General Comments at the IRIS April Bi-Monthly Meeting

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My comments address these points:

1. Thanks to EPA for listening to stakeholders in December.
2. Are there additional improvements possible for Step 1 meetings to maximize Early Detection of Issues?
3. How can NCEA be as efficient as possible in increasing constructive interaction with stakeholders?
4. Whose meetings are these, anyway?

2.Early Detection of Issues

- An analogy: Medical doctors are rightly focused primarily on curing or treating disease.
  - However, early detection of disease can make curing the disease easier, hence improving the final outcome.
  - Therefore developing effective methods of early detection across a wide range of diseases is a key priority.
- NCEA has rightly been focused on “cures” (e.g., how to craft better assessments)
  - But developing a set of early detection methods across a wide range of possible issues should be a priority.
  - Some analysis is needed; not a casual matter.

How to develop early detection methods?

- Suggested joint analytical effort:
  - Develop a list of most important TYPES of issues where early detection can help prevent costly delays and re-work.
  - Examine what NCEA can do to trigger the early identification of issues.
- Progress is already being made in these Step 1 meetings; MORE IS POSSIBLE.

Early Detection of Issues at Step 1

Type of issue frequently raised in past by stakeholders	
1. Priority: Is assessment low priority?	
2. Enough to Proceed: Is there enough information?	
3. Missing Study: Literature review missed a study?	
4. Excluded Study: Did criteria exclude important study from evidence tables?	
5. Significance of effect: Effect questioned with regard to human health significance?	

Early Detection of Issues at Step 1

Type of issue frequently raised in past by stakeholders	More types of issues frequently raised by stakeholders
1. Priority: Is assessment low priority?	6. MOA: Should assessment be significantly influenced by MOA?
2. Enough to Proceed: Is there enough information?	7. Strengths and Weaknesses: What factors of particular studies need to be weighed in assessment
3. Missing Study: Literature review missed a study?	8. Key studies: Has NCEA identified these? Should they, and are they correct?
4. Excluded Study: Did criteria exclude important study from evidence tables?	9. Interpretation: Other interpretation disagreements
5. Significance of effect: Effect questioned with regard to human health significance?	10. Needed research: Has gap-filling research been identified?

3. How Achieve more Efficient Communication with Stakeholders

One suggestion: Use the web more

- As we all gain experience, more and more of these preliminary discussions can take place interactively on the web, making these in-person meetings even more effective and efficient.
- Use the web to communicate with stakeholders, thereby reducing stakeholders' uncertainties and helping everyone get ready for "next steps" for each chemical.

What information would be useful for a chemical-specific webpage: Page 1

1. Name of chemical and Docket #
2. Page updated last on [date]
3. IRIS Assessment Manager: [contact info]
4. Status:

Date	Status
9/03/14	Example: Draft assessment released for public comment
	NOTE: Older entries should be retained here to show history

What information would be useful for each IRIS chemical: Page 2

5. Next Expected Major Milestone [estimated calendar quarter if known]
6. Problem statement [why NCEA is giving this chemical assessment priority]
7. Health and other endpoints planned to be addressed in the assessment [e.g. cancer, neurotox, developmental, ecological]

What information would be useful for each IRIS chemical: Page 3

8. Significant non-routine scientific issues planned to be addressed in this assessment [e.g. “relevance of dermal exposure”, “biological significance of thyroid hormone level changes.”]
9. Significant and possibly relevant on-going research known to NCEA [e.g. research identified in “stopping rule” research plan.]

What information would be useful for each IRIS chemical: Page 4

10. Key past milestones [dates and links. For example, holding of problem formulation meeting.]
11. Key documents to date [with links]
    - Report from Problem Formulation Meeting
    - Literature Search and search criteria
    - Latest evidence tables (current as of [date])
    - Graphical display of studies

What information would be useful for each IRIS chemical: Page 5

11. Key Documents—continued
    - Comments of Federal agencies on draft assessment (together with draft assessment)
    - Draft assessment and draft charge questions released for public comment
    - Public comments on draft assessment and charge questions.
    - Final charge questions and final draft assessment sent to peer review panel.

What information would be useful for each IRIS chemical: Page 6

11. Key documents—continued
    - Report of the Peer Review Panel
    - Agency response to peer review and public comments.
    - Comments of Federal agencies on final draft assessment
    - Final assessment [link] and key findings of the assessment [cancer classification, unit risk, RfD, RfC, etc.]
12. Ability for stakeholder to be notified of changes on this specific webpage.

4. Whose Meetings are these, anyway?

- These bi-monthly meetings still have a "command and control" feel to them—a one-sided EPA meeting.
  - Should it be just an EPA meeting? or
  - Should it be a JOINT EPA/stakeholder meeting?
- EPA obviously needs to bring considerable material to the table, but early detection of issues is a two-way street…..

Whose meeting?

- Could stakeholders play a larger role?
  - How about an agreement on what stakeholders need to bring to the table for a particular meeting?
  - Joint Agenda
    - Solicit/research issues and put them on agenda
    - Get rid of the 5 minute rule
    - Leave plenty of time for general issues
- A pre-meeting planning session makes sense for efficiency reasons.

Summary

1. Thanks for the progress being made.
2. More joint analysis is needed on methods of early detection of issues
3. The web offers opportunities for more and better communication
4. Let’s make Step 1 meetings a joint affair.