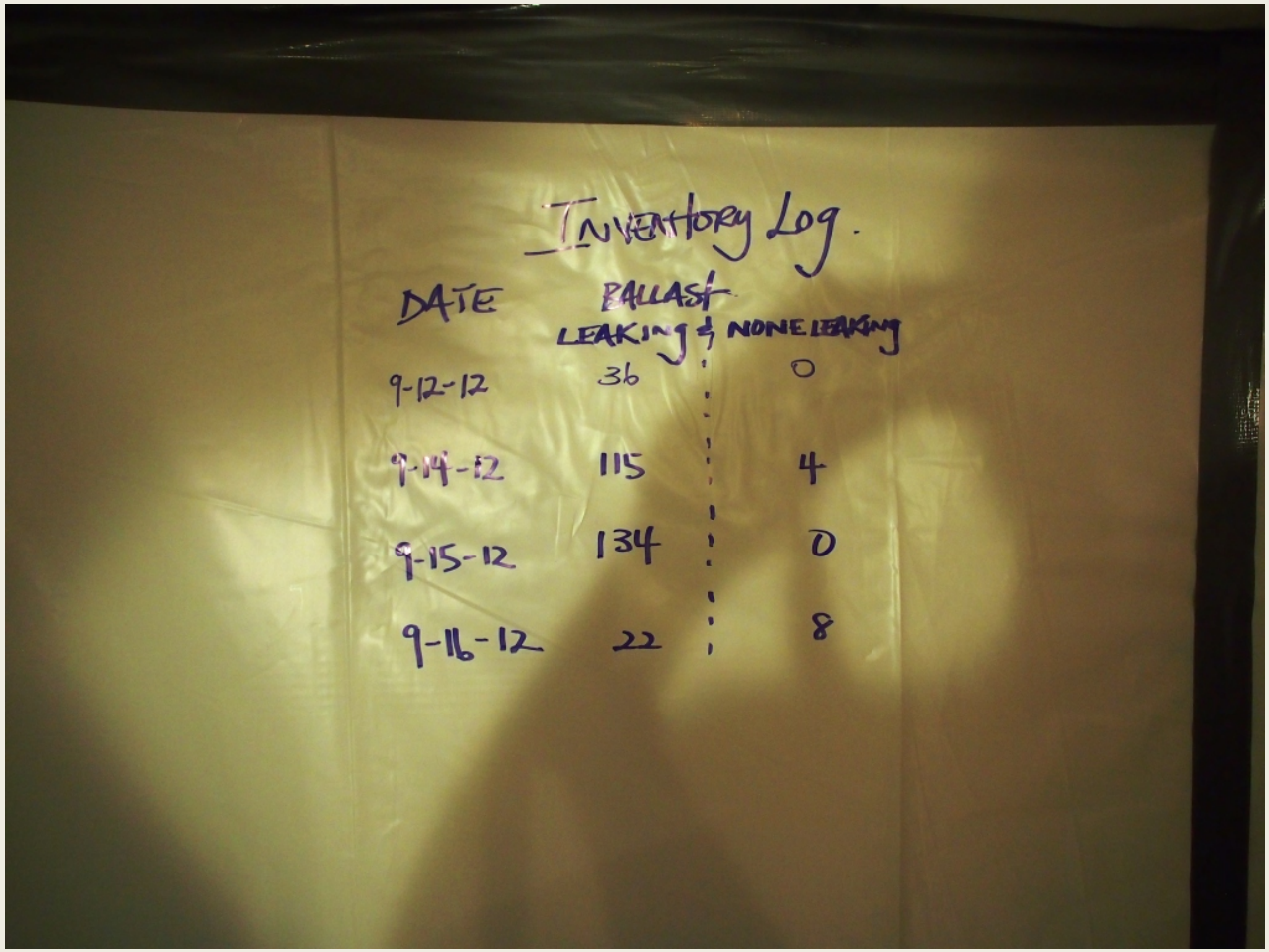



- **PCB Ballast Leaks on 5th-Grader in Staten Island Classroom** By Pei-Sze Cheng

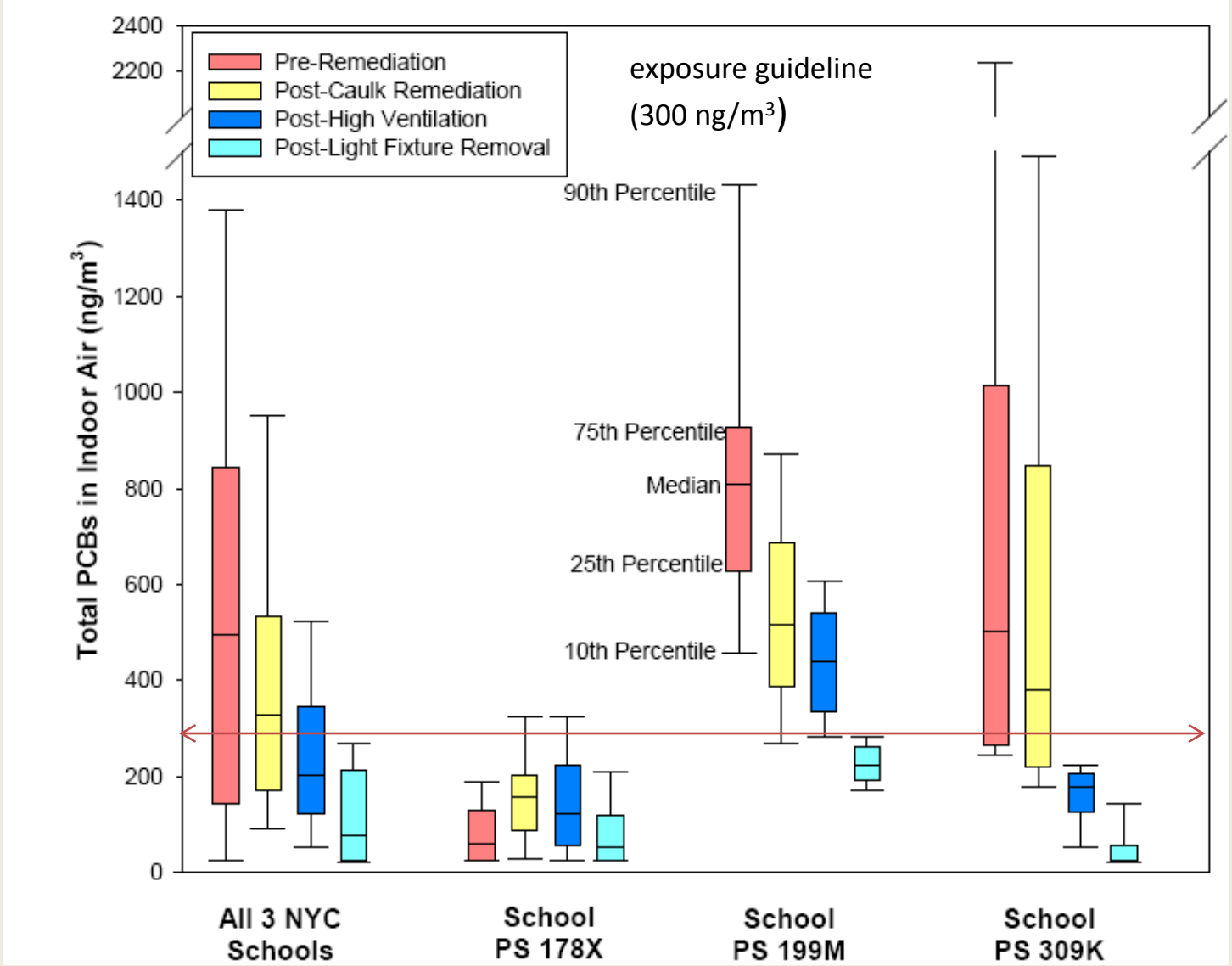
  Wednesday, Sep 12, 2012



Fluorescent Light Ballast Survey - P.S. 41R



Comparison of PCBs in Indoor Air in Three Schools



PCB Inhalation Exposure Guidelines

- Current exposure guideline (300 ng/m^3) relies on route-to-route extrapolation from the oral RfD for Aroclor 1254

- Draft IRIS Toxicity Assessment (2011)
  - RfC of 3×10^{-7} mg/m^3 (.3 ng/m^3) was calculated from a LOAEL of 0.0009 mg/m^3 for thymic atrophy, urinary bladder epithelial hyperplasia, and alterations in open field behavior in adolescent 8 male rats exposed via inhalation for 23 hours per day for 30 days to a mixture of PCB congeners volatilized from Aroclor 1242 (Casey et al., 1999)
  - A total UF of 3,000 was used:
    - 3 for interspecies extrapolation from rats to humans;
    - 10 for interindividual variability;
    - 10 for extrapolation from a subchronic study to a chronic exposure scenario; and
    - 10 for the use of a LOAEL as a POD.
  - Other limitations
    - Chamber (whole body) study - concern with secondary oral exposure
    - Small N

- need a more robust inhalation study
  - Working with IRIS, NIEHS/SRP and U of Iowa to design study
  - Pilot nose only study suggests lower toxicity by inhalation route

Thank you!

Questions?

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