

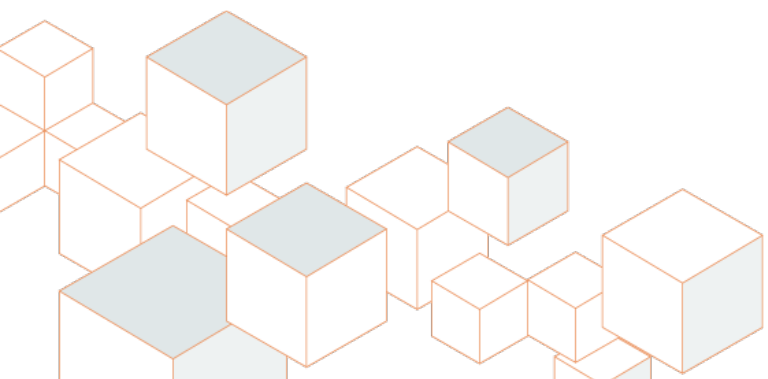
November 13, 2012

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# IRIS Public Stakeholder Meeting

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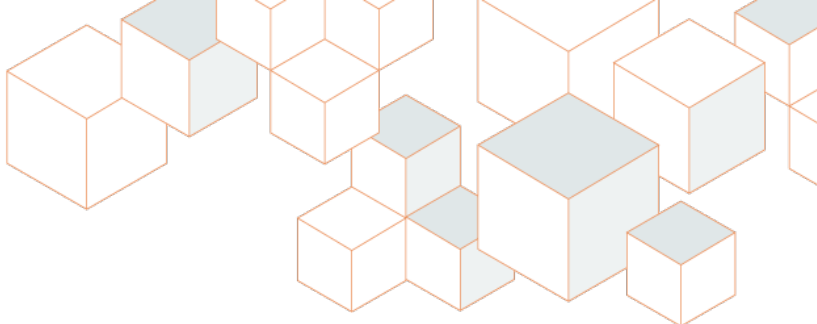
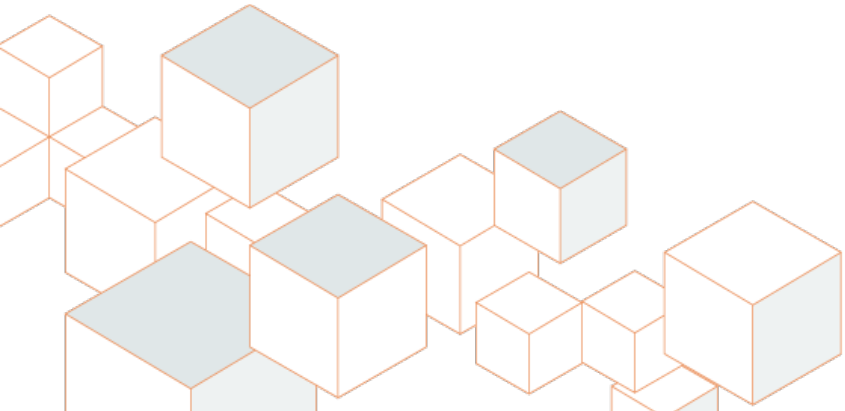


# Introduction


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- The NAS, GAO and Congress have expressed strong concerns regarding longstanding problems with IRIS.
- Fixing IRIS will improve the accuracy and usefulness of assessments as the basis for future regulation and timely decisions to protect human health and the environment.
- ACC has been actively and constructively engaged in scores of IRIS assessments, and continues to advocate for significant fundamental improvements.
- EPA has begun to acknowledge problems and make modest changes to IRIS.
- ACC believes that enhancements to IRIS, if properly implemented, will improve:
  - the scientific quality,
  - transparency and
  - the pace of IRIS assessments.
- IRIS improvements may be applicable to other programs, including the RoC.

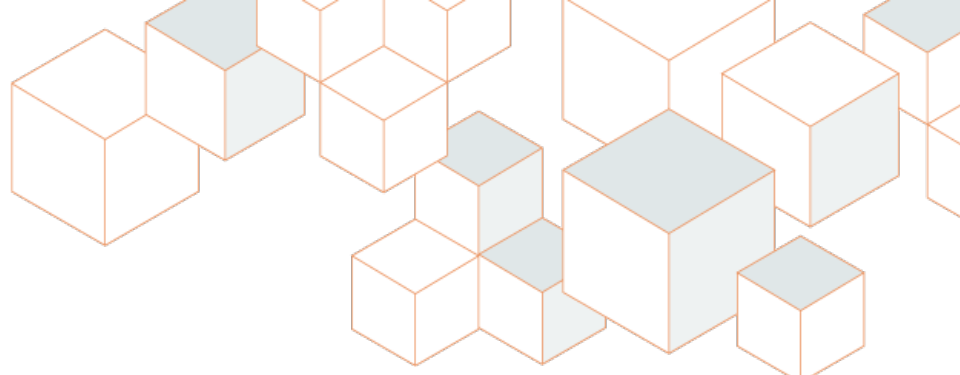
# Success Indicators in Reforming IRIS

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1. Transparency and Reproducibility
  2. Meaningful stakeholder input
  3. Robust peer review
  4. Improved responsiveness to stakeholder and peer review comments
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# 1. Transparency and Reproducibility

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- The new Preamble is a step in the right direction, but does not delineate the criteria relied upon by EPA in either selecting studies or assessing their quality.
  - Use of weight of evidence framework to weigh the best available science, including mode of action (MOA)
    - During its review of formaldehyde, the NAS concluded that EPA had not applied a WOE framework in assessing LHP cancer causality.
    - More recent assessments do not indicate how EPA assigns weight to studies or how much weight is assigned.


## 2. Meaningful Stakeholder Input

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- EPA has made important strides in converting the listening sessions into active dialogue sessions.
  - The scoping and problem formulation step, however, has yet to be fleshed out and applied to an IRIS assessment.

### 3. Robust Peer Review

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- ACC applauds EPA's commitment to providing stakeholders with an opportunity to contribute to peer review charge questions.
  - Stakeholders should be afforded sufficient time to present comments to and dialogue with peer reviewers.
  - EPA has also proposed revising draft assessments to reflect public input before the assessment is peer reviewed.
    - EPA should ensure that it builds into the process sufficient time to fully consider public comment and amend the draft assessment before peer review.
  - ACC does not support concurrent public and interagency review.
  - HR 6564 - the SAB Reform Act - would strengthen SAB review.

## 4. Improving Responsiveness to Public and Peer Review Comments

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- Assessing the adequacy of EPA's response to public and peer review comments could be the role of:
    - SAB staff and subset of peer review panel?
    - Independent ombudsman?
    - Other options?

# Additional Short-term Recommendations to Improve IRIS

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- EPA should use [regulations.gov](https://www.regulations.gov) to post all IRIS assessment documents, comments, peer review drafts, etc.
- For all IRIS assessments underway, EPA should either apply systematic approaches to data evaluation and weight of evidence or explain the rationale for not doing so.