

Framework for Human Health Risk Assessment to Inform Decision Making

ARA Workshop IV

May 22, 2012

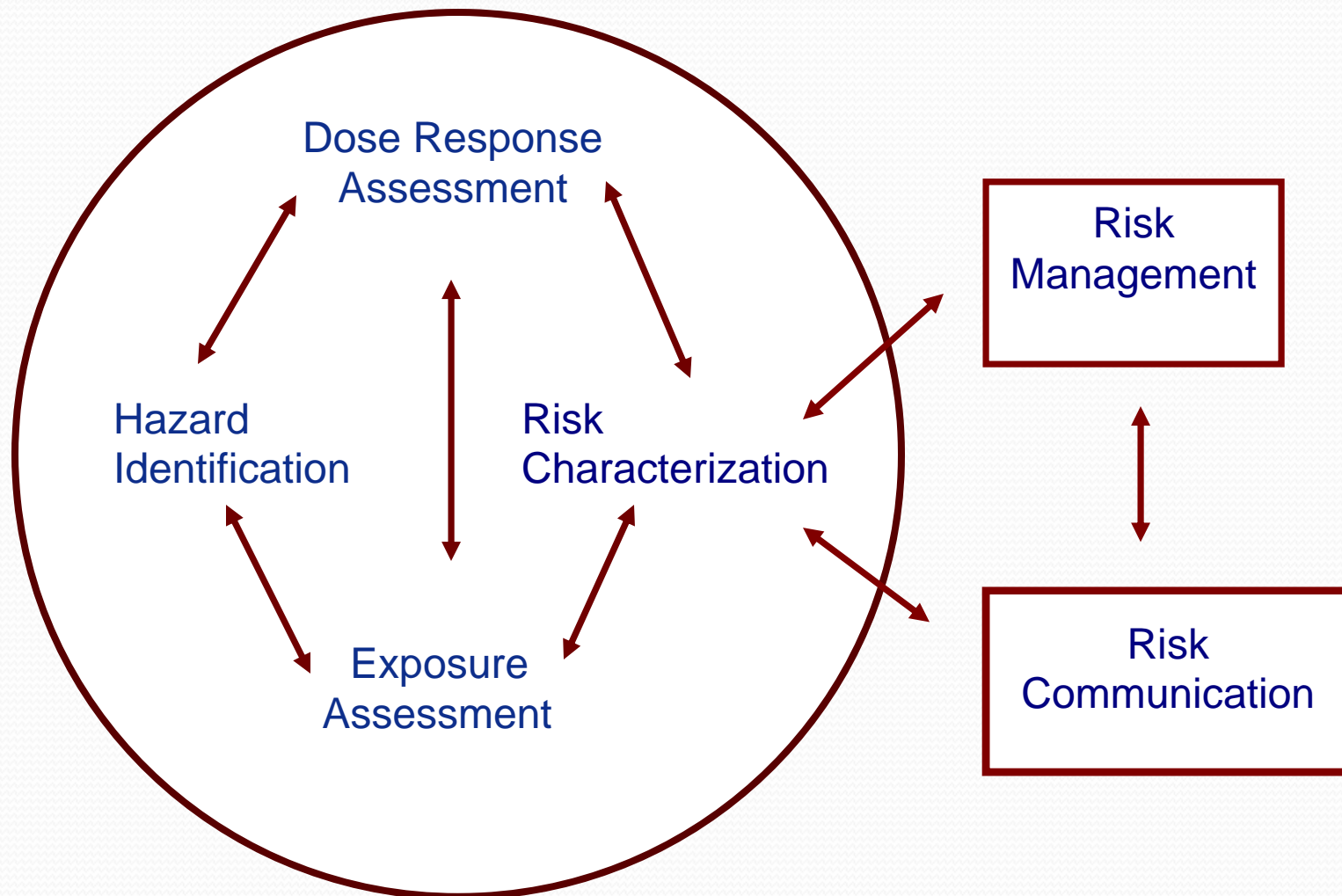
Rita Schoeny, Ph.D.
Acting Senior Science Advisor
Office of Science Policy, USEPA / ORD

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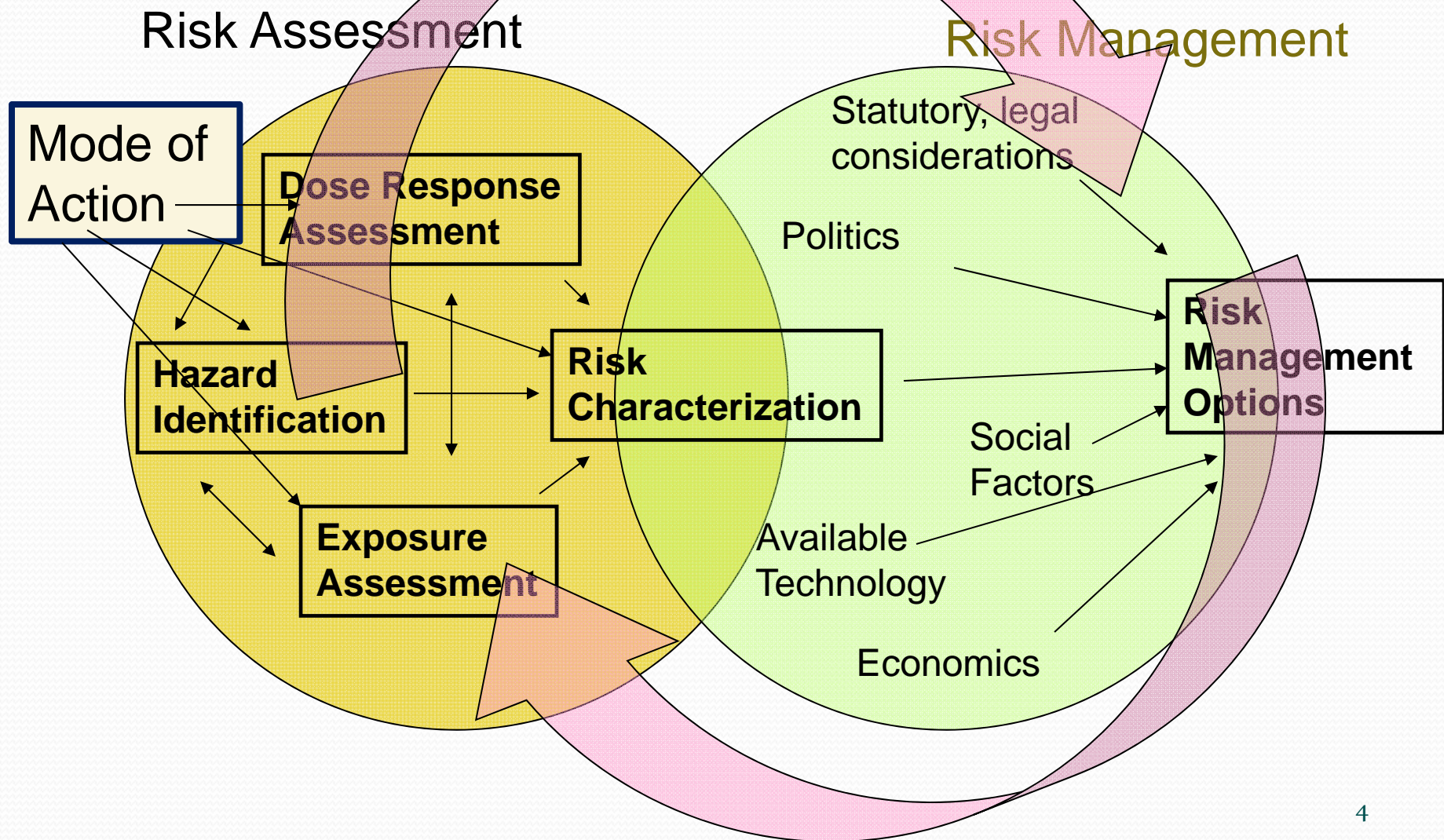
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Except when they do

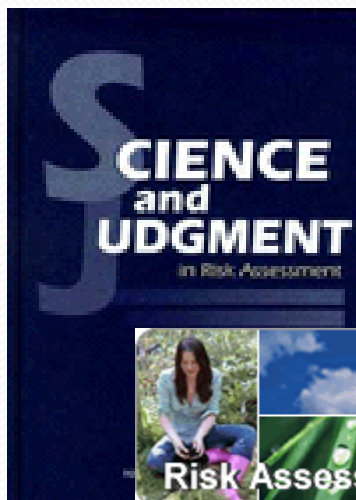
NRC Risk Assessment Paradigm



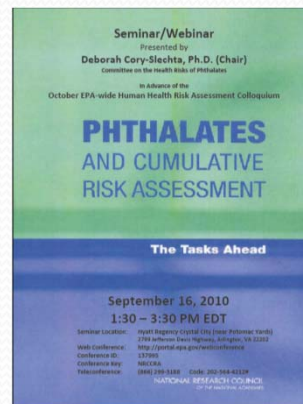
'83 Risk Assessment Paradigm '12?



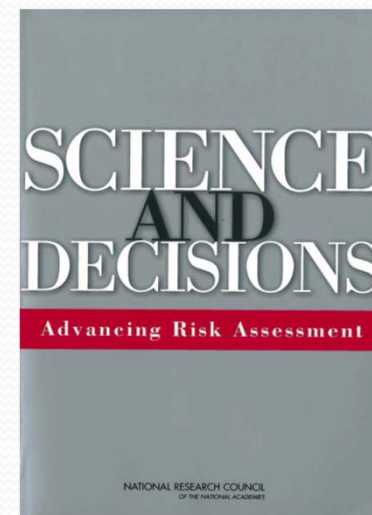
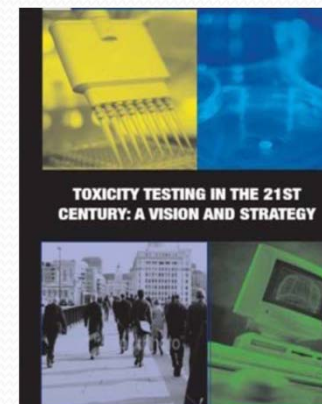
A lot has changed since '83



IPCS FRAMEWORK FOR ANALYSING THE RELEVANCE OF A CANCER MODE OF ACTION FOR HUMANS



Office of the Science Advisor
STAFF PAPER



Framework for Human Health Risk Assessment

- NRC Silver Book recommendation (Chapter 8 “Improving Utility of Risk Assessment”)
 - *To make risk assessments most useful for risk management decisions, the committee recommends that EPA adopt a framework for risk-based decision-making . . . that embeds the Red Book risk assessment paradigm into a process with initial problem formulation and scoping, upfront identification of risk-management options and use of risk assessment to discriminate among these options.*



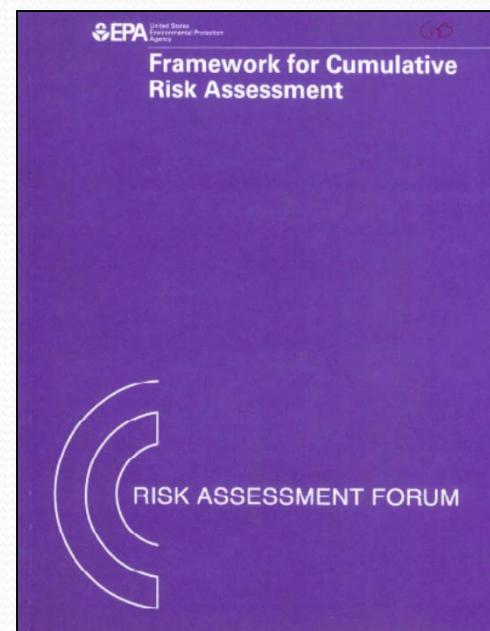
Advantages (Silver Book)

- Systematically identify problems and options
- Expand the range of effects assessed beyond individual end points
- Integrate regulatory policy with other decision-making options and strategies
- Serve needs of a expanded number of decision-makers
- Increase understanding of the strengths and limitations of risk assessment by decision-makers at all levels.

RAF Human Health Risk Colloquium

10/11

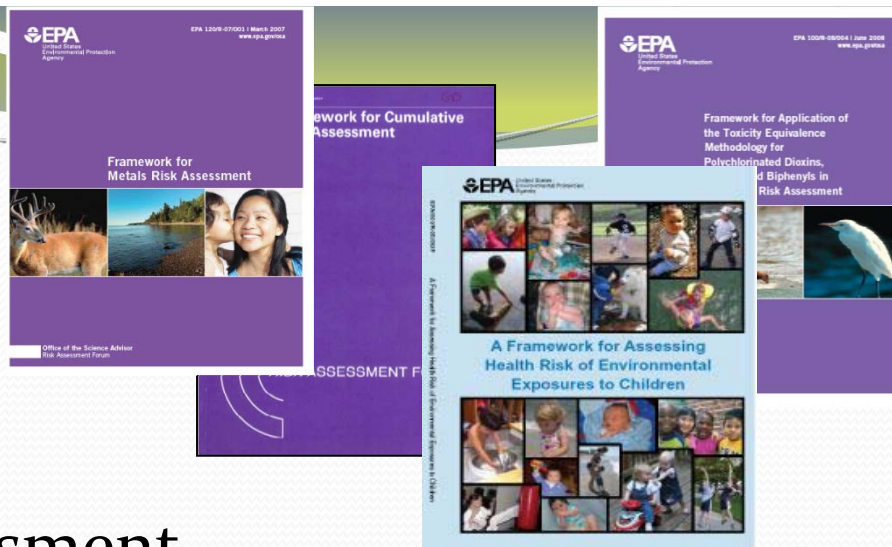
- Brought 120 EPA risk assessors and managers together to focus on advancing human health risk assessment
 - NRC Recommendations
 - *Science and Decisions*
 - *Phthalates and Cumulative Risk*
 - *Toxicity Testing in the 21st Century*
 - Administrator Jackson's Priorities
 - Environmental Justice
 - Children's Health Protection



U.S. EPA RAF Technical Panel on HHRA Framework

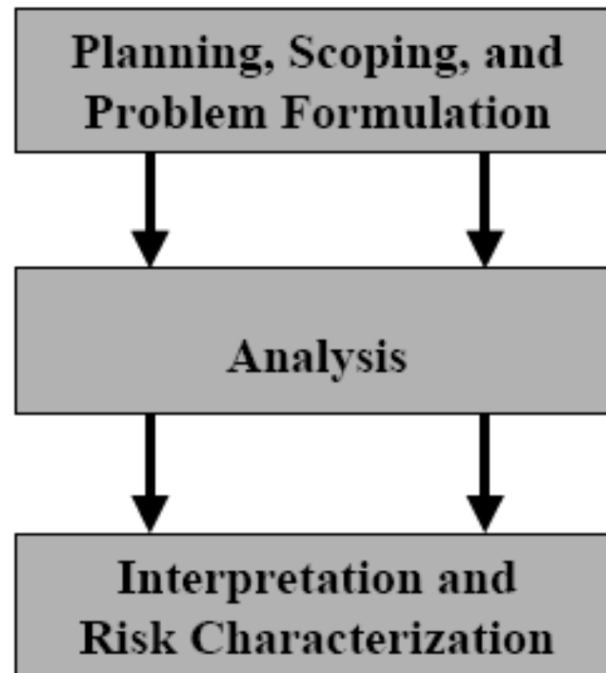
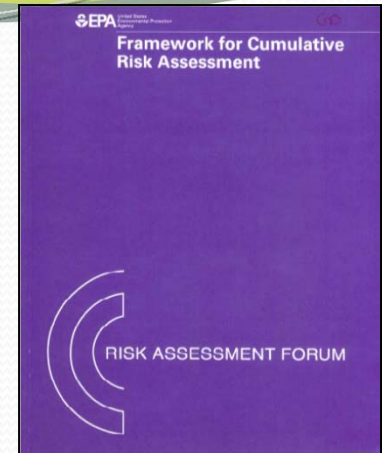
- In prep for colloquium, planning group polled EPA risk assessors and managers
- Two points of view
 - We could use guidance on planning/ scoping/ problem formulation .
 - We do this all the time – in a more or less formal way.
- RAF tech panel embraced both points of view and collected info on EPA experience

EPA Frameworks

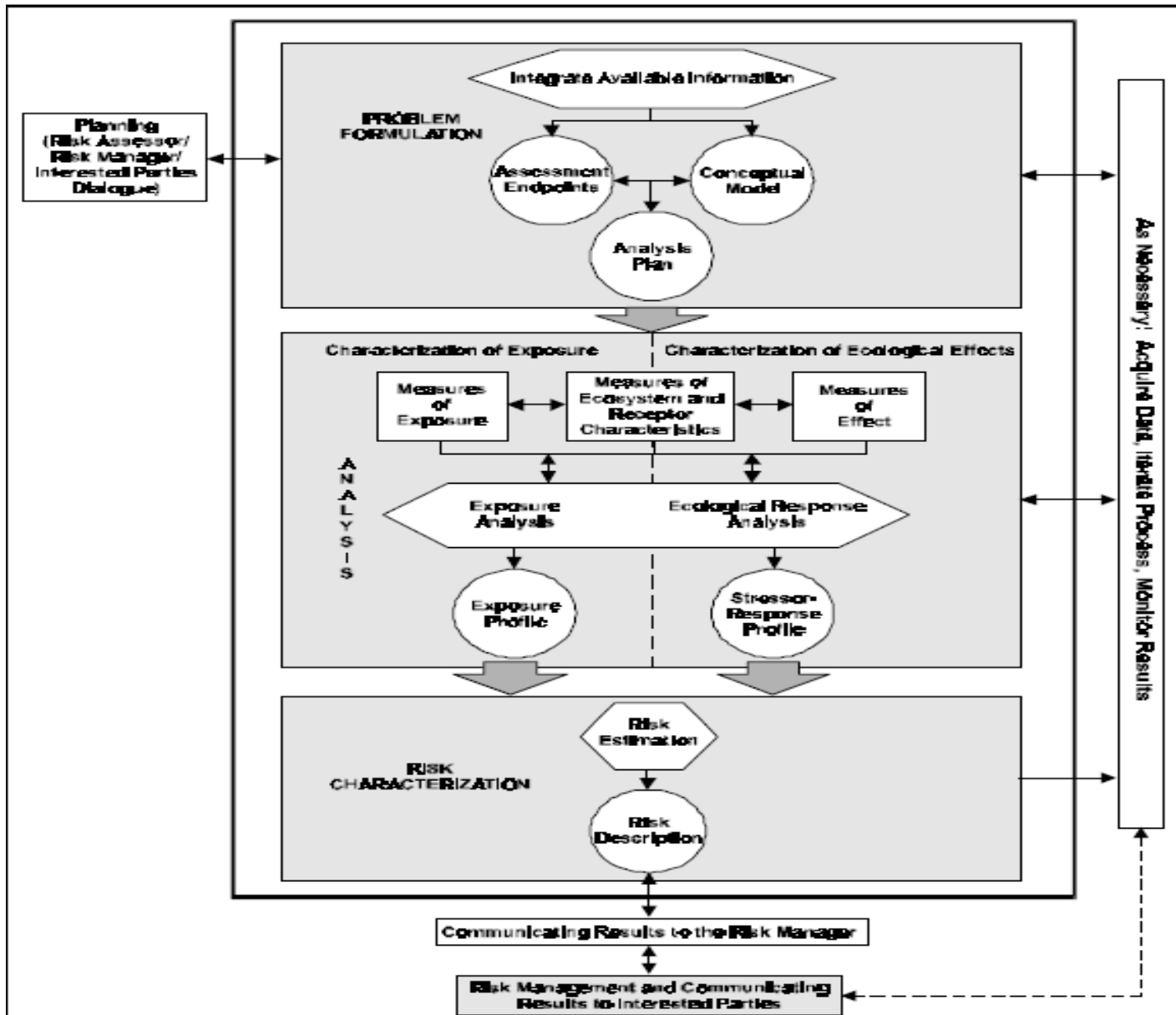


- RAF Ecological risk assessment
- RAF Framework for Cumulative Risk Assessment
- OAR residual risk framework
- Risk Characterization Handbook
- RAF Microbial Risk Assessment
- A Framework for Assessment Health Risk of Environmental Exposures to Children
- Risk Assessment Guidance for Superfund Part A
- OPPT/ OCSPP Risk Assessment Division

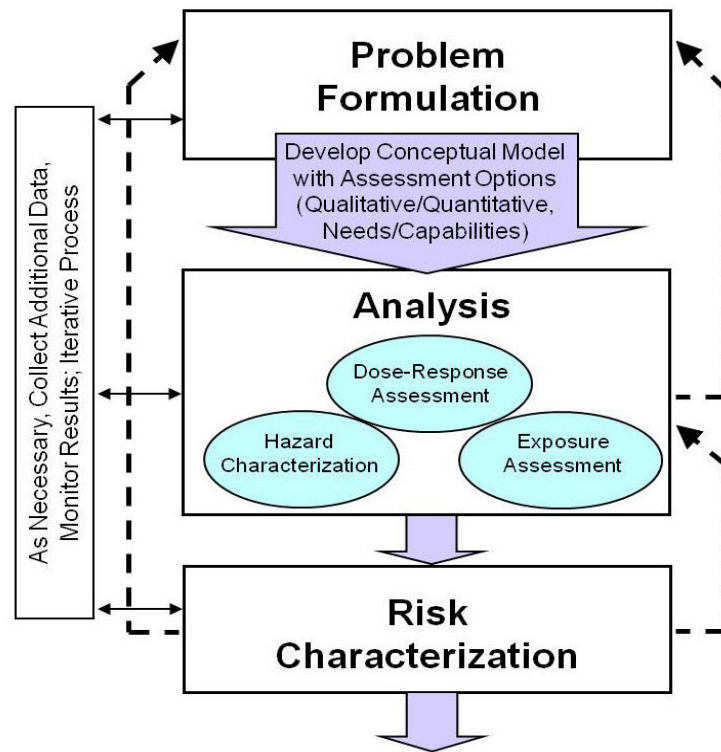
Cumulative Risk 1997



Ecological Risk Assessment Framework



Example: OPPT / OCSP



Risk Communication/Management

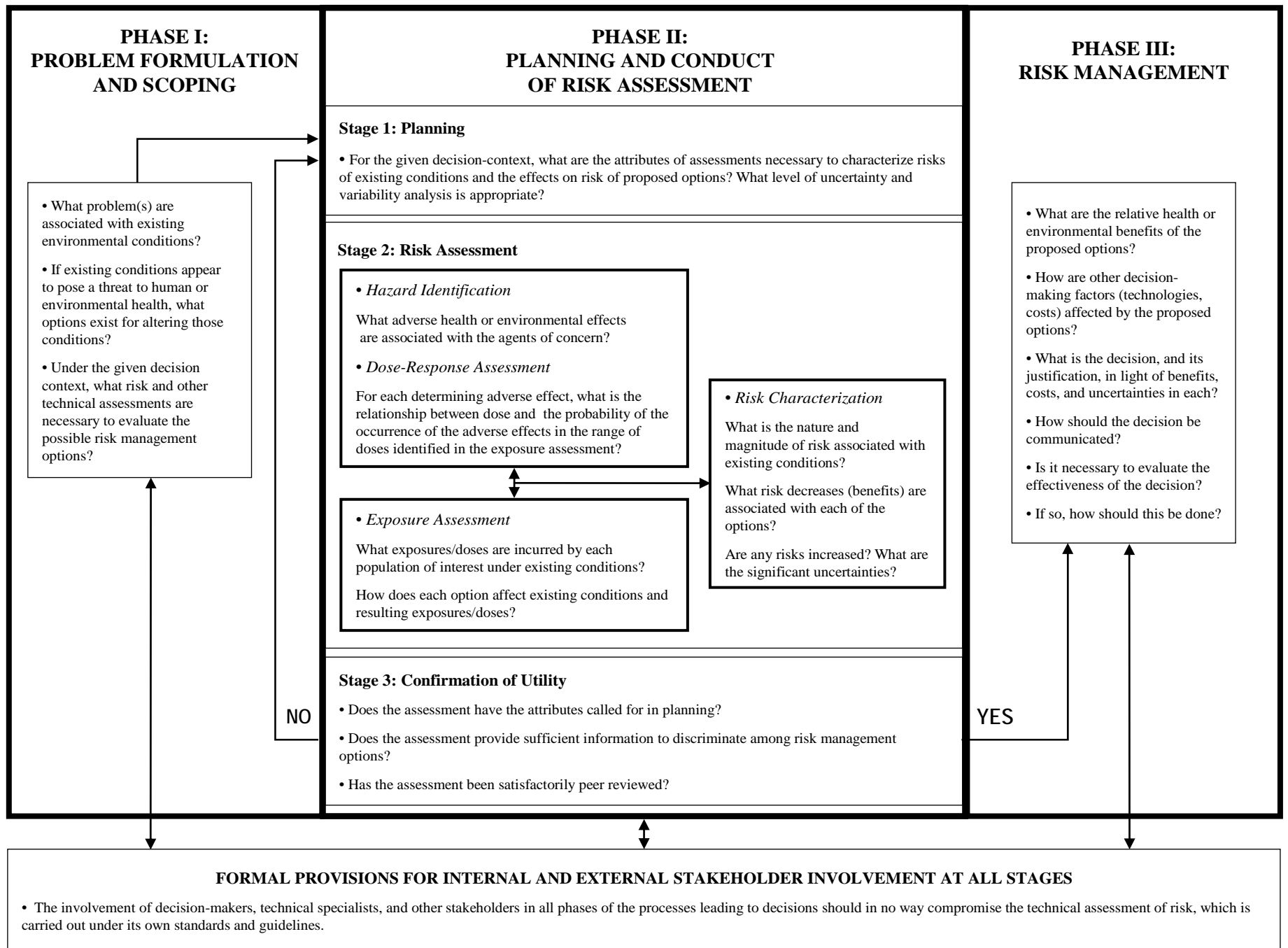
<http://intranet.epa.gov/opptwork/divisions/rad/index.html>

Most Frameworks Include

- Problem Formulation, scoping, planning
- Analysis
- Risk Characterization

What about Silver Book ?





NRC Silver Book Figure 8-1

Phase 1: Problem formulation and Scoping

- What is the problem to be investigated, and what is its source?
- What are the possible opportunities for managing risks associated with the problem? Has a full array of possible options been considered, including legislative requirements?
- What types of risk assessments and other technical and cost assessments are necessary to evaluate existing conditions and how the various risk-management options alter the conditions?
- What impacts other than health and ecosystem threats will be considered?
- How can the assessments be used to support decisions?
- What is the required timeframe for completion of assessments?
- What resources are needed to undertake the assessments?

Silver Book

Phase 2: Planning and Conduct of Risk Assessment

- **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?
- **Stage 2: Risk Assessment**
- **Stage 3: Confirmation of the 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?

Silver Book



Phase 3: Risk Management

- What are the relevant health or environmental benefits of the proposed risk-management 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?

Silver Book

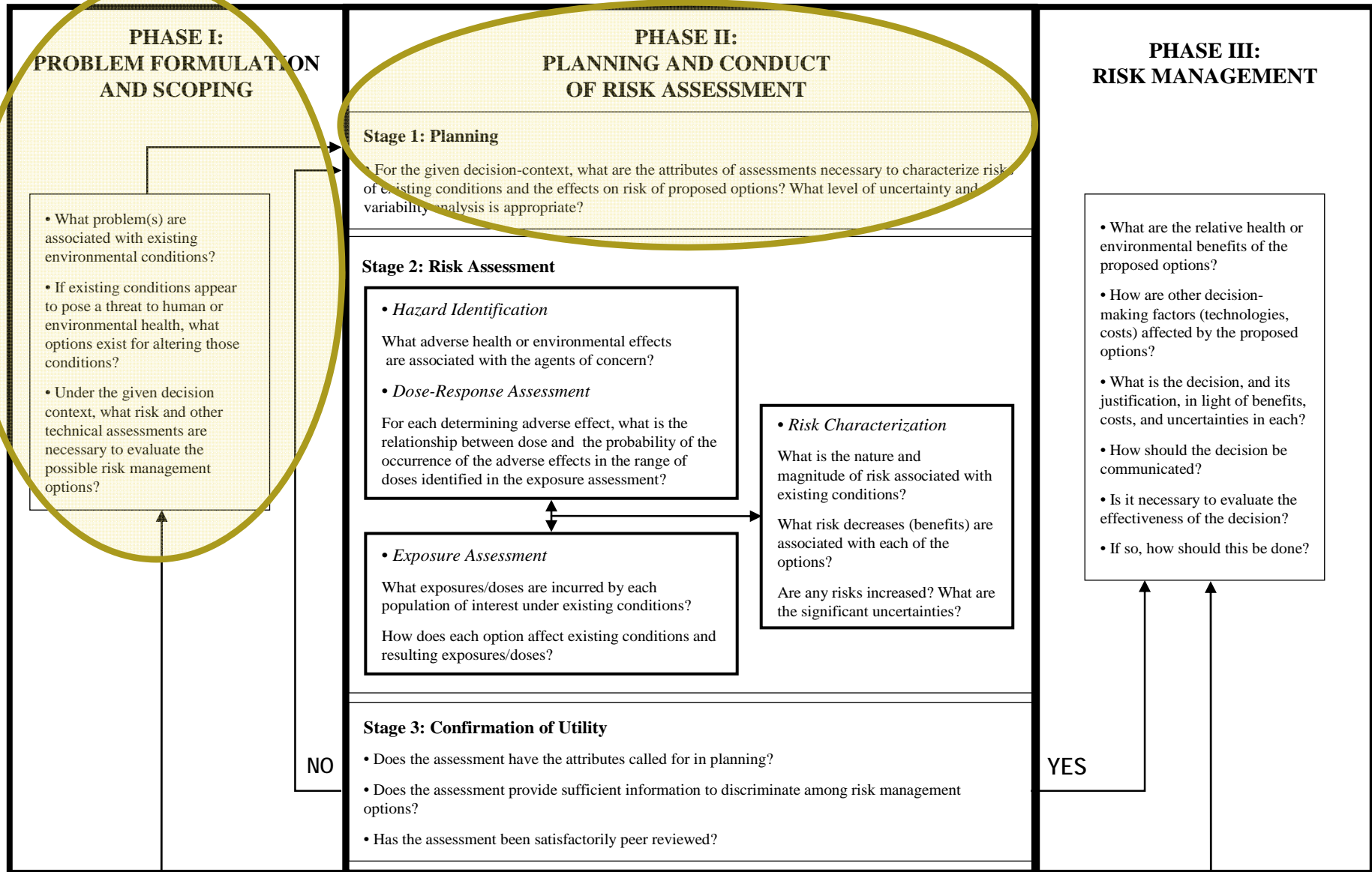
Why Not Just Adopt the Silver Book Framework?





Some General Points

- This framework represents an organizing process. It is not to subsume or replace any existing or developing guidance or Guidelines. Rather it presents a series of questions or issues to consider in formulating a risk assessment.
- The purpose is to develop an overarching human health risk assessment framework consistent with NRC recommendations in Science and Decisions and existing EPA guidance

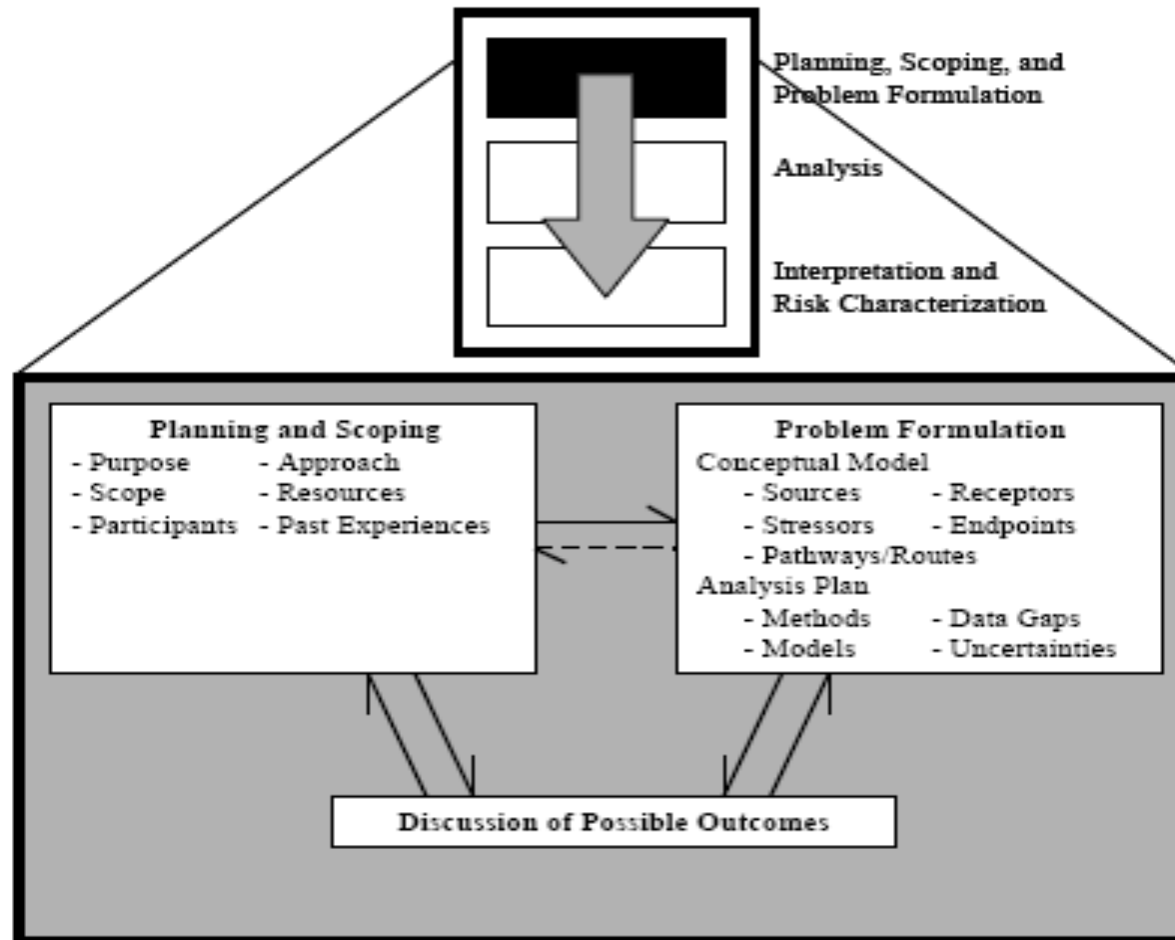


FORMAL PROVISIONS FOR INTERNAL AND EXTERNAL STAKEHOLDER INVOLVEMENT AT ALL STAGES

- 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.

NRC Silver Book Figure 8-1

Cumulative Risk: P&S vs. PF



Planning and Scoping

- *Overall purpose and general scope of the risk assessment*
- *Legal considerations*
- *RA products for informed decision-making, or for other analyses (e.g. economic)*
- *Resources (e.g. data, models, \$, personnel available or pending)*
- *Coordination with other organizations*
- *Identification of those involved and their roles (e.g. technical, legal, or stakeholder advisors)*
- *Schedule to be followed (including peer review)*

Problem Formulation

- *Approaches, including a review of the risk factors and technical elements that may be evaluated in the assessment*
- *Relationships, if established, among potential assessment end points {e.g., magnitude of estimated health outcomes and risk metrics} and risk management options*
- *Analysis Plan and Conceptual Model*

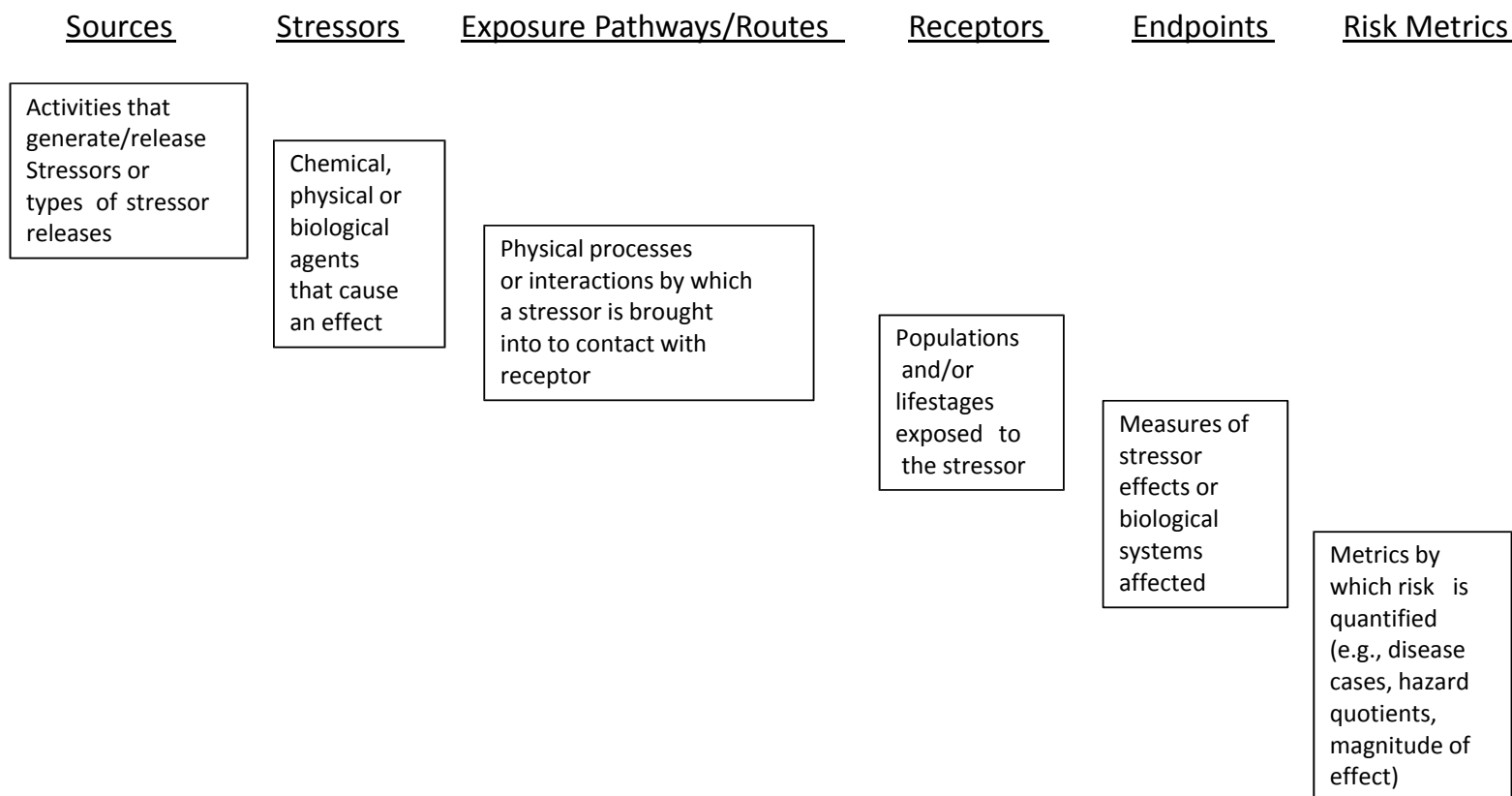


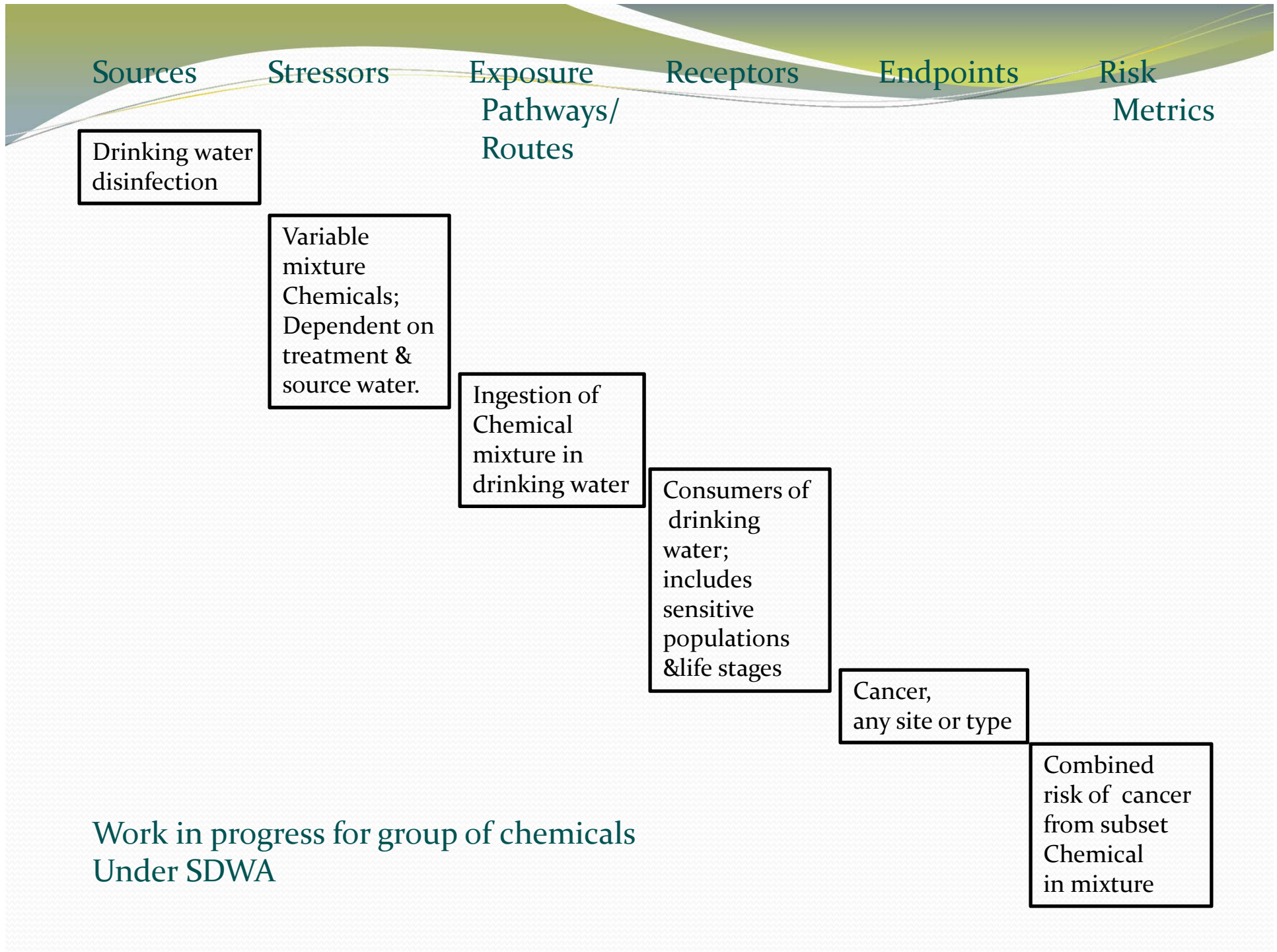
Conceptual Model

- Consists of
 - written description
 - visual representation
- Describes actual or predicted relationships between humans (or populations or population segments) and the chemicals or other stressors to which they may be exposed.

A Generalized Conceptual Model

with example of possible elements and linkages (adapted from USEPA, 2002; 2003)







Some Lessons Learned

- Many plans and conceptual models can benefit from peer review
- Data quality objectives should be designed, stated early in the process
- Each new assessment may not need a new Problem Formulation
 - Some boundaries are set by legislative mandate
 - Some standard operating procedures can be set
- Benefits of transparency are worth the investment

A Big Lesson

- Confirmation of utility is not a final step
- Fit for purpose of the risk assessment must be considered in all phases

- “In EPA’s Framework described here, the utility of risk assessment is not something that is evaluated as a separate step in the process or a final check that occurs once the risk assessment is completed. Rather, consistent with the NRC’s emphasis on consideration of risk management needs early in the process, our Framework emphasizes attention to utility throughout the process, beginning with planning and scoping, and including a specific focus on the applicability of the risk assessment for informing risk management decisions. “

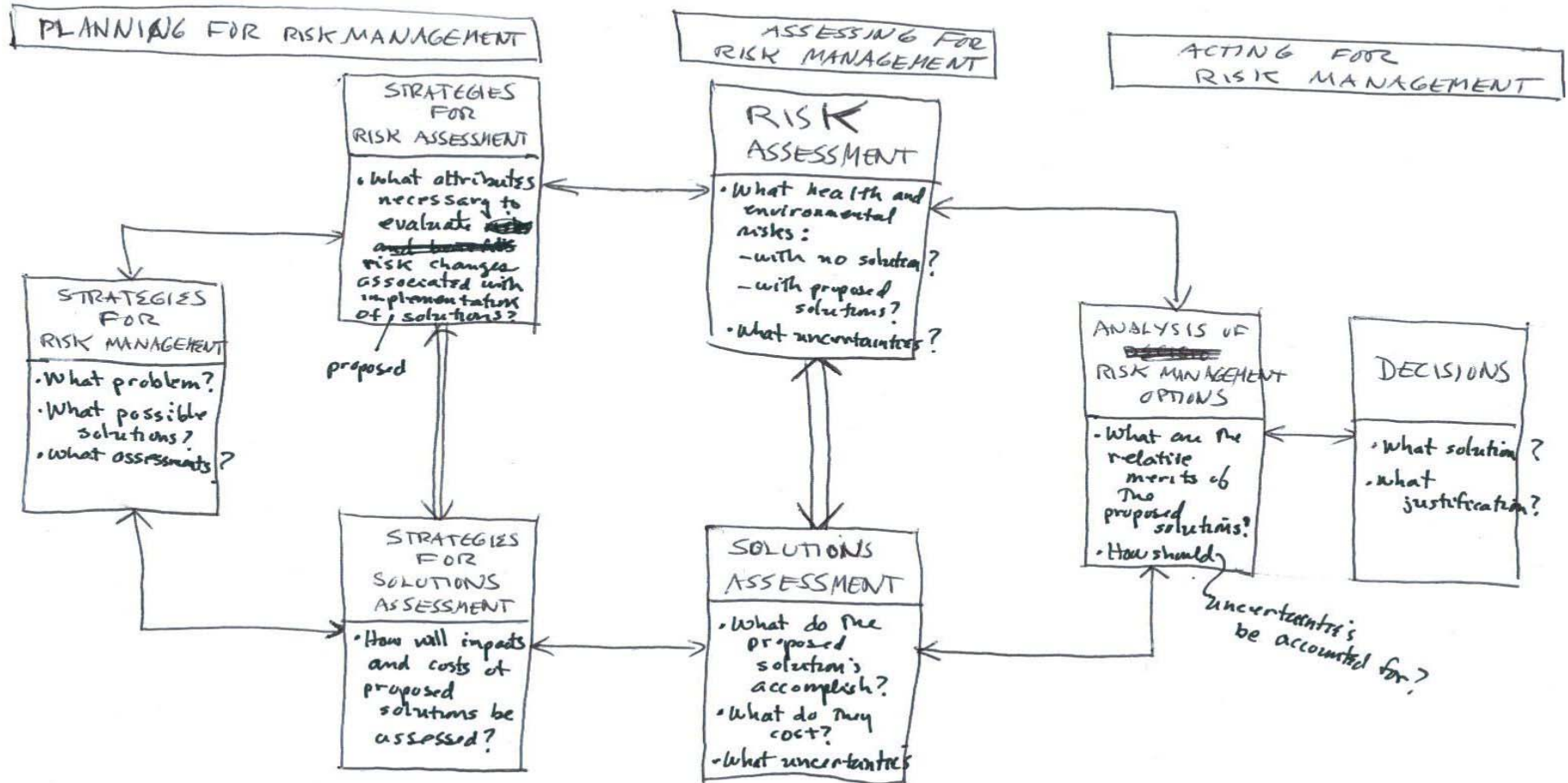


Some Questions from NRC

- Does the assessment design meet the objectives and have the attributes identified in the problem formulation step?
- Does the assessment, as implemented, meet the initial objectives? Or, if the initial objectives have been modified (e.g., as a result of changed risk management options or issues) does the assessment meet the modified objectives?
- Does the assessment have the attributes identified in planning?
- If the assessment requires peer review, has this been done appropriately and have the issues raised during the peer-review been addressed?
- How will the results of the risk assessment be communicated to the risk managers and stakeholders?
- Does the assessment inform choices among risk management options? Are there any additional risk assessment needs for discriminating between or implementing risk management options?

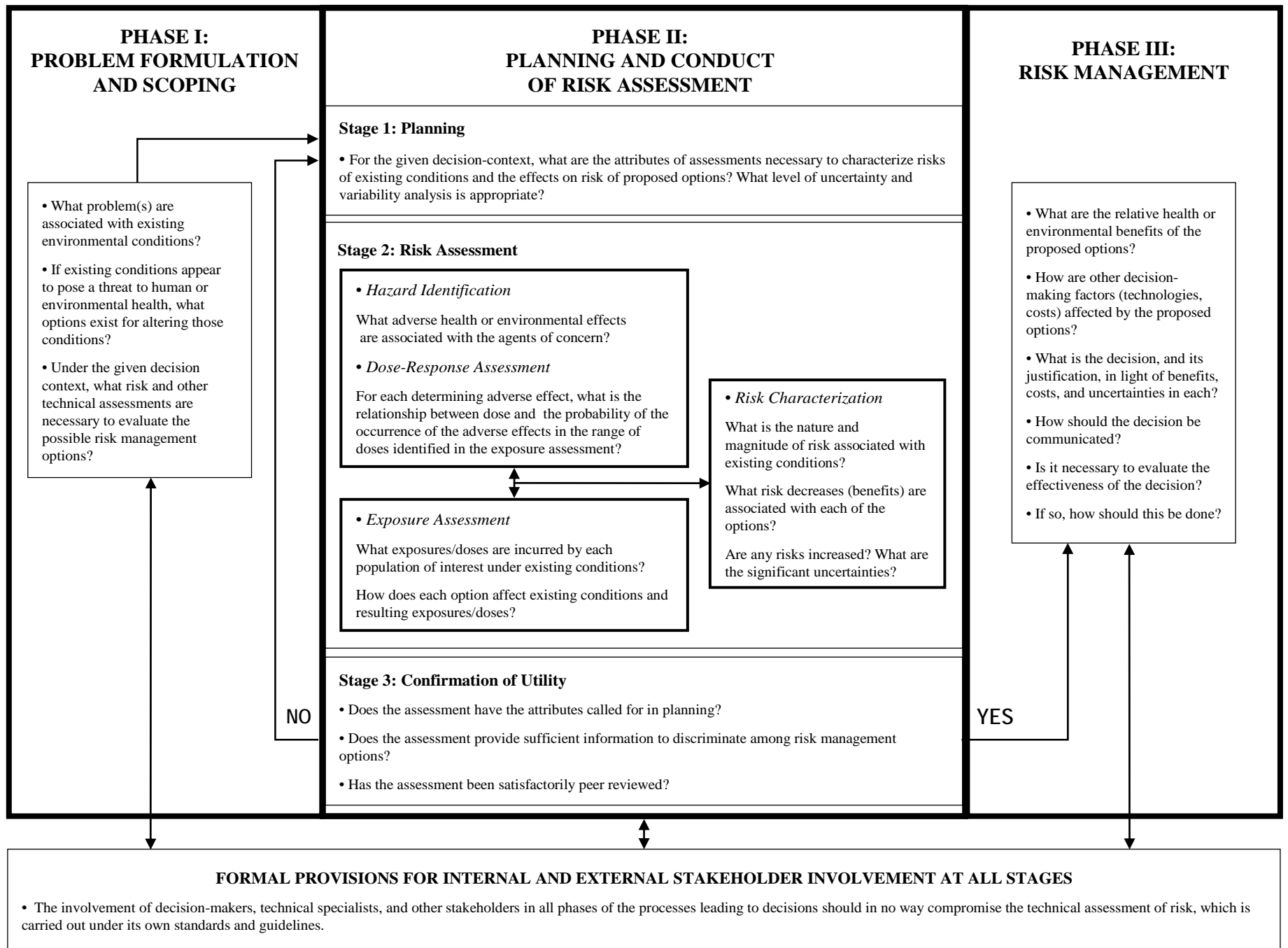
Original Silver Book Framework

FIG 9.1 A SOLUTIONS-BASED FRAMEWORK FOR IMPROVED RISK MANAGEMENT
 Improving RISK ASSESSMENT Requires Embedding it in a Problem-Solving Framework
 (See TEXT for discussion of steps in the Framework)



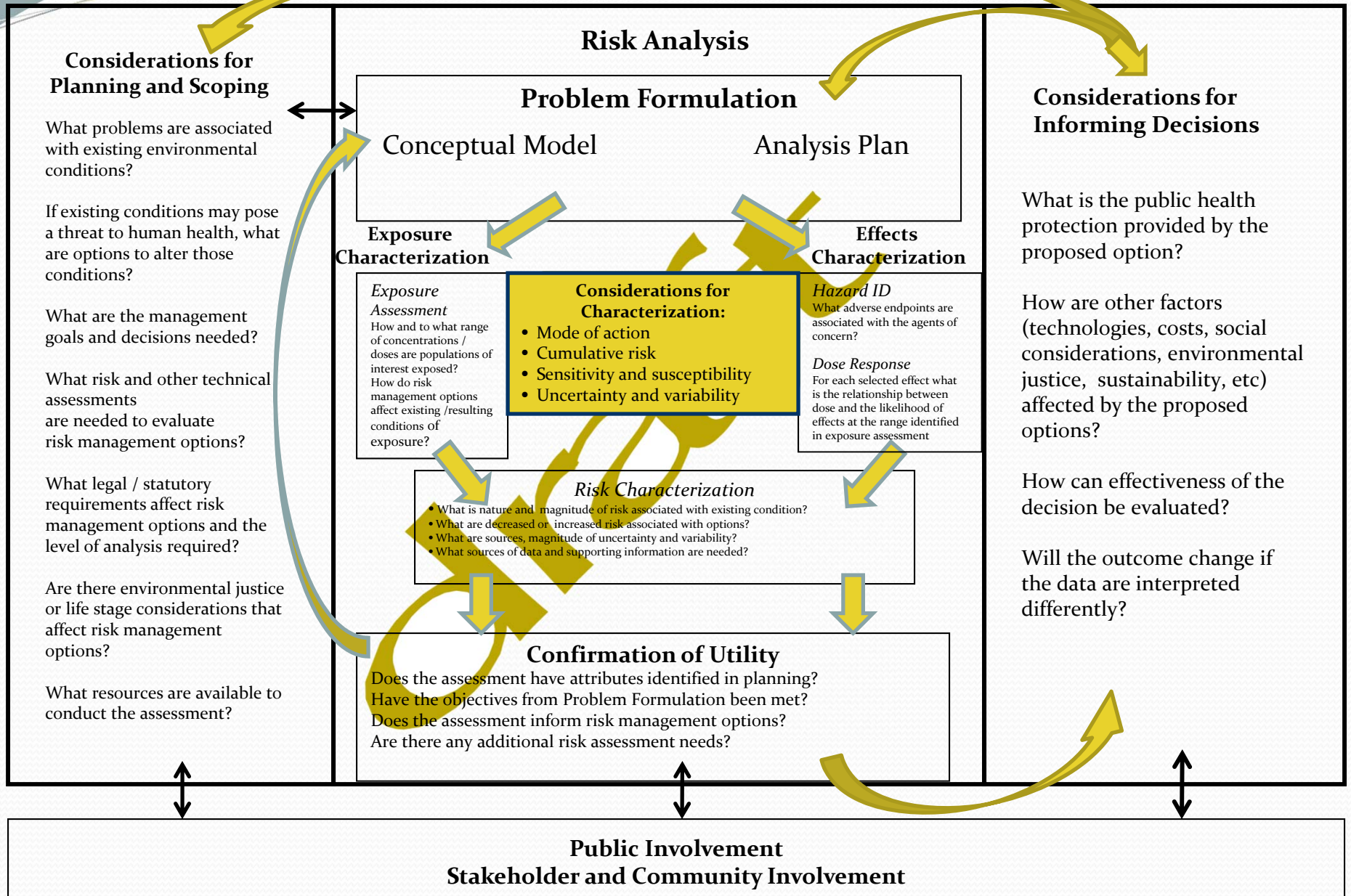
• FORMAL PROVISIONS FOR STAKEHOLDER INVOLVEMENT AT ALL STAGES •

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 it.

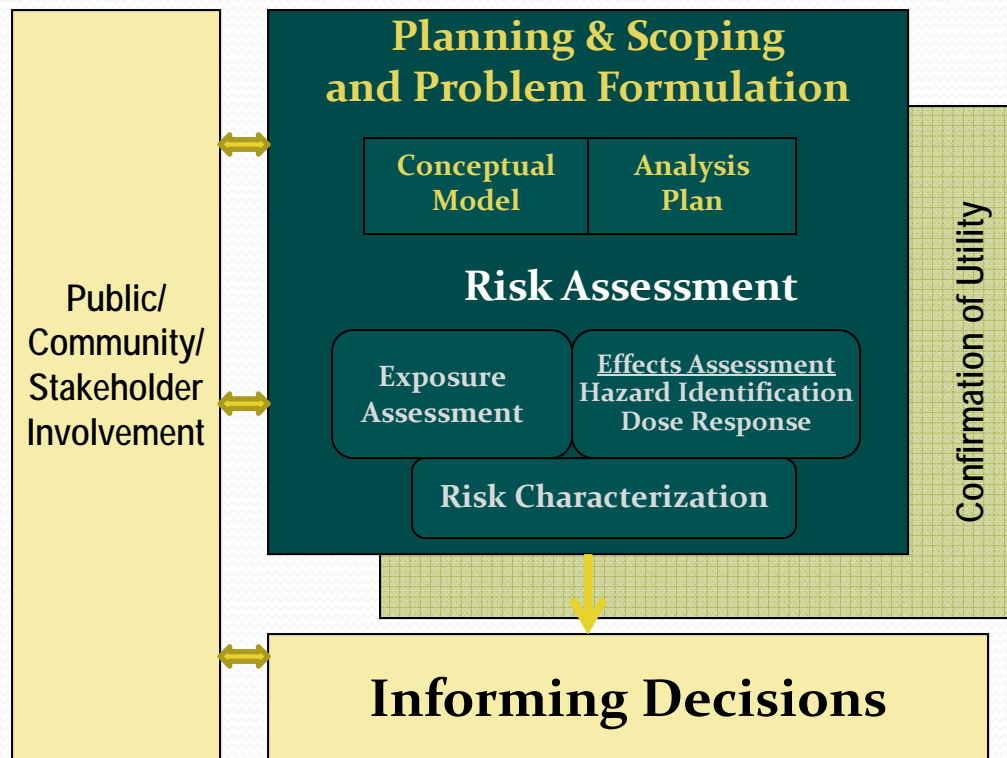


NRC Silver Book Figure 8-1

Framework for Human Health Risk Assessment to Inform Decision Making



Very Draft EPA Framework



Silver Book on Utility
“Risk assessments should not be conducted unless it is clear that they are designed to answer specific questions, and that the level of technical detail and uncertainty and variability analysis is appropriate to the decision context” (NRC 2009, p. 247).

Conclusions

- Framework does not determine the outcome of assessment
 - Framework does
 - Facilitate data organization
 - Prompts description of decision rationales
 - Can improve consistency and transparency
 - Fit for purpose is a good thing
- Next Steps
 - Complete responses to internal (EPA) reviewers
 - Send for external peer review





RAF Technical Panel

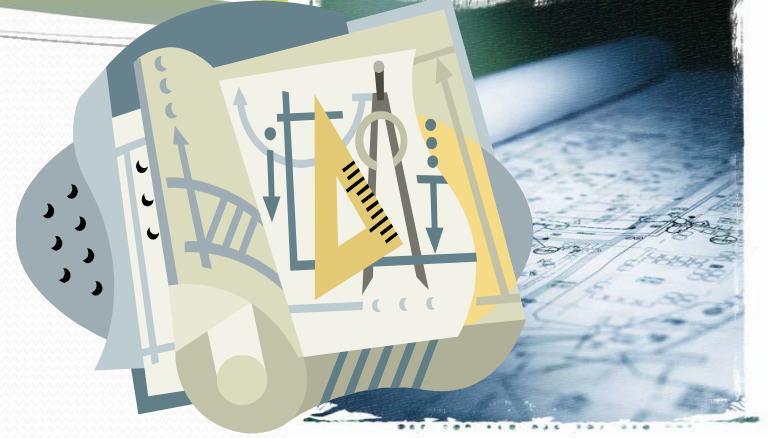
- Kathryn Gallagher Co-chair OW
- Rita Schoeny, Co-chair ORD
- Kacee Deener, ORD
- Chris Dockins Office of Policy
- Michael Firestone OCHP
- Margaret McDonough, Region 1
- Dierdre Murphy OAR
- Marian Olsen, Region 2
- Kathleen Raffaele, OSWER
- Julie Fitzpatrick, OSA/RAF Staff



Questions?

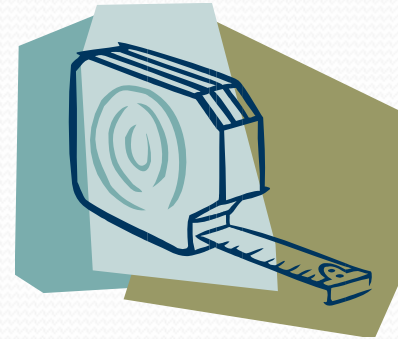
Analysis Plan

- How are we going to do this?
- May include
 - Assessment design and rationale for relationships addressed,
 - Data and information, methods and models to be used in the analyses, (including the uncertainty analyses),
 - Associated data gaps.
- May be phased or tiered risk approach to facilitate management consideration, scientific review and/or public involvement.
- As long and explicit as it needs to be

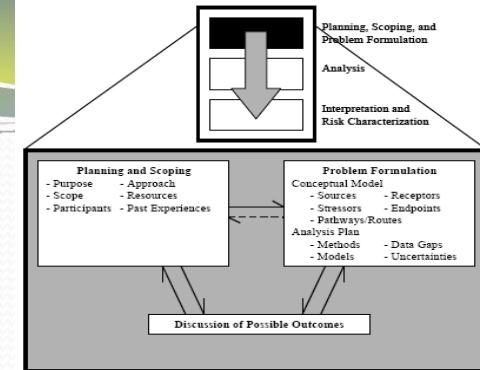


More on Analysis Plan

- Risk metrics should be defined
- Examples
 - Incidence of specific health outcomes;
 - Risk of specific health outcomes;
 - Occurrences of exposures above health-based benchmarks or comparison points;
 - Potential for occurrence of exposure above health-based benchmarks;
 - Margins of Exposure
 - Hazard Quotients



Problem Formulation



- EPA's *Guidelines on Ecological Risk Assessment*
 - the analytical phase of the assessment wherein “the purpose for the assessment is articulated, the problem is defined, and a plan for analyzing and characterizing risk is determined”
- Part of the planning process that systemically identifies the major factors to be considered in a particular assessment
 - Draws from the regulatory and policy context of the assessment
 - Provides the foundation for the technical approach of the assessment.
- Comprised of
 - Conceptual Model
 - Analytic Plan