

*Challenges for  
Policy Makers and Practitioners:  
Uncertainty, Expert Judgment,  
and the Regulatory Process*

**Robert Hetes, U.S. EPA**

National Health and Environmental  
Effects Research Laboratory

## Caveat

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- This presentation reflects personal views based on experience and discussions with the EPA's EE Task Force. It is not intended to reflect Agency policy.

# Outline

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- Growing interest in use of EE
  - Need for Task Force
- EE versus Expert Judgment
- EPA experience with EE
  - Lessons learned
- Uncertainty and the Regulatory Process
  - Issues of uncertainty
  - Issues specific to EE
- General conclusions on use of EE

# Why the increased Interest in Expert Elicitation (EE)?

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- Greater interest in probabilistic assessments
  - EPA Staff paper on RA practices (2004)
  - RAF Forum (2004)
  - EPA Probabilistic Risk Work Group (2005)
  - SOT/SRA Workshop on Probabilistic Assessment (2005)
- Greater interest in Expert Elicitation
  - NAS (2002) *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*
  - OMB Circular A-4
  - EPA Cancer Risk Assessment Guidelines (March 2005)

# Why the need for an Intra-Agency Task Force?

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- EPA Acknowledges the potential value of this method to support decisions but recognizes:
  - Most EPA analysts and decision makers are unfamiliar with this method
  - No clear guidelines on how to conduct within EPA (or elsewhere)
  - Desire to promote consistency
  - Consider the potential impacts of precedents from near-term projects utilizing EE
  - Need to promote technically defensible assessments
  - Broad range of statutory, regulatory, policy issues to be addressed

# Distinguishing EE within the Context of Expert Judgment

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- Expert judgment is inherent to the scientific process and covers a range of activities
  - Analysis – problem formulation and scoping, analytical/model choices
  - Evaluation and interpretation of results
- Expert peer review commonly provides expert judgment and feedback on planned or completed products and projects
- Expert Elicitation (EE) is a formal systematic process of obtaining and quantifying expert judgment
  - Ensures quality output which is consistent with demands of OMB guidelines etc

# What is EPA's Experience with EE?

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- Office of Air and Radiation
  - 1977-78 Ozone NAAQS Review
    - SAB Subcommittee on Health Risk Assessment established in 1979
  - Lead health risk assessment for 2 endpoints (1986)
  - Chronic ozone lung injury assessment
  - Fine particulate matter (PM<sub>2.5</sub>) mortality for health benefits
    - pilot project (2004) – used in non-road RIA benefits analysis
    - full elicitation– 2005/2006 underway
  - Radioactive Waste Disposal – 40 CFR 194.26 (July 2003)
  - Climate change example

# Lessons Learned

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- EE is an accepted methodology
- Early efforts (late 1970s) criticized due to lack of experience and formal methods
  - Highlights the importance of the collaborative efforts to move the method along
  - Similar activities will likely be needed to promote the use in other program offices
    - Quality
    - Relevance



# Uncertainty and the Regulatory Process

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- **Uncertainty analysis in general**
  - Essential to understand implications of findings
  - Concern that reflects criticism of assessment -- inadequate
  - Opens decisions to legal challenge
  - Can be misused to delay appropriate actions
- **Decision Analytic approaches**
  - Formalized framework reduces flexibility in decisions

## EE-Specific Issues or Concerns

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- Trust and credibility are critical
  - Transparency
  - Rigor
- Resource intensive and time consuming
- Rigor of the effort depends on the intended purpose and use
- Methodological

# Nature of the Regulatory Process

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- Complex multi-factor problems
  - Risk, legal, science, economic, social, political
- Multiple stakeholders – each with their own positions, frames, and agendas
- Adversarial -- challenging

Necessitates a high degree of scrutiny

## Factors which influence the defensibility and acceptability of an EE

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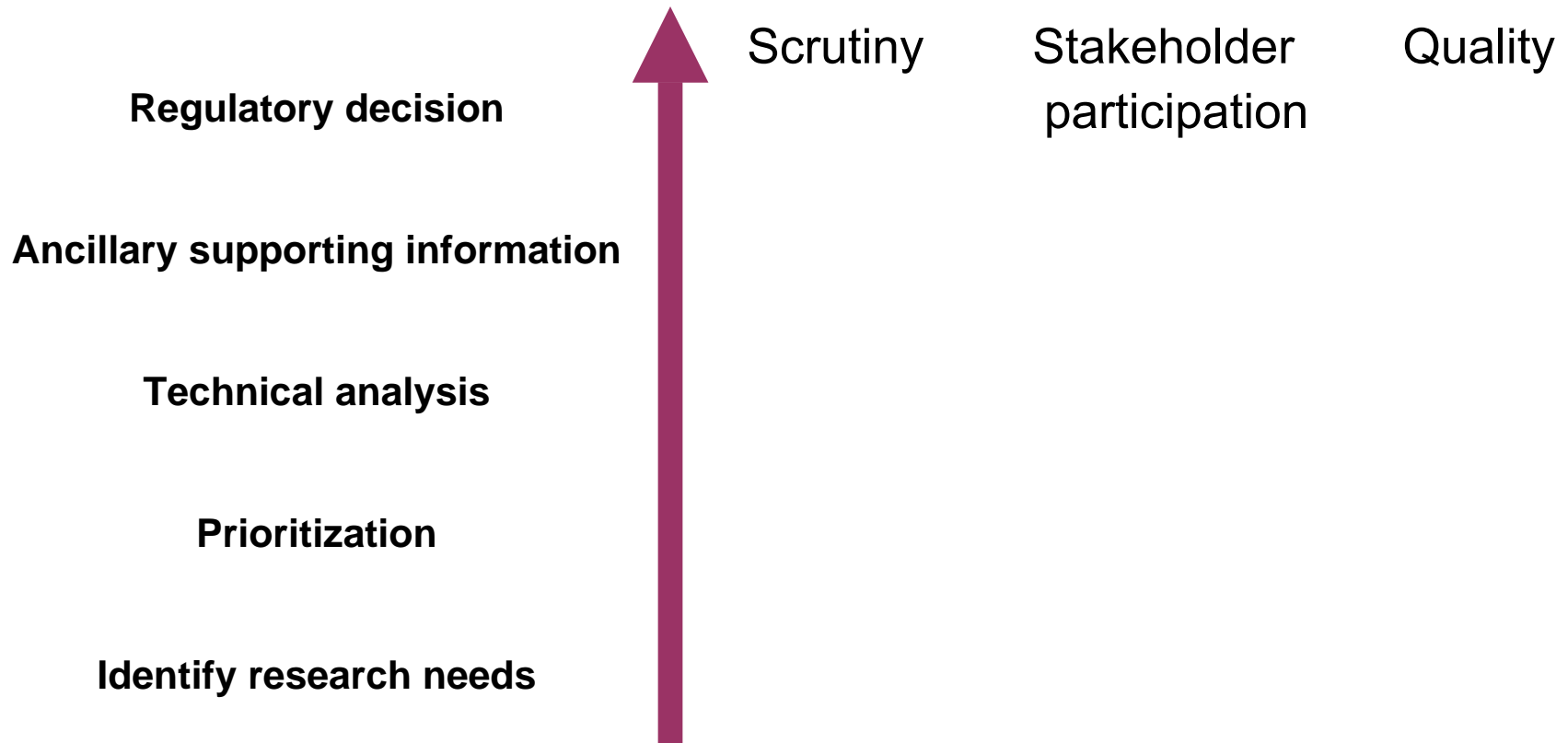
EE is perceived by some as easily a manipulated “black box” and arbitrary and non-scientific

Defensibility is improved by the degree to which the EE addresses the following dimensions

- Transparency
- Credibility – use of reasonable evidence
- Objectivity -- unbiased and balanced
- Rigor - control of heuristics and biases
- Relevance

## **Intended Use / Activity**

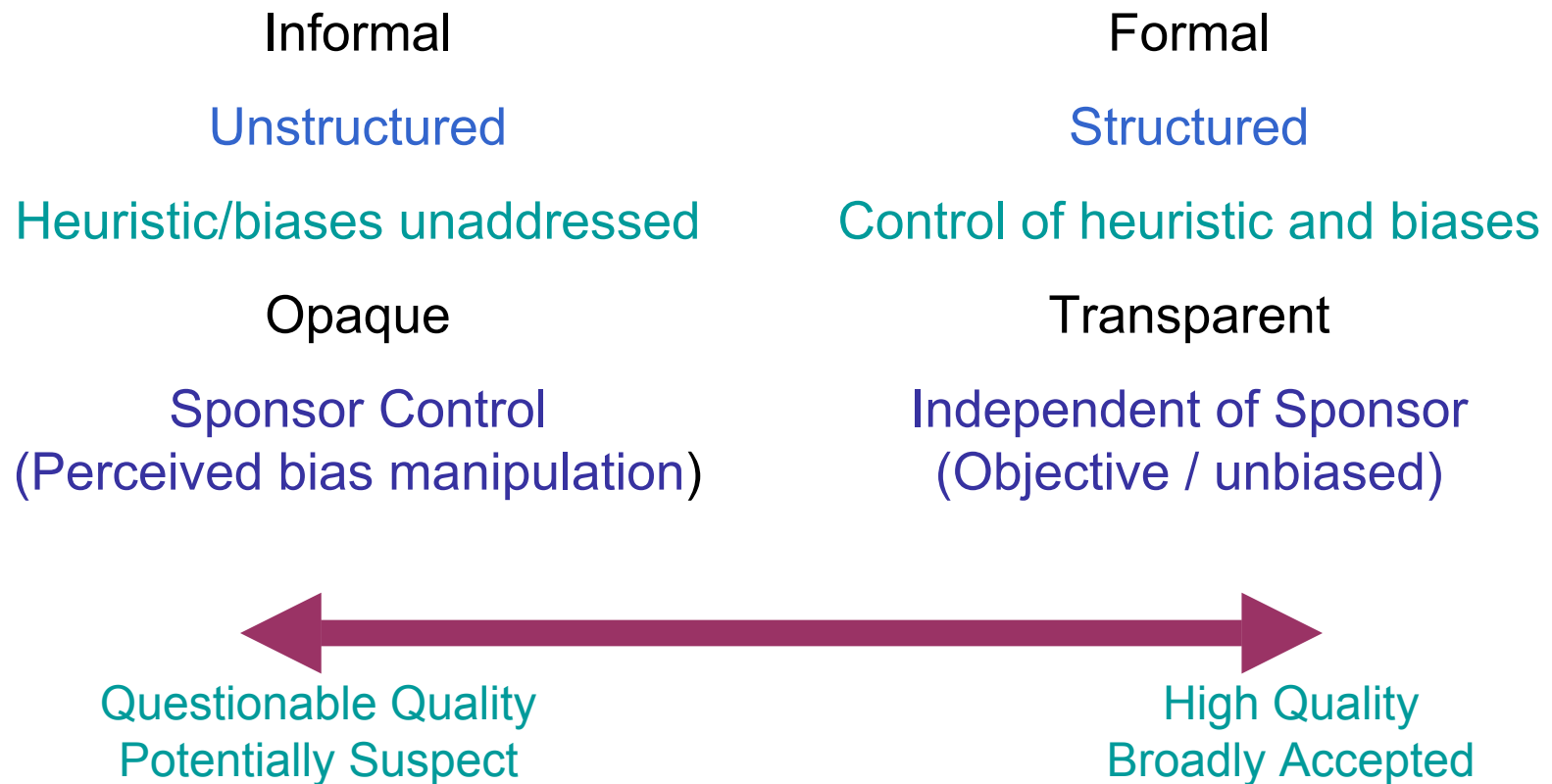
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Note: impact of any decision or activity provides another dimension in determining necessary quality

# Factors influencing quality, defensibility, and acceptability

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**Sponsor Control  
(Perceived bias manipulation)**

**Independent of Sponsor  
(Objective / unbiased)**



- Sponsor includes stakeholders, control includes influence
- Control over any particular element
  - problem definition
  - selection of experts
  - characterization and use of results
- Especially important in a political setting that one must protect against even the appearance of undue influence and control
- Also applies to considering use of 3<sup>rd</sup> party assessments

## Other factors to consider in deciding when and how to conduct EE

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- Importance of characterizing critical uncertainties
- Nature of the debate – analytical v. deliberative
- Perceived major bias among stakeholders
- Nature of available data – sufficient data to carry out EE or use empirical-based methods
- Relative value of EE v other uncertainty methods
- Role of peer review -- same pool of experts, experts excluded from peer review



# Well-conducted EE is time and resource intensive

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- Resources
  - technical skills – availability and LOE internal/external
  - Cost – most > \$100K
  - Time –  $\geq$  1 yr to design/implement
- Pressure to reduce these demands
  - Numerous methodological adjustments can be implemented to lower level of effort and resource needs
  - Can affect the overall quality and therefore acceptability of the result

## Guidance and/or Minimum Standards Needed

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- To insure the acceptability of EE
  - Minimum quality standards dependent on intended use of the results
  - Guidance on applicability of results beyond intended use (secondary use)
  - Describe pedigree of findings

# Methodological Considerations

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- Who selects experts
- Anonymity of experts
- Combining expert judgments
- Number of experts – ICR limits

## Conclusions / Discussion

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- EE is a powerful and accepted tool to characterize uncertainty / provide estimates for specific data gaps
- EE is one of several tools and not a panacea
- EE properly conducted is resource intensive and time consuming
  - Not appropriate for all applications
- Many factors (technical, administrative, political, procedural) should be considered in deciding when and how to conduct an EE, and how to use its results