DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institute for Occupational
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November 30, 2006

Mr. Pete Stafford
Executive Director
The Center to Protect Workers' Rights
8484 Georgia Avenue, Suite 1000
Silver Spring, MD 20910

Dear Mr. Stafford:

Thank you for your letter of September 18th that provides your review comments on the new OCAS Technical Information Bulletin, OTIB-0052, *Parameters to Consider when Processing Claims for Construction trade Workers*. I apologize for the lateness of this response, but as usual, there have been a number of competing and conflicting demands for our resources. Please do not consider the delay in my response to be an indication of the priority that OCAS places on this issue. I assure you that NIOSH is committed to a full, timely, and public review of this important document.

As you probably are aware, NIOSH provided a briefing on OTIB-0052 to the Advisory Board on Radiation and Worker Health at their recent meeting in Las Vegas, Nevada. After some discussion, the Board requested that their support contractor, Sanford Cohen and Associates (SC&A) review OTIB-0052. Further, at their next meeting on October 17th, held via teleconference, the Board formed a new procedures review working group. During their discussion, it was suggested that the SC&A review of OTIB-0052 would likely be the first task that this new group would undertake. You should also know that the Advisory Board has been provided a copy of your letter and is aware of the issues of concern to CPWR. This being the case, the technical issues raised in your letter will be the subject of detailed discussion among NIOSH, the Advisory Board and SC&A. In accordance with past practice, these working group discussions will be open to the public with *verbatim* transcripts posted on our website. After OTIB-0052 has been thoroughly reviewed and discussed in this open forum, we believe that NIOSH will be better positioned to respond to the detailed technical issues raised in your letter.

While I would like to postpone our detailed response until after the deliberation of the technical issues by the Advisory Board, I would like to take this opportunity to respond to the more general issues raised in your letter. OCAS responses to these selected issues are provided in Attachment 1. The issues contained in your letter are reproduced in italics followed by our response in normal font.

I would like to again thank you for taking the time to review OTIB-0052. As this is an essential component of our process for reconstructing doses for unmonitored construction trades workers,

we take your comments very seriously. I also would like to stress our complete commitment to the Advisory Board's review of this document and commit that we will keep you informed of any scheduled meetings the working group holds. Further, once the review process is complete, OCAS will provide you a complete update on the status of the resolution of all review comments. Please feel free to contact me or Dr. Jim Neton of my staff at (513) 533-6825 if you have any additional comments or questions.

Sincerely,

Larry J. Elliott, MSPH, CIH
Director
Office of Compensation Analysis and Support

Attachments

cc: Dr. Paul Ziemer, Chair, ABRWH
Dr. Lew Wade

Attachment 1
OCAS Responses to General Issues Raised in the CPWR Letter
Dated September 18, 2006

Issue 1.1 – Definitions

The lack of definitions makes it hard to interpret the document.

We offer the following definitions for the examples provided by CPWR:

- Average Dose: Is the arithmetic mean of the doses
- Mean Dose: Is the arithmetic mean of the doses and is equal to the average dose
- 50th Percentile Dose: Dose corresponding to the rank of 50% (the middle value) in a given distribution of values
- External Dose: Dose resulting from radiation sources that are located outside the body
- External Non-penetrating Dose: Dose resulting from radiation sources that are located outside the body and that do not penetrate deeper than 0.007 centimeters in soft tissue
- External Penetrating Dose: Dose resulting from radiation sources that are located outside the body and that penetrate to a depth of 1 centimeter or more in soft tissue
- Internal Dose: Dose resulting from radiation sources located inside the body

Issue 2.4 - Adjustment Factors

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

The adjustment factor of 1.4 for external penetrating dose is the ratio of the penetrating dose for CTWs to the penetrating dose for All Monitored Workers (AMWs) when the ratio is greater than or equal to 1.2. As described in sections 4.2 and 7.1, this is the highest observed ratio for any of the penetrating doses in any of the datasets examined by OCAS.

For internal dose, the Hanford facility is the only site for which an adjustment factor was found to be necessary. That is, none of the internal bioassay results for CTWs in the other facility datasets examined by OCAS were found to exceed the values measured for AMWs. For Hanford, the adjustment factor is applied to the internal dose, based upon the comparisons of Pu-239 urinalysis results for the 50th and 84th percentiles between CTWs and AMWs, as shown in Figures 6-2 and 6-3.

Issue 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?

OCAS reviewed DOE activities to identify where a large number of Construction Trades Workers (CTWs) would be utilized that also had the potential for exposure to both internal and external radiations. These activities included uranium enrichment, fuel fabrication, fuel

processing, reactor operations and maintenance, waste processing, weapons component fabrication and testing, and research and development. The activities carried out at Rocky Flats, Savannah River Site, Y-12, K-25, and X-10 (Oak Ridge National Laboratory) encompassed all the selected DOE activities. These sites also utilized large numbers of CTWs who had a potential for exposure to both internal and external radiations. In addition, Hanford and INL are included in the analysis to represent the DOE complex as a whole, but are not included in Figure 5-1 because only the average doses are available as opposed to the 95th percentile.

Issue 4 – Findings and Conclusions

How did NIOSH derive at an external dose adjustment factor of 1.4?

Using the external monitoring data for the approximately 1.2 million individual results available to OCAS, the ratio of the annual pre-1961 doses for CTWs to that for AMWs was evaluated. The largest ratio for the three facilities evaluated was taken as the adjustment factor to be applied to all DOE sites for all years.

How did NIOSH derive at an internal dose adjustment factor of 2 for Hanford?

An adjustment factor of 2 for Hanford was the consensus of the internal dose reconstruction experts on the ORAU team. The average of the CTW/AMW plutonium-239 ratios was less than 1.5 for the years with available data for the 50th and 84th percentiles. The ratios only exceeded 2 for 8 of 112 possible quarters. Most of the CTW samples appeared to have been the result of incidents, rather than routine samples that would have provided results for typical rather than highly-exposed workers. Since CTWs could only be separated from AMWs for a limited number of years, the conservative value of 2 was deemed appropriate for Hanford.

Issue 6 – Coordination with Other OTIB

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?

The purpose of OTIB-0052 is to provide guidance for performing internal and external dose reconstructions for unmonitored CTWs. It is not intended to correct any deficiencies in other OTIBs.

OTIB-0018 is a generic overestimating technique that is not appropriate for application to individuals who should have been monitored (i.e., had a significant potential for intakes) but have no bioassay results. The approach used by OCAS is to rely whenever possible on coworker distributions, as described in OTIB-0020. OTIB-0052 specifically addresses the application of coworker data to construction workers.

Issue 7 - Impact on CWT 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?

In accordance with the language contained in 42 CFR Part 82, NIOSH will reevaluate all CTWs cases that were previously competed using a methodology that differs from that contained in OTIB-0052. The procedure that describes this is contained in, OCAS-PR-008, *Preparation of Program Evaluation Reports and Program Evaluation Plans*. A copy of this procedure is provided in Attachment 2.

Attachment 2
Copy of OCAS PR-008
Preparation of Program Evaluation Reports and Program Evaluation Plans

Office of Compensation Analysis and Support	Document Number: OCAS-PR-008 Effective Date: 11/14/2006 Revision No. 1
Preparation of Program Evaluation Reports and Program Evaluation Plans	Page 1 of 15
Approval: Signature on File	11/14/2006
Signature Stu Hinnefeld, Health Science Administrator *Name*	*Date*
Concurrence: Signature on File	11/14/2006
Signature J. W. Neton, Associate Director for Science *Name*	*Date*

RECORD OF ISSUE/REVISIONS

ISSUE AUTHORIZATION DATE	EFFECTIVE DATE	REV. NO.	DESCRIPTION
5/12/2006	5/16/2006	0	New document to establish the requirements for the conduct, documentation, and performance of Program Evaluation Reports (PER). Initiated by Peter Darnell.
11/14/2006	11/14/2006	1	Added language to accommodate the issuance, when necessary, of a Program Evaluation Plan (PEP) prior to the completion of a Program Evaluation Report (PER).

1.0 PURPOSE

The purpose of this procedure is to provide the process for evaluating the effect programmatic changes might have on previously completed dose reconstructions. This procedure also describes the general format and content of Program Evaluation Reports (PERs) and Program Evaluation Plans (PEPs) that are used to document the results of these evaluations.

2.0 SCOPE

This procedure applies to OCAS personnel involved in preparing PERs and PEPs. A PER evaluates the effect that programmatic changes may have on previously completed dose reconstructions (DR). A PEP describes the potential scope of the PER.

3.0 REFERENCES

3.1. OCAS-PR-005, Conduct of Assessments

3.2. 42 CFR 81, Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000

3.3. 42 CFR 82, Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000

3.4. External Dose Reconstruction Implementation Guideline, OCAS-IG-001

3.5. Internal Dose Reconstruction Implementation Guideline, OCAS-IG-002

4.0 GENERAL

A PER consists of six distinct sections: the Description, Issue Evaluation, Probability of Causation Evaluation, Resolution or Corrective Actions, Summary, and References. Each section is described as follows:

4.1. Description

4.1.1. This introductory section of the report establishes the scope, or parameters, of the evaluation. This section describes the aspects of the program that staff reviewed. It also briefly explains the methodology (the techniques used to collect and

analyze the information) and the standards followed in conducting the evaluation.

4.1.1.1. As needed, the Description should also contain the following:

4.1.1.1.1. The date the issue was discovered.
4.1.1.1.2. The timeframe in which dose reconstructions (DRs) are affected.
4.1.1.1.3. Additional information that would be useful to understand the scope of the PER.
4.1.1.1.4. A list of DRs which may be affected.[a]

4.1.1.2. The Description should contain a concise definition of the issue found in the group of DRs, program documentation, or other program aspect.
4.1.1.3. As needed, develop and publish a Program Evaluation Plan (PEP) to summarize the scope of the potential PER. In general, the PEP is the Description Section of the PER. The PEP is published primarily for formal notification of the impending PER.

4.2. Issue Evaluation

4.2.1. This section of the report focuses on the specific methods used to evaluate the issue(s) defined by the PER. This includes quantitative as well as qualitative reviews to determine how the individual DRs are affected.
4.2.2. As needed, the Evaluation should also contain the following:

4.2.2.1. Clearly identify the number of DRs affected.

4.2.2.1.1. For small numbers of affected DR, the DRs and their changes should be listed in the Evaluation.
4.2.2.1.2. For large numbers of affected DR, a sample of the DRs and their changes should be listed in the Evaluation.
4.2.2.1.3. Include a complete listing of affected DRs as an attachment to the PER.[a]
4.2.2.1.4. Include a discussion of how the affected DRs were determined.

[a] Because PERs and PEPs will be published on the OCAS website, the list of affected DRs should not be provided using personal identifiers such as OCAS case number or SSN. The PER or PEP author should, however, prepare a separate list with these identifiers that can be provided to the Department of Labor. This list should be maintained in a separate file by the OCAS administrative support staff as Privacy Act controlled information.

4.2.2.2. Specific factors potentially impacted, such as:

4.2.2.2.1. The age group of the energy employees;
4.2.2.2.2. The ethnicity group of the energy employees;
4.2.2.2.3. The smoking history of the energy employees;
4.2.2.2.4. Environmental exposures;
4.2.2.2.5. Specific Department of Energy (DOE) or Atomic Weapons Employer (AWE) sites;
4.2.2.2.6. Incidents at a specific DOE or AWE sites.
4.2.2.2.7. The affect of the issue on individual DR (i.e., the Ambient Dose in the DR was 0.030 rem too low).

NOTE: This list is illustrative and does not represent a comprehensive listing of information that may go into a PER. The HP conducting the PER should use professional judgment on what information to include in the PER.

4.2.2.3. The net effect (e.g., the external dose is 15% low, etc.) should be defined and discussed.

4.2.3. The methods used to conduct the evaluation should be based upon the issue defined by the PER. There is no single method that will fit the varying types of issues possible under the PER process.

4.3. Probability of Causation Evaluation

4.3.1. This section of the report focuses on the effect the issues have on the Probability of Causation (PC). This includes quantitative as well as qualitative evaluations to determine how the PC is affected on the group of DRs studied.
4.3.2. The PC evaluation should be determined at the 99^{th} percentile credibility limit.
4.3.3. The guidelines used to conduct the Evaluation should also be used to conduct the PC evaluation.
4.3.4. The Interactive RadioEpidemiological Program (IREP) cancer risk model(s) and, if appropriate, other relevant factors (e.g., number of years between exposure and diagnosis, age at diagnosis, etc.) associated with the PER should be identified.
4.3.5. All changes should be documented including those that reduce the probability of causation.

4.3.6. The PC evaluation must also assess the effect that other PERs could have on the individual DRs currently under review.

4.4. PER Conclusion

4.4.1. This section of the report focuses on the results of the evaluations documented earlier in the PER. The possible outcomes may include:

4.4.1.1. Immediate actions such as pending a number of claims. All claims affected by the PER should be listed in an attachment to the PER.

4.4.1.2. DR rework.

4.4.1.3. No action required, with a justification (e.g. identified issue will result in lower PC for all affected claims).

4.4.2. This section of the report should also state whether further reviews are required.

4.5. Summary

4.5.1. The summary should be a concise statement of the conclusion reached after conducting the evaluation. Use the summary to make a recommendation for correction of the issues mentioned in the conclusion statement.

4.5.2. The summary must contain a statement of the problem, results, conclusions, and recommendations.

4.5.3. The summary is a fully developed 'mini' version of the PER, written in straightforward, simple language.

4.6. References

List the references used in this section of the report.

5.0 PROCEDURE

5.1. Identify the Issue

OCAS HP

5.1.1. Through the course of technical document modification, programmatic improvement, or other means, identify issues or policy changes that may affect previously completed DRs.

5.1.2. Notify the HP Team Leader of the issue(s), inaccuracies, or policy changes that affect DR.

5.2. Determine if a PER is Required

OCAS HP Team Leader

5.2.1. Evaluate the program, documentation, or policy changes for relevance to DR.

5.2.2. Brief the OCAS Associate Director for Science and obtain concurrence to conduct a PER. Depending upon the scope of the PER, determine if a PEP is required.

5.2.3. As needed, assign the PEP to an OCAS HP.

5.2.4. Assign the PER to an OCAS HP.

5.3. Schedule a PER

OCAS Health Science Administrator

5.3.1. Enter the PER into the project planning schedule.

5.4. Conduct a PER

OCAS HP

5.4.1. If required, conduct a PEP as described in Section 5.0, above. Document the PEP in a report.

5.4.2. Conduct a PER as described in Section 5.0, above. Document the PER in a report.

5.4.3. Complete a PER Data Form for each effected DR.

5.4.4. Submit the completed PER to the OCAS HP Team Leader.

5.5. PER Report Review

OCAS HP Team Leader

5.5.1. As needed, review the PEP for technical accuracy. This review may be delegated to an OCAS HP.

5.5.2. Review the PER for technical accuracy and corrective actions. This review may be delegated to an OCAS HP.

5.5.3. Submit the results of this review and recommendations for corrective actions to the OCAS Associate Director for Science.

OCAS Associate Director for Science

5.5.4. As needed, review and approve the PEP.

5.5.5. Review PER recommendations from the OCAS HP Team Leader.

5.5.5.1. Determine if corrective actions are warranted.
5.5.5.2. Determine if these actions will produce the desired correction.
5.5.5.3. If the corrective actions are not acceptable, return the PER to the OCAS HP Team Leader for rework.

5.5.6. If corrective actions are acceptable, direct OCAS Staff to implement corrective actions.

OCAS Health Science Administrator

5.5.7. As needed, enter the PER Conclusion (i.e., DR rework, other reviews required, corrective actions, etc.) into the project planning schedule.

5.6. Documenting and Publishing the PER

OCAS Associate Director for Science

5.6.1. As needed, sign and date the PEP for approval.

5.6.2. Sign and date the PER for approval.

OCAS Administrative Support Staff

5.6.3. Save and maintain an electronic file of completed PEPs (and associated data) from OCAS HPs.

5.6.4. Save and maintain an electronic file of completed PERs (and associated data) from OCAS HPs.

5.6.5. Publish the approved PEP as an OCAS Controlled Document.

5.6.6. Publish the approved PER as an OCAS Controlled Document.

Public Health Advisor

5.6.7. Enter the PER Data Form into NOCTS.

OCAS HP Team Leader

5.6.8. Notify the DOL National Office health physicist of the PEP.

5.6.9. Notify the DOL National Office health physicist of the PER. Include a summary of the affected cases. The summary may be in the form of an Excel spreadsheet or other simplified document.

OCAS Communications Team Leader

5.6.10. Post copies of all approved PERs and PEPs on the OCAS Website.

5.6.11. Prepare brief descriptions (e.g., talking points) of completed PEPs and PERs and distribute to members of the OCAS Communications and Information Team.

6.0 RECORDS

The following records are generated as applicable.

6.1. Program Evaluation Plan

6.2. Program Evaluation Report

6.3. PER research data – electronic file only

6.4. PER Data Form

7.0 APPLICABLE DOCUMENTS

7.1. Forms

7.1.1. PER Data Form

8.0 DEFINITIONS

8.1. None

Attachment 1

Example PER Data Form

Program Evaluation Report Data

PER Number and Revision: PER-000, Revision 00

Date of PER: 2/20/1957

NIOSH ID Number and Revision: 000000, Revision, 00

This dose reconstruction was re-evaluated in accordance with the above referenced Program Evaluation Report. The main purpose of this PER is:

(Unlimited text entry allowed)

NIOSH has determined that the effect of application of the PER referenced above to this dose reconstruction would be to:

☐ Increase the probability of causation at the 99th percentile from <50% to ≥50%, therefore the claim has been reworked.

☐ Increase the probability of causation at the 99th percentile, but the resulting probability of causation would still be <50%, therefore no change is warranted at this time. Should this dose reconstruction be re-opened in the future, this change will be applied.

☐ Decrease the probability of causation at the 99th percentile. Since this dose reconstruction currently has a probability of causation less than 50%, no change is warranted at this time. Should this dose reconstruction be re-opened in the future, this change will be applied.

The basis for this determination is described in the PER.

HP completing this form:

Name:

Title:

Date: 2/20/1957