Message

From: Guyton, Kate [Guyton.Kate@epa.gov]
Sent: 7/8/2013 6:33:53 PM
To: Guyton, Kate [Guyton.Kate@epa.gov]; Caldwell, Jane [Caldwell.Jane@epa.gov]; Chiu, Arthur [Chiu.Arthur@epa.gov]; Chiu, Weihsueh [Chiu.Weihsueh@epa.gov]; Fritz, Jason [Fritz.Jason@epa.gov]; Gibbons, Catherine [Gibbons.Catherine@epa.gov]; Gwinn, Maureen [gwinn.maureen@epa.gov]; Keshava, Channa [Keshava.Channa@epa.gov]; Keshava, Nagalakshmi [Keshava.Nagu@epa.gov]; Lambert, Jason [Lambert.Jason@epa.gov]; Lee, Janice [Lee.JaniceS@epa.gov]; Petersen, Dan [Petersen.Dan@epa.gov]; Pratt, Margaret [pratt.margaret@epa.gov]; Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]; Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]
Subject: RE: July 2 meeting summary and formaldehyde files
Attachments: Substantive Comments by Issue Cancer & NonCancer MOA.docx; Chapter 3 Formaldehyde Prepub-MOA Issues.doc; example review.docx

Hi everyone,

Hope you all had an excellent 4th of July "weekend"! ☺ Here are a few more clarifications on our formaldehyde review assignments.

First, many thanks to Sury for preparing the appended excerpt of NRC comments relevant to the MOA discussions that we will be reviewing. These may be of help re: question #4 below.

Second, I thought we had an excellent discussion at Vince's IRIS meeting last Wednesday about the workgroups. Let me emphasize that Ravi, Weihsueh and I remain very open to your feedback. We see this as very much a team effort and want to be as inclusive as possible. Several of you have very little (ie 10%) of your FTE allocated to this task; with the bulk of your attention focused elsewhere, we will count on you folks informing us when you CAN participate in our activities. All others, please let us know when you CANNOT. This will help us plan our work, AND communicate to your managers on your level of effort: ie, Kate read all sections assigned to the group; she ate some chocolate at the group meeting, and made several interesting comments; OR Kate couldn't attend the meeting due to a conflict, but she read the materials and gave comments on the final review....OR Ravi was away during the assignment and we all missed him. ☺

Third, some suggestions on format. For our current assignment, I'd suggest:
1) Everyone spend 2-3 hrs reading the assigned sections (lead reviewers should focus on their sections first, and move to others only as time permits)
2) Be prepared to discuss an outline of the answers to the below key questions—ie,
a. yes/no;
b. if not, why not (all of it, or which section needs the most attention?), listing in order of relative importance (ie, major then minor)
c. for each, provide a specific suggestion on how can it be improved?

In case it may be helpful, I've appended an example (note some key details have been changed to protect the innocent/guilty) of the review format I usually use for manuscripts, reports, (and yes!) assessments. In brief, it covers 3-5 major issues; then 3-5 minor ones; then lists typos noted in review. 2-3 pages in total, with specific suggestions for revision.

Thanks, all!
Kate

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From: Guyton, Kate
Sent: Tuesday, July 02, 2013 5:36 PM
To: Caldwell, Jane; Chiu, Arthur; Chiu, Weihsueh; Fritz, Jason; Gibbons, Catherine; Gwinn, Maureen; Keshava, Channa; Keshava, Nagalakshmi; Lambert, Jason; Lee, Janice; Petersen, Dan; Pratt, Margaret; Subramaniam, Ravi; Vulimiri, Suryanarayana
Subject: July 2 meeting summary and formaldehyde files

Hi everyone!

Welcome to the Tox Pathways Workgroup! Thanks to everyone who was able to join the meeting today. Following is a summary of our meeting and action items, do let me know of any needed corrections. I will be scheduling meetings for next week and the week after and look forward to working with you all on our immediate task, the review of the formaldehyde assessment… and beyond!

1. Review of formaldehyde assessment.
A. Scope of review

Our comments are due in 2-3 weeks, thus we will focus on priority areas for comment/revision within and across each section. The review will focus on:

1. Are the sections you reviewed clear, convincing, and objective?
2. Are the conclusions supported by the evidence presented?
3. Are the science issues addressed effectively, with alternative perspectives discussed where appropriate?
4. Are the issues raised by the NRC review of April 2011 addressed effectively?

You need not review the original literature. Begin with the evidence tables and see whether the synthesis follows logically and clearly. If not, that is a comment to take up within the Workgroup.

Also ALL edits to the text should be in Comment Bubbles—instead of extensive track-changes in the files, providing editorial comments in comment bubbles will be more helpful for revisions because the document is not static at this point.

See additional notes in Excel file.

The NRC report is here, let me know if you'd like a copy emailed **Ex. 6 Personal Privacy (PP)**

B. Assignments

Lead reviewers: we nominate lead reviewers for our sections as follows (congratulations!!):
- MOA discussion for NPC: **Jason Fritz**
- MOA discussion for LHP and other cancers: **Jane Caldwell**
- Susceptible Populations and ADAF (1.4.3 and 2.2.4): **Janice Lee**
- Review of Genotoxicity - Appendix B.5: this will be handled separately by the genetox subgroup

Activities:
- **Everyone (this includes you!)** should read all relevant sections and be prepared to discuss.
- **Lead reviewers (Jason F, Jane, Janice)** will send to me next week a bulleted list/outline covering up to 3-4 "key" review topics for each of the four review questions. The objective at this stage is to identify key issues for more focused effort. I will circulate to the team for comment, and we will have a group discussion of these late next week.
- Thereafter, **lead reviewers (Jason F, Jane, Janice)** will provide me detailed comments (either in text or with "comment bubbles", note that in-line edits are strictly forbidden to facilitate document merge). I will circulate these for group review. We will discuss the week of July 15, and the leads will finalize by July 19/22.

- **Sury and Kate** will circulate a list of NRC comments relevant to the MOA sections.

2. Operation of workgroup

- Ravi and Kate are your co-chairs. We will work together closely and will cover for each other during absences. We welcome your feedback, and aim to provide opportunities for everyone within the group. You may also contact our management lead (Weihsueh) or provide an anonymous comment to Vince at

Ex. 6 Personal Privacy (PP)

- Please attend all workgroup meetings; I will send minutes out after each. If you are unable to attend due to a conflicting meeting or scheduled leave, feel free to contact me/Ravi and we will bring you up to speed.
- Overall, our group will advance development of mechanistic sections across assessments. Initially, we will be in review mode. Formaldehyde will occupy us during the next few weeks. We will then review the pipeline of assessments for review/drafting.
- We value your contributions to the workgroup, and are happy to provide feedback to your managers. Any issues/concerns, do let me know.

Thanks everyone!
Kate

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