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September 18, 2006

Larry Elliott
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Re: ORAU-OTIB-0052
Parameters to Consider When Processing Claims for Construction Trades Workers

Dear Larry:

Thank you for sharing OTIB 0052 with us. As mentioned in our call today, CPWR has performed a review of this document using a group of internal and external advisors. The group met by conference call for two hours on September 7. The group raised a number of questions concerning the documents which are included below. While the group provided the input that has been used to formulate this response, the group has not reviewed this response, and CPWR is solely responsible for the content of this response.

Also, OTIB 0052 relies on methods and data included in previous ORAU internal documents, DOE reports and unpublished DOE site reports, and we have not examined the validity of each of these. In light of the many questions we have raised below, we think it is important that the OCAS Advisory Board perform a detailed review of OTIB 0052 which also includes consideration of the supporting documentation.

COMMENTS ON THE TECHNICAL APPROACH

1. General Approach

1.1 Definitions

The lack of definitions makes it hard to review the document. Examples:

- Average dose; 50th percentile dose; mean dose

- External dose; external non-penetrating dose; external penetrating dose
- Internal dose

1.2 Underlying Assumptions

We were unable to ascertain the assumptions that NIOSH has incorporated into this analysis since they are not stated. As near as we can tell, the analyses that have been performed have had to assume at a minimum that:

- Unmonitored CTWs have the same work and exposure patterns as monitored workers.
- DOE sites with electronic radiation monitoring data bases are representative of sites without such data bases.
- Exposures recorded are representative of all exposures experienced by workers.
- Exposure data for both CTWs and AMWs are log normal.
- The recorded doses in electronic data bases are representative of doses recorded in paper records.
- Factors or conditions that lead to missed dose are the same for CTWs and AMWs.

How were these (and any other) assumptions justified?

2. **Concerns about Internal Validity**

2.1 Q-A on Data Sets Used

The analysis relied on electronic data bases even though references to problems in the data bases appear in several places in the document, e.g.:

- For Rocky Flats, workers with very high exposures were excluded because their data could reflect multiple samples being taken in a given year (p. 14);
- The Hanford data could be biased as a result of a high percentage of special bioassay samples being included in some years (p. 29).

It does not appear that any quality assurance validation of these data sets was performed. It would be useful for the authors to include more detail on the data sets used and an analysis of their strengths and limitations based on an audit against paper records. This was an important recommendation from the joint CPWR/NIOSH July 27, 2005 meeting. For instance,

- The combined data set used in Table 5-1 shows exposures all the way back to 1943 even though the site-specific data bases seem to start around 1953. Where did the data for the first 10 years of operation (1943-53) come from?
- K-25 data were used even though K-25 is an SEC site, which presumably means that its dose data are not reliable. How was it determined that the K-25 data are valid?
- SRS data are based on the HPAREH data base. The report implies that HPAREH includes all monitoring records from 1953-1999. And, as far as we know, the HPAREH data base from SRS covers only monitored doses for workers employed on January 1, 1979 or thereafter; therefore, any recorded dose for any worker who left employment before 1979 is

not included. This could dilute average dose for the years prior to 1979 significantly—the more so the farther back one goes. Dr. John Dement matched a cohort of approximately 3,000 workers from the SRS Building Trades Former Worker Medical Screening Program to HPAREH. He found that a large number of CTWs in monitored jobs were not in the data base, even workers employed after 1979. Were such factors considered in the analyses?

- In the Rocky Flats data set (and possibly also other data sets) the data for CTWs were grouped into multi-year bundles in order to get statistical significance; yet they were compared to annual average dose for AMWs. Did this affect the findings?
- The Hanford data do not appear to have come from a single data set, but rather many different sources, including “1960-73, various Hanford letter reports; 1975-1990, DOE annual dose reports; 1991-2005, DOE REMS data base.” How much confidence can be placed in these various sources?

2.2 Missing Doses

Reliance on external radiation dose and only PU internal dose could lead to an understatement of dose. For instance, this analysis does not appear to consider tritium dose, or alpha emitters, at least in the early years. How did the analyses adjust for such missing dose?

2.3 Reliance on Crude Data

It appears that average annual dose was derived by adding up all recorded doses for CTWs and dividing them by the total number of CTWs with a recorded dose, and then doing the same for AMWs. This could dilute the CTW/AMW dose ratio, since CTWs are often employed for short-term assignments, while AMWs are mostly permanent employees. Was that considered in these analyses?

2.4 Adjustment Factors

The document does not describe the method used to derive at the adjustment factors. Please explain.

2.5 Other Analysis

The following analyses included only 20th and 85 percentile results. The 85 percentile on a log normal scale is only one standard deviation from the mean. Please explain why the 95th percentile results were not included in the following analyses:

- ORNL internal dose (plutonium and uranium)
- Hanford penetrating dose
- Hanford Pu-39 results.

3. External Validity

The document states that five DOE sites (Rocky Flats, Savannah River and three Oak Ridge facilities: Y-12, K-25, and Oak Ridge National Laboratory) were selected for the initial analysis "to represent the DOE complex as a whole." How did NIOSH reach this finding?

As mentioned earlier, K-25 is included even though it is an SEC site, presumably included in the SEC because of a determination that radiation monitoring data are deficient. Please explain the rationale for including K-25.

Subsequently, two additional sites were added: INL and Hanford. The document does not state why these were included, and why others were not. Please explain.

4. Findings and Conclusions

- a. Based on the lack of uniformity in findings between the DOE sites included in the analysis, it is difficult to determine how NIOSH was able to conclude that findings from them are representative for those sites not included. From these data, the variability in the CTW/AMW ratio between sites appears to be very high. Please explain.
- b. Given the great variability between sites, how can findings from one composite data set (as presented in Fig 5-1) be applied with confidence to individual sites?
- c. The general conclusion that CTW doses are bounded by AMW doses does not appear to be valid. If we exclude K-25, then CTW doses were bounded at three sites (SRS, Rocky Flats, and Y-12) but not at three other sites (ORNL, INL, Hanford.) Please explain how this conclusion was reached.
- d. Given that almost all of these data sets do not appear to contain data from before 1953, how can the conclusions be valid for the period from 1943 to 1953?
- e. How did NIOSH derive at an external dose adjustment factor of 1.4?
- f. How did NIOSH derive at an internal dose adjustment factor of 2 for Hanford?

5. Limitations and Applications

- a. Penetrating dose: At least based on the ORNL data, a claimant favorable adjustment factor of 1.4 appears to be too low for the years after 1969. Is this correct?
- b. Non-penetrating dose: The guidance not to make any adjustments for non-penetrating dose appears to be based only on data from SRS and Rocky Flats. It does not appear to be supported by the data from Rocky Flats, particularly after 1990. Please explain the rationale for this guidance.
- c. Internal dose:
 - a. Because of the great variability of CTW/AMW ratios between sites is there sufficient data to conclude that the only site where an adjustment should be made is Hanford?
 - b. For Hanford, how does NIOH justify its adjustment factor given that it did not perform an analysis for 95th percentile results?
 - c. For Hanford, how does NIOSH know that the adjustment factor is valid for the period before 1960 given that there were no available data?

6. Coordination with Other OTIBs

The document makes reference to OTIB 0020. It makes no reference to OTIB 0018. It is our understanding that OTIB 0052 is to correct deficiencies in OTIB 0018 for CTWs. Is this correct?

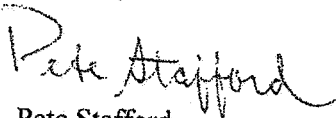
How do dose reconstructors know when they should rely on one OTIB or another?

7. Impact on CTW DRs Performed to Date

Is NIOSH planning to go back and examine the CTW DRs performed to date in light of the guidance in this DR? If so, what are procedures it plans to follow?

I look forward to hearing back from you.

Sincerely,



Pete Stafford
Executive Director