

Compilation of SAB Member Comments for September 5, 2007 Telecon

1. Homeland Security Advisory Committee Letter on ECAT and MRA Consultation:

a) Lead Reviewers

i) Dr. Jill Lipoti:

A consultation does not require consensus from the committee, so much of the advice to the Agency is provided by individual members of the committee. In order to get a sense of the discussion which took place, I looked at the minutes of the HSAC meeting. The minutes were word-for-word what was in the letter to the administrator, but attached to them was individual advice from each of the committee members, which appeared to have been assembled after the conclusion of the meeting. I compared the advice from each of the members to what was written as the summary to make sure that the important points were raised.

Emergency Consequence Assessment Tool (ECAT)

- Many shortcomings of ECAT are pointed out in these comments. So many shortcomings were enumerated, I wondered if it was worth the time of the agency to correct the problems. It certainly didn't seem to support the sentence in the letter that "the HSAC was very impressed by the hard and thoughtful work done by the Agency's scientists." Perhaps this could be omitted.
- In #3, the committee might consider adding that ECAT does not include guidance on determining the safety perimeter for people to be evacuated. If it does not have clear criteria for taking protective actions, it will not be useful for even the second phase responders. (See comments from Dr. Watson.)
- The addition of a decision rules (discussed in #4) should be further emphasized, including some sort of diagnostic approach (as suggested by Dr. Parkin).
- The value of ECAT may be only as a training tool, and as a way to get discussion going among second phase responders so that they can plan for a coordinated approach. This was in #1, and was emphasized in the comments by Dr. Walsh, who also said that ECAT should be released promptly so that it would not be dropped onto responders for the first time in the heat of a real emergency. From the comments, it appears that ECAT is too unwieldy to be useful if first encountered during a stressful response situation. This piece of advice is not in the letter. As a practical matter, I also thought that Dr. Walsh's suggestion for an "ECAT-lite" for download to

responders' laptops was appealing. Dr. Zimmerman's comments also support that idea.

- The risk communication theme was supported and elaborated in several commenters' remarks. The letter reflects all of their points.

Incident-based Microbial Risk Assessment Framework

- In #3, there is a recommendation that EPA must consider local roles and objectives. This statement does not really capture the comment by Dr. Bellamy that the framework should define the roles of all responsible agencies, including how CDC might be expected to interact with EPA. This should be included.
- Most of the commenters mentioned the importance of developing data on background levels of biological contaminants, and the eventual determination of "how clean is clean?" This was adequately covered in #6. Without this determination, it seems that the MRAF is of limited usefulness. The comments by Royal Nadeau were particularly depressing. It would lead to the question about whether EPA should continue to put money and time into further development of MRAF or concentrate on other research.

ii) Dr. Michael McFarland:

Emergency Consequence Assessment Tool (ECAT) and Incident-based Microbial Risk Assessment Framework - Quality Review

On the whole, the SAB panel (Panel) is commended for providing a clear, logical and well written draft letter report highlighting the salient findings and recommendations from its consultative review of the EPA's Emergency Consequence Assessment Tool (ECAT) and Incident-based Microbial Risk Assessment (MRA) Framework. Given its potential to address the large uncertainties associated with effectively managing civilian responses to chemical and/or biological agent releases, the Panel's overarching recommendation that the Agency establish a scientifically-defensible risk communication research program is strongly supported.

In the case of a willful and/or inadvertent release of a chemical or biological agent, ensuring the effective and timely diffusion of relevant and accurate information to the appropriate incident management personnel and other key decision-makers is vital if the adverse impact to public health and the environment is to be minimized. Moreover, a well established risk communication research program will enable the Agency to effectively identify, prioritize and systematically address the myriad of uncertainties associated with emergency response and crisis management information flow including characterizing how such information informs and influences the actions of key decision-makers. In the absence of such

a program, the Agency will continued to face a formidable challenge in meeting its national security mission requirements including those specified under Homeland Security Presidential Directives 7, 9, and 10.

The following section summarizes the responses to the specific SAB quality review charge questions.

- Were the original charge questions adequately addressed in the draft report?

With regard to ECAT, the Agency submitted nine (9) multiple-part charge questions many of which had overlapping themes. The Panel provided clear and sufficient responses to each of these charge questions focusing on both the advantages and limitations of ECAT in meeting the operational and decision-making needs of the various potential users (e.g., risk assessors/health advisors, on scene responders and risk managers/decision-makers).

The Agency posed twelve (12) multi-part charge questions to the Panel with respect to the Incident-based Microbial Risk Assessment (MRA) framework whitepaper. In general, the Panel was disappointed with the level of oversimplification and general lack of risk assessment specificity furnished in the MRA framework whitepaper. The Panel concluded that, until the white paper had been sufficiently revised to include greater scientific detail, it would be premature to provide comment on the specific charge questions.

In the draft letter report, the Panel highlighted many of the scientific deficiencies encountered in the MRA framework. To its credit, the Panel acknowledged that the MRA framework is an important first step in providing public health and emergency management decision-makers with the necessary tools for characterizing the potential threat associated with a biological agent release and offered its assistance in conducting a future scientific review when a more fully developed MRA methodology were made available.

- Is the draft report clear and logical?

The Panel's draft letter report is clear and logical. The Panel provides compelling public health arguments for the need to establish a scientifically rigorous risk communication program to ensure that the output from ECAT, MRA framework or any other threat evaluation tool fully supports the needs of its intended users.

- Are the conclusions drawn and recommendations made supported by information found in the body of the draft report?

The Panel's conclusions and recommendations pertaining to both the ECAT and MRA framework are summarized in the draft letter report. The Panel provides clear and unambiguous advice to the Agency with respect to the utility of ECAT and MRA framework in their present versions as well as identifies and outlines specific opportunities for their future refinement.

iii) **Dr. Tom Theis:**

The HSAC has made several important suggestions to the Agency regarding the further development of the Emergency Consequence Assessment Tool (ECAT) and the Incident-based Microbial Risk Assessment Framework (IMRAF). Particularly relevant are the suggestions to apply ECAT to, first, threat scenarios and, subsequently, to actual events as a means of gaining experience with its use, acquiring knowledge on its parameterization, understanding its limitations, and assessing its overall robustness. Likewise HSAC has offered useful guidance on the further development of IMRAF, particularly the need to incorporate a more realistic approach to crisis management.

These suggestions and thoughts are very important, and seem to represent the major output of the Committee. They are contained in the transmittal letter to the Administrator. Since this was a "consultation", the only other record of Committee deliberations are the meeting notes (i.e. there is no formal report), thus the letter's content and tone are a critically important part of the review process. In this regard, several suggestions are made for improving its clarity and usefulness:

- It is difficult to determine if the charge to the Committee has been adequately addressed because the transmittal letter is organized not by charge question or topic, but rather by Committee suggestions for improvement. As stated, while these suggestions are important, it would seem that all or portions of ECAT charge questions 2, 3, 4, 5, 7, and 8 have not been answered. Perhaps the Committee suggestions could be incorporated into more direct answers to the ECAT charge. If, as seems likely, the Committee found itself unable to respond to the charge questions because ECAT is insufficiently developed then it might be best to state this as a major conclusion to which the Committee's suggestions are directed.
- The Agency's approach to ECAT stresses "simplicity" and "screening" level capabilities (a frequently-used term that the Agency has not consistently defined). The Committee's responses stress scientific complexity and specificity of applications (actually the word

“specific” is used 12 times in the letter of transmittal—nine in one paragraph). Yet the charge for both ECAT and IMRAF consists for the most part of very specific questions. There would seem to be a mismatch among the level of sophistication of the tool and framework, the detail of the charges, and the expectations of the Committee. My experience is that this is a fairly common occurrence, but that it is best to *not* hide this through indirect or non-responses to the charge.

- Similarly, the Agency charge for IMRAF consists of twelve rather specific questions, only one of which (charge #4 under “uncertainties”) is answered (letter p.4 #5). Again, it appears that the Committee has found that the original charge is for the most part not answerable given the information provided.
- The Committee may wish to refer, and perhaps request that the Agency incorporate, the latest thinking on emergency response as outlined in DHS’s National Response Plan as part of ECAT and IMRAF.
- The letter suffers somewhat from confusing word usage. Item #5 (page 2) refers to “domains” and “areas”, but it is not clear what these mean (e.g. “area” could mean the same as domain in the context of “uses” or “users”, but might also refer to different types of scenarios, cases, or submodels/modules). The terminology “MRA” (I realize EPA has coined this, not the Committee) as an acronym is redundant with the Agency’s 3MRA modeling system (I don’t know if there is an Agency “acronym policeman”, and some duplication is probably inevitable, but if only for helping search for things on the EPA website acronym uniqueness should be encouraged).
- Since the Letter of Transmittal is the main form of communication for this consultation, it is to be expected that it will be a little longer than most SAB letters to the Administrator. Still, there are two parts (page 1, first paragraph, lines 5-10), and page 4 “General Comments” and following) that have little to do with answering the charge. While it is traditional in these letters to offer justified praise to the Agency and staff involved in the review (as is done on page 1, lines 12-14), for the Committee to draw attention to itself in this manner seems unnecessary and self-serving. In this case these passages also add 20 lines to the text.

b) Other SAB members

i) **Dr. Rogene Henderson:**

➤ **The Emergency Consequence Assessment Tool**

The letter is clear and logical. The comments provided do not go down the list of charge questions, providing specific answers, but rather take into account the broad overall approach and offer relevant advice to aid the Agency in taking the next steps to

improve their ECAT. I found this more helpful than if the group had only answered the specific charge questions given.

➤ **Incident-based Microbial Risk Assessment Framework**

The development of a microbial risk assessment framework is a difficult task, as is well described in the Charge to the SAB Panel. The specific charge questions, which are broad and general, reflect the quandary the Agency faces in trying to develop such a framework. The draft letter report indicates that the white paper also “covers broad topics in very general style.” This apparently limited the panel’s ability to provide advice on many specific methodological issues. However the panel was able to provide sound, reasonable advice in some areas in response to the charge questions. So I would say the response was reasonable and logical and as complete as could be expected at this early stage in the development of the framework.

➤ **General Comments**

General Comments: I thought it was most appropriate to emphasize that the HSAC was available for advising the NHSRC in more detail if better feedback mechanisms and more frequent consultations could be established.

ii) **Dr. James Galloway:**

Since there is no report that goes along with the letter, I suggest the following.

- The letter be greatly decreased in length and focus on the top 2-4 recommendations total for the ECAT and Microbial Risk portions.
- an appendix to the letter be added that gives specific answers to each of the questions that the SAB was asked to comment upon.

iii) **Dr. Valerie Thomas:**

The letter to the Administrator is clear and helpful and addresses significant points. The letter does not address the charge questions for either ECAT or MRA; it addresses larger, overarching points. I have no problems with this approach.

iv) **Dr. James Bus:**

Consultation on ECAT

The Letter identifies seven general observations regarding the ECAT prototype which do not directly correlate with nine charge questions posed to the SAB panel. As such, the Letter is difficult to interpret regarding the

Panel's actual perspectives on the value of the prototype to its intended audiences, and the appropriateness of the science and data underpinning the prototype development. The Letter should consider restructuring its responses to more directly mirror the charge questions rather than leaving the reader to indirectly infer primary conclusions and recommendations. Examples of this potential lack of clarity are described below.

- Item 1: Although this item clearly identifies likely target audiences for ECAT, the statement ECAT has “particular promise as a training tool” infers that the SAB does not have confidence in its use as primary tool for advising field responses to real-world events, i.e., is SAB meaning to say that the target audiences should only rely on ECAT for scenario training and not actual field decisions? Thus the consultation lacks a clear bottom-line statement regarding the SAB's position on the value and feasibility of ECAT implementation.
- Item 2: The Letter advises developing only one to two threat scenarios, thus inferring ECAT is potentially a long way from being prepared to address its intended all-hazard scope. This recommendation also infers a lack of confidence that the all-hazard approach of the prototype lacks necessary scientific support, and that significant research and development effort remains before ECAT should be considered for release (even if limited to 1-2 scenarios).
- Items 3 and 4: The recommendation to evaluate ECAT outputs against actual events infers the SAB lacks confidence that ECAT outputs will provide effective advice to emergency scenarios.
- Items 6-7: The SAB has clearly and appropriately emphasized the need for an effective dissemination plan for ECAT which must contain a rigorous consideration of the implications of public communications flowing from ECAT evaluations.

Consultation on Incident-based Microbial Risk Assessment

All of the items appear to suggest the Whitepaper falls significantly short of providing an appropriate framework for responding to microbial contamination events. If this is so, the Letter should contain a bottom-line opening statement to that end, which is supported by text provided in Items 1-7.

c) **Dr. Steven Roberts:**

Unless I missed something, the product of the HSAC efforts is simply the letter to the Administrator. While I have no criticism of the points raised in the letter, they do not appear to address (or address incompletely) the charge questions posed to the committee. [Note: A similar issue came up in review of a consultation at the last SAB meeting.]

d) **Dr. Meryl Karol:**

This is a well organized response to the ECAT and MRA. My only suggestion is to clarify the response to item 1 (P. 2) by modifying the final sentence as follows: *However, because the EPA is not the lead responder in the first 24 hr, its use by first responders in the initial hours of an emergency would not be feasible.*

e) **Dr Kathleen Segerson:**

ECAT/MRA letter to Administrator:

- The tone at the beginning and end of the letter is unusual for a letter to the Administrator (at least the ones I've seen). The end of the first paragraph seems to include some self-praise. Although this praise is well-deserved, I'm not sure why it is included in this letter. Why does the committee feel compelled to point out to the Administrator that it is well-qualified and committed? The fact that the letter also ends with some discussion about the committee's qualifications and role leaves the reader with the impression that perhaps there is some underlying tension between the committee and the Agency regarding this. If the committee is unhappy with the extent to which EPA has sought its advice, there may be better or more appropriate ways to express this. If not, then it is unclear why the letter begins and ends with statements about the committee's expertise and role.
- The comments in the letter regarding ECAT are very general, while the charge questions from EPA were quite specific. The general impression one gets from the letter is that EPA needs to be asking "big questions" about ECAT and its usefulness, while the charge questions seem focused on specific details of the tool. If the committee is, in fact, concerned about the usefulness of EPA's current effort and the direction it is taking, then perhaps that should be stated more explicitly in the letter.

2. Radiation Advisory Committee Advisory on BEIR VII White Paper

a) Lead Reviewers

i) **Dr. Lauren Zeise:**

The report is very well written and succinctly addresses the charge questions. A few mostly minor issues that surfaced in my review of the report are discussed below. This is followed with some comments and suggestions that are editorial in nature.

Page 20, bottom; page 2, line 23 The statement that non-melanoma skin cancers should not be included in total mortality estimates because it is

inappropriate seems unnecessary. The low mortality of skin BCC means that it will not be a large contributor. The EPA's decision to leave out skin squamous cell carcinoma (SCC) is not explicitly addressed on page 20 by the RAC. It should be since this cancer is not without individual or social cost - Removal can cause significant cosmetic deformity and requires short term and continuing follow-up because of potential metastasis. A clear comment agreeing or disagreeing with the proposal to leave SCC out could be given.

Page 9, uncertainty discussion. The description of figure 10-1 in BEIR VII is a bit off. The figure shows the slope at high doses and then the slope in the low dose region explicitly stating that it is the tangent at zero, not the "progression of linear approximations" stated at line 24 in the RAC report.

Page 12, lines 37-41. "The RAC's approach to giving advice to the EPA is predicated on the basic premise that risk estimates are for use in assessing population risk, rather than risk to a specific individual." EPA in some risk and decision making contexts does consider subgroups at higher risk and it is unclear why this restriction is needed. The general response to charge question 2a regarding stationary populations would work if EPA decided to address a subgroup. EPA has recently adopted a policy for addressing potential increased cancer risk from exposure at young ages in its 2005 *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*. The RAC also states that there is little known about the degree or causes of variation in individual susceptibility. In contrast, the 1998 International Commission on Radiological Protection (ICRP) report *Genetic Susceptibility to Cancer* selected a single best estimate of a 10-fold increase in risk as "appropriate for the purposes of modelling radiological impact" after reviewing human and animal data.

Page 15, lines 1-12. The logic of model geometric averaging was not entirely clear. An alternative for the agency would be to use the plausible models to articulate model uncertainty and then given the uncertainty to select a default. It is also unclear how the averaging enables risk from chronic lifetime exposure if the component models do not (line 12).

Page 24, top. Supralinearity associated with dose fractionation is also seen in animal studies with alpha radiation and could be noted.

Page 2 and page 25. If the new review is going to cover important new data on radiogenic thyroid cancer this should be noted.

In the appendix discussion, the findings of the large collaborative Cardis et al. study showing increased cancer risk in occupational workers at exposures within an order of magnitude of natural background is worth

mentioning in the appendix. In this regard, the discussion called for on page 4 at line 20 perhaps might also take this into account.

Editorial Comments

Letter

The letter to the administrator is well written and is a good summary of the RAC report. However, it includes a lot of detail and could be shortened considerably.

Page 1 line 20 could delete “radiogenic” to remove redundancy
Page 2, line 16 bone is capitalized while other bullet headers aren’t

Page 3 line 29 LSS has not been defined in the letter

Report

Page 8, lines 7-9. Whether or not the factor 2 DDREF applied both to low and high LET radiation should be specified.

Page 8, lines 13-24. BEIR VII focused on low-LET radiation. This should be noted here to provide context for the discussion a little later in this section

Page 9, line 28. word “mandate” is awkward here

Page 22, line 25 would add “major” after “all” since that is an impossible task

b) Other SAB members

➤ **Dr. Rogene Henderson:**

I found this to be an exceptionally fine report on an important topic. The Agency should benefit greatly from the review by RAC. All of the charge questions were answered in a clear, logical, and reasonable manner. The conclusions and recommendations were supported by the text. I found it especially worthwhile to include Appendix A, because of the current controversy and the influx of new information concerning the shape of the dose/response curve at low doses.

➤ **Dr. Granger Morgan:**

Looks fine.

- One page 3 start of line 28, there is an extra "in"
- Page 4 lines 5-7 are unclear. Some editing would help.
- Page 4 line 10 I'd drop the "In addition,"
- Page 4 line 32 I'd prefer to drop "(qualitative)"

➤ **Dr. Rebecca Parkin:**

Here are my responses re. the white paper reviewed by the RAC.

Cf. SAB charge questions:

- The committee has addressed the charge questions in a systematic and thoughtful manner.
- The report is clear, logical and well-written.
- The conclusions in the report are largely supported by information provided in the report. While the committee members likely know the literature very well, many readers will not. Therefore, this reviewer suggests that some uses of citations be clarified. For example, clarify in the report that Karagas et al (1999) on p. 3 was a study of New Hampshire cancer rates, and not the entire U.S. Without that specification, the reader is not aware that Karagas et al only speculated that their NH findings might apply elsewhere.

➤ **Dr. James Galloway**

- The only comment I have on the 'advisory' is that the committee has done a fine job.

➤ **Dr. Michael McFarland:**

In general, the Radiation Advisory Committee (Committee) provided a comprehensive and well written advisory draft report summarizing their evaluation of the Agency's intention of basing its future estimates of low dose radiogenic cancer risk on recommendations found in BEIR VII. The Committee's responses to the four (4) multipart Agency charge questions were clear, scientifically sound and logical. The report's conclusions and recommendations summarized in the letter to the administrator were strongly supported by the scientific findings described in the Executive Summary as well as in the body of the report.

Although I have a limited knowledge of radiation terminology, in my opinion, it may have been difficult for the uninitiated reader to follow some of the report's discussion. To alleviate some of this difficulty, I would strongly recommend that all acronyms be spelled out fully when they are first used in the report. For example, the acronym BEIR (Biological Effects of Ionizing Radiation) should have been defined early in the report (in addition to Page 37 – List of Acronyms). Other critical terms whose

definitions were necessary for following the scientific discussion, e.g., Sv (Sievert), RBE (Relative Biological Effectiveness) etc. should have been defined earlier in the report as well.

In addition, it may have been helpful to readers if there had been some historical discussion of the fact that BEIR VII is a National Academy of Sciences (NAS) report on radiation risk (issued in July 2005). It may also have been helpful to acknowledge that the NAS BEIR series of reports are the most authoritative basis for radiation risk estimation and radiation protection regulations in the United States (according to the Institute for Energy and Environmental Research). Again, for the uninitiated reader, these facts may be important.

Finally, pending minor editorial revisions, I believe that the advisory report fully addresses the Agency charge questions and provides scientifically-defensible conclusions and recommendations. Given the report's exceptional quality, I strongly support its approval.

➤ **Dr. Valerie Thomas:**

The Draft Report does respond to the charge questions.

➤ The report is not clear in its discussions of low-dose risk estimation. It is evident that the Committee has discussed this issue at length and has put considerable thought to crafting its statements. However, by repeating three times – in the letter to the Administrator, the Executive Summary, and the body of the Report, the discussion that begins: “RAC had to consider the important distinction between the current state of scientific knowledge and the need for a practical, operational public health approach...”, the report makes this a central focus. The implication of this discussion, and of the material in the appendix, is that the science used in BIER VII for low dose exposures is weak, but the SAB nevertheless endorses its continued use for a short period of time. The impression is that this was a borderline decision, that the RAC could just as well have decided to promote a different approach to low dose risk assessment. The report is equivocal. It seems that the science is not clear, and the report is correspondingly unclear. This issue is important enough for the Committee to emphasize it multiple times, yet not important enough for the Committee to recommend that EPA change its approach. If this issue is not of central importance, it should not be emphasized so much; if it

is of central importance, then it is not clear why the Committee endorses EPA's continuing approach.

- The draft report repeatedly says, in effect, that the state of scientific knowledge can't or shouldn't be applied in a practical, operational approach to public health. These statements may cause continuing questions and difficulties in understanding what SAB is trying to say.
- There are also a number of minor respects in which the report is not clear. The Letter to the Administrator largely repeats material in the Executive Summary, but leaves out key information that makes the Letter to the Administrator harder to understand than the Executive Summary. For example, on p. 1, the paragraph with "... the important distinction between the current state of scientific knowledge and the need for a practical, operational public health approach..." is especially hard to understand because the paragraph that follows from the Executive Summary was not included in the Letter, so the basis for the distinction between "science" and "practicality" is especially hard to grasp. Also, on p. 2 line 18, the acronym RBE is used before it is defined. The Letter to the Administrator need not be a repetition of the Executive Summary. A short letter could be better and clearer.
- There are a number of places in the Introduction (p. 6) in which it appears that the Agency has written the text, not the RAC. The independence of RAC from the Agency is not clear. For example, p. 6 line 38, "ORIA was interested in vetting ideas..." It would be better to say that ORIA asked for a review. On p. 7, in that same paragraph, is the statement "RAC was not asked to provide policy direction, and therefore RAC did not consider the implications to EPA standards..." Putting these statements together into one paragraph implies that EPA asked RAC not to consider the implications to EPA standards. Again, on p. 9., lines 11-18, there is text that appears to have been written by the Agency, not by RAC, "At this point... the EPA is seeking advice from the Agency's Science Advisory Board...the Agency plans to implement changes in their methodology..." I assume this text was lifted from the original charge to the committee; this needs to be changed because it implies that EPA wrote parts of the report. Again, p. 9 lines 31-32, "The EPA does not propose to quantify the uncertainty pertaining to low-dose extrapolation, but it would provide a brief discussion of the issue." Again, this appears to have been lifted from communication from EPA to SAB, and shouldn't be included in the report to the EPA.
- The discussion of DDREF is most clear in the appendix (p. 33 lines 21-22); there it is stated that the DDREF corrects for the

decreased biological effectiveness of low dose and dose-rate exposures. This clarification could be moved up to the first time the DDREF is mentioned (in the current version, that is in the Letter to the Administrator). Currently the Letter to the Administrator simply defines the DDREF as a ratio of slopes; the reason for different slopes at different doses isn't mentioned.

➤ **Dr. Steven Roberts:**

The RAC report is well written and clearly addresses the charge questions. The basis for conclusions and recommendations are reasonably clear. Other than correcting a few minor typographical errors, I have no suggestions for change.

➤ **Dr. Kathleen Segerson**

It is clear from the committee's report that the committee carefully considered and responded to the charge questions. My only comment on this is that the letter to the Administrator seems unnecessarily detailed. The main message of the letter seems to be that the committee endorses EPA's proposed modifications. It does not appear to have identified any major concerns. It seems that this message could (and should) be conveyed in a shorter, less technical letter to the Administrator. The technical summary of the committee's findings that is currently in the letter would perhaps be more appropriate for the executive summary.