Final Draft Report

NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH ADVISORY BOARD ON DOSE RECONSTRUCTION

TASK 3

THE REVIEW OF NIOSH/ORAUT PROCEDURES AND METHODS USED FOR DOSE RECONSTRUCTION

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EXECUTIVE SUMMARY

Under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) and Title 42, Part 82, *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*, of the *Code of Federal Regulations* (42 CFR Part 82), the Advisory Board on Radiation and Worker Health is mandated to conduct an independent review of the methods and procedures used by the National Institute of Occupational Safety and Health (NIOSH) and its contractors for dose reconstruction.

As contractor to the Advisory Board, S. Cohen & Associates (SC&A) has been charged under Task 3 to support the Board in this effort by completing the following two work products:

(1) Develop a Formal Review Protocol for the Evaluation of Procedures Used in Dose Reconstruction — The purpose of a review protocol is to ensure a structured and systematic review process that determines whether procedures are consistent with the philosophy, intent, and/or statutory directives cited in EEOICPA and comply with the general requirements, methods, and guidance provided in 42 CFR Part 82.

In behalf of the first work product, SC&A submitted a report entitled *A Protocol for the Review of Procedures and Methods Employed by NIOSH for Dose Reconstruction*, which was approved by the Board in April 2004. The Board-approved version of this report is enclosed as an addendum.

(2) Conduct a Critical Review of Methods and Procedures Used by NIOSH for Dose Reconstruction — The Board identified a total of 33 procedural documents for SC&A's review that included implementation guidelines, procedures, technical information bulletins, and plans. These documents were evaluated against seven major review objectives, which define SC&A's review protocol. The main text of this report contains SC&A's evaluation of these procedures. A brief summary of the review findings is presented below.

Summary Findings

The 33 documents identified to SC&A for review represent a sizeable body of written text that embraces a wide array of complex topics and clearly reflects an intense effort by many individuals who are regarded as scientific experts in their fields. However, these documents were created by the Office of Compensation Analysis and Support (OCAS) and the Oak Ridge Associated University Team (ORAUT) over a 3-year period in a fragmented fashion and on an as-needed basis. It is important to note that none of the 33 documents contain site-specific data that are **essential** to dose reconstruction. Only Site Profiles that have been or continue to be developed contain site-specific data, as well as guidance that may significantly differ and **supercede** guidance provided by the 33 documents under review in Task 3.

It is equally important to note that some of the 33 documents have been revised and are likely to be revised in the future due to the fact that these documents are regarded as "living documents." The need for living documents, as explained to SC&A by NIOSH, reflects the urgent demand for NIOSH to begin the adjudication of claims by a progressive selection process that started with claims requiring the least amount of procedural guidance and data. Future, more complex dose reconstructions may, therefore, require further procedural revisions and/or the development of additional procedures.

In brief, SC&A's review of the methods and procedures used for dose reconstruction must be viewed with some caution since these findings are not only limited to generic procedures, as they exist **currently**, but more importantly do **not** include the role of Site Profiles in dose reconstruction.

An overview of SC&A's findings is given below in behalf of the seven general review objectives identified by SC&A in its review protocol. Due to the large number of documents and their heterogeneous contents, some comments may not apply to all documents and, in select instances, may only apply to one or a few procedures.

Objective 1: Determine the degree to which procedures support a process that is expeditious and timely for dose reconstruction.

A well-written procedure presents all required data in a logical, concise, unambiguous, and prescriptive manner. Frequently, SC&A found that poorly structured procedures sequester the key information or guidance in the final section. This requires the dose reconstructor to read through voluminous and frequently irrelevant background information. An improved format would provide the essential guidance and data for dose reconstruction at the front of the procedure. **Relevant** background or technical support data would be more effective as addenda that the dose reconstructor could consult if needed.

Objective 2: Determine whether procedures provide adequate guidance to be efficient in select instances where a more detailed approach to dose reconstruction would not affect the outcome.

SC&A understands the benefit of and endorses the need for an **efficient** dose reconstruction process that, in appropriate instances, either avoids a full-blown dose reconstruction (i.e., when a partial dose reconstruction yields a probability of causation (POC) > 50%) or simplifies a dose reconstruction by means of worst-case assumptions/dose assignments for claims with a low POC. A sizeable number of procedures, while making reference to the likely or unlikely compensability of a claim, provide little or no guidance to the dose reconstructor for prejudging a claim. (It should be noted that ORAUT-PROC-0006 potentially may negate this concern by implying that a preliminary assessment by "Task 2 personnel" will identify the likely compensability of a claim to the dose reconstructor.)

Objective 3: Assess the extent to which procedures account for all potential exposures and ensure that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.

This objective was assessed at two levels. The first is based on the structure, format, and scope of the Computer Assisted Telephone Interview (CATI) process. SC&A identified several limitations and deficiencies by which CATI data are obtained and integrated into the dose reconstruction process.

The second level focused on claims for which assignment of external and internal doses must be scientifically defensible and invariably requires site-specific information relating to time-dependent health physics practices, personnel monitoring, dosimeter and bioassay performance criteria, etc. With some exceptions, most procedures under review are generic and contain no site-specific information.

A simple resolution to this deficiency would be to integrate all relevant portions of generic OCAS and ORAUT procedures into each Site Profile. This would eliminate redundancy and reduce the number of documents necessary for dose reconstruction for any given site to a single document.

Objective 4: Assess procedures for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.

In order for the adjudication process to be fair to claimants, the process of dose reconstruction must attempt to remain **consistent** over time and space. Consistency implies that the same procedures are applied to claims that share a high degree of commonality. SC&A's review of procedures shows that some of the procedures tend to overlap, which presents the dose reconstructor with multiple options. In other instances, the absence of clear guidance requires the dose reconstructor to make independent and subjective decisions that are prone to variability. Other **potential** sources of inconsistency (that is not subject to review under Task 3) are the Site Profiles and their interpretation and adoption of generic guidance contained in the 33 documents. (An evaluation of consistency among Site Profiles and between a given Site Profile and generic NIOSH/ORAUT procedures will be reported by SC&A under Task 1.)

Objective 5: Evaluate procedures with regard to fairness and the extent to which the claimant is given the benefit of doubt when there are unknowns and uncertainties concerning radiation exposures.

The statutory requirement of a claimant-favorable dose reconstruction process is achieved by (1) giving the benefit of doubt when there are **unknowns**, and (2) defining uncertainties for measured data and selecting the 99th percentile value of a Monte Carlo distribution.

SC&A's review of procedures suggests that the method for determining the **uncertainty** of personnel dosimeters may have been incomplete and significantly underestimated. In instances of unknowns, select procedures either lack the necessary guidance or employ default values that

would be inappropriate. For example, limited guidance is given for situations when monitoring data are missing or lost, and questionable default values are used in instances when a claimant was not monitored.

Objective 6: Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.

The input to the Interactive Radioepidemiological Program of **annual** external doses as measured by weekly, monthly, or quarterly assigned film or thermoluminescent dosimeters not only requires an estimate of uncertainty for each individual dosimeter (i.e., film or thermoluminescent dosimeter), but also considers the collective uncertainty of the **annual** dose that may correspond to as many as 52 dosimeters for a weekly exchange frequency.

While all external dosimetry procedures reference the need to include uncertainty, only OCAS-IG-001 attempts to explain how this is to be done. However, guidance in OCAS-IG-001 is inadequate and scientifically questionable, as described below in the review of Implementation Guide OCAS-IG-001. The treatment of uncertainty pertaining to internal exposures as assessed by bioassay techniques is equally deficient.

Objective 7: Assess the scientific and technical quality of methods and guidance contained in procedures to ensure that they reflect the proper balance between current/ consensus scientific methods and dose reconstruction efficiency.

The seventh and final review objective not only assessed the scientific credibility of procedural methods, but also the EEOICPA directive that the methods and procedures must achieve a balance between technical precision and dose reconstruction efficiency.

SC&A's review of procedures identified a number of technical inaccuracies and errors. Many prompt the dose reconstructor to pursue levels of detail that would not reasonably be obtained.

On a more subjective level, SC&A believes that currently select portions of the dose reconstruction process demand a high degree of sophistication and detail that goes well beyond the regulatory requirement of a "reasonable dose estimate" and comes at the expense of reducing process efficiency.

1.0 INTRODUCTION

1.1 STATEMENT OF PURPOSE

The purpose of this draft report is to assist the Advisory Board in fulfilling its mandate to review the methods and procedures used by the National Institute of Occupational Safety and Health (NIOSH) and its contractors in the performance of dose reconstruction, as directed by the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) and Title 42, Part 82, *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of* 2000, of the *Code of Federal Regulations* (42 CFR Part 82).

Specifically, Section B of 42 CFR Part 82 Final Rule identifies the following statutory requirement for:

> . . . *The Advisory Board on Radiation and Worker Health to* ***independently*** *review the methods established by this rule and to verify a reasonable sample of dose reconstructions established under these methods.* [Emphasis added.]

Section P of 42 CFR Part 82 Final Rule restates this requirement, but further directs the Advisory Board to **identify** those procedures that are to be reviewed by the Board, as stated in the following:

> *As described above under the discussion of statutory provisions related to the rule, EEOICPA requires the Board to conduct an independent review of a sample of NIOSH dose reconstruction. 42 U.S.C. 7348 n(d). Since this review is specified to be independent, the* ***Board****, rather than HHS, must determine the procedures for the* ***Board's*** *review of NIOSH dose reconstructions. Moreover, this level of* ***autonomy*** *is important for the credibility of the review.* [Emphasis added.]

1.2 IDENTIFICATION OF PROCEDURES SUBJECT TO REVIEW

Based on the above-cited statutory and regulatory requirements, the Board provided S. Cohen and Associates (SC&A) with an electronic file of those procedures that must be assessed to satisfy the requirement of an "independent review." Procedural documents issued and used by the Office of Compensation Analysis and Support (OCAS) and the Oak Ridge Associated University Team (ORAUT) for dose reconstruction are described below.

1.2.1 OCAS Implementation Guides

OCAS-IG-001 — External Dose Reconstruction Implementation Guideline

This document contains the core guidance on the components, standards, and methods of external radiation dose reconstruction for probability of causation (POC) calculations in support

of the EEOICPA. It is a core document in the reconstruction of external doses and provides very comprehensive guidance.

OCAS-IG-002 — Internal Dose Reconstruction Implementation Guideline

This document provides basic information on the methods to be employed in internal dose reconstruction. The dose reconstruction should result in the calculation of claimant-favorable reasonable estimates of the equivalent dose received by the worker, in individual calendar years, to the organ of interest, as well as the uncertainty associated with the dose.

1.2.2 OCAS Technical Information Bulletins

OCAS TIB 001 — Interactive Radioepidemiological Program Issues

This Technical Information Bulletin (TIB) clarifies three issues related to using the Interactive Radioepidemiological Program (IREP). The document provides specific instruction in the use of IREP when (1) choosing the exposure type for radon, (2) handling cases involving leukemia and thyroid latency, and (3) determining the use of the "should alternate cancer be run" field.

OCAS TIB 002 — Tritium Calculations with Integrated Modules for Bioassay Analysis

This TIB provides guidance on how to use Integrated Modules for Bioassay Analysis (IMBA) for calculating tritium gas doses.

OCAS TIB 003 — Interactive Radioepidemiological Program Requirements for Multiple *Cancers*

This TIB contains specific IREP program instructions for dose calculations involving multiple primary cancers, as well as cases where no primary cancer is provided.

OCAS TIB 004 — Naming Conventions

This TIB is an administrative document containing the naming convention to be employed for documents that are included in the Administrative Record.

OCAS TIB 005 — Dose Reconstruction Cancer Data Requirements

This TIB is an administrative document that defines the NIOSH OCAS Claims Tracking System requirements and business rules governing cancer data requirements for performing dose reconstructions and conducting IREP runs at OCAS and ORAU.

OCAS TIB 006 — Interpretation of External Dosimetry Records at Savannah River Site

This document provides guidance on the interpretation of Savannah River Site (SRS) dosimetry from 1973 through 1988.

OCAS TIB 007 — *Neutron Exposures at Savannah River Site*

This TIB provides guidance on the inclusion of neutron exposures in SRS dose reconstructions prior to the implementation of the thermoluminescent neutron dosimeter (TLD) in 1971.

OCAS TIB 008 — Use of ICRP 66 to Calculate Respiratory Tract Doses

This TIB provides guidance on the assignment of the appropriate tissue to serve as the surrogate to the internal dose to specific organs/tissues associated with or near the respiratory tract.

1.2.3 OCAS Program Evaluation Reports

OCAS-PER-001 — Misinterpreted Dosimetry Records Resulting in an Underestimate of Missed Dose in Savannah River Site Dose Reconstructions

This report evaluates the programmatic effect of an error in the interpretation of incomplete SRS dosimetry records between 1973 and 1988. Data gaps during this time period were interpreted as not monitored and may have resulted in an underestimation of missed dose.

OCAS-PER-002 — Error in Surrogate Organ Assignment Resulting in an Underestimate of X-Ray Dose in Savannah River Site Dose Reconstruction

This report evaluates the programmatic effect of an error in surrogate organ assignment resulting in potential underestimation of X-ray dose for certain SRS dose reconstructions.

1.2.4 OCAS Procedures

OCAS-PR-003 — Performing and Reporting Dose Reconstructions

The purpose of this procedure is to provide guidance for the OCAS staff and its technical support contractors in the performance, review, and documentation of dose reconstructions for covered employees with cancer per the requirements of 42 CFR Part 82. The basic principle of dose reconstruction is to characterize the radiation environments to which workers were exposed, and to then place each worker in time and space within this exposure environment.

1.2.5 ORAUT Plans

ORAUT-PLAN-0001 — Quality Assurance Program Plan

This plan is an administrative document describing the organizational structure, functional responsibilities, levels of authority, and interfaces for those personnel managing, performing, and assessing the quality of work performed.

ORAUT-PLAN-0002 — Internal Management Review Plan

This administrative document provides guidance for the management reviews of activities for the ORAU Team Dose Reconstruction Project.

ORAUT-PLAN-0003 — Information Systems Quality Assurance Plan

This is an administrative document for attesting to the quality of data and information management practices used. The plan presents a strategy to promote processes and/or procedures for their utility in identifying and/or limiting vulnerabilities to data quality.

ORAUT-PLAN-0004 — Records and Information Management Plan

This is an ORAU administrative document that provides the requirements and responsibilities for a functional records and information management system for the ORAU Team Dose Reconstruction Project.

1.2.6 ORAUT Procedures

ORAUT-PROC-0001 — Document Program

This administrative procedure provides the process for development, revision, cancellation, and control of documents generated by the ORAU Team Dose Reconstruction Project for NIOSH.

ORAUT-PROC-0002 — Use of Integrated Modules for Bioassay Analysis

This document serves as an administrative procedure which provides instructions on how to use the software IMBA.

ORAUT-PROC-0003 — Internal Dose Reconstruction

This procedure is mostly administrative and addresses steps to be taken to assure that internal dose reconstructions are sufficiently complete, correct, and consistent for determining the POC of a covered employee's specified cancer(s).

ORAUT-PROC-0004 — Scheduling Telephone Interviews

This ORAU administrative document provides instructions on the process for the scheduling of Computer-Assisted Telephone Interviews (CATI).

ORAUT-PROC-0005 — Performing Telephone Interviews

This procedure provides ORAUT personnel with instructions on the process for the performance of CATIs.

ORAUT-PROC-0006 — External Dose Reconstruction

This procedure provides specific steps and instructions for performing external dose reconstructions based on principles contained in OCAS-IG-001 guidelines.

ORAUT-PROC-0007 — Reviewing Telephone Interviews

This administrative document provides instructions on the process for reviewing and processing documents created within the ORAU Team Dose Reconstruction Project as part of the telephone interview process.

1.2.7 ORAU Technical Information Bulletins

ORAUT-OTIB-0001 — Maximum Internal Dose Estimates for Savannah River Site Claims

To facilitate timely processing of SRS claims under the EEOICPA, this document specifies the method for evaluating internal dose to cases that meet specific criteria.

ORAUT-OTIB-0002 — Maximum Internal Dose Estimates for Certain Department of Energy Complex Claims

This TIB expedites the processing of claims that involve cancer in an organ with little or no reported internal dose from internally deposited radionuclides that might be associated with work at U.S. Department of Energy (DOE) complex sites.

ORAUT-OTIB-0003 — Savannah River Site Tritium Dose Assignment

This TIB provides guidance for the evaluation of tritium dose for SRS dose reconstruction and is based on the SRS Technical Basis Document.

ORAUT-OTIB-0004 — Technical Basis for Estimating the Maximum Plausible Dose to Workers at Atomic Weapons Employer Facilities

For the purpose of expediting the processing of claims, this TIB describes an efficient process for estimating the maximum plausible annual organ dose to workers at Atomic Weapons Employer facilities.

ORAUT-OTIB-0005 — Integrated Modules for Bioassay Analysis Organ, External Dosimetry Organ, and Interactive Radioepidemiological Program Model Selection by ICD-9 Code

This TIB provides guidance on selecting appropriate International Committee for Radiological Protection (ICRP)-modeled organs/tissues in the IMBA software program to estimate the internal dose for specific ICD-9 codes, the appropriate organs/tissues to estimate external dose, and the appropriate model in the IREP.

ORAUT-OTIB-0006 — Dose Reconstruction from Occupationally Related Diagnostic X-Ray Procedures

This TIB is a generic document that provides guidance on the performance of a dose reconstruction associated with occupationally related diagnostic x-ray procedures.

ORAUT- OTIB-0007 — Occupational Dose from Elevated Ambient Levels of External Radiation

This TIB discusses the issue of determining whether external dosimeter results represent occupational doses that have been separated appropriately from potentially elevated environmental doses.

ORAUT-OTIB-0008 — Standard Complex-Wide Conversion/Correction Factor for Overestimating External Exposures Measured with Thermoluminescent Dosimeters

The objectives of this TIB are to discuss the degree of standardization of DOE TLD measurements and develop a standard correction factor that will overestimate dose. This document examines the performance of TLD dosimeters, discusses the application of a standard correction factor to overestimate doses, and addresses specific sources of uncertainties.

ORAUT-OTIB-0010 — Standard Complex-Wide Conversion/Correction Factor for Overestimating External Exposures Measured with Film Badge Dosimeters

This TIB presents external radiation dose assumptions that may be applied to dose reconstructions involving cases where dose estimates are based on recorded deep and/or shallow doses using film badges. Information in this document supports radiation dose estimates for complex-wide cases covering the time period of 1970 and after.

1.3 SC&A'S APPROACH FOR TASK 3

Phase 1 of Task 3. Under Task 3, SC&A was directed to review the methods and procedures used in dose reconstruction by means of a **Board-approved** methodology. Accordingly, the first phase of Task 3 stated that SC&A ". . . develop a methodology for conducting the baseline review. This methodology will be provided to the Advisory Board for review and approval prior to initiating the baseline review."

Technical Issues. In the Statement of Work specified by NIOSH for Task 3, key **technical** elements to be addressed in the review included the following:

(a) Review the internal and external radiation dose reconstruction technical basis documents (including procedure for performing internal dose reconstructions and external dose reconstructions)

(b) Review of methods for estimating "missed dose" and "unmonitored dose" (for cases related to monitoring technology and for cases where monitoring was not performed, monitoring data are not available or incomplete, or otherwise inadequate)

(c) Review of the statistical approaches developed for multiple dose reconstructions

(d) Review procedures used for determining whether data are sufficient to make a reasonable dose estimate

(e) Review methods or procedures used for substituting exposure information for unavailable or incomplete information

(f) Review methods for estimating uncertainty in dose and uncertainty distributions surrounding internal and external dose reconstructions on a facility- and time-specific basis, and evaluate whether the benefit of the doubt was resolved in favor of the claimant where there were uncertainties

(g) Review procedures and questionnaire used for work history telephone interview (includes review of CATI scheduling, performance, and review procedures)

(h) Review quality assurance plan and related procedures

(i) Review procedures related to document acquisition (records request, management, assembly and handling)

(j) *Review procedures related to completing a Site Profile (Site and Exposure Profiles), Worker Profiles, and Special Exposure Cohort petition review and procedures on how Worker Profile and Site Profile data will be used for individual case dose reconstruction

(k) Review the NIOSH methods, procedures, and performance in evaluating, analyzing, and validating all contractor work products

* Note: In behalf of Task 3, this element was excluded from the review process.

Nontechnical Issues. In addition to technical elements, SC&A also recognized that the review of methods and procedures must also address nontechnical issues that reflect the philosophy, intent, and/or statutory directives cited in EEOICPA and the Final Rule for 42 CFR Part 82.

The Act (as stated in the Final Rule) requires that ". . . HHS establish by regulation, methods for arriving at **reasonable estimates** of the radiation doses incurred by covered employees in connection with claims seeking compensation for cancer . . ." [Emphasis added].

Other directives issued to the U.S. Department of Health and Human Services (HHS) mandated the establishment of, by regulation, methods that are (1) **efficient**, (2) **consistently applied**, (3) **reasonable dose estimates**, (4) **complete**, and (5) **well grounded in the best available science**.

As acknowledged in the Act, the level of effort involved in dose reconstructions depends largely on the quantity and quality of available dose monitoring data and the extent to which these data are, in fact, complete. The EEOICPA further recognized the complexity of **traditional** approaches for dose reconstruction, which frequently require extensive research and analysis,

and in instances of ". . . health research studies dose reconstruction may take from months to years to complete."

Owing to the large number of claims requiring dose reconstruction, Section 7384 of EEOICPA specifically states that ". . . one of the purposes of the compensation program is to provide for **timely compensation**" [Emphasis added], and Section E of 42 CFR Part 82 Final Rule states that ". . . An additional **critical** factor affecting how doses are reconstructed is the amount of time available . . . In compensation programs, however, a balance must be struck between **efficiency** and **precision**." [Emphasis added.]

According to these directives, SC&A's evaluation of procedures cannot limit itself to a process that simply determines whether applicable procedures are technically correct and make use of the most current ICRP biokinetic models, dose conversion factors, cancer risk coefficients, computer codes, etc., but must equally address the more difficult and subjective question of whether a proper balance has been struck between efficiency and precision.

SC&A's review of the technical and scientific methods prescribed in applicable procedures must, therefore, also assess nontechnical issues and the impacts of scientific detail that are required procedurally, and weigh the incremental precision gained against the reduced efficiency and higher costs for reconstruction and added delay in the adjudication of claims.

In brief, SC&A identified the following objectives in its protocol to the Board, which form the basis for conducting the review:

Objective 1: Determine the degree to which procedures support a process that is expeditious and **timely** for dose reconstruction.

Objective 2: Determine whether procedures provide adequate guidance to be **efficient** in select instances where a more detailed approach to dose reconstruction would not affect the outcome.

Objective 3: Assess the extent to which procedures account for all potential exposures, and ensure that resultant doses are **complete** and based on adequate data.

Objective 4: Assess procedures for providing a **consistent** approach to dose reconstruction regardless of claimants' exposures by time and employment locations.

Objective 5: Evaluate procedures with regard to **fairness** and the extent to which the claimant is given the **benefit of doubt** when there are unknowns and uncertainties concerning radiation exposures.

Objective 6: Evaluate procedures for their approach to quantifying the **uncertainty** distribution of annual dose estimates that is consistent with and supports a U.S. Department of Labor POC estimate at the upper 99% confidence level.

Objective 7: Assess the scientific and technical quality of methods and guidance contained in procedures to ensure that they reflect the **proper balance between current/ consensus scientific methods and dose reconstruction efficiency**.

A report of the draft protocol was reviewed by the Board and approved for use during a public meeting held in Richland, Washington, on April 20-23, 2004. For convenience, the full text of the final report, entitled *A Protocol for the Review of Procedures and Methods Employed by NIOSH for Dose Reconstruction,* is included as an addendum to this report.

1.4 STRUCTURE AND ORGANIZATION OF THE REPORT

Structure. For each of the above-cited seven general objectives, the review protocol was structured on a series of relevant questions contained in a checklist, which the SC&A reviewer used for rating a given procedure. A rating system of 1 through 5 corresponded to the following answers: 1=No (or Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (or Always). For example, Objective 1 focused on timeliness. The need for NIOSH to perform large numbers of dose reconstructions in a **timely** manner places specific demands on procedures and the dose reconstruction process as a whole. SC&A's evaluation of procedures for their support of a **timely** reconstruction process was, therefore, based on rating the answers to the following questions:

- Is the procedure written in a style that is concise and unambiguous?
- Is the procedure written in a manner that presents the data in a logical sequence?
- Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?
- Is the procedure consistent with and does it avoid duplication of other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?
- Is the procedure sufficiently prescriptive to minimize the need for subjective decisions and data interpretation?

Answers that resulted in a rating other than a 5 (or a perfect score) in the checklist were supported with specific review Comments. Table 1 below identifies the Procedure Review Outline/Checklist that was used whenever applicable in the review of the 33 procedures/ documents identified by the Board for review.

Organization. The individual procedures/documents for review are grouped by topic in the following sections:

- Section 2.0, External Dosimetry Procedures/Documents
- Section 3.0, Internal Dosimetry Procedures/Documents
- Section 4.0, IREP Requirements/Issues Procedures/Documents
- Section 5.0, Telephone Interview Procedures/Documents
- Section 6.0, Quality Assurance Procedures/Documents
- Section 7.0, Documentation/Records Management Procedures/Documents

For a specific section, procedures/documents are sequenced as given in the table of contents for this report.

Table 1.4-1. Procedure Review Outline/Checklist

Document No.:	**Effective Date:**
Document Title:	
Reviewer:	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?		
1.2	Is the procedure written in a manner that presents the data in a logical sequence?		
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?		
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?		
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?		
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?		
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?		
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?		
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?		
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?		
3.1.4	Is the interview process sensitive to the claimant?		
3.1.5	Does the interview process protect information as required under the Privacy Act?		

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)		
3.2.2	In vivo/In vitro bioassays		
3.2.3	Missing dosimetry data		
3.2.4	Unmonitored periods of exposure		
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?		
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?		
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?		
5.2	Is the procedure claimant favorable in instances of unknown parameters effecting dose estimates?		
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?		
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?		
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?		
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?		
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?		

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

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2.0 EXTERNAL DOSIMETRY PROCEDURES/DOCUMENTS

2.1 OCAS-IG-001 — EXTERNAL DOSE RECONSTRUCTION IMPLEMENTATION GUIDELINE

The review of Office of Compensation Analysis and Support (OCAS)-IG-001, *External Dose Reconstruction Implementation Guideline*, Rev. 1, dated August 2002, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on January 11, 2005.

2.1.1 Purpose of Procedure

The purpose of this guide is stated in the preface of the implementation guideline and is cited verbatim below:

> *. . . to provide basic information on the methods employed in reconstructing doses under the Energy Employees Occupational Illness Compensation Program Act of 2000. The intent of this guide is to assist a qualified health physicist in determining annual organ dose from exposure to various sources of external radiation. Because not all possible exposure scenarios can be foreseen, this guide* ***does not provide step by step instructions*** *for how the dose reconstruction should be performed. It is recognized there will be situations for which the methods outlined in this guide result in underestimates or overestimates of a claimants actual dose. In these cases, care must be exercised that the doses are* ***conservative (claimant friendly)*** *but* ***reasonable*** *for the claimant's exposure scenario.* [Emphasis added.]

The introduction of OCAS-IG-001 further states:

> *The purpose of this section is to provide guidance on the components, standards, and methods of external radiation dose reconstruction for probability of causation calculations in support of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). . .*

2.1.2 Review Protocols

As one of two primary guidance documents, OCAS-IG-001 fulfills the requirements set forth in the EEOIPCA. As such, this document represents the principal source of (1) technical support and background information and (2) procedural guidance for implementing the reconstruction of **external** exposure doses from **photons**, **electrons**, and **neutrons** under a variety of exposure conditions, which may or may not have been recorded.

SC&A's evaluation of OCAS-IG-001 is summarized in Table 2.1-1 below. Table 2.1-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

Table 2.1-1. Procedure Review Outline/Checklist

Document No.: OCAS-IG-001	**Effective Date:** August 2002
Document Title: External Dose Reconstruction Implementation Guide	
Reviewer: U. Hans Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	3	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	3	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	3	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	3	See Review Comments
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	3	See Review Comments
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	3	See Review Comments
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	4	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	4	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	4	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	3	See Review Comments
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	3	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	3	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.1.3 Review Comments

Review Objective 1.1

Due to the complexity and potential level of detail that would be required for dose reconstruction, the dose reconstructor will consult OCAS-IG-001for each step of the external

dose reconstruction process. A key element for **efficiency** in completing a dose reconstruction is that the procedure provides a logical sequence for the dose reconstructor to follow.

The structure employed by OCAS-IG-001 is **fragmented** and, therefore, inefficient and time consuming. Guidance for external dose reconstruction is spread over the following three major sections of the implementation guide:

(1) Section 2.0, *External Dose Reconstruction — Monitoring Data*; Section 3, *External Dose Reconstruction — Incomplete, Missing or No Monitoring Data*; and Section 4.0, *Conversion to Organ Dose*, represent the overwhelming portion of OCAS-IG-001.

(2) In turn, each of these three sections has separate discussions/guidance for (1) photon dose, (2) neutron dose, and (3) electron dose.

(3) For example, the reconstruction of a photon dose, therefore, requires the dose reconstructor to consult Sections 2.0, 3.0, and 4.0.

A more efficient structure would eliminate this **fragmented** approach by separating select information for photons from Sections 2.0, 3.0, and 4.0 and consolidating this information into a single section. For example, Sections 2.1, 3.1, and 4.1 dealing with photons could be integrated more efficiently into a single comprehensive section for estimating external photon dose from monitored data, incomplete data, and missing/no monitoring data. (Note: ORAUT-PROC-0006, *External Dose Reconstruction,* has in fact revised its structure in accordance with the above-cited recommendation.)

A related but more significant issue centers on information that was introduced into core text of the implementation guide, which is of limited value/use to the dose reconstructor. For each of the five major sections of OCAS-IG-001, a substantial body of data and/or historical background information is provided. It is not only time-consuming, but also confusing and distracting for the dose reconstructor to read and comprehend this information. In many cases, what appears to be procedural guidance for dose reconstruction cannot be implemented due to the lack of data, complexity, or need for timeliness and process efficiency. This has apparently been recognized by the National Institute for Occupational Safety and Hazard (NIOSH)/OCAS since, near the end of each major topic/section of the implementation guide, procedural guidance ignores preceding information by recommending the use of (1) a simplified approach, (2) a table of default values, or (3) a complete substitution of data. For illustration, several examples are provided below. This problem characterizes nearly all other procedures as well.

- Example 1: Section 2.1, Photon Dose. This section provides a detailed discussion as well as equations for dosimeter uncertainties that are unique to film and thermoluminescent dosimeter (TLD) photon and neutron dosimeters. Unfortunately, neither data nor resources are available to the dose reconstructor to make any functional use of this guidance. OCAS-IG-001 concludes with a simplified dosimetry uncertainty, as provided in Section 2.1.1.3.3. (Additional comments pertaining to the treatment of uncertainty are discussed below.)

- Example 2: Section 2.1.3, Occupational Medical Dose. This section identifies the variable operating parameters of an x-ray machine (i.e., kVp, mA, duration msec, filtration, and distance) that define the skin entrance dose described as kinetic energy released in material or air, or kerma. This information provides **no** useful information to the dose reconstructor for assessing occupational medical dose. (Note: A separate procedure exists for occupational medical exposures but is not referenced in the OCAS-IG-001; under Task 3, S. Cohen & Associates (SC&A) also reviewed ORAUT-OTIB-0006, *Occupational Medical X-ray Exposure*, and provided comments.)

- Example 3: Section 2.2, Neutron Dose, and Section 3.2.3, Neutron Dose Reconstruction-Source Term Data. In Section 2.2, OCAS-IG-001 provides an ambiguous, historical discussion of nuclear track emulsion (NTA) neutron dosimeters, their limitations, and their potential use in dose reconstruction. In Section 3.2.3, OCAS-IG-001 proposes to reconstruct neutron doses when neither dosimeter nor survey data are available. The proposed protocol involves a calculational method that would require the dose reconstructor to first derive a neutron fluence (n/sec) from a source (e.g., reactor), and then determine a neutron dose based on the reconstructor's knowledge regarding (1) shielding components, (2) distance between work and source, and (3) duration of exposure. While this type of reconstruction may be reasonable in instances of a single acute event, such as a criticality accident, it cannot be viewed as a reasonable approach for dose reconstruction in instances of long-term routine neutron exposures.

- Limitations of this type have clearly been recognized by NIOSH/Oak Ridge Associated Universities Team (ORAUT). Thus, Site Profiles, such as the Savannah River Site (SRS) ORAUT-TKBS-0003, have simply **excluded** NTA neutron data and provided guidance for neutron dose reconstruction via neutron to photon dose ratios.

- Example 4: Section 4.0, Conversion to Organ Dose. This section provides various references and a detailed discussion/data regarding the relationship between air kerma and the more conventional units of radiation exposure/dose, as well as converting such units of exposure to organ dose based on the radiation energy and exposure geometry. Because this information is unlikely to be used, the OCAS-IG-001 again presents a dose conversion factor (DCF) simplification (Section 4.1.3.), which refers the dose reconstructor to a simple set of DCFs contained in Appendix B.

- SC&A concludes that, for improved clarity and efficiency, the extensive amount of historical and support data that are currently the main body of the implementation guideline should be separated from specific dose reconstruction guidance representing the core of the document. In a series of referenced appendices, this background information and support data would still provide the dose reconstructor with the option of understanding the technical basis for guidance contained in the implementation guideline.

Review Objective 1.3

In order for a procedure to be highly usable and effective, it should confine itself to a protocol that can reasonably be followed, as well as provide relevant and required data. OCAS-IG-001 frequently recommends protocols that are unrealistic in scope and fails to provide data that are essential. For practical reasons, an exhaustive citation is beyond the scope of this review. For illustration, the following examples are provided that deal with the important issue of dosimeter uncertainty.

- Example 1: Section 2.1.1.3.1, Film Badge Uncertainty. This section contains the following statement:

  The uncertainty associated with each dosimeter reading is assumed to be normally distributed, where the dosimeter reading is the mean and the upper 95% confidence dose is calculated by multiplying the uncertainty factor K(E) by each dosimeter reading using the following equations:

  $$K(E) = 1 + 1.96\left[\frac{\sigma(E)}{E}\right]$$

  $$\sigma(E) = \frac{\sigma^*}{D_\infty \gamma} e^{\gamma E}$$

  where: E *= Exposure in roentgen*
  σ^* *= Densitometer reading uncertainty (typically 0.015 density units)*
  D_4 *= Saturation density of film (e.g., Dupont 502 = 2.8)*
  γ *= Film sensitivity (e.g., Dupont 502 = 0.25)*

  Reviewer's Comments

  To comply with this procedure, for each film badge reading, the dose reconstructor would have to pursue information pertaining to the type of film used, the densitometer's sensitivity, and the film's sensitivity and saturation density. Even if OCAS-IG-001 provided all necessary data, it would, nevertheless, be unreasonable to determine the uncertainty for each dosimeter reading since there were times in the 1950s and 1960s when film badges were exchanged **weekly**. For long-term energy employees, this recommended procedure for assigning film badge uncertainties could easily involve data gathering for **hundreds** of film dosimeter cycles/reading, corresponding to an unreasonable level of effort. At this time, SC&A has completed its review of the first 20 dose reconstruction claims and has noted that calculation of dosimeter uncertainty has either been ignored or avoided in all applicable cases.

- Example 2: Section 2.1.1.3.2, TLD Uncertainty. For TLDs, OCAS-IG-001 recommends that uncertainty be derived by the following equation:

$$\sigma_t^2 = \sigma_n^2 + \sigma_\mu k_t^2$$

where: σ_t = standard deviation of total air kerma
σ_n = standard deviation of null readings
σ_μ = relative standard deviation observed at high air kerma
k_t = total air kerma

The OCAS-IG-001 further states " . . . data for σ_n and σ_μ should be readily available from most DOELAP accredited programs."

Reviewer's Comments

To comply with this procedural recommendation, the dose reconstructor is asked to contact individual Department of Energy (DOE) sites for values of σ_n and σ_μ and then apply such data to each individual TLD reading. Beyond the inordinate amount of time needed to obtain these data and calculate uncertainties for each TLD reading, at least two technical issues would affect the use and validity of this procedure. First, TLDs are/were generally not calibrated in the unit of air kerma. Second, Department of Energy Laboratory Accreditation Program (DOELAP) accreditation for most DOE sites did not take place prior to the 1990s, at which time DOE introduced the state-of-the-art Panasonic 802 dosimeter. Therefore, DOELAP values for σ_n and σ_μ cannot be assumed to apply to different TLDs that were used as early as the 1960s and 1970s.

- Example 3: Section 2.1.1.3.4, Uncertainty Combination. This section states, ". . . the uncertainty from **each** film dosimeter should be calculated and the **combined annual** uncertainty **should** be calculated using standard error propagation methodology (square root of the sum of the squares), as shown in the following equation." [Emphasis added.]

$$\sigma_D^2 = \sigma_1^2 + \sigma_2^2 + \sigma_3^2 + \ldots \sigma_i^2$$

where: σ_D = uncertainty of annual dose
σ_i = uncertainty of a **single** dosimeter

Reviewer's Comments

As previously stated, procedural guidance that requires the dose reconstructor to define **annual** dosimeter uncertainty through individual dosimeter uncertainties by means of standard error propagation methodology appears excessive and inefficient, and places an unreasonable burden on the dose reconstructor for securing the necessary data.

- Example 4: Section 2.1.3, Occupational Medical Dose. The practice of subjecting employees to medical exams that involved diagnostic x-rays (i.e., chest x-rays and photofluoroscopic exams) was confined to employment periods of the 1940s and early 1950s. Section 2.1.3 of OCAS-IG-001 acknowledges (1) the need to include such exposure in dose reconstruction and (2) the likely absence of dosimetry data for

occupational medical exposure. Therefore, OCAS-IG-001 provides a significant amount of information that explains the relationship of several critical x-ray machine operating parameters and suggests that, when the dose from a diagnostic procedure is unknown but the **operating parameters** of the x-ray machine are known (e.g., kVp, mA, total aluminum filtration, exposure duration, and skin-to-tube distance), the air kerma may be estimated, as cited in the example in Section 2.1.3.4.

It is highly unlikely that such detailed data were ever recorded or are available at this time. Thus, to suggest to the dose reconstructor that such data are available and should, therefore, be pursued is unrealistic and misleading. Any attempt to pursue such data will result in the loss of valuable time or in subjective assumptions that lead to inconsistencies among dose reconstructors.

Review Objectives 1.4 and 1.5

By design, OCAS-IG-001 provides basic information on the methods for dose reconstruction with which secondary procedures must comply and be consistent. There are numerous instances in which secondary procedures that include Site Profiles differ with the basic guidance provided in OCAS-IG-001. For example, OCAS-IG-001 consistently specifies that missed dosimeter dose for photons, electrons, or neutrons be defined in terms of the limit of detection (LOD) divided by 2 for each cycle (i.e., LOD/2) and assigned an uncertainty for the assumed lognormal distribution. This protocol is described as one that is likely to overestimate the true dose and is, therefore, regarded as claimant favorable.

There are, however, other procedures that, at the discretion of the dose reconstructor, allow missed dose to be defined as (1) LOD, a point estimate representing the 95th percentile value of a lognormal distribution (ORAUT-PROC-0006, Attachment D-2), or (2) ORAUT-OTIB-0008 and ORAUT-OTIB-0010.

In summary, missed dosimeter dose may be derived by LOD/2 or LOD, which results in assigned missed doses that differ by a factor of 2.

Inconsistencies of this type are common among procedures, and selection of the approach to apply is determined by the magnitude of the **anticipated** probability of causation (POC) value of the claim. For example, LOD/2 is minimally claimant favorable and is used in instances where the POC is close to or exceeds the 50% value; conversely, LOD is recommended when there is **no** possibility of compensating a claim. It is SC&A's opinion that variable approaches of this nature for dose reconstruction are not scientifically valid and **cannot** be justified on the basis of process efficiency.

Review Objective 2.0

As specified in Title 10, Section 82.10(k), of the *Code of Federal Regulations* (42 CFR 82.10(k)), Section 1.4, *Initial Dose Assessment*, of OCAS-IG-001 acknowledges the

recommendation of a limited/partial dose reconstruction for claims where it is readily evident that the outcome will be unaffected by a more detailed and complete analysis.

However, little or no guidance is provided regarding specific criteria for identifying a claim with a low probability for compensation and the constraints (if any) that apply to the use of worst-case assumptions.

Without stating so, OCAS-IG-001 merely implies that the identification of a claim with either a high or low POC value rests with the individual dose reconstructor. This conflicts with ORAUT-PROC-006, which makes reference to ". . . a preliminary assessment performed by **Task 2 personnel** . . ." [emphasis added], who classify claims as either >50% POC or <50% POC along with the appropriate instructions for conducting an abridged dose assessment.

A future revision to OCAS-IG-001 should identify the role of the **Task 2 personnel** and their role in preclassifying claims with high or low POCs.

Review Objective 3.2.1

Section 2.1.1.3.2 discusses **TLD uncertainty** and provides a formula for deriving the **standard deviation** of the total air **kerma**, as cited by Hirning (1992). This formula is used for each recorded TLD dose and requires input data for (1) σ_n, the standard deviation of the null readings, and (2) σ_μ, the standard deviation observed at high air kermas.

The implementation guide states that ". . . data for σ_n and σ_μ should be **readily available** from most DOELAP accredited programs. . . ."

In Section 2.1.1.3.3, the implementation guide states, "While site-specific data, if available, should be used, in **many instances** this data will not be known . . . [and] the simple estimate of uncertainty is proposed based on the general equation provided by Hirning (1992)." [Emphasis added.]

Reviewer's Comments

(1) If in fact data for σ_n and σ_μ are readily available, a more efficient procedure would provide such data to avoid the repetitious need for each dose reconstructor to obtain it from the DOE.

(2) Section 2.1.1.2 states, "At most, large facilities . . . multi-element TLDs have been used since the **mid 1960s"**; and Section 2.1.1.3.2, *TLD Uncertainty*, recommends the use of site-specific data from DOELAP accredited programs, which only came into existence in the late **1980s**. Since the introduction of TLDs, these devices have undergone many design changes and improvements. As such, it is unreasonable to assume that the uncertainty parameters that define current and state-of-the-art TLDs also apply to DOELAP TLDs of the 1960s and 1970s. In fact, OCAS-IG-0001, Section 2.1.1.1, clearly acknowledges this in the statement, "Through the years, technological developments have

greatly improved the **accuracy** and **sensitivity** of the dosimeters." [Emphasis added.] Thus, the use of present-day uncertainty parameters as surrogate values for past TLDs cannot be considered **claimant favorable**.

(3) Because OCAS-IG-001 only **recommends** the use of site-specific data "if available," it provides the dose reconstructor the option of using the simplified dosimetry uncertainty described in Section 2.1.1.3.3, even when site-specific data are available. When multiple options of this nature may be selected at the discretion of the individual dose reconstructor, a critical concern is the potential **lack of consistency** of the dose reconstruction process.

Review Objective 4.0

Over the period of time during which claimants may have been exposed/monitored, there have been substantial changes in radiological practices and technological improvements, as noted in OCAS-IG-001, Section 2.1.1.1, which states the following:

> *Since the beginning of nuclear weapons research and production, individual workers have been monitored using personal dosimeters at **many facilities**. . . . Through the years, technological developments have greatly improved the **accuracy** and **sensitivity** of the dosimeters.* [Emphasis added.]

Thus, the accuracy and sensitivity of dosimeters and their use varied with time and location. Nevertheless, the OCAS-IG-001 approach for defining the uncertainty of film and TLDs does not address the variability of uncertainty with time and space. Section 2.1.1.3.1 states, "For simplicity, the approach outlined by the National Research Council (1989) will be employed for dose reconstruction under EEOICOPA."

However, in its evaluation of film badge dosimetry used between 1945 and 1962 for the 19 nuclear weapons test operations, the National Research Council/National Academy of Sciences (NRC/NAS) Committee on page 80 concluded that "Each test operation was **different** in some aspect of personnel film badge dosimetry. . . . To assure that all these different factors affecting film dosimetry programs were considered, the film dosimetry bias and uncertainty for **each** test operation were analyzed separately." [Emphasis added.]

Equally, Fix et al. (1994), who assessed the bias and uncertainty in recorded external dose for Hanford, stated the following (pages 2.11 and 2.12):

> *Dosimetry practices at Hanford changed over time as technology evolved, resulting in improved capabilities to measure a wide range of energies and types of radiation . . . . Because of the different capabilities of dosimeters used in different time periods, separate evaluations **of bias and uncertainty** are presented for the period 1944-56, 1957-71, and 1972-93.* [Emphasis added.]

The extent to which **Site Profiles** may provide time- and facility-specific data for defining dosimeter uncertainty remains undetermined at this time. This review does not intend to be critical of the OCAS-IG-001 simplified approach for defining uncertainty; however, such a simplified/generic method for defining uncertainty must provide assurance of claimant favorability by applying the highest observed uncertainty value(s) to the entire time period.

A more extensive evaluation of the OCAS-IG-001 dosimeter **uncertainty** methodology is provided below under Review Objective 6.0.

Review Objective 5.0

In behalf of Review Objective 5.0, five issues were identified, which are discussed separately below.

Issue 1: Limits of Detection

Section 2.1.2 discusses the LOD for personnel dosimeters and the use of LOD values for assigning missed dose. Table 2.1 provides LOD values for 1956 through 1960, which range from 30 millirem (mrem) to 10 mrem. As early as 1959, the LOD value of **10 mrem** is cited. For the stated time periods, these values are inconsistent with Site Profiles and other reported values.

For example, in its investigation of film dosimeters used during atmospheric testing that extended until 1962, the NRC/NAS Committee concluded that "For most test series, the minimum detectable level was determined to be approximately **40 mR**." [Emphasis added] (NRC 1989, page 3).

An LOD value of 40 mR is also cited for dosimeters worn at the Rocky Flats Plants (RFP) during the 1950s and 1960s. Table 6-9 of the RFP Technical Basis Document provides photon LOD values from 1951 through 2003, as reproduced below (ORAUT-TKBS-0011-6, Table 6-9, page 26):

Table 6-9. Photon limit of detection for RFP dosimeters.

Year	LOD	Year	LOD	Year	LOD	Year	LOD	Year	LOD	Year	LOD
1951	40 mR	1961	40 mR	1971	20 mR	1981	20 mR	1991	20 mrem	2001	10mrem
1952	40 mR	1962	40 mR	1972	20 mR	1982	20 mR	1992	20 mrem	2002	10mrem
1953	40 mR	1963	40 mR	1973	20 mR	1983	20 mrem	1993	10 mrem	2003	10mrem
1954	40 mR	1964	40 mR	1974	20 mR	1984	20 mrem	1994	10 mrem		
1955	40 mR	1965	40 mR	1975	20 mR	1985	20 mrem	1995	10 mrem		
1956	40 mR	1966	40 mR	1976	20 mR	1986	20 mrem	1996	10 mrem		
1957	40 mR	1967	40 mR	1977	20 mR	1987	20 mrem	1997	10 mrem		
1958	40 mR	1968	40 mR	1978	20 mR	1988	20 mrem	1998	10 mrem		
1959	40 mR	1969	20 mR	1979	20 mR	1989	20 mrem	1999	10 mrem		
1960	40 mR	1970	20 mR	1980	20 mR	1990	20 mrem	2000	10 mrem		

In summary, the NRC/NAS Committee and RFP data are inconsistent with LODs cited in OCAS-IG-001, Table 2.1; the use of Table 2.1 values would clearly not be claimant favorable.

OCAS-IG-001 also implies the assumption that, for a given dosimeter, the LOD for deep dose from gammas may also be applied to the electron dose, which would have involved the "open window" or the 7 mg/cm^2 shallow dose (see Sections 2.3.2.3 and 2.3.2.4). Historical data consistently show that the uncertainty, and therefore the LOD of the shallow dose, which includes the electron dose, is considerably higher than the deep dose or $H_P(10)$.

Issue 2: Failure to Include Potential Exposures From Electrons to Lens of Eye

Section 1.2.3 of OCAS-IG-001 describes electron (beta particle) exposure and states that:

> *Generally, external electron exposures are only important for surface tissue such as skin. Thus, for skin cancer, a dose reconstruction from exposure to electrons is required. . . . The other two organs for which external electron exposure from high energy electrons (> 1 MeV) might be significant are the* ***testes*** *and the* ***breast.*** [Emphasis added.]

Among the cancers eligible for compensation is eye cancer (Interface Control Document (ICD)-9 Code 190), with the lens of the eye as the external dose organ. Given the lens' shallow tissue depth of ~300 mg/cm^2 (or about 3 mm), it would appear reasonable to include the eye for electron dose estimates along with tissues of the testes and breast. Moreover, unlike the testes and breast, which may benefit from the added shielding affects of clothing, the eye (in the absence of eyeglasses) is not shielded.

Issue 3: Assumed Limitations of NTA Neutron Dosimeters

Section 2.2.1of OCAS-IG-001 acknowledged several limitations for NTA film dosimeters. A serious limitation of fast neutron dosimetry by track analysis is its insensitivity to neutrons. OCAS-IG-001 has assumed that NTA film dosimeters were insensitive to neutrons below 500 keV. This value significantly differs from the 1 MeV value cited by others, including Fix et al. (1997), whose work is heavily referenced throughout this procedure, as summarized below.

Fix et al., (1997). Fix's reference to a lower energy neutron cutoff of about **1 MeV** is cited on pages iv and v of the executive summary. On page 3.3 of Section 3.2, Fix et al. state that ". . . tracks of length less than about 3 microns are difficult to identify at Hanford, the observation of a track was confined to tracks with four or more grains. . . . As such, the lower energy threshold for the Hanford NTA film dosimeters is expected to be about 1 MeV, particularly when photon 'fogging' is present."

Hine and Brownell (1956). In their classic reference text *Radiation Dosimetry*, Hine and Brownell assume a similar value, as described on page 338, which is reproduced below:

> *A serious limitation on fast-neutron dosimetry by track analysis is its unsuitability at lower energies. Tracks of length less than perhaps 3 μ (proton energy of about 0.3 Mev) are difficult to distinguish from the change alignment of fog grains. Since three-tenths of the proton recoils from 1-Mev neutrons are of energy less*

> *than 0.3 Mev, the* ***error introduced by neglecting to count the shorter tracks is large at neutron energies this low.*** [Emphasis added.]

In summary, 500 keV threshold value assumed by OCAS-IG-001 appears inconsistent (and not claimant favorable) when compared to the 1 MeV value cited by others.

Issue 4: Reconstruction of Neutron Dose(s) from Survey Data or Source Term Data

Section 2.2.2.1 of OCAS-IG-001 states, "Neutron monitoring was not fully implemented, or was generally inadequate, until the late 1950s . . . even though large-scale operations were ongoing since 1945." In the absence of data for this 12-year period, Sections 3.2.2 and 3.2.3 discuss methods for neutron dose reconstruction by means of **survey data** and **source term data**. For claims that may have involved individuals with neutron exposures under variable and complex conditions, as well as over extended periods of time, the suggested methods do **not appear practical/achievable/defensible**.

OCAS-IG-001, Section 2.2.2.1, acknowledges that neutron exposures occur in combination with photon exposures and references the work of Watson (1959), who correlated the magnitude of neutron exposures with photon exposures. However, OCAS-IG-001 **dismisses** the potential use of a neutron-to-photon dose ratio as a viable method and concludes that ". . . at most facilities, neutron exposures were generally less than **20%** of the photon exposures."

Not acknowledged by OCAS-IG-001 is the fact that the **neutron to photon ratio** method for estimating neutron doses prior to 1971 has been adopted for dose reconstruction at SRS and, therefore, conflicts with the OCAS-IG-001 statement. In fact, neutron/photon ratios of up to 2.4 are cited in the SRS Technical Basis Document (ORAUT-TKBS-0003), which is 12 times higher than the 20% stated in OCAS-IG-001.

Also, **not** acknowledged by OCAS-IG-001 is the retrospective calculation of neutron doses and their relationship to recorded photon doses by Fix et al. (1997) in behalf of 14 Hanford workers (exposed between 1950-1961). These data are summarized by Fix et al. (1997) in Table 4.2 of Section 4.4 and reproduced below for verification (Table 2.1-2). Depending upon the method used to recalculate neutron dose, its value may be as much as 75% of the deep dose.

It is recommended that this section be revised to acknowledge the likely use of the neutron/photon ratio method in neutron dose reconstruction in lieu of survey data or source term data.

Table 2.1-2. Comparison of Integrated Neutron Dose Component, 1950-1961
(Source: Fix et al. 1997)

Worker	Recorded Dose [(a)]				Method Used to Recalculate Neutron Dose				
	Shallow	Deep	X-ray	Neutron	1	2	3	4	5
1	15,190	13,880	3,090	130	2,900	1,018	846	494	540
2	17.760	14,100	0	40	5,531	1,937	1,547	778	914
3	33,760	24,960	0	80	3,420	1,457	1,172	823	868
4	18,520	13,580	2,080	1,000	4,974	2,228	1,826	1,212	1,210
5	20,340	18,570	1,840	1,850	8,023	3,987	3,528	2,482	2,669
6	14,010	4,890	10	730	3,149	1,684	1,524	1,179	1,170
7	19,120	17,530	0	220	4,300	1,667	1,340	616	763
8	17,250	7,300	20	1,360	1,873	1,186	1,162	1,018	943
9	23,450	22,030	2,630	4,150	7,932	4,356	4,038	3,259	3,026
10	17,010	13,780	3,220	920	5,381	2,341	2,063	1,173	1,329
11	32,960	26,230	0	130	3,456	1,150	771	376	472
12	4,420	3,980	0	50	2,994	1,151	825	418	496
13	20,460	14,060	1,090	2,750	4,699	2,647	2,505	2,129	1,937
14	8,030	6,810	0	0	4,882	1,798	1,373	729	839

(a) Whole-body skin dose = Shallow + 65% of x-ray + neutron
Whole-body deep dose = Deep + 35% of x-ray = neutron

Issue 5: OCAS-IG-001, Appendix B, DCFs for Bone Surface and Red Marrow

At low photon energies, absorption is principally by means of the photoelectric effect and varies with the atomic number (z) of the absorbing medium. The variation with atomic number is not straightforward but is complicated by a rapid rise at discrete absorption degrees that define K-shell, L-shell, and other electrons. At photon energies above the absorption edge, the photoelectric cross section per **electron** varies as z^3 and per atom as z^4.

This phenomenon is exploited in diagnostic radiography in which bone tissue is readily distinguishable from soft tissue. Thus, simple depth dose curves derived from unit density phantom measurements cannot be applied to convert dosimeter data to bone doses.

Spiers (1946) has corrected the standard depth dose for this effect, and his results are shown below in Figure 2.1-1, in which a beam of 200-kv radiation, HVL 1.5 mm Cu, is passed through successive layers of skin, fat, muscle, and bone. Curve A is the standard depth dose curve, and curve B is the corrected curve. In the region beyond the bone, the actual depth dose is about one-half the expected value. Spiers has calculated the energy absorption, and this is shown by curve C of Figure 2.1-1. If there were no discontinuities, the energy absorption would be proportional to the depth dose curve, but with the bone present, the energy absorption is increased by a factor of about 5. **In this case, more energy is delivered to the bone layer at a depth of 6 to 9 cm than is delivered to the skin of the patient**. Figure 2.1-1 further shows that the average dose over a bone thickness of 2 cm is greater than (1) the entrance dose and (2) the $H_P(10)$ deep dose. The higher bone surface and red marrow doses defined by Spiers (1946) conflict with the lower DCFs contained in Appendix B of OCAS-IG-001.

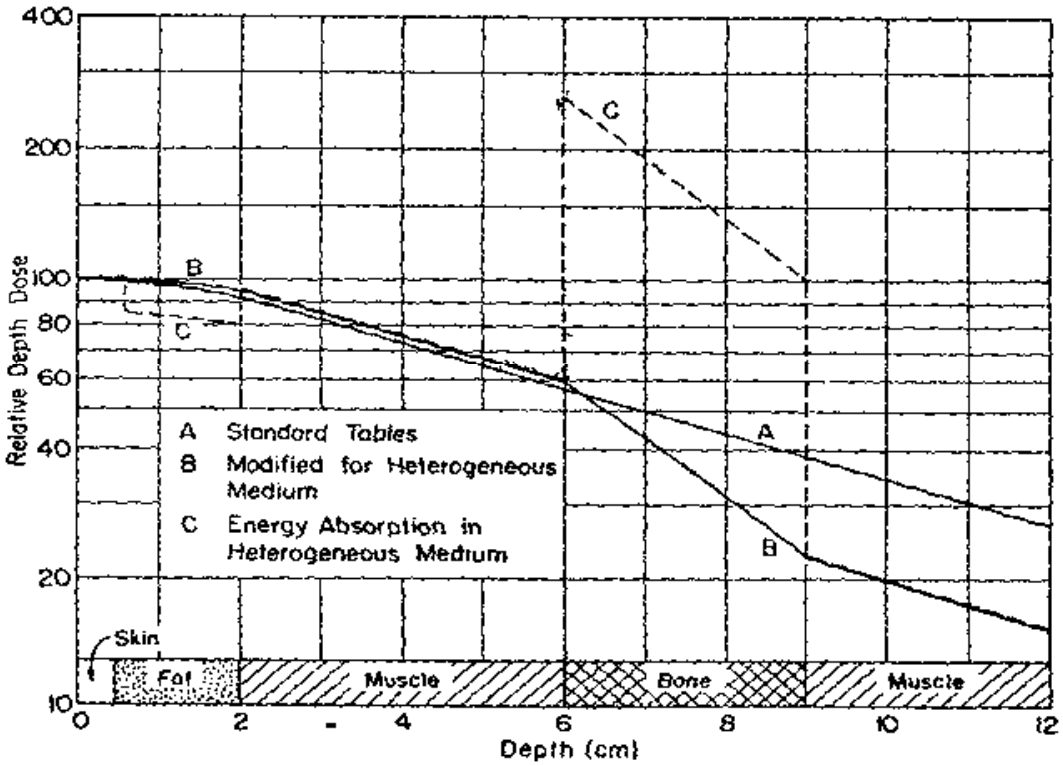


Figure 2.1-1. Relative Depth Dose in a Phantom Consisting of Layers of Skin, Fat, Muscle, and Bone. Field size 100 cm^2, TSD 50 cm, HVL 1.5 mm Cu. (Spiers 1946)

Potential Effects on Marrow Doses. Spiers (1949) investigated the effects of the higher atomic number and density of bone from another point of view. The trabecular cavities within bone are filled with the highly sensitive bone marrow stem cells. Spiers investigated the shift of electron equilibrium that takes place at the soft tissue to bone interphase and ionization within these small cavities. Some of his results are shown below in Figure 2.1-2 for three types of radiation. For low-energy radiation, the ionization within a small 1-μ cavity is 9.6 ions per cubic micron; whereas for a large cavity, 100 μ in diameter, the ionization at the center of the cavity is only 1.8 ions per cubic micron and rises to about 5 ions per cubic micron at the edge of the cavity. The range of the electrons, which are set in motion by low-energy radiation, is small; and none of the electrons set in motion in the walls of the cavity reach the center. The ionization density at the center of a large cavity is, therefore, nearly the same as for soft tissue. The results for medium-energy radiation are shown in Figure 2.1-2(b) and the high-energy radiation in Figure 2.1-2(c). For high-energy radiation, the range of the electrons is considerable, and the ionization density is essentially uniform throughout the cavity.

In summary, marrow contained in small bone cavities may receive doses that are several times higher than that assumed for full electron equilibrium in soft tissue.

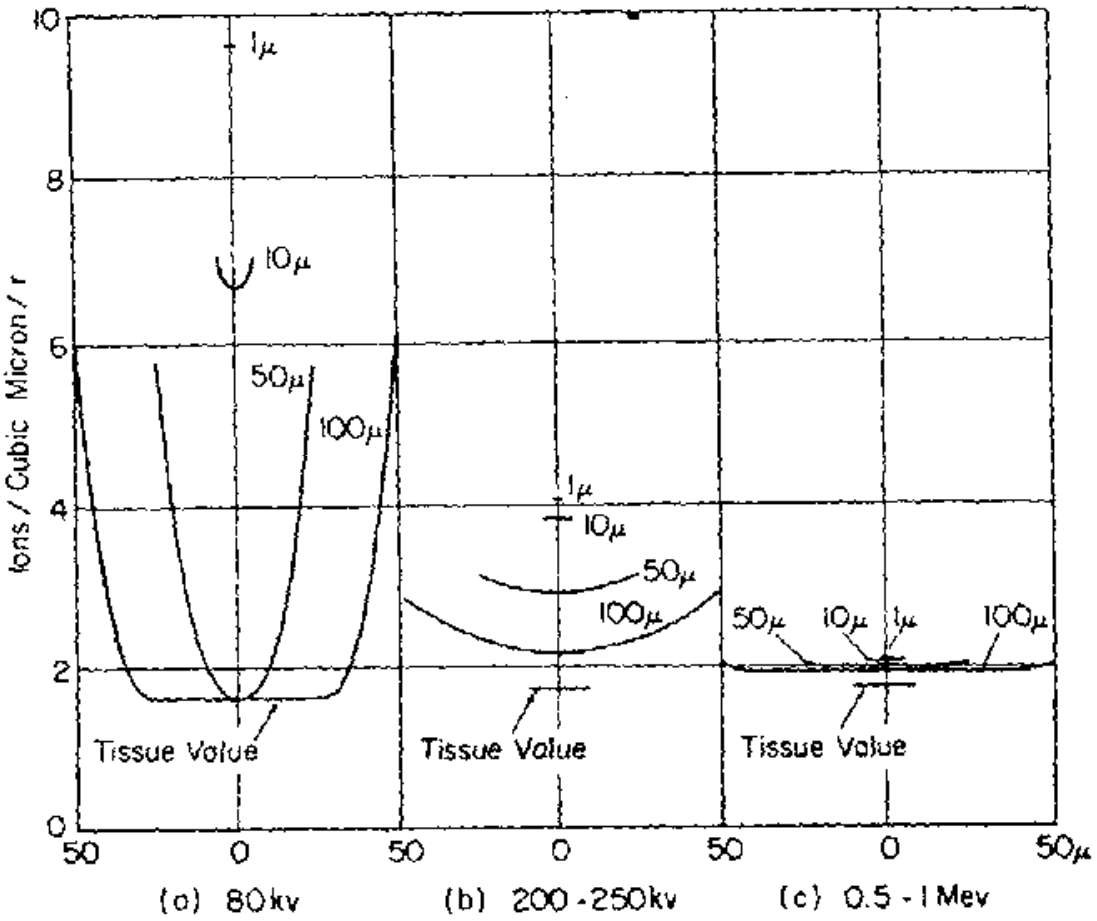


Figure 2.1-2. Ionization in Soft Tissue Inside Bone Cavities for Radiation Generated at 80 kv, 200 to 250 kv, and 0.5 to 1.0 MeV

In summary, data show that, when soft radiation is used (i.e., 30-250 keV), the layers of red marrow tissue adjacent to the bony structure receive a larger dose than tissue at the center of a larger cavity. Depending on the size of the bone cavity, the dose to bone marrow may vary significantly.

It appears that DCFs for bone surface and bone marrow derived from International Commission on Radiological Protection (ICRP) 74 data may not have taken these two effects into account.

Review Objective 6.0

Section 2.1.1.3 of OCAS-IG-001 discusses the **uncertainty** of personnel dosimeters. It provides the following statement for film badges (discussed in Subsection 2.1.1.3.1):

> *A technical committee appointed by the National Academy of Sciences outlined three components **(laboratory**, **radiological**, and **environmental**) of uncertainty in personal dosimetry for film badge dosimetry used during atmospheric nuclear*

tests (NRC 1989). The uncertainty in the environmental component is discussed in section 2.1.3, and the radiological component is discussed in the exposure geometry section 4.4. Thus the laboratory uncertainty is the only source of uncertainty addressed in this section. [Emphasis added.]

In summary, the NRC/NAS Committee identified the three separate components for uncertainty: laboratory, radiological, and environmental. The following discusses issues of concern related to each of the three components.

Issue 1: Laboratory Uncertainty

A review of the above-referenced NRC (1989) report reveals the following:

Page 68:

This category includes all the uncertainties introduced in film calibration, chemical processing of films, reading their optical densities, comparing these densities with the densities of unexposed and calibration films, and in interpreting the measured densities in terms of exposure.

Even under the best controlled laboratory conditions, laboratory uncertainties [K(E)] are a strong function of exposure levels, ***particularly at low exposure levels.*** [Emphasis added.]

Page 71:

The 95% uncertainty factor for the additional uncertainty for exposures ***below 0.2 R*** *is obtained as*

$$K^*(E) = e^{\sqrt{(\ln^2 K(E) - \ln^2 1.2}},$$

where $K(E) = 1 + 0.042\, e^{0.25E}/E$ *for Du Pont 502 film. Values of K*(E) are given in Table 5-1.*

Table 5-1 Additional Uncertainty Factors for Film Badge Readings Below 0.2 R

E(R)	*K(E)*	*K*(E)*
0.02	*3.11*	*3.07*
0.04	*2.06*	*2.01*
0.06	*1.71*	*1.66*
0.08	*1.54*	*1.47*
0.10	*1.43*	*1.36*
0.12	*1.36*	*1.28*
0.14	*1.31*	*1.22*
0.16	*1.27*	*1.17*
0.18	*1.24*	*1.13*

> *These factors are to be combined with uncertainties from other sources as usual, including the "standard" laboratory uncertainty factor, which is **1.2 or 1.3** for most test series.* [Emphasis added.]

The above-cited table from NRC (1989) not only identifies **standard uncertainties** (i.e., K(E)) that parallel the assumed value of 1.3 by OCAS-IG-001, but also additional uncertainties (i.e., K*(E)) for exposures below 0.2 R.

However, OCAS-IG-001, Section 2.1.1.3.1, states that:

> *. . . For simplicity, the approach outlined by the National Research Council (1989) will be employed for dose reconstruction under EEOICPA. However, the additional uncertainty discussed for exposures below 200 mR will not be employed, since routine monitoring is generally more precise than large sampling events such as atmospheric test monitoring. . . .*

OCAS-IG-001 provides no technical support for this nonconservative/nonclaimant-favorable assumption that excludes the additional uncertainty associated with exposures of less than 200 mrem.

Issue 2: Radiological Uncertainties — DCFs for Posterior to Anterior (PA) Exposure Geometry

NRC 1989 identifies the following three areas of uncertainty in behalf of the **radiological category**: photon energy, body wearing position, and radiation backscatter. It states the following:

> *. . . A film badge is normally expected to be worn on the **chest**. At such a position, it is not experiencing the same radiation field as if it were freely exposed in air because body attenuates radiation from the back. The presence of the body on which a badge is worn [also] increases the radiation field . . . because the body backscatters photons.*

OCAS-IG-001 considers photon energy and discusses radiological uncertainties in Section 4.4 in behalf of four exposure geometries; and Appendix B provides tissue/organ DCFs in behalf of three energy intervals and four exposure geometries.

SC&A's review of **radiological uncertainties** and exposure-geometry-specific DCFs presented in Appendix B of OCAS-IG-001 has led to the conclusion that PA geometry DCFs are in error, as explained below.

DCFs for PA Exposure Geometry. OCAS-IG-001, Section 1.5 (page 11), states that ". . . typically, film badge and TLDs were worn on the **upper front torso** of the body." Therefore, on the assumption that personnel dosimeters were commonly worn on the **chest**, the DCF_{PA} values given in Appendix B for photons and neutrons appear in error. SC&A has concluded that DCFs

for PA geometry given in Appendix B wrongly assumed that the measured dosimeter dose was worn on the **posterior** of the torso instead of the **anterior**. The consequence of this error would be most pronounced for those tissues/organs that are located at/near the posterior surface of the body (e.g., female breast, male testes, eye, thyroid).

For example, for photons between 30 and 250 keV, Appendix B gives a thyroid DCF_{PA} value of 0.298 rem for a recorded deep dose ($H_p(10)$) of 1 rem. If the recorded deep dose involved a dosimeter (either film or TLD) worn on the chest, the assigned thyroid DCF_{PA} of 0.298 is in error, as shown in the diagram below:

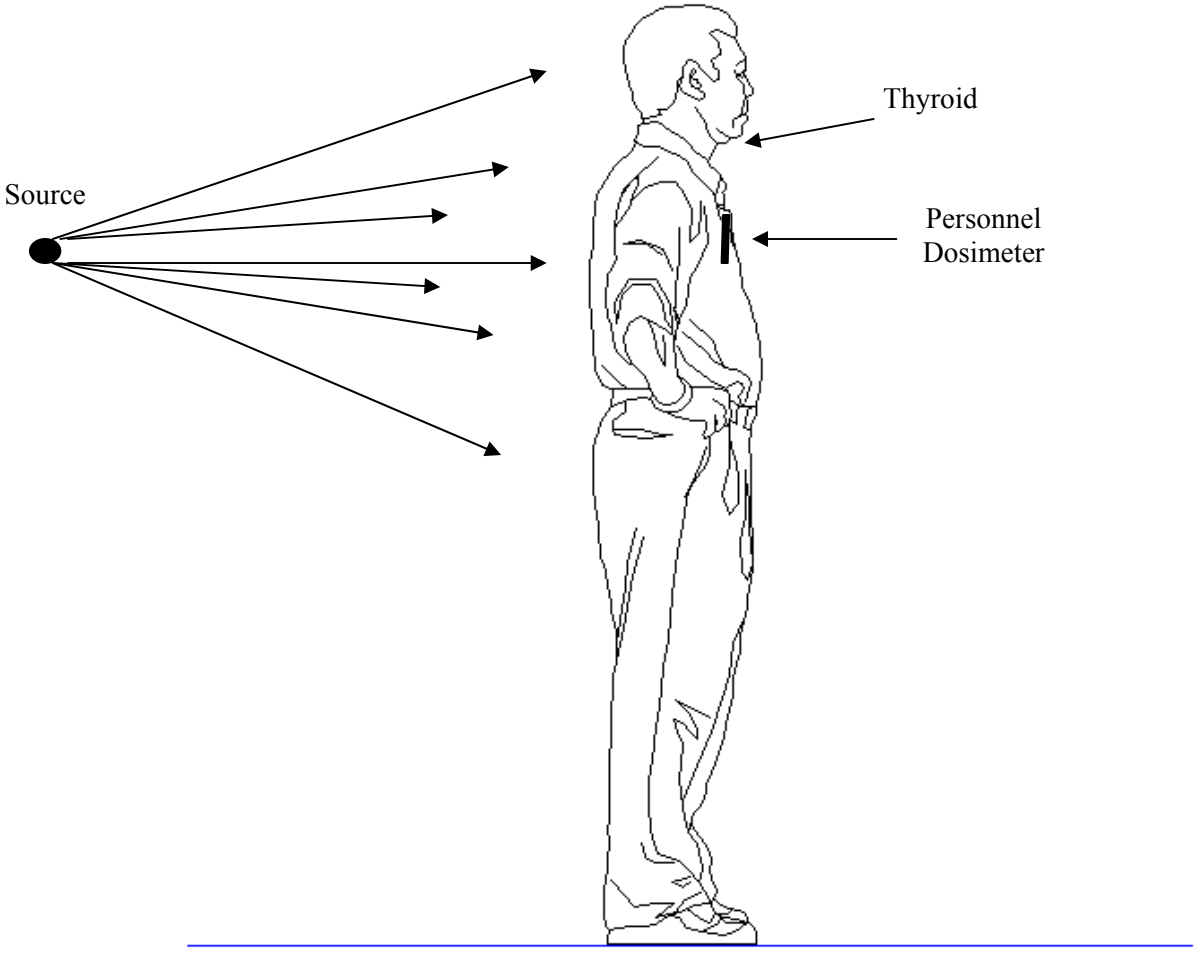


Figure 2.1-3. Worker Receiving Radiation Exposure From Posterior Geometry

(1) the personnel dosimeter received radiation that is attenuated by the full thickness of the chest
(2) the thyroid receives radiation that is attenuated by tissues that are limited to the neck
(3) additionally, tissues/organs within the body would also receive exposure from **backscatter,** which would **not** be recorded on an anterior-worn dosimeter that is subjected to a PA exposure geometry

In fact, for a recorded $H_p(10)$ dosimeter reading of 1 rem, the dose to the thyroid must be assumed at 1 rem or greater and, therefore, corresponds to a DCF_{PA} of ≥ 1.

It appears that the DCF_{PA} values given in Appendix B for photons and neutrons erroneously assumed that the dosimeter of record was worn on the body surface facing the source of radiation. For a PA exposure geometry, this would falsely assume that the dosimeter was placed on the posterior-side of the individual.

If this interpretation is correct, than DCF_{PA} values for **all** tissues should be ≥ 1.0 with the highest DCF_{PA} values for (1) low-energy radiation and/or (2) tissues/organs located near the posterior portion, since these tissues are subject to a beam that is **least** attenuated and subject to a maximum backscatter.

The likelihood that DCFs cited in Appendix B are inappropriate for the reconstruction of doses for energy employees (who must be assumed to have worn their personnel dosimeter on the body at the center of the chest) is validated by data presented in Figure 2.1-4 below, which has been taken directly from National Council on Radiation Protection and Measurements (NCRP) Report No. 122, 1995 (see Figure 3.1, page 19 of NCRP No. 122).

Figure 2.1-4 reproduces the conversion coefficients provided by the International Commission on Radiation Units and Measurements (ICRU) (1988) for the ratio $H_E/H_P(10)$, where $H_P(10)$ is the measured dose equivalent at a depth of 10 mm in the ICRU sphere and H_E is the effective dose equivalent defined as:

$$H_E = \sum W_T H_T$$

Where: W_T = tissue weighting factor
H_T = dose equivalent to the various tissues/organs irradiated.

Conversion coefficients for $H_E/H_P(10)$ are given for personnel monitors located either (1) on the body at the center of the chest (i.e., front) or (2) the center of the back for the following exposure geometries:

<u>Personnel monitor located on the front of the body (i.e., at the center of the chest)</u>

- AP—broad parallel beam from front to back (anterior to posterior)
- PA—broad parallel beam from back to front (posterior to anterior)
- LAT—broad parallel beam from either side (lateral)
- IS—isotropic field
- PL.IS—planar isotropic field, perpendicular to body axis

<u>Personnel monitoring location on the back of the body (i.e., at the center of the back)</u>

- AP—broad parallel beam from front to back (anterior to posterior)
- PA—broad parallel beam from back to front (posterior to anterior)

The critical difference in the $H_E/H_P(10)$ coefficient for a dosimeter that **in fact is worn on the front**, but is wrongly assumed to have been worn on the back, is dramatized by comparing the curves represented by Λ and □. The difference is most pronounced for low-energy and low-penetrating photons. For example, for 30 keV photons in cases in which the dosimeter is worn on the back, the coefficient is about 0.14; when the dosimeter is worn on front, the $H_E/H_P(10)$ coefficient is about 100, or nearly 1,000 times higher.

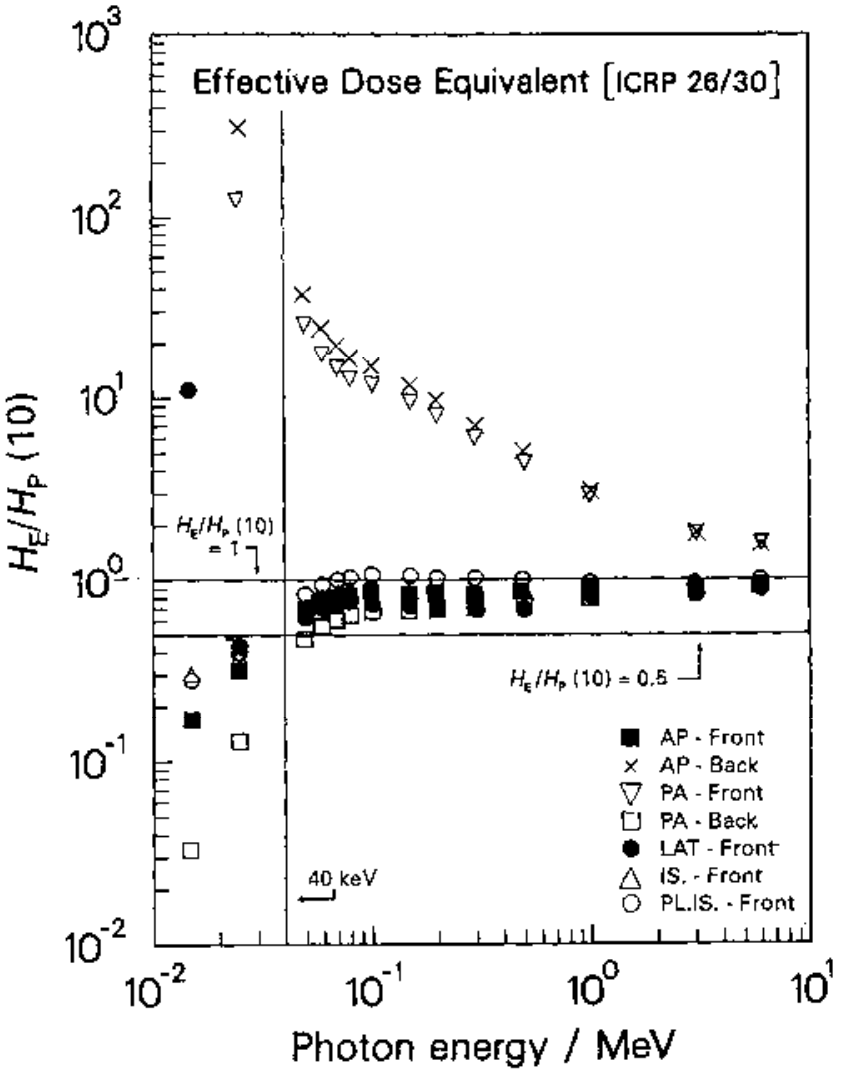


Figure 2.1-4. Ratio of H_E to $H_P(10)$ as a Function of Photon Energy

As previously stated and verified in Figure 2.1-4, for all photon energies, the ratio of organ dose to recorded $H_P(10)$ must be greater than unity when the recorded dose was measured on the body's anterior and when exposure corresponds to a PA geometry.

It is, therefore, concluded that PA DCFs cited in Appendix B for photons and neutrons were erroneously based on the assumption that the recorded dose represented a dosimeter that had

been placed on the back of the wearer. For low-energy photons, the resultant error in assigned dose may be greater than 100 times the true value.

Issue 3: Radiological Uncertainties and Potential Errors with Other Exposure Geometries/DCFs

A similar discrepancy for cited DCFs appears to apply to the **rotational** and **isotropic** exposure geometries. Under rotational exposure geometry, a dosimeter would be subject to a small fraction of photons that define the undisturbed radiation field. The balance of photons would be variably attenuated, as determined by the amount of tissue that must be traversed prior to reaching the dosimeter. With linear attenuation, a tissue/organ (e.g., lung) that falls at or near centerline to the vertical axis of the body would be expected to receive a dose that is essentially equal to the recorded deep dose ($H_P(10)$) of a dosimeter. This relationship is supported by Fix et al. (1994) and NRC (1989), which produced the following statements and data:

Fix et al. (1994) (page VI):

> *In general, **deep dose** slightly overestimates lung dose for the anterior-posterior geometry and slightly **underestimates** lung dose for the rotational geometry. . . . Deep dose is a **fairly accurate** estimate of red bone marrow dose for the rotational geometry, but overestimates red bone marrow dose substantially for the anterior-posterior geometry. . .* [Emphasis added.]

Fix et al. (1994) (page 2.10):

> *. . . Tables are available in the scientific literature (ICRP 1987, ICRU 1988) that provide factors for converting . . . deep dose to doses to various organs. These relationships, which depend on both energy and geometry, are based on computer calculations of particle fluency, exposure, deep dose based on the International Commission on Radiation Units and Measurements (ICRU) 30-cm diameter sphere, and the effective dose equivalent on an anthropomorphic phantom for different photon energies and exposure geometries. Tables . . . 2.3 and 2.4 show the respective relationship between . . . deep dose and bone marrow dose, and deep dose and lung dose. . . .*

Pertinent data from Tables 2.3 and 2.4, cited above, are presented in Tables 2.1-3 and 2.1-4 below. The data show marrow doses that are equal to or greater than the deep dose equivalent.

Table 2.1-3 Ratio of Red Bone Marrow Dose to Deep Dose Equivalent
(Source: Fix et al., 1994)

Photon Energy (keV)	Rotational Irradiation
70	1.0
100	0.99
120	1.0
200	1.04
500	1.0
662 (Cs-137)	1.0
1,000	1.0

Table 2.1-4. Ratio of Lung Dose Equivalent to Deep Dose Equivalent
(Source: Fix et al., 1994)

Photon Energy (keV)	Rotational Irradiation
70	1.13
100	1.13
120	1.12
200	1.12
500	1.07
662 (Cs-137)	1.07
1,000	1.07

Similar findings are reported in the 1989 NRC report:

NRC (1989) (page 78):

> *The relationship between effective dose equivalent and deep-dose equivalent for . . . rotational exposure geometries is presented in Table 5-2. For the rotational geometry, the deep-dose equivalent and the effective dose equivalent are nearly identical for photon energies above 0.08 MeV. . .*
>
> *Deep-dose equivalent does not indicate dose equivalent to [any] specific organs. To assess the risk of a clinically detectable effect (e.g., cancer) to a* ***specific*** *organ, it [is] necessary to estimate the dose equivalent to that organ. Calculations may be performed to estimate an organ-dose equivalent from deep dose equivalent. Tables 5-4 and 5-5 are examples for red bone marrow and lung, respectively, for rotational irradiation.* [Emphasis added.]

Tables 5.2, 5.4, and 5-5 from NRC 1989 are provided below as Tables 2.1-5, 2.1-6, and 2.1-7, respectively.

Table 2.1-5. Generic Ratios of Organ Effective Dose Equivalent H_E to the Deep-Dose Equivalent, $H_P(10)$
(Source: NRC 1989)

Photon Energy (MeV)	Anterior-Rotational Irradiation
0.05	0.87
0.08	1.06
0.10	1.09
0.20	1.06
0.40	1.03
0.60	1.03
0.80	1.02
1.00	1.02
2.00	0.99

Table 2.1-6. The Ratio of the Red Bone Marrow-Dose Equivalent to the Deep-Dose Equivalent, $H_P(10)$
(Source: NRC 1989)

Photon Energy (MeV)	Ratio for Rotational Irradiation
0.05	0.69
0.08	0.92
0.10	0.99
0.20	1.04
0.50	1.00
1.00	1.00

Table 2.1-7. The Ratio of the Lung-Dose Equivalent to the Deep-Dose Equivalent, $H_P(10)$
(Source: NRC 1989)

Photon Energy (MeV)	Ratio for Rotational Irradiation
0.05	0.93
0.08	1.12
0.10	1.14
0.20	1.12
0.50	1.08
1.00	1.07

The ratios of organ dose to deep dose equivalent for red bone marrow and lung cited by Fix et al. (1994) and NRC (1989) are identical for rotational exposure geometry and for photon energies above 0.08 MeV (80 keV), equal or exceed unity (i.e., $\exists$1.0).

These ratio values (or DCFs) should be compared to $DCFs_{Rot}$ given in OCAS-IG-001, Appendix B, and reproduced in Table 2.1-8 below. When, for example, the 30-250 keV energy values are compared to the 400 keV values cited by Fix et al. (1994) and NRC (1989), a difference of a

factor of 2 is noted and suggests that organ doses reconstructed by DCF_{Rot} may have been significantly **underestimated**.

Table 2.1-8. DCF_{Rot} Values for Red Bone Marrow and Lung Cited in Appendix B

Photon Energy	Bone (Red Marrow)	Lung
< 30 keV	0.036	0.052
30 – 250 keV	0.482	0.552
> 250 keV	0.760	0.802

Issue 4: Radiological Uncertainty — Angular Sensitivity

A serious limitation involving personnel dosimeters (film and TLD) used to assess photon and neutron exposures concerns angular sensitivity, as determined by body-wearing position relative to the radiation field. When personnel dosimeters are calibrated, the incident radiation is normal (i.e., 0E) to the plane of the dosimeter, yielding a dose response (i.e., calibration factor) that is optimal. At incident angles that deviate from 0E, the response of the dosimeters can be greatly diminished, which leads to an **underestimate** of the true exposure that is measured.

Empirical measurements of angular sensitivity of film to photons and neutrons have been reported by Hine and Brownell (1956) and are reproduced below in Tables 2.1-9 and 2.1-10.

Table 2.1-9. Sensitivity of NTA Film Badge in Free Air to Neutrons from Two Sources Incident at Various Angles
(Source: Hine and Brownell 1956)

Angle of Incidence	Po-B Neutrons	Po-Be Neutrons
0E	1	1
90E	0.63	0.50
0-90E (rotating)	0.72	0.65

Table 2.1-10. Relative Film Badge Sensitivity in Free Air for Gamma-Rays Incident at Various Angles
(Source: Hine and Brownell 1956)

Angle of Incidence	0.11 MeV	0.20 MeV	1.2 MeV
0E (perpendicular incidence)	1.00	1.00	1.00
22.5E	0.87	0.92	0.97
45E	0.46	0.73	0.91
67.5E	0.33	0.45	0.92
90E	0.16	0.41	0.94

The above data identify a significant reduction in response based on the angle of incidence. Thus, an **assumed** constant anterior to posterior (AP) exposure geometry for a recorded dosimeter that in reality represents exposure angles that may vary between 0E and ∀ 90E would significantly underestimate the person's true exposure.

The need to assess angular dependence is specifically addressed by the DOE in Section 3.3, *Angular Dependence of the Department of Energy Standard for the Performance Testing of Personnel Dosimetry Systems, DOE Laboratory Accreditation Program from Personnel Dosimetry* Systems, of DOE/EH-0027 (1986). DOE's recommended procedure for assessing angular dependence includes the rotation of an on-phantom dosimeter through at least seven different angles of incidence from -85E to +85E, including 0E, with the results of the angular dependence expressed as the ratio of the dose equivalent response to the administered dose equivalent at 0E.

Section 4.4 of OCAS-IG-001 identifies four exposure geometries and provides tissue-specific organ DCFs for each exposure geometry in Appendix B. However, these DCFs merely reflect the extent of beam attenuation for these tissues under these exposure geometries and range of energies, and do **not** account for angular sensitivity of the personnel dosimeter.

In summary, it is unclear whether the dose reconstruction protocol defined by OCAS-IG-001 incorporates angular dependence of personnel dosimeters in the overall uncertainty of these devices. As shown by Hine and Brownell (1956), the impact of angular dependence on uncertainty is significant and can easily parallel the magnitude assigned to **laboratory uncertainty**.

Issue 5: Radiological Uncertainty — Backscatter

Backscatter may significantly influence the dose-response of a dosimeter and reflects the calibration protocol. Fix et al. (1994) states that " In 1984, the dosimeter calibration procedure was changed to "on-phantom" as opposed to "in-air" to better simulate the dose to workers."

This implies that, prior to 1984, dosimeters were calibrated in free air and, after 1984, calibration of personnel dosimeters was performed on-phantom. For these two calibration conditions, the recorded dose may significantly differ.

For illustration, suppose that a dosimeter is placed at the point *P* on the surface of the phantom and that the amount of radiation is measured in a given length of time. Then suppose that the phantom is removed, leaving the dosimeter *P* at exactly the same point in space, and the exposure is run for an equal length of time. It will be found that the dose recorded by the dosimeter at *P* will be considerably less in the second case, because part of the radiation observed in the first case is radiation that is scattered back from the phantom to the point *P*. The backscatter factor is defined as follows:

$$Backscatter\ \ factor = \left(\frac{D_s}{D_a}\right)$$

The percentage backscatter is defined as

$$Percentage\ backscatter = \left(\frac{D_s - D_a}{D_a}\right)$$

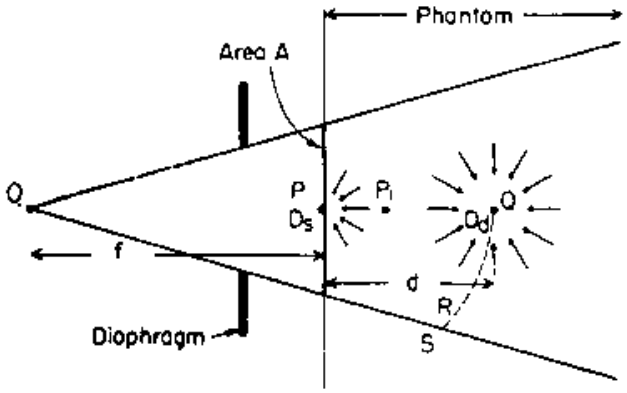
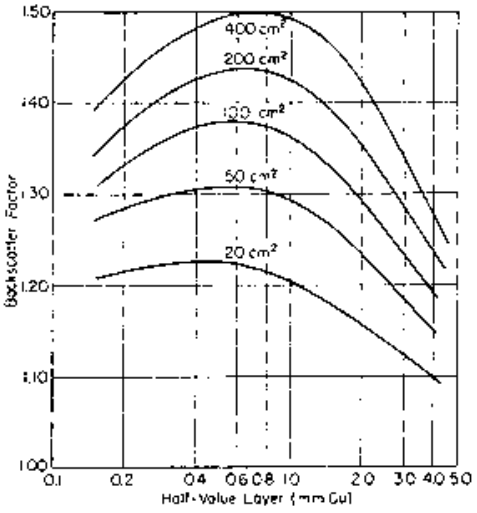


Figure 2.1-5. Diagram to Illustrate the Meaning of Surface Backscatter and Percentage Depth Dose

Here, D_a stands for the dose measured by the dosimeter in air, and D_s is the corresponding dose with the scattering material (i.e., phantom) in place.

Hine and Brownell (1956) evaluated backscatter and concluded that it depends (1) in a complex way on the energy of the radiation, (2) the area of the field, and (3) thickness of the scattering medium. The percentage of backscatter may be as high as 50% for a large field, adequate thickness, and select photon energy. Backscatter factors related to radiation quality and field size are summarized in Figure 2.1-6. The data indicate that, for photons with HVL between 0.6 mm Cu and 1.0 mm Cu (or ~60 keV-80 keV), the backscatter factor for a dosimeter worn on the upper torso of an adult could reach a value of about 1.5. Such a backscatter factor would apply to DCFs with photon energies between 30 and 250 keV, as given in OCAS-IG-001.



Equivalency between HVL and Photon Energy

HVL (Cu)	keV
0.1	37
0.2	45
0.4	55
0.6	64
0.8	70
1.0	77
2.0	110
3.0	135
4.0	155
5.0	185

Figure 2.1-6. Variation of the Backscatter Factor with the Quality of the Radiation for a Number of Field Sizes
(Source: Hine and Brownell 1956)

Since DCFs provided in OCAS-IG-001 do not distinguish between dosimeter readings as pre- or post-1984 when the conversion of free air to on-phantom calibration took place, questions that must raised include the following:

(1) Was the difference between free-air versus on-phantom calibration (and, therefore, the impact of backscatter) considered in the derivation of DCFs cited in Appendix B?

(2) If backscatter was factored into DCFs, what values were assigned in order to ensure conservatism and claimant favorability?

SC&A concludes that **radiological** uncertainty was not addressed in the overall uncertainty estimate for dosimeter readings.

Issue 6: Dosimeter Uncertainty — Environmental

The third and final category of uncertainty associated with personnel dosimeters was termed **environmental** by the NRC/NAS Committee (NRC 1989). **Environmental** uncertainty is the collective impact of environmental factors that include high temperatures, humidity/moisture, light, pressure, reactive chemicals, and radioactive contamination to which the dosimeter may be exposed in the field during the wear period. For adverse environmental conditions, the environmental uncertainty ($K_{ENV.}$) was estimated at 1.3 (NRC 1989).

As previously mentioned, OCAS-IG-001, Section 2.1.1.3.1, identifies environmental uncertainty in the following passage:

> *A technical committee appointed by the National Academy of Sciences outlined three components (laboratory, radiological, and **environmental**) of uncertainty in personal dosimetry for film badge dosimetry used during atmospheric nuclear test (NRC, 1989). The uncertainty in the environmental component is discussed in section 2.1.3 . . .* [Emphasis added.]

The referenced "Section 2.1.3," in fact, provides a discussion of occupational medical dose and makes **no** mention of environmental uncertainty.

It is likely that the intent was to identify Section 2.1.4, *Environmental Dose*, along with Section 2.1.4.3, which discusses the **uncertainty** for quantifying the **environmental dose**. However, the NRC (1989) definition of environmental uncertainty in dosimeter response to environmental factors, such as heat and humidity, has no relation to the discussion in OCAS-IG-001, Section 2.1.4.3, of environmental uncertainty associated with onsite ambient radiation doses to unmonitored personnel. SC&A concludes that environmental uncertainty was not addressed in OCAS-IG-001.

In summary, OCAS-IG-001 extensively references the study results of NRC (1989), Fix et al. (1996), Hine and Brownell (1956), and others without acknowledging their recommendations and findings, including dosimeter uncertainty categorized as **radiological** and **environmental**.

The discussion of **uncertainty** in OCAS-IG-001, therefore, appears **incomplete** and leaves several questions unanswered as to what was and what was **not** included, and whether the more restrictive treatment of uncertainty is truly claimant favorable. It would be helpful if OCAS-IG-001 provided summary uncertainty data similar to the sample data shown in Tables 2.1-11 and 2.1-12 below that was given in NRC (1989).

Table 2.1-11. Sample Data for Bias (B) and Uncertainty (K) for Operation CROSSROADS
(Source: NRC 1989)

Source	B	K
Laboratory	1.0	1.3
Radiological		
Spectrum	1.3	1.3
Wearing	0.8	1.3
Backscatter	1.1	1.1
Total Radiological	1.1	1.5
Environmental	1.0	1.3
Overall (Exposure)	1.1	1.7
Conversion to Deep-Dose Equivalent	1.3	1.2
Overall (Deep-Dose Equivalent)	1.5	1.8

Table 2.1-12. Sample Data for Deep-Dose Equivalent and 95% Confidence Limits for Operation CROSSROADS
(Source: NRC 1989)

Film Badge Exposure (R)	Best Estimate of Deep-Dose Equivalent (rem)	95% Confidence Limits fro Deep-Dose Equivalent (rem)
0.04 (MDL)	0.03	(0.00, 0.07)
0.05	0.03	(0.01, 0.08)
0.06	0.04	(0.02, 0.09)
0.07	0.05	(0.02, 0.10)
0.08	0.05	(0.03, 0.11)
0.09	0.06	(0.03, 0.12)
0.10	0.07	(0.03, 0.13)
0.12	0.08	(0.04, 0.15)
0.14	0.09	(0.05, 0.17)
0.16	0.11	(0.06, 0.20)
0.18	0.12	(0.07, 0.22)
0.20	0.13	(0.07, 0.24)
>0.20	0.67 E	(0.37 E, 1.20 E)

where E is the film badge exposure (R)

Issue 7: Uncertainty Distributions

Section 5.0 of OCAS-IG-001 describes the need to assess the uncertainty of the **total** organ dose, which may involve annual doses (and their uncertainties) from dosimeter readings, missed dose, medical dose, and environmental doses.

The following guidance is provided in OCAS-IG-001, Section 5.2:

> *The compiled distribution is likely to be either normally or log normally distributed. The tendency will most likely be highly dependent on the ratio between the missed dose (log-normal distribution) and the dosimeter dose (normal distribution). Therefore* ***some statistical test*** *should be applied to determine which distribution is more appropriate. The statistical test can be conducted manually* ***using any variety of methods or by using standard statistical software such as SAS®, StatGraphics® or SYSTAT®. Since the sampled dose distribution is likely not to fall strictly into one distribution or another, some professional judgment should be used to determine the best fit to the data.*** [Emphasis added.]

First, the option to apply "some statistical test" raises the question of consistency, and it is questionable whether the average dose reconstructor is sufficiently knowledgeable and experienced to ". . . exercise some professional judgment."

More importantly, there is no need for the dose reconstructor to manually compile a composite dose distribution. The Interactive RadioEpidemiological Program (IREP) allows for independent distributions and point estimates to be entered for doses, including dosimeter dose, missed dose, occupational medical dose, and onsite ambient dose.

Review Objective 7.0

There are numerous instances in which OCAS-IG-001 provides data and guidance that are of questionable value/significance, impractical, and excessively time-consuming, when viewed in the context of process efficiency. For illustration, the following two examples are provided.

Example 1: Conversion of Monitored Dose to Organ Dose

Section 4.0 of OCAS-IG-001 describes the basis and methods for converting **monitored** dose to the organ dose of interest. OCAS-IG-001 states that ". . . most early monitoring data was [sic] reported in the units of exposure and not a deep dose at 10 mm . . . ." **Thus, at DOE facilities, the recorded dose was principally in the unit of R and in later years as a 10 mm deep dose in rem**. Nevertheless, Section 4.1.1.2 describes the method from converting the **deep dose** ($H_P(10)$) and the **ambient dose equivalent** (H*(10)) to free-air kerma, a unit that is **not** normally used in personnel monitoring.

Table 4.1 of OCAS-IG-001 also provides factors that allow converting exposure to the ambient deep dose equivalent (H*(10)) and the free-air kerma (K_a) to the ambient deep dose equivalent (H*(10)). The unit of ambient dose equivalent is also not a unit that the DOE used for personnel monitoring.

Section 4.1.1.2 states that "Once the dose is converted to free-air kerma, the organ dose is a straight forward multiplication of the dose conversion (D_T/K_a) listed in Table A.2-A.20 of ICRP 74 (1996)."

Reviewer's Comments

If the OCAS-IG-001 requires the dose reconstructor to make use of ICRP 74 Tables A.2 through A.20 for converting the recorded dose (R or rem) to organ dose, the **19 tables** contained in ICRP 74 for organ-specific DCFs should have been provided in the document for timeliness and dose reconstruction efficiency. However, their use would require the dose reconstructor to know or assume the specific photon energy for the recorded exposure.

This problem is recognized, and the use of ICRP 74 tables is subsequently discouraged in Section 4.1.3, which states that "Since ICRP 74 lists the dose conversion factor for multiple energies [for a total of 23 photon energies], some simplification is needed for dose reconstruction under EEOICPA. . . . Appendix B lists the simplified dose conversion factors by reporting unit (**exposure, ambient dose (H*(10)**), or **deep dose equivalent ($H_P(10)$)** for the three photon energy bands." [Emphasis added.]

This is one of many examples where data are presented that have little value to the dose reconstructor and at best may be regarded as window dressing that could more appropriately be introduced in an appendix, as discussed above under Review Objective 1.0.

Example 2: DCF Simplification

The **simplification** for deriving organ doses from recorded doses by means of DCFs found in Appendix B is also puzzling. As stated in the OCAS-IG-001, ". . . personnel dosimeters commonly recorded doses in either **air exposure** (R) or in **deep dose equivalent at 10 mm** expressed in rem." Yet, Appendix B defines organ-specific DCFs in behalf of two other units: air kerma and ambient dose equivalent (H*(10)).

To the best of this reviewer's knowledge, neither air kerma nor ambient dose equivalent is commonly used in operational settings for the calibration and measurement of personnel exposures and ambient dose rates. In fact, a search of standard operational health physics reference texts fails to even identify or define the unit of **ambient dose equivalent**. Its definition, as given in ICRU 39–1983, ICRU 43–1988, and ICRP 51–1988 and cited below, provides no meaningful insight regarding its use in operational health physics.

> *The dose equivalent that would be produced by the corresponding aligned and expanded field, in the ICRU sphere at a depth, d, on the radius opposing the direction of the aligned field . . . .*

Thus, while the units of kerma free in air and ambient dose equivalent may have their value in select laboratory environments, their use in operational health physics and, therefore, dose reconstruction is questionable. Moreover, inspection of the four different DCFs cited in Appendix B for a given organ shows differences that range from less than 1% to a few percent, which in the overall scheme of dose uncertainty is insignificant.

It appears that the level of detail and scientific sophistication displayed in Section 4 and Appendix B are prime examples that demonstrate the failure of the procedures to (1) balance precision against efficiency, (2) limit dose reconstruction to reasonable estimates, and (3) support a timely resolution of claims.

The limited need to provide DCFs for four different units of radiation measurement is further supported by the fact that even the units of R and rem have historically been used interchangeably and considered equivalent. For example, in reviewing historical radiological safety practices during the period of atmospheric tests of nuclear weapons, the Defense Nuclear Agency (DNA) in its 1982 report offered the following (pages 94 and 95):

> *The radsafe criteria measuring units were the roentgen (R) and the rem. The roentgen, a measure of radiation in air, denotes an exposure intensity. The rem is a unit of radiation dose, i.e., a measure of radiation energy deposited within the body that takes into account its capability of causing an effect. . . . Another unit often used in discussing radiation doses is the rad. The rad is a measure of radiation energy deposited in any material; for biological tissue, a rad of low-quality radiation such as from gamma- or X-rays essentially equals a rem.*
>
> *At the time of the CASTLE series [1954] the distinction was usually* ***not*** *made between exposure (properly expressed in units of roentgens) and absorbed dose (properly expressed in units of rem, although at the time often expressed in roentgens); presumably external whole-body exposure and absorbed dose were assumed equivalent. This history expresses the measured data in exposure units (roentgens). Although the original references often referred to dose, there is no evidence that whole-body energy deposition was determined, nor that dose was indeed measured.* [Emphasis added.]

The practice of using R, rad, rem interchangeably was equally recognized (and accepted) by the Nuclear Regulatory Commission for decades. In 10 CFR Part 20 regulations that existed until the early 1990s (at which time select changes were made), the following regulatory standards were given under 10 CFR 20.4, *Units of Radiation Dose*, which discusses/defines the units R, rad, and rem:

> 10 CFR 20.4(c):
>
> *For the purpose of the regulations in this part, any of the following is considered to be equivalent to a dose of 1 rem:*
> *(1) A dose of 1 r due to X- or gamma radiation;*
> *(2) A dose of 1 rad due to X- or gamma radiation;*
> *(3) A dose of 0.2 rad due to neutrons or high energy protons; . . .*

For neutrons, Appendix B of OCAS-IG-001 provides organ DCFs for neutron exposures measured in (1) ambient dose equivalent and (2) deep dose equivalent and for calculated neutron

exposure defined by neutron fluence (i.e., n/cm^2). Here too, the value of providing neutron DCFs for ambient dose equivalent is questionable; even more questionable is the likely need for dose reconstructors to calculate neutron dose based on source term(s), shielding, distance, and time-in-area for **routine** exposure in workers who were either not monitored or whose dosimetry records are missing. It is highly unlikely that, for the thousands of claims that will be evaluated, there will be even a single instance where a neutron dose is reconstructed based on source term.

2.2 OCAS-PR-003 — PERFORMING AND REPORTING DOSE RECONSTRUCTION

The review of OCAS-PR-003, *Performing and Reporting Dose Reconstruction*, Rev. 0, dated September 24, 2002, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on January 11, 2005.

2.2.1 Purpose of Procedure

The stated purpose of this procedure "is to provide guidance for OCAS staff and its technical support contractors in the performance, review, and documentation of dose reconstructions for covered employees with cancer per the requirements of 42 CFR Part 82, *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*."

2.2.2 Review Protocol

SC&A's evaluation of OCAS-PR-003 is summarized in Table 2.2-1 below. Table 2.2-1 is a checklist containing the objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

2.2.3 General Comments

Section 5.0 of this procedure summarizes the stated policy, structure of the dose reconstruction process, and specific requirements that must be met for its completion, as defined in 42 CFR Part 82, Subpart C, *Dose Reconstruction Process*, and Subpart D, *Reporting and Review of Dose Reconstruction Results*.

Key elements cited in Section 5.0 of this procedure include (1) the need to be conservative such that uncertainties concerning data quality or dose are handled in a manner favorable to the claimant, (2) an iterative process that expedites the processing of claims in instances where an **initial dose evaluation** suggests a POC that is highly likely to be either **well above** or **far below** the 50% value, and (3) the need for a detailed/comprehensive and technically defensible dose reconstruction in instances where the POC is not evidently clear.

Attachment 1 of the procedure depicts the decision logic and algorithm that is to be employed in the conduct of dose reconstruction.

Section 6.0 represents the main body of this procedure and provides an itemized step-by-step outline of the dose reconstruction process that starts with the receipt of a claim (Section 6.1) and ends with the distribution of the final report (Section 6.18) and the closing of the claim (Section 6.19).

Table 2.2-1. Procedure Review Outline/Checklist

Document No.: OCAS-PR-003	**Effective Date:** 09/24/2004
Document Title: Performing and Reporting Dose Reconstruction	
Reviewer: U. Hans Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	3	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	3	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	3	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	3	See Review Comments
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	3	See Review Comments
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	3	See Review Comments
3.2.2	In vivo/In vitro bioassays	3	See Review Comments
3.2.3	Missing dosimetry data	2	See Review Comments
3.2.4	Unmonitored periods of exposure	2	See Review Comments
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	3	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	4	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	4	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	4	See Review Comments
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	1	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	1	See Review Comments
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.2.4 Review Comments

Review Objective 1.1

There is a significant amount of ambiguity regarding the individual(s) who is responsible for the various steps of the dose reconstruction process. Section 4.0 of OCAS-PR-003 identifies only (1) the records management team leader, (2) the health physicist(s), and (3) the OCAS Health Science Administrator. Clearly, other individuals/groups of individuals are involved in the process as outlined in the procedure.

Additionally, it is unclear who is referenced as the "health physicist" in terms of affiliation (i.e., NIOSH/OCAS versus ORAU and its contractors). It would appear that the health physicists whose responsibilities are defined in Section 6.2, *Evaluate Available Data/Information*, are OCAS health physicists, while responsibilities defined in Sections 6.7, 6.8, 6.9, 6.10, 6.11, and 6.12 belong to health physicists affiliated with ORAUT.

Review Objective 1.2

Several subsections of Section 6 of OCAS-PR-003 appear out of order. For example, Section 6.6.1 on page 11 identifies the step in which the OCAS Health Science Administrator ". . . assigns claim to Health Physicist for **evaluation**" who in turn ". . . ensures that . . . the claimant meets the definition of a **covered employee** . . . " [Emphasis added.]

For efficiency, this step should precede the extensive investment of effort and time required of the health physicist to **evaluate** available data/information as defined earlier in Section 6.2 (pages 7-10).

Review Objective 1.3

OCAS-PR-003, Section 3.0 (page 4), identifies only five references that assumedly apply to this procedure. A review of the listed references reveals that both OCAS and ORAU have prepared numerous procedures that have direct applicability to dose reconstruction, which should be cited in the list of references and acknowledged in the text of this procedure.

Among the more important documents and procedures that should be acknowledged are the Site Profiles, procedures defining the interview process (ORAUT-PROC-004; ORAUT-PROC-005; and ORAUT-PROC-006), and ORAUT's detailed procedures for performing internal and external dose reconstruction, as defined in ORAUT-PROC-0003 and ORAUT-PROC-0006, respectively. (It is the opinion of this reviewer that, on the basis of the improved guidance provided by ORAUT-PROC-0003 and ORAUT-PROC-0006, there is a questionable need for OCAS-PR-003.)

Lastly, Reference 3.4 should be updated. It identifies 42 CFR Part 82 as the "**Interim** Final Rule with Request for Comments" [Emphasis added].

Review Objectives 1.4 and 1.5

When compared to guidance provided by ORAUT-PROC-0003 and ORAUT-PROC-0006, OCAS-PR-003 suffers from a limited number of inconsistencies, but more importantly, it lacks the level of detail and structure related to dose reconstruction contained in these two procedures.

Review Objective 2.0

OCAS-PR-003, Sections 6.9 and 6.10 (pages 12 and 13), provide only a limited verbal description as guidance for conducting dose assessments that potentially yield a low or high POC. Here too, when compared to guidance provided in Attachment D of ORAUT-PROC-0006, the procedural guidance provided in OCAS-PR-003 is sparse/insufficient.

Review Objective 3.1

OCAS-PR-003, Section 6.3 (page 10), **briefly** identifies the interview with the claimant and its intended objectives but makes no references to the scope, method(s), and conduct of the claimant interview. The procedure's deficiencies regarding the interview process are readily explained by the fact that the effective date for OCAS-PR-003 is given as September 24, 2002. This date precedes the issue dates for the interview procedures ORAUT-PROC-0004, -0005, and -0007.

Review Objective 3.2

In instances where the POC is **not** evidently clear, the iterative process may require a highly detailed and exhaustive dose reconstruction process. This type of claim will maximally challenge the dose reconstruction and require the largest amount of time. This category of claims is only **briefly** mentioned in Section 6.11, *Refining Dose Reconstruction*. As such, less than one-half page is less than adequate.

Many of the elements that are likely to be used in such an exhaustive dose reconstruction process are inappropriately identified in Subsections 6.2.8 through 6.2.15. These subsections, however, are part of Section 6.2, which deals with the **initial evaluation** of available data/information following the receipt of a claim. As examples, Subsections 6.2.8.3, 6.2.8.4, 6.2.8.5, and 6.2.8.6 identify incident investigation reports, performance characteristics of dosimeters for different radiation types, dosimeter exchange frequencies, and area radiation survey measurements, etc., but provide limited guidance for employing such data in instances of (1) missing dosimetric data or (2) unmonitored periods of exposure.

While it is recognized that in most instances such site-specific data may be available in the **Site Profiles**, there are exceptions. A review of the SRS Profile and discussions with the authors of the Site Profile revealed that many of these data are not provided in the SRS Site Profile. According to the authors, they excluded these data because the Site Profiles generally contain only that information needed to assist in the reconstruction of doses for select categories of workers, and because additional site data will be incorporated into the Site Profile as needed to support dose reconstruction.

Review Objective 4.0

OCAS-PR-003 makes **reference** to 42 CFR Part 82 and Implementation Guides 001 and 002. Although these documents clearly define the need to adhere to a prescriptive process and a hierarchical process for dose reconstruction, Section 6.2 of OCAS-PR-003 fails to prioritize dosimetric data in the dose reconstruction process.

Review Objective 5.0

Sections 5.0 and 6.0 of OCAS-PR-003 make reference to the use of worst-case assumptions and claimant-favorable assumptions as if these two terms were interchangeable. A strong distinction should be made when worst-case values are **selected** solely for process efficiency in claims predetermined as **noncompensable**, as opposed to the **unconditional** use of worst-case assumptions in instances of unknowns. Only the latter case qualifies as claimant favorable.

SC&A notes that other OCAS and ORAUT procedures equally misuse the term claimant favorable when used for process efficiency in noncompensable claims.

In summary, it is this reviewer's opinion that a distinction should be made when worst-case assumptions are employed for reasons of **expediency**, as opposed to their surrogate and truly claimant-favorable use in instances of unknowns.

Review Objective 6.0

OCAS-PR-003 only mentions the need to address the uncertainty of dose estimates in the following statements, but provides no further guidance that is considered useful to the dose reconstructor. For example, Section 5.2 (page 5) states the following:

> *Dose reconstructions will be performed in a conservative manner such that uncertainties concerning data quality or dose are handled in a manner favorable to the claimant.*

Section 6.12.2.8 (page 20) merely states:

> *The estimate of annual dose will be characterized with a probability distribution that accounts for the uncertainty of the estimate.*

Review Objective 7.0

Subsections 6.2.8.1 through 6.2.8.15 identify an extensive list of **potential** sources of data that may be used for dose reconstruction. However, their conditional use, as stated in Section 6.2.8, minimizes the value of this document as a functional procedure in dose reconstruction:

> *Obtain the type of information described in this section for dose reconstruction, **as necessary and available***. [Emphasis added.]

2.2.5 Conclusions

This procedure is among the first issued by OCAS and, therefore, predates many subsequent procedures that provide more definitive guidance on dose reconstruction. On a relative scale, OCAS-PR-003 provides at best an overview of the reconstruction process without the necessary guidance provided by other/subsequent procedures. Its current value and use in dose reconstruction is, therefore, questionable.

2.3 ORAUT-PROC-0006 — EXTERNAL DOSE RECONSTRUCTION

The review of ORAUT-PROC-0006, *External Dose Reconstruction*, Rev. 00, dated June 28, 2003, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on January 11, 2005.

2.3.1 Purpose of Procedure

As stated in Section 1.0 of ORAUT-PROC-0006:

> *The purpose of this procedure is to implement the requirements of 42 CFR 82 and provide guidance for technical support contractors of the Office of Compensation Analysis and Support (OCAS) in the performance of external dose reconstructions under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). For each covered employee under this program, the dose reconstructions are performed using the data provided by the United States Department of Energy (DOE) and the Department of Labor (DOL) along with other supplementary records or information.* ***This procedure provides specific steps and instructions for performing dose reconstructions based on the principles contained in OCAS-IG-001, External Dose Reconstruction Implementation Guideline (IG).*** [Emphasis added.]

2.3.2 Review Protocol

The evaluation of ORAUT-PROC-0006 is summarized in Table 2.3-1 below. Table 2.3-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

2.3.3 General Comments

To a large extent, this procedure includes general/technical background information that is verbatim or closely parallels information presented in OCAS-IG-001. For this reason, some of SC&A's technical concerns given in behalf of OCAS-IG-001 apply equally to ORAUT-PROC-0006. For expediency, these comments are not repeated here but are merely noted in Table 1.

A major difference between OCAS-IG-001 and ORAUT-PROC-0006 is an improved format and the inclusion of Attachment D, *Desk Instructions for External Dose Reconstruction*. Attachment D provides **specific**, step-by-step instructions for performing dose reconstructions by providing seven separate sets of instructions that differ on the basis of (1) the claim's potential for compensability, (2) the availability of monitoring data, and/or (3) the type of exposure. Step-by-step desk instructions are provided in Attachments D-1 through D-7 for the following categories of claims:

- Attachment D-1: *Likely >50% POC Cases*
- Attachment D-2: *Likely <50% POC Cases for Monitored Covered Employees*
- Attachment D-3: *Likely <50% POC Cases for Unmonitored Covered Employees*
- Attachment D-4: *Certain Skin Cancer Cases*
- Attachment D-5: *Cases Not Pre-Classified as Likely >50% POC or Likely <50% POC and for Which Monitoring Data Exist*
- Attachment D-6: *Cases for Which Monitoring Data Do Not Exist but Co-Worker Data Are Available*
- Attachment D-7: *Special Cases Requiring Unique Dose Reconstruction Approaches*

Attachments D-1 through D-7 provide specific instructions that greatly enhance the **efficiency** and **timeliness** in completing a dose reconstruction and satisfy several concerns raised under SC&A's Review Objectives 1, 2, and 7. ORAUT-PROC-0006 further states that ". . . the **list** of individual desk instructions that have been developed for use by External Dose Reconstructors is likely to be modified as the project progresses and each desk instruction will be periodically revised as necessary."

User efficiency has also been improved by eliminating the fragmented format of OCAS-IG-001 (as noted by SC&A). ORAUT-PROC-0006's improved format has consolidated all relevant topics in a logical sequence and within a single section. Thus, essential topics for photon dosimetry are contained in Section 6.1, while those for neutrons and electrons are presented in Section 6.2 and Section 6.3, respectively.

A side-by-side comparison between ORAUT-PROC-0006 and OCAS-IG-001 shows that several technical issues of concern that SC&A raised in behalf of the IG were also addressed in ORAUT-PROC-006. For example, Section 5.2 of this procedure conditionally includes the **eye** as a target organ in instances of high-energy electron exposures; and Section C.2 of Attachment C acknowledges the potential difficulty and subjective nature for the assignment of a distribution (i.e., normal versus lognormal) to the final organ dose by informing the dose reconstructor that ". . . additional instructions will be provided in a separate procedure that describes the preparation of data for, and operation of, the IREP codes."

ORAUT-PROC-006 also stresses the role and importance of site-specific data and acknowledges that ". . . due to the complexity of dose reconstruction, the methods provided in site-specific Technical Basis Documents may supercede the methods provided in this procedure."

Table 2.3-1. Procedure Review Outline/Checklist

Document No.: ORAUT-PROC-0006, Rev. 00	**Effective Date:** 06/28/2003
Document Title: External Dose Reconstruction	
Reviewer: U. Hans Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comment 1.1 in behalf of OCAS-IG-001
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comment 1.3 in behalf of OCAS-IG-001
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	3	See Review Comment 1.4 in behalf of OCAS-IG-001
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	3	See Review Comment 1.5 in behalf of OCAS-IG-001
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	3	See Review Comment 3.2.1 in behalf of OCAS-IG-001
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	4	See Review Comment 4.0 in behalf of OCAS-IG-001
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	4	See Review Comment 6.0 in behalf of OCAS-IG-001
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	3	See Review Comment 6.0 in behalf of OCAS-IG-001
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	3	See Review Comment 7.0 in behalf of OCAS-IG-001
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	3	See Review Comment 7.0 in behalf of OCAS-IG-001

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.3.4 Review Comments

Because of similarities between ORAUT-PROC-0006 and OCAS-IG-001, review comments considered relevant to ORAUT-PROC-0006 were stated in behalf of OCAS-IG-001, as noted above in Table 2.3-1.

2.4 ORAUT-OTIB-0010 — A STANDARD COMPLEX-WIDE CORRECTION FACTOR FOR OVERESTIMATING EXTERNAL DOSES MEASURED WITH FILM BADGE DOSIMETERS

The review of ORAUT-OTIB-0010, *A Standard Complex-Wide Correction Factor for Overestimating External Doses Measured with Film Badge Dosimeters*, Rev. 00, dated January 12, 2004, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on January 11, 2005.

2.4.1 Purpose of Procedure

The following statements are in the procedure's foreword and define its purpose:

> *This technical information bulletin (TIB) presents external radiation dose assumptions that **may** be applied to dose reconstructions involving cases for which dose estimates may be prepared based on recorded deep and/or **shallow dose** that incorporate dose monitoring information during the later film badge era. Information in **this TIB supports radiation dose estimates for complex-wide cases covering the time period of 1970 and after**.*
>
> *It is possible to apply reasonable, overestimating complex-wide assumptions for interpreting recorded photon dose for select cases. The methodology described below will generate a reasonable overestimate of external radiation dose for cases that are likely **non**-compensable. In accordance with the process of efficiencies discussed in 42 CFR 82, use of an overestimated dose allows the expeditious processing of likely non-compensable cases.* [Emphasis added]

2.4.2 Review Protocol

The evaluation of ORAUT-OTIB-0010 is summarized in Table 2.4-2 below. Table 2.4-2 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

2.4.3 General Comments

In brief, the **expeditious** dose reconstruction for **noncompensable** claims contains three elements for maximizing **organ** doses in behalf of claimants monitored after 1970 by means of a

four-element film badge and whose exposure reflect photon energies between 30-250 keV. These three elements are summarized below:

(1) For missed dose (i.e., zero dose recordings), assume the LOD of 40 mrem and multiply the LOD times the assumed monthly exchange frequency.

(2) Use a standard correction factor of 2 to ". . . compensate for uncertainty from potential variance in site-specific exposure conditions and calibration practices . . . [and] to convert the dose as measured from site to site to a standard value of $H_p(10)$ . . . ."

(3) Select an organ DCF from Appendix B of IG-001 that involves the exposure (R)-to-organ (H_T) DCF unless that value is less than unity, in which case the DCF will be assumed to have a value of 1.

Section 4.0 (page 9) of ORAUT-OTIB-0010 states the following:

> *Standard values for energy distribution, missed dose, organ dose conversion factors and exchange frequencies are given in Table 4-1 below. These may be applied to recorded doses from the late film badge era.*

Table 4-1, as it appears on page 9 of ORAUT-OTIB-0010, is reproduced below as Table 2.4-1 and will be referenced in review comments that follow.

Table 2.4-1. Standard Assumptions for Overestimating Dose Measured with Film Badges

Period of applicability	Photon energy range (keV)	Missed dose per cycle	Standard correction factor	Exposure-to-Organ (Ht) DCF	Assumed exchange frequency
1970 onward	100% 30–250	0.040	2.0	≥ 1[a]	Monthly

[a] From Appendix B of the OCAS-IG-001, *External Dose Reconstruction Implementation Guideline*: a value of 1.0 or the table value (typically assume 100% AP geometry), whichever is greater.

Table 2.4-2. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0010	**Effective Date:** 01/12/2004
Document Title: A Standard Complex-Wide Correction Factor for Overestimating External Doses Measured with Film Badge Dosimeters	
Reviewer: U. Hans Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	3	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	4	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	N/A	
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	3	See Review Comments
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	3	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.4.4 Review Comments

Review Objective 1.1

In select areas, the information and guidance contained in this procedure are ambiguous, and even after several careful readings, several unanswered issues remain about its proper use, including those discussed below.

Issue 1: Missed Dose

It is assumed that for missed dose the LOD value of 40 mrem is used for each cycle. It is unclear, however, by **how many** cycles the 40 mrem/cycle should be multiplied. Table 4-1 suggests that the dose reconstructor **assumed** a **monthly** exchange frequency, which for a **full** year would result in a maximum missed photon dose of 480 mrem. Such an assumption would imply that there was **no** recorded dose for the year (i.e., 12 recorded monthly doses of zero). Thus, the procedure provides no guidance for treating dosimetry data in which the number of zero readings is fewer than 12 in any given year. Although it is further assumed that any missed dose based on LOD (as opposed to LOD/2) represents the 95th percentile value and, therefore, requires no uncertainty input value for IREP, this procedure fails to acknowledge this to the dose reconstructor.

Issue 2: Evaluation of Shallow Dose

The procedure contains the following statements that appear contradictory:

Page 7, Foreword of ORAUT-OTIB-0010:

> *This technical information bulletin (TIB) presents external radiation dose assumptions that may be applied to dose reconstructions involving cases for which dose estimates may be prepared based on recorded deep and/or **shallow dose** . . .* [Emphasis added]

Page 9, Section 5.0 of ORAUT-OTIB-0010:

> *This TIB is **not** to be used for evaluation of shallow doses. (Note: for breast and testicular cancer cases, this TIB can be used for calculating the deep dose component only.)*

Review Objective 1.2

The TIB provides a substantial body of background information in Section 2.0 that gives technical support for the methodology used to maximize external dose data, as summarized in Table 2.4-1 above. The dose reconstructor, therefore, must read through page 8 of the procedure before encountering procedural guidance for maximizing doses, as defined by post-1970 four-element film dosimeters.

Furthermore, a substantial part of these background data involves deficiencies and performance characteristics of the **two**-element film dosimeters, which are **not** relevant to the implementation of this procedure (i.e., the implementation of this procedure is limited to "later film badge era") that is defined by the four-element film dosimeter.

For improved efficiency in the routine use of this TIB by dose reconstructors, Section 4.0 and Table 4-1 should be relocated to the front of the procedure.

Review Objectives 1.3 and 1.5

This reviewer interprets the "standard correction factor" identified in Table 2.4-1 above as a simple multiplier that is to be used **only** for any **recorded** photon dose. Thus, in behalf of this procedure, a monthly dosimeter reading of 50 mrem would be multiplied by 2 for an **assigned** dose of 100 mrem. An unresolved question about the standard correction factor is its use when the recorded dosimeter dose is greater than zero but less that LOD (i.e., 40 mrem). A statement that the use of the **standard correction factor** eliminates the need for identifying the uncertainty as parameter #2 of the IREP input code is also missing.

Review Objective 1.4

Multiple options exist in terms of procedures that a dose reconstructor may follow. For claims that are prejudged as noncompensable (i.e., likely < 50% POC), the dominant procedure is ORAUT-PROC-0006, Attachment D-2: *External Dose Reconstruction Desk Instruction for Likely < 50% POC Cases for Monitored Covered Employees*. This procedure states that:

> *In general, this instruction applies to maximizing assumptions for both recorded and potentially unrecorded doses to ensure that the covered employee's dose and probability of causation (POC) are not underestimated.*

And,

> *This instruction applies to claims that were **pre-classified** "likely < 50% POC" and considers only those cases for which routine external dose monitoring data are available.* [Emphasis added.]

A comparison of ORAUT-PROC-0006 with ORAUT-OTIB-0010 shows the following differences:

(1) For recorded film dosimeter photon doses, ORAUT-PROC-0006 provides the following guidance in Section 5.0:
   - Multiply dosimeter dose(s) with exposure (R) to organ dose values from Attachment B and assign a DCF of 1.0 if table value is < 1.0.
   - "Apply an appropriate uncertainty factor . . ." to the above derived organ dose. (Note: ORAUT-PROC-0006 does **not** employ a **standard correction factor.**)

(2) For post-1970 four-element film dosimeter data, ORAUT-OTIB-0010 uses the standard correction factor of 2 as a multiplier for recorded dosimeter readings, an organ DCF that is similar to that recommended by ORAUT-PROC-0006 but with **no uncertainty**.

Review Objective 4.2

The TIB does not identify its **hierarchical** position among other competing procedures/ documents that could be used in its place or could require this TIB's support. Questions regarding the use of this TIB for dose reconstruction include the following:

(1) Does the use of ORAUT-OTIB-0010 for dose reconstruction require that the claim be **preclassified** as "likely <50% POC" (as is the case for ORAUT-PROC-0006)?

(2) For claims with recorded exposures that meet the conditions specified in ORAUT-OTIB-0010, does the dose reconstructor have the option to use either the desktop instructions provided in Attachment D-2 of ORAUT-PROC-0006 with site-specific data or use the generic default value provided in ORAUT-OTIB-0010?

Review Objective 6.0

Issue 1: Uncertainty

Although the TIB does not contain any explicit statement, SC&A has interpreted the use of the standardized correction factor of 2 as a "worst-case" assumption for which there is no further assignment of uncertainty. Given that NIOSH's assessment of dosimeter uncertainty does not address the contribution of **radiological** and **environmental** uncertainty (see SC&A's comments pertaining to Review Objective 6.0 in behalf of OCAS-IG-001), the standardized correction factor of 2 that the TIB describes as one ". . . that takes a large number of programs and features into account [and] must admit a **great deal of error** into any estimate it modifies" [emphasis added] does **not** appear excessively conservative (and claimant favorable) or result in an extreme/improbable value. A review of the 1989 NRC report, which assessed film badge uncertainty for all 19 atmospheric nuclear test operations, reveals that the 95th percentile deep dose equivalent value was **routinely** twice the best estimate of the deep dose equivalent.

The TIB's description of this standardized correction factor as claimant **favorable** is also highly conditional and, therefore, misleading. In Section 1.0, *Introduction*, the TIB initially states that the error of overestimating the dose ". . . is permissible under the **claimant's favor**. Specifically, any error must overestimate rather than reduce the claimant's probability of causation" [emphasis added], but concludes with the following statement, which reveals the true purpose, ". . . As the intent is to overestimate the dose to **take advantage** of an **efficiency** progress [sic], this methodology proposed here is useful **only for likely noncompensable claims**" [Emphasis added].

The use of overestimated dose(s) to expedite a claim is fully endorsed by SC&A, but when restricted to claims that have been firmly established as noncompensable, a reference to being "claimant favorable" is misleading.

Issue 2: Limits of Detection

Section 3.2 of ORAUT-OTIB-0010 discusses the LOD of film dosimeters and references the 1989 NRC with the following statements:

> *A typical value of film sensitivity is 0.5 NOD units per 400 milliroentgens exposure CETS 1989. This translates to a lower limit of detection of between 10 and 20 milliroentgens for films with this sensitivity, for* ***photons above a few hundred keV*** *. . . For the purpose of* ***overestimating****, the typical value of 40 mrem as listed in the CETS 1989 reference will be assumed.* [Emphasis added.]

The extent to which the assumed film dosimeter LOD value of 40 mrem is highly conservative and represents an **overestimation** is questionable for the following reasons:

(1) The above-cited quotation (regarding the 0.5 NOD as equivalent to a 40 mR value, which translates to a 10 to 20 mR LOD) does appear in the 1989 NRC report on page 17. However, this range of values corresponds to controlled laboratory conditions of film exposure, which avoids laboratory and environmental uncertainties discussed in Chapter 5 of the 1989 NRC report. More importantly, however, is that these low LODs are restricted to ". . . photon above a **few hundred keV**." ORAUT-OTIB-0010, however, applies to photon energies between 30 and 250 keV.

(2) The 1989 NRC report cites 40 mR as the standard MDL value for **all** 19 test operations that start with Project Trinity (1945) and end with Operation Dominic II (1962).

In brief, a default LOD value of 40 mR is more likely a typical value than an overestimate, even after 1970. What remains conservative in overestimating the missed dose for the post-1970 film-badge era is the TIB's recommendation not to divide the LOD by a factor of 2.

2.4.5 Conclusions

Although the intent and general scientific basis for this procedure are endorsed by SC&A, this procedure lacks structure, clarity, and consistency. A good indication about the effectiveness of a procedure is its successful application. At the time of this review, SC&A (under Task 4) had the opportunity to review the first 20 dose reconstructions selected by the Advisory Board/NIOSH for audit, and 15 of the 20 claims involved non-Atomic Weapons Employer facilities for which procedures under SC&A's review apply. For the dose reconstruction of Claim 006290, a key procedure was ORAUT-OTIB-0010. Errors and misinterpretation of ORAUT-OTIB-0010 by the dose reconstructor illustrate some of SC&A's concerns raised in this review, as explained below.

For **missed dose**, the dose reconstructor provided the following explanation in the *Dose Reconstruction Report*:

> *Based on information provided in Technical Information Bulletin: Overestimating External Doses Measured with Film Badge Dosimeters,[8] the total number of dosimeter cycles assigned was 252 for photons. This number was based on a claimant-favorable assumption of 12 badge exchanges each full or partial year of employment and was maximized to ensure that all possible instances of a zero badge reading were accounted for in this dose reconstruction. Based on information provided in the Technical Information Bulletin: Overestimating External Doses Measured with Film Badge Dosimeters,[8] this results in a maximum potential missed dose . . . [for claimant] of 21.363 rem from photons. For the purpose of calculating probability of causation, this value was divided by 2 in accordance with the External Dose Reconstruction Implementation Guideline.*

In behalf of **uncertainty**, the dose reconstructor provided the following:

> ***Uncertainty***
> *Except for missed dose, point estimates (constant values) were used for organ dose input into the NIOSH-Interactive RadioEpidemiological Program (NIOSH-IREP). Missed doses were divided by 2 and a lognormal distribution was applied in accordance with the NIOSH External Dose Reconstruction Implementation Guideline.*[3]

SC&A's audit of Claim 006290 identified four misinterpretations of ORAUT-OTIB-0010, as summarized below:

(1) In addition to using the LOD of 40 mrem x 12 monthly cycles/year, the dose reconstructor erroneously also applied the standard correction factor of 2.

(2) The dose reconstructor corrected the first error by subsequently dividing the above-derived value by 2 ". . . in accordance with the NIOSH External Dose Reconstruction Implementation Guideline."

(3) For the IREP input, the dose reconstructor erroneously defined values derived in step 2 as values defined by a lognormal distribution and assigned a geometric standard deviation (GSD) of 1.52 for parameter 2 in the IREP input code. (Note: Since LOD defined the 95th percentile value of a missed dose, there is **no** need to include uncertainty.)

(4) In behalf of Claim 006290, the dose reconstructor applied the ORAUT-OTIB-0010 methodology for a period of 20 years starting in 1973 through 1993. ORAUT-OTIB-0010, however, states that this procedure only applies to the "late film badge era" that is defined by the four-element film badge. For Claimant 006290, who was employed at ORNL, the four-element film badge was replaced by a site-specific TLD in 1976. Thus, the procedure ORAUT-OTIB-0010 can only be applied for 1973, 1974, and 1975; starting with 1976 through 1993, the dose reconstructor should have employed ORAUT-

OTIB-0008, *Technical Information Bulletin for a Standard Complex-Wide Conversion/Correction Factor for Overestimating External Doses Measured with Thermoluminescent Dosimeters*.

The fact that these errors were consistently claimant favorable is fortunate but does not negate SC&A's concern about the quality/user-friendliness of this (and other) procedures used in dose reconstruction.

2.5 ORAUT-OTIB-0008 — TECHNICAL INFORMATION BULLETIN FOR A STANDARD COMPLEX-WIDE CONVERSION FACTOR FOR OVERESTIMATING EXTERNAL DOSES MEASURED WITH THERMOLUMINESCENT DOSIMETER

The review of ORAUT-OTIB-0008, *Technical Information Bulletin for a Standard Complex-Wide Conversion Factor for Overestimating External Doses Measured with Thermoluminescent Dosimeter*, Rev. 00, dated November 7, 2003, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on January 11, 2005.

2.5.1 Purpose of Procedure

The purpose of this procedure is provided in the following statements contained in the foreword to the TIB:

> *The present document is intended to provide assumptions to apply to a limited set of cases for specific sites only during delimited periods of applicability. Specifically, this technical information bulletin (TIB) presents external radiation dose assumptions that may be applied to dose reconstructions involving cases for which dose estimates may be prepared based solely on **recorded deep** and/or **shallow dose** that incorporate dose monitoring information only from years when monitoring was performed with TLDs.* [Emphasis added.]

In brief, the expeditious protocol for dose reconstruction of **noncompensable** claims contains the following elements for maximizing organ doses in behalf of claimants who were monitored for external exposure to photons by TLDs:

- Missed Dose. For missed dose (i.e., zero-dose recordings), assume a LOD value for TLDs of 30 mrem/cycle. A monthly exchange frequency may be assumed, but the **actual** exchange frequency should be considered. The procedure further states, "**Additional** claimant-favorability may be applied at the discretion of the dose reconstructor by (1) applying the missed dose to all badge cycles in addition to the **recorded** value, and (2) **not** applying the 'LOD/2' approach to missed dose described in the OCAS-IG-001 (NIOSH 2002)." [Emphasis added.]

- Recorded TLD Dose. For a **recorded deep dose(s)** by a TLD, a **standard overestimating conversion/correction factor of 2** should be used as a multiplier.

- $H_P(10)$-to-organ Dose Conversion Factor (DCF_{Max}). To maximize the photon organ dose, a single generic DCF of 1.100 should be assigned.

Table 5-2, as it appears on page 13 of ORAUT-OTIB-0008, is reproduced below as Table 2.5-1 and summarizes key elements for maximizing organ doses for **noncompensable** claims in behalf of TLD-monitored persons.

Table 5-2. Standard Overestimating Correction/Conversion (C/C) Factor and Standard Missed Dose for TLDs

Period of Applicability (by site)	Missed Dose Per Cycle (rem)	Assumed Exchange Frequency	Standard Overestimating C/C Factor
From Table 5-3	0.03	Monthly	2

2.5.2 Review Protocol

The evaluation of ORAUT-OTIB-0008 is summarized in Table 2.5-2 below. Table 2.5-2 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

2.5.3 General Comments

This procedure applies to recorded exposures by means of TLDs and closely parallels the intent of ORAUT-OTIB-0010, *A Standardized Complex-wide Correction Factor for Overestimating External Doses Measured with Film Badge Dosimeters*. Therefore, several comments previously submitted in behalf of ORAUT-OTIB-0010 also apply to this procedure and will be reiterated only briefly as part of the Procedure Review Checklist and associated comments that follow.

Table 2.5-2. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0008	**Effective Date:** 11/07/2003
Document Title: Technical Information Bulletin for a Standard Complex-Wide Conversion Factor for Overestimating External Doses Measured with Thermoluminescent Dosimeter	
Reviewer: U. Hans Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	3	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	3	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	N/A	
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	4	See Review Comments
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	4	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.5.4 Review Comments

Review Objective 1.1

This procedure lacks clarity. A full understanding of the guidance presented in this procedure and its proper implementation required multiple readings by several SC&A reviewers. In

support of this contention, the conclusions of this review provide an example of how one NIOSH dose reconstructor misinterpreted/misapplied this procedure in behalf of a claimant.

Review Objective 1.2

Sections 2.0, 3.0, and 4.0 of this procedure provide a substantial body of background information that provides technical support for the choice of parameters used to maximize the dose, as defined in the final Section 5.0. Thus, the dose reconstructor must read through page 11 of the procedure before encountering implementation guidance.

While SC&A recognizes the value of relevant background information, for improved efficiency in the routine use of this procedure, Section 5.0 should be relocated near the front of this procedure.

Review Objective 1.4

Multiple options exist in terms of procedures that a dose reconstructor may follow. For claims that are prejudged as noncompensable (i.e., likely < 50% POC), the dominant procedure is ORAUT-PROC-0006, Attachment D-2, *External Dose Reconstruction Desk Instruction for Likely < 50% POC Cases for Monitored Covered Employees*.

Key differences between ORAUT-PROC-0006 and ORAUT-OTIB-0008 involve (1) the use of a standard overestimating correction/conversion factor, (2) selection and value of the dosimeter-to-organ DCF, (3) selection/value of the TLD LOD, and (4) options for selecting dosimeter exchange frequency.

Because the TIB does not identify its **hierarchical** position among other competing procedures/documents that could be used in its place or require this TIB's support, questions regarding the use of the TIB for dose reconstruction include the following:

(1) Does the use of ORAUT-OTIB-0010 for dose reconstruction require that the claim be **preclassified** as "likely <50% POC" (as is the case for ORAUT-PROC-0006)?

(2) For claims with recorded exposures that meet the conditions specified in ORAUT-OTIB-0010, does the dose reconstructor have the option to use either the desktop instructions provided in Attachment D-2 of ORAUT-PROC-0006 with site-specific data or use the generic default value provided in ORAUT-OTIB-0010?

Review Objective 6.1

Although the dose reconstructor should conclude that the use of the standard overestimating correction/conversion factor for recorded TLD dose (i.e., the use of *n*LOD for missed dose) obviates the need for uncertainty, the procedure should nevertheless provide a statement to this effect as a reminder. This is particularly true since the procedure also permits missed dose to be derived by means of *n*LOD/2, in which case uncertainty must be defined for IREP.

2.5.5 Conclusions

Although the intent and general scientific basis for this procedure are endorsed by SC&A, there is a need to improve the procedure's structure, clarity, and consistency with other procedures.

Under Task 4, SC&A had the opportunity to review the first 20 dose reconstructions selected by the Advisory Board/NIOSH for audit, and 15 among the 20 claims involved non-Atomic Weapons Employer facilities for which procedures under SC&A's review apply. For the dose reconstruction of Claim 008121, a key procedure was ORAUT-OTIB-0008. Errors and misinterpretations of ORAUT-OTIB-0008 by the dose reconstructor illustrate some of SC&A's concerns raised in this review.

For TLD recorded dosimeter and missed dosimeter dose, the dose reconstructor provided the following explanation on page 5 of the dose reconstruction report:

> *To ensure that the estimated dose has been maximized, a multiplication factor of 2 has been applied to the **reported** and **missed annual doses**. Application of this multiplication factor overestimates dose to **account for uncertainty in dosimeter response and in variability for the dose conversion factor across all organs**. . . .*
>
> *Missed dose was assigned to each **actual** or **potential dosimeter cycle** to maximize the external dose estimate. Missed dose represents the dose that may have been received but not recorded because of dosimeter detection limits or site reporting practices. Based on the Technical Information Bulletin: Overestimating External Doses Measured with Thermoluminescent Dosimeter,[8] the total number of dosimeter cycles assigned was **60 for photons**. This number was based on a claimant-favorable **assumption** of 12 badge exchanges each full or partial year of employment to ensure that all possible instances of a zero badge reading were accounted for in this dose reconstruction. Based on information provided in the Technical Information Bulletin: Overestimating External Doses Measured with Thermoluminescent Dosimeter,[8] this results in a maximum missed dose of 3.600 rem from photons. For the purpose of calculating probability of causation, this value was divided by 2 in accordance with the **External Dose Reconstruction Implementation Guideline**.[3]* [Emphasis added.]

Misinterpretation of ORAUT-OTIB-0008

Recorded Dose. SC&A reviewed the TLD records for Claim 008121 and verified the total recorded deep dose of 240 mrem. In compliance with guidance contained in ORAUT-OTIB-0008, the dose reconstructor applied the standard overestimating correction/conversion factor of 2 and thus doubled the recorded dose of 240 mrem to 480 mrem. Doubling the dose eliminates the need to include an estimate of uncertainty. For input to IREP, ORAUT-OTIB-0008 also identifies a single generic $H_P(10)$-to-organ dose conversion factor (DCF_{Max}) of 1.1, which the dose reconstructor did **not** apply. However, the substitution of 1.0 for 1.1 as the DCF represents a minor error.

Missed Dose. According to Table 5-2 of ORAUT-OTIB-0008, missed dose may be calculated by multiplying the LOD_{TLD} value (assumed at 30 mrem) for each cycle in which the dose is recorded as zero. In the **absence** of site-specific data, a **monthly** exchange frequency may be assumed. Accordingly, an **annual** missed photon dose of *n*LOD corresponds to 12 cycles x 30 mrem/cycle or 360 mrem/yr. In the absence of site-specific data, the claimant's 5-year employment corresponds to a missed photon dose of 1800 mrem.

In applying ORAUT-OTIB-0008, the dose reconstructor misinterpreted/misapplied the following:

- The dose reconstructor erroneously applied the standard overestimating C/C factor of 2 and derived the above-cited total of 3.600 rem:

  Total Missed Dose = (30 mrem/cycle)(12 cycles)(5 years)(2)
  = 3.600 rem

- Next the dose reconstructor **cancels** the first error (i.e., the misuse of the standard overestimating factor of 2) by dividing the dose estimate by 2 and explains this by the following statement, ". . . for the purpose of calculating probability of causation, this value was **divided** by 2 in accordance with the External Dose Reconstruction Implementation Guideline.[3]" (Note: OCAS-IG-001 provides **standard** guidance for missed dose expressed as *n*LOD/2 and a GSD of 1.52 for uncertainty; OCAS-IG-001 is **not** intended to be combined with ORAUT-OTIB-0008.)
- The use of LOD (as opposed to LOD/2) for estimating missed dose per cycle represents the 95th percentile value and, therefore, precludes the need to incorporate uncertainty in the dose estimate. The dose reconstructor erroneously applied the GSD of 1.52 for uncertainty to a dose derived by LOD.
- The assumption of 12 cycles per year applies to situations in which data are lacking. Dosimetry records provided by DOE in behalf of Claim 008121 clearly indicate that the individual was monitored on a quarterly (**not** monthly) basis.

While the combination of procedural misinterpretations had only marginal impacts on assigned dose and clearly did not significantly affect the POC (and the compensability of the claim), it does demonstrate various difficulties associated with the implementation of this procedure.

2.6 ORAUT-OTIB-0007 — TECHNICAL INFORMATION BULLETIN: OCCUPATIONAL DOSE FROM ELEVATED AMBIENT LEVELS OF EXTERNAL RADIATION

The review of ORAUT-OTIB-0007, *Technical Information Bulletin: Occupational Dose from Elevated Ambient Levels of External Radiation*, Rev. 00, dated November 12, 2003, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on January 11, 2005.

2.6.1 Purpose of Procedure

The purpose of this procedure is to acknowledge that in select instances the dose of record associated with personnel film dosimeters and TLDs represents a **net** dosimeter readout that may have resulted in underestimating the true occupational exposure of the monitored person. This underestimation occurs because a standard practice for recording individual doses associated with film dosimeters and TLDs involves subtraction of "background radiation recorded on control dosimeters." While **natural** background radiation is justifiably **not** considered occupational exposure, background radiation that may have resulted from elevated ambient levels of external radiation (i.e., EALER) due to site operations would, in fact, be considered occupational exposure.

The need to account for EALER as occupational exposure is largely based on the relative location of the control dosimeter(s) (i.e., where was it stored?) and the assigned personnel dosimeter (i.e., where was the individual monitored?) relative to any EALER. Thus, if the control badges were stored at a location **unaffected** by EALER, there is no need to adjust the individual's dose; but when control badges were subjected to EALER and such exposures were wrongly subtracted from personnel dosimeters, such exposures must be viewed as missing exposure and accounted for as occupational exposure.

2.6.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0007 is summarized in Table 2.6-1 below. Table 2.6-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

2.6.3 General Comments

The need to account for EALER-associated occupational doses that were wrongly subtracted by means of EALER-exposed control dosimeters is based on (1) the regulatory requirement to account for all occupational exposures that may have been received by a claimant, and (2) their potential for significant contribution to total occupational exposure.

As pointed out in Section 2.0 of ORAUT-OTIB-0007, EALER exposures ". . . could have been as high as a few millirem per day in some cases . . . [and] at Hanford as high as 36 mrad/day, averaging 8.5 mrad/day between April 1952 and November 1954."

However, the **functional** value and use of this procedure to the dose reconstructor is limited as indicated in Table 2.6-1 and explained in comments to specific review objectives that follow.

Table 2.6-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0007	**Effective Date:** 11/12/2003
Document Title: Technical Information Bulletin: Occupational Dose from Elevated Ambient Levels of External Radiation	
Reviewer: U. Hans Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	1	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	N/A	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	4	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	4	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	4	See Review Comments
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	2	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	2	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.6.4 Review Comments

Review Objective 1.0

Unaccounted doses to EALER are likely to have involved exposures to ground contamination, transient plume immersion, and/or cloudshine that reflect site-specific activities/events. In turn, resultant exposures may have been chronic, episodic, and highly variable by location.

From the foregoing, it is clear that extensive site-specific data are required to account for missed EALER doses. Such data are currently not provided in this procedure and may only partially be available in Site Profiles. (At this time, SC&A did not review Site Profiles to ensure their adequacy for this use.) Section 4 of this TIB concludes only that ". . . subsequent revision to this document will provide **specific** dates for each site establishing when it is known that control badges were stored in **appropriate** locations, which will allow for environmental doses to **not** be evaluated for certain sites prior to 1980." [Emphasis added.]

In summary, the procedure in its current form is incomplete and does not provide sufficient data to account for EALER missed doses.

Review Objective 4.1

Beyond identifying EALER as a potential area of missed occupational dose, ORAUT-OTIB-0007 provides no specific instructions on processing such data for amending a claimant's occupational exposure record. For example, given that a monthly **control badge** subjected to EALER would record a time-integrated dose representing about 720 hours, what fraction of the control badge dose should be added to the claimant's monthly dose of record? On the assumption of a chronic EALER exposure, a realistic approach would assume that the worker maymight have been exposed for about 170 hours/month, which corresponds to about 24% of the dose recorded by the control badge. In contrast, a more conservative, but not improbable scenario, would assume that the EALER dose represented a brief episodic exposure and mandate that 100% of the control dosimeter dose be added to the claimant's monthly dose of record.

A second issue that requires clarification concerns the issue of skin dose (i.e., shallow dose or 7 mg/cm^2 dose). EALER involving plume immersion and/or exposure to ambient ground contamination involving beta and low energy photon emitters are unlikely to have been recorded by control badges, because ambient dosimeters typically recorded only the dose from penetrating radiation and not the shallow dose. Hence, since the shallow dose is generally significantly larger than the deep dose, adding in the dose from ambient dosimeters to account for EALER could result in a significant underestimate of the shallow dose. This potential deficiency may affect claims involving skin cancers and to a lesser extent select surficial tissues such as the eye, testes, etc.

Review Objective 7.0

A procedural approach to amend occupational exposure from EALER as suggested by the currently incomplete ORAUT-OTIB-0007 could require extensive site-specific data over several decades pertaining to (1) site operations, (2) environmental releases/incidents, (3) environmental monitoring data and practices, and (4) health physics practices pertaining to control badge storage practices.

Assuming that such data are even available, **monthly** dose corrections for EALER would be time-consuming and require a substantial effort by the dose reconstructor. This reviewer believes that such an effort would significantly undermine the **efficiency** of the dose reconstruction process while contributing a questionable improvement for technical precision.

An efficient and claimant-favorable approach might involve the use of claimant-favorable default values or the addition of a fixed monthly EALER dose to all film dosimeters and TLDs processed prior to 1970 (or 1980) that is site specific and reflects onsite environmental monitoring data, as described in Section 5.1.4 of ORAUT-PROC-0006.

2.7 ORAUT-OTIB-0006 — DOSE RECONSTRUCTION FROM OCCUPATIONALLY RELATED DIAGNOSTIC X-RAY PROCEDURES

The review of ORAUT-OTIB-0006, *Dose Reconstruction from Occupationally Related Diagnostic X-Ray Procedures*, Rev. 2, dated December 29, 2003, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on January 11, 2005.

2.7.1 Purpose of Procedure

Under EEOICPA, diagnostic x-rays, specifically chest x-rays, were required as a condition of employment and are included as part of the total occupational radiation exposure to the atomic worker. This document was published by ORAUT as a TIB to be used for DOE and Atomic Weapons Employer sites relating to "…detailed methodology for dose reconstruction from diagnostic medical x-rays that were sustained by workers as a condition of employment, and provides the technical basis for dose reconstruction in the absence of specific dose measurements or records of technique factors." This TIB further states that "this report supplements and expands upon the guidance provided in . . . OCAS-IG-001."

2.7.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0006 is summarized in Table 2.7-1 below. Table 2.7-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

Table 2.7-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0006	**Effective Date:** 12/29/2003
Document Title: Dose Reconstruction from Occupationally Related Diagnostic X-Ray Procedures	
Reviewer: U. Hans Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	3	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	3	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2= Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). NA indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	3	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	3	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.7.3 Review Comments

Review Objectives 1.0 and 7.0

For a procedure to support a dose reconstruction process that is expeditious and timely, the procedures should prioritize its content with the most important/relevant information presented first, followed by technical support data and data that are interesting but not essential.

Section 2.0 of this TIB provides a lengthy and detailed technical explanation regarding various parameters (i.e., beam kilovoltage, current, filtration, collimation, exposure time, distance, and waveform) that affect the beam output and, **if known**, can be used to estimate the potential air dose to a patient for a given diagnostic x-ray.

However (and not surprisingly), the TIB acknowledges the **unlikely** availability of such data (i.e., kVp, mA, filtration, distance, and exposure time), but not until Section 3.0, page 12, of the TIB, which states the following:

> *X-ray output measurements are likely to be **un**available, particularly prior to about 1980 [when occupational x-rays probably ceased to be required for employment]. In the **absence of suitable measurement** data, medical diagnostic x-ray dose reconstruction can be accomplished using **technique factors** along with published output data that provide beam intensity per mAs as a function of kVp, filtration, and distance.* [Emphasis added.]

The **unlikely** availability of beam measurement data is restated several more times:

Section 3.1, page 12:

> *Although beam output measurements may typically be unavailable, diagnostic medical x-ray dose reconstruction using actual measurement data is the **preferred** method for determining the dose to the worker from this source, so much so that **special effort** to determine if such measurements have been made is **justifiable**.* [Emphasis added.]

Section 3.1, page 13:

> *If the actual beam quality is **unknown**, **as is likely the case**, to ensure claimant favorability, a higher rather than lower HVL should be assumed.* [Emphasis added.]

Section 3.2, page 17:

> *When beam measurement data are **unavailable**, **as is likely to be the case**, technique factors can be used to obtain reasonable estimate**s of exposure. The basic data required are kVp, filtration,** exposure in **mAs,** and **distance**. Beam output data are available from a number of publications, including NCRP Report No. 102 (NCRP, 1989). Table B.3 in this report (p. 99) provides average air kerma rates for medical diagnostic x-ray equipment operating at various kVps with 2.5 mm Al filtration at distances from 30 to 182 cm from the source. Correction for different thickness of Al filtration can be made by reference to Table 2.6-1. Alternatively, Figure B.1 (p. 109) in NCRP Report No. 102 provides a graphical representation of air kerma at 100 cm for various values of kVp and filter thickness > 2.5 mm Al. Using theses tables, a reasonable estimate of beam*

> *output and hence entrance kerma can be obtained. Once the entrance kerma has been determined, organ doses are determined in the manner described above for reconstruction using measurement data.* [Emphasis added.]

The difference between **measurement data** and **technique factors** for deriving dose estimates is trivial, since both techniques require knowledge about kVp, mA, filtration, distance, and exposure time that the procedure warns "are unlikely to be available." By far, the most probable method for estimating medical occupational exposures will involve the use of **default values**, which the procedure does not address until the very end.

In summary, this document is poorly structured and reads more like an introductory reference text on medical x-rays than a procedure. It not only presents an excess of background information that is well understood by a dose reconstructor, but is also of limited use since the required data are "unlikely to be available." In spite of the unlikely availability of data, the procedure, nevertheless, justifies the need for the dose reconstructor to make ". . . that special effort to determine if such measurements have been made. . . ."

The large investment of time and effort required to pursue the unlikely existence of such data is difficult to justify in context with a dose reconstruction process that is expected to strike a balance between the need for technical precision and process efficiency.

Reconstruction by means of default values as given in Section 3.3 of this procedure appears adequate and claimant favorable. As such, Section 3.3 should have been the principal component of this procedure.

Review Objectives 4.0

There is some ambiguity regarding the use of default values. Table 3.3-1 identifies a default value of 3.0 cGy entrance kerma for photofluorographic chest examination, and proceeds to apply this value to default organ dose values given in Table 4.0-1 of Section 4.0. Section 5.0 of the TIB provides some historical dose data in behalf of photofluorography that include a 1959 study of Hanford by Rising and Soldat. Here, air **upper-bound** entrance skin exposure (ESE) for photofluoroscopic chest examination of 1.53 R is identified with the following recommendation:

> *Thus, although the Hanford measured value is likely an upper limit and hence an overstatement of the actual exposure from photofluorography to the average patient, this 1.53 R ESE value should be used in the absence of data to ensure claimant favorability.*

Thus, the TIB provides two default values for photofluorography, which differ by a factor of 2 (i.e., 3.0 cGy entrance kerma versus 1.53 R (ESE)). This raises two questions: (1) is the 1.53 R default value uniquely applicable to Hanford and (2) if so, is there a defensible explanation for a two-fold higher value for all other DOE/AWE sites? The absence of a defensible explanation clearly raises the question regarding **consistency** of the dose reconstruction process.

2.8 OCAS-TIB-006 — INTERPRETATION OF EXTERNAL DOSIMETRY RECORDS AT THE SAVANNAH RIVER SITE (SRS)

The review of OCAS-TIB-006, *Interpretation of External Dosimetry Records at the Savannah River Site (SRS)*, Rev. 1, dated February 20, 2004, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on January 11, 2005.

2.8.1 Purpose of Procedure

As stated in Section 1.0, *Purpose*, of this TIB,

> *The purpose of this Technical Information Bulletin (TIB) is to provide guidance on the interpretation of Savannah River Site, dosimetry from 1973 through 1988. In addition, guidance on how the shallow dose should be reconstructed is also included.*

2.8.2 Review Protocol

SC&A's evaluation of OCAS-TIB-006 is summarized in Table 2.8-1 below. Table 2.8-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

2.8.3 General Comments

This brief procedure addresses two issues:

(1) It alerts the dose reconstructor that the SLHP3 form contains dosimetry data from archived records, which in turn only provide dosimetry data for monitoring cycles for which the dosimeter yielded a positive reading (i.e., > LOD). In the absence of a positive dosimeter reading between 1973 and 1988, it should not therefore automatically be assumed that a given individual was **not** monitored.

(2) It identifies a potential underresponse of SRS dosimeters (used between 1954-1980) to low-energy photons due to the presence of aluminum filtration on the SRS dosimeter, and provides "guidance on how the Low Energy photon dose should be determined for workers primarily exposed to plutonium."

Table 2.8-1. Procedure Review Outline/Checklist

Document No.: OCAS-TIB-006	**Effective Date:** 02/20/2004
Document Title: Interpretation of External Dosimetry Records at the Savannah River Site (SRS)	
Reviewer: U. Hans Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	N/A	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	3	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	3	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.8.4 Review Comments

Review Objectives 1.1, 1.4, and 1.5

Regarding the need to correct the response of SRS dosimeters with aluminum filtration for the period 1954-1981, the TIB provides the following guidance:

> Shallow Dose Interpretation
>
> *During the period 1954-1981, aluminum filtration on the SRS dosimeter may have diminished the deep dose response to low energy (< 30 keV) photons. This could have affected dose for plutonium workers at 321-M, 221-HP, 221-FB, Plutonium Storage, 772-F, 235-F, 773-A and 736-A. For this period, low energy (< 30 keV) photon dose should be determined by subtracting the reported deep dose from the shallow dose. In order to maintain consistency, the shallow dose quantity should be corrected using the H_P (1)) correction factor (1.119). The deep dose quantity during this period should be classified as intermediate energy photons (30 – 250 keV). For the period 1982 – present, the guidance provided in Savannah River Site Technical Basis Document should be used to determine the photon energy distribution of the deep dose (i.e., 25% < 30 keV and 75% 30-250 keV). Inclusion of the shallow dose quantity for this time period would not be needed unless the energy employee had testicular, breast, or skin cancer. In these cases the shallow dose (without deep dose subtracted would by [sic] categorized as < 30 keV photons.)*

The above-cited procedural guidance is **confusing** in terms of its instructional content. It is also uncertain as to which dosimetry data require this refinement (i.e., is it limited to the above-cited work locations where exposure is known/suspected to be dominated by Pu, or does it apply to any dosimeter data in which the ratio of the open-window (or 7 mg/cm^2) shallow dose to the 1000 mg/cm^2 deep dose suggests a large contribution of low-energy photons?).

It is also uncertain whether the above-cited guidance replaces guidance provided in Section 5.4.3.1 of the *SRS Site Profile/Technical Basis Document*, ORAUT-TKBS-003. Guidance provided in TBD ORAUT-TKBS-003, Section 5.4.3.1, only identifies the "two-element film dosimeter" and includes the following statements:

> *Based on the collective information, SRS dosimeters are expected to reasonably measure the $H_p(10)$ under **all** SRS workplace radiation fields. The SRS historical practice, for the **two-element film dosimeter** in **plutonium** facilities characterized by predominant photon energies < 100 keV, to calculate the total whole-body deep dose by summing the shallow dose from the open window film response based on a 16 keV fluorescent x-ray calibration and the deep dose from the 1 mm silver filtered film response based on a Ra-226 calibration, will result in a over-estimate of the actual $H_P(10)$ dose. . . . The respective SRS dosimeters have filtration of approximately 1000 mg/cm^2 (i.e., nearly equivalent to 1 cm depth in*

> *tissue) for those regions of the dosimeter used to measure the whole body dose. . . As such, a reasonable estimate of deep dose, compared to $H_P(10)$ is expected for SRS beta/photon workplace radiation.* [Emphasis added.]

Additionally, Section 5.3.3.1 (as well as Section 5.4.1) of ORAUT-TKBS-0003 identifies the need for additional $H_P(10)$ correction factors as given in the following statements:

> *. . . Taylor et al. (1995) describes adjustments to SRS recorded dose estimate $H_P(10)$ based on SRS preparations for DOELAP performance testing in the mid-1980s. At that time, it was concluded that:*
>
> - *Prior to January 1986 the recorded dose of record (i.e., photon) dose should be multiplied by a factor of 1.119 (11.9%).*
> - *Prior to January 1987 recorded dose of record (i.e., photon) should be multiplied by a factor of 1.039 (3.9%).*

Lastly, there is a question regarding the specified timeframe during which the shallow dose requires interpretation. As stated in the above quotation, the need to interpret shallow dose covers the period 1954-1981 and is the result of "**aluminum** filtration on the SRS dosimeter [that] may have diminished the deep dose response to low energy (< 30 keV) photons." [Emphasis added.] A review of dosimeters employed at SRS between 1954-1981 (as given in Attachment A of ORAUT-OTIB-008) identifies four different dosimeters with the following filters:

Years	Dosimeter	Filter
'51-'58	ORNL Two Element Film Badge	OW, Cd 1 mm
'59	SRS Two Element Film Badge	OW, Cd 1 mm
'59-'70	Multi-Element Film Badge	OW Al Ag
'70-'81	SRS TLD	multiple filters

Only the multi-element film badge used between 1959-1970 specifies aluminum filtration.

In summary, the implementation of this procedure is complex, confusing, and provides insufficient guidance for amending SRS dosimeter data in select instances of surficial target tissues in which the shallow dose component from low-energy photons is a significant component of the $H_P(10)$ deep dose.

Since the purpose of this procedure is limited to amending dosimetry data that are specific for SRS, perhaps a more efficient and appropriate approach would simplify the guidance provided and incorporate this TIB into Section 5.0, *Occupational External Dosimetry*, of the *Technical Basis Document for the Savannah River Site*, ORAUT-TKBS-0003.

2.9 OCAS-PER-001 — MISINTERPRETED DOSIMETRY RECORDS RESULTING IN AN UNDERESTIMATE OF MISSED DOSE IN SRS DOSE RECONSTRUCTION

The review of OCAS-PER-001, *Misinterpreted Dosimetry Records Resulting in an Underestimate of Missed Dose in SRS Dose Reconstruction*, Rev. 0, dated September 8, 2003, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on January 11, 2005.

2.9.1 Purpose of Procedure

This document evaluates the programmatic effect of the misinterpreted dosimetry records that resulted in an underestimate of the missed dose for workers at the SRS. This error pertains to SRS dosimetry records between 1973 and 1988 on Form SLHP3 only containing positive dosimeter readings (either shallow or deep) for a given dosimeter wear cycle. Since only positive dosimeter readings are cited on the SLPH3 form, there is a risk that the absence of cycle dosimeter data may be falsely interpreted to mean that the individual was **not** monitored when, in fact, he/she was monitored, but had a net dosimeter reading below LOD. The result of this misinterpretation would result in **missed** dose for the years 1973-1988.

During the time period of 1973-1988, personnel monitoring involved (1) the SRS TLD dosimeter (with the laboratory minimum detection level (MDL) of 15 mrem) for the period 1970-1983, and (2) the Panasonic TLD (with the laboratory MDL of 5 mrem) for the period 1984-1988. Based on the LOD/2 accounting method for missed dose, the annual missed doses for the two time periods involved 90 mrem and 30 mrem, respectively.

Section 2.0 of this document, OCAS-PER-001, identifies a second error, as given in the following statements:

> *During August 2003, the ORAU team recognized that the SRS Technical Basis Document (ORAUT-TKBS-0003, Rev. 0) contained a significant **overestimate** of the onsite ambient dose between 1974 and 1998. Since this error resulted in an overestimate of the energy's employee's onsite ambient dose (claimant friendly), no formal Program Evaluation Report (PER) was written. These values were corrected and noted in the revision of ORAUT-TKBS-0003, Rev. 01, approved on August 21, 2003.* [Emphasis added.]

These two opposing errors were evaluated by ORAU with regard to their magnitude and to their net impacts on the POC for the top 10 cancer claims for SRS. The procedures concluded that, in combination, the two errors have the net effect of nearly canceling each other, with a slight bias in a claimant-favorable direction (i.e., higher POC value), and no further evaluation was necessary.

The approach to resolution/corrective action for this combination of errors was twofold: (1) revise the SRS TBD, and (2) provide additional guidance as set forth in OCAS-TIB-0006,

issued September 8, 2003. This TIB provides guidance on the interpretation of the SRS dosimetry Form SLHP3. SC&A's review of guidance contained in OCAS-TIB-0006 is presented next.

2.9.2 General Comments

OCAS-PER-001 is a program evaluation report (PER) and, therefore, does not serve the purpose of a procedure. A PER formally acknowledges potential deficiencies that may have affected the dose reconstruction process and evaluates the potential impact(s) on previously assessed claims.

SC&A critically evaluated the approach taken in OCAS-PER-001 for quantifying the magnitude of these errors and their impacts and concludes that the analysis is technically correct and fair to the claimant.

SC&A does not consider it appropriate to further evaluate OCAS-PER-001 by means of its Procedure Review Outline/Checklist.

2.10 OCAS-TIB-007 — NEUTRON EXPOSURES AT THE SAVANNAH RIVER SITE

The review of OCAS-TIB-007, *Neutron Exposures at the Savannah River Site*, Rev. 0, dated September 17, 2003, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on January 11, 2005.

2.10.1 Purpose of Procedure

This procedure provides **supplemental** guidance pertaining to potential neutron exposure at SRS for workers under the following conditions:

(1) The energy employee worked at SRS **prior** to the implementation of the thermoluminescent neutron dosimeter (TLND) in 1971;

(2) The energy employee (prior to 1971) was monitored with Type A (NTA) film, which underresponded to neutrons below 500 keV;

(3) The energy employee may have been "intermittently" exposed to neutrons post-1971 and after the implementation of TLND, but **not** monitored because the "general criteria" between 1970 and 1980 was to only monitor personnel exposed to neutron fields in excess of 1 mrem/hr. As a result ". . . non routine workers might or might not have been adequately monitored."

2.10.2 Review Protocol

SC&A's evaluation of OCAS-TIB-007 is summarized in Table 2.10-1 below. Table 2.10-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

2.10.3 General Comments

This procedure attempts to satisfy the regulatory requirement under 42 CFR 82.15, 42 CFR 82.16, and 42 CFR 82.17 for a complete accounting of neutron exposure that a claimant may have experienced as a result of deficiencies/limitations of personnel dosimeters and monitoring practices.

The guidance provided in this TIB is far too complex, excessively detailed, and time-consuming to be of efficient use to those dose reconstructors who are not **thoroughly** familiar with SRS facility operations that span several decades; secondly, the guidance places an undue burden on the dose reconstructor to make subjective decisions; thirdly, select guidance presented in this TIB is incomplete and in some cases contradictory; lastly, and perhaps most relevant, dose reconstructors are **not** currently making use of NTA neutron data prior to 1971. Due to the unreliability of NTA dosimeters, neutron doses prior to 1971 are currently estimated based on neutron to photon ratios and contradict Section 4.0 of this TIB. Specific examples of these deficiencies are provided in the checklist comments that follow Table 2.10-1.

Table 2.10-1. Procedure Review Outline/Checklist

Document No.: OCAS-TIB-007	**Effective Date:** 09/17/2003
Document Title: Neutron Exposures at the Savannah River Site	
Reviewer: U. Hans Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	3	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	3	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	3	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	4	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	3	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	3	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

2.10.4 Review Comments

Review Objectives 1.0 and 7.0

Section 2.1 of the TIB identifies numerous locations within the 100, 200, 300, and 700 Areas as work locations where neutron dose should be included for the conditions cited above. For example, in behalf of the five reactors (i.e., Reactors C, K, L, P, and R) in the 100 Area, the TIB cautions that "Only **certain occupations** [are] involved in neutron exposure, see section 2.2 for further guidance." These "certain occupations" for the 100 Area are assumedly identified in Section 2.2.2 and include the occupation defined as "etc. . .," as given in the following statement:

> *Neutron exposures should only be considered for energy employees who might have been involved in maintenance activities in the **crane wash areas** of the reactors. These occupations would include mechanics, pipefitters, electricians, carpenters, sheetmetal workers, etc… There is also a potential for neutron exposures for radiological control technicians, health physicist and possibly reactor operators, since these individuals were generally responsible for workplace safety.* [Emphasis added.]

Section 2.2 addresses the condition in which the **work area is unknown or not clear** and provides the following subjective guidance that in some cases is contradictory:

> *When the work area is not known or is not clear, a Health Physicist should use **professional judgment** to determine whether neutron exposures should be included. Thrse is no single definitive source document that can be used to determine whether an energy employee was exposed to neutron, however, from the weight of evidence investigation, a Health Physicist should be able to determine the neutron exposure potential. The Health Physicist should keep in mind the claimant favorable approach to dose reconstruction under EEOICPA and when there is equal evidence of potential exposure, the approach should be to include the neutron exposure. Listed below is some **general guidance** that can be used to assist in determining whether an individual was potentially exposed to neutrons*. [Emphasis added]

The "general guidance" to be followed by the dose reconstructor includes three conditions given in Section 2.2.1, *General Indications of Potential Neutron Exposure*. Condition 2 states the following:

> *External dosimetry records indicate the 17 keV calibration curve was used for interpretation of the shallow dose. This is an indication of exposure to plutonium and therefore neutrons. This indicator could be for work in the 100, 200, or 300 areas.*

In Section 2.2.2, the dose reconstructor is cautioned about the limited value/use of the high shallow to deep dose ratio when applied to the 200 and 300 Areas, as given in the following two statements:

> *The high shallow to deep dose ratio is not always a clear indicator of neutron exposure in the 200 area. For example, if there is numerous enriched uranium bioassay measurements in the 200 area, the energy employee most likely worked on the A lines and would have received little to no neutron exposure. The high shallow dose is the result of beta exposure from uranium daughter products.*

And,

> *Generally this area was a uranium fuel fabrication area. There were certain campaigns (time periods), however, in which plutonium-aluminum (Pu-Al) targets were manufactured in the 321-M facility. These Pu-Al targets emitted neutrons. Generally, there will also be indications that the 17 keV calibration curve was used to interpret the shallow dose. The use of this calibration curve is an indicator of potential neutron exposure. Currently research is being conducted to better determine the time periods in which the 300 area manufactured Pu-Al targets. Research to date has indicated this work was conducted in late 1964 through at least 1967. This work was most likely conducted in later time periods as well, however this information has not been located.*

The TIB concludes with the following guidance, as contained in Section 5.0, *Summary*:

> *For further information on whether neutron dose should or should not be included in the Savannah River Dose reconstructions, documents listed in the reference section of this bulletin provide additional* ***details of SRS operations*** *and associated neutron exposures.* [Emphasis added.]

2.10.5 Conclusions

The principal objective of this procedure is to account for unmonitored/unrecorded neutron doses during **specific** time periods in behalf of **select** workers who may have been **intermittently** exposed to neutrons at dose rates of less than 1 mrem/hr. On the basis of this objective, it is reasonable to conclude that such doses are likely to have been small relative to **recorded** external whole-body photon doses and neutron doses, and internal exposures.

To achieve this objective, the successful implementation of this procedure requires either (1) a high degree of personal familiarity with historic SRS facility operations that predate 1971, or (2) an extensive and time-consuming research effort on the part of the individual dose reconstructor. Even when all potential data are available, this procedure still requires the dose reconstructor to make numerous subject decisions and data interpretation in behalf of doses that are likely to have limited relevance to a claim. Additionally, the subjective treatment of data by different dose reconstructors is also likely to raise questions about the **consistency** of the dose reconstruction process and fairness to the claimant.

It is, therefore, SC&A's opinion that a detailed accounting of neutron exposure as suggested by the guidance contained in this procedure is excessive and inconsistent with regulatory directives for NIOSH to apply methods that yield "**reasonable estimates**" that are "**consistent**, **fair** and as **timely** as possible" and "which may **differ** substantially from those that would be produced under a scientific research protocol when the principal objective is to produce maximally complete and precision estimates."

For consistency, fairness, and timeliness, a simplified process that provides a surrogate approach would assign a neutron dose to any **intermittently exposed** worker who, on the basis of job description, work location, and employment period, had the potential for a neutron exposure at 1 mrem/hr level. Additional model assumption might include the use of a triangular distribution that defines a range and mode (e.g., 0 to 1000 mrem/yr with a mode of 200 mrem/yr).

Lastly, this site-specific procedure should be integrated into Section 5 of the SRS Site Profile, ORAUT-TKBS-0003.

2.11 OCAS-PER-002 — ERROR IN SURROGATE ORGAN ASSIGNMENT RESULTING IN AN UNDERESTIMATE OF X-RAY DOSE IN SRS DOSE RECONSTRUCTION

The review of OCAS-PER-002, *Error in Surrogate Organ Assignment Resulting in an Underestimate of X-ray Dose in SRS Dose Reconstruction*, Rev. 1, dated December 15, 2003, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on January 11, 2005.

2.11.1 Purpose of Procedure

This document is a PER, which alerts dose reconstructors of an error contained in various approved and draft Technical Basis Documents specific for various DOE sites. For OCAS-PER-002, the error involves the assignment of the ovary dose as a surrogate organ for the **liver**, **gall bladder**, and **spleen** for exposures involving collimated medical chest x-ray examination.

Based on anatomical proximity, the more appropriate choice for a surrogate organ dose is the lung. The revised surrogate use of the lung dose corresponds to the following additional doses to the liver, gall bladder, and spleen per x-ray exam:

- Pre-1971 — 43 mrem
- 1972-1985 — 27 mrem
- 1986-present — 20 mrem

2.11.2 General Comments

The revised use of lung dose as a surrogate for the liver, gall bladder, and spleen in instances of medical occupation exposures from chest x-ray exams is technically correct and claimant favorable.

An assessment of potential adverse impacts on past claims that were evaluated prior to this procedure revealed three claims involving one liver and two gall bladder cancers. In all three cases, the additional assignment of organ doses resulted in a net average increase of 0.5% in the POC without affecting the decision for compensation.

However, as part of the resolution/corrective action, this PER instructs ORAUT to revise all Technical Basis Documents and ensure that the lung is assigned as the surrogate organ for the **liver**, **gall bladder**, and **spleen**.

SC&A initially reviewed this PER regarding the magnitude of the error, its associated impacts, and OCAS' proposed resolution/corrective action. SC&A has concluded that this PER properly evaluated past claims that may have been adversely affected by this error and has taken corrective actions that are biased in favor of the claimant.

Because a PER is not intended to provide procedural guidance for dose reconstruction, it is not subjected to SC&A's procedure review process that includes the Procedure Review Outline/Checklist.

REFERENCES

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3.0 INTERNAL DOSIMETRY PROCEDURES/DOCUMENTS

3.1 OCAS-IG-002 — INTERNAL DOSE RECONSTRUCTION IMPLEMENTATION GUIDELINE

The review of OCAS-IG-002, *Internal Dose Reconstruction Implementation Guideline*, Rev. 0, dated August 2002, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

3.1.1 Purpose of Procedure

According to the preface, the stated purpose of this guide is:

> *. . . to provide basic information on the methods employed in reconstructing doses under the Energy Employees Occupational Illness Compensation Program Act of 2000. The intent of this guide is to assist a qualified health physicist in determining annual organ dose from exposure to various sources of internal radiation. Because not all possible exposure scenarios can be foreseen, this guide does not provide step by step instructions for how the dose reconstruction should be performed. It is recognized there will be situations for which the methods outlined in this guide result in underestimates or overestimates of a claimants actual dose. In these cases, care must be exercised that the doses are conservative (claimant friendly) but reasonable for the claimant's exposure scenario.* [Emphasis added.]

The introduction states:

> *The purpose of this document is to provide guidance on the methods and approaches that can be used to reconstruct occupational radiation dose from internally deposited radionuclides in support of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA, 2000). . . . The end result of the internal dose reconstruction will be the dose, expressed in cSv (rem), received in individual calendar years to the organ of interest along with the uncertainty associated with the dose. 42 CFR part 82 (2002) governs the process of reconstructing doses to individuals.*

3.1.2 Review Protocol

S. Cohen & Associates' (SC&A's) evaluation of OCAS-IG-002 is summarized in Table 3.1-1 below. Table 3.1-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

Table 3.1-1. Procedure Review Outline/Checklist

Document No.: OCAS-IG-002	**Effective Date:** August 2004
Document Title: Internal Dose Reconstruction Guideline	
Reviewer: Joyce Lipsztein	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	3	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	5	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	NA	
3.2.2	In vivo/In vitro bioassays	5	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	5	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	3	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	5	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	3	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	3	See Review Comments
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). NA indicates not applicable.

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.1.3 Review Comments

Review Objectives 1.1 and 1.5

Objectives 1.1 and 1.5 were designed to assess whether a procedure is unambiguous and sufficiently prescriptive to minimize subjective decisions. SC&A fully understands that, due to the complexity of internal dosimetry and the limitations and uncertainties surrounding bioassay measurements, subjective decisions are an inherent part of the interpretation of results for internal dose calculations. They are also inherent to the process of determining whether the exposure to radiation is at least as likely as not to have caused a particular cancer. Therefore, it is important that OCAS-IG-002 clearly identifies those circumstances that may require professional judgment. SC&A's review of the implementation guide has identified some sections in which the writing style is not clear and ambiguous. Section 6.0, *Preliminary Dose Estimates*, and Section 7.0, *Detailed Dose Estimates*, of OCAS-IG-002 do not provide clear, straightforward instructions on how to conduct an internal dose reconstruction. The example given in Section 8.0, *Example Dose Estimates*, of OCAS-IG-002 shows how difficult it is to follow the guidance in Sections 6.0 and 7.0 without making subjective decisions. For example, the following paragraphs are cited under OCAS-IG-002, Section 8.3, *High Dose Potential Preliminary Estimate*, pages 35 and 36:

> *An underestimate can be accomplished by estimating the dose received from the large intake during the 1/20/73 incident alone. In determining the amount of the acute intake on 1/20/73, it is indicated that the concentration in the urine should drop off much faster than the data show. While the cause of this is unclear, all that matters is that there are credible reasons for the observations, such as the incident contaminated the work area* ***enough to deliver a chronic intake each day for some time. With that assumption stated, the underestimate was performed by modeling the intake as two back-to-back chronic exposures. The first of 2000 pCi per day from 2/7/73 to 4/17/73 and the second of 1000 pCi per day from 4/18/73 to 8/7/73. . . .*** [Emphasis added.]
>
> *. . . Had the probability been below the compensation level,* ***the estimate could be refined easily by adding another chronic exposure to account for the time frame when he received several detectable intakes.*** [Emphasis added.]

It is not clear how the two values of 2,000 and 1,000 pCi per day were calculated and when chronic intake should be assumed. There is also no clear indication of methods for refining the estimate and which doses to add. The dose reconstructor is left to make subjective decisions without clear, straightforward instructions on conducting the dose reconstruction.

As a further example, the following paragraphs are cited under OCAS-IG-002, Section 8.5, *High Dose Potential Preliminary Estimate*, pages 39 to 41:

Intake #1: . . . *Subsequently, the two samples were averaged and* ***assigned*** *a date of 2/6/70 . . . the intake date and amount was* ***adjusted*** *to achieve a good fit with the two points (12/6/69 & 2/6/70).* [Emphasis added.]

Intake #2: . . . *The two that were nearly zero could not be reconciled with any possible scenario associated with intake #1.* ***This led to the decision to disregard these near zero samples*** *and concentrate on the remaining samples*. [Emphasis added.]

Intake #3: . . . *Due to the fast clearance, intake #3* ***was assumed*** *to be acute and to have occurred near the sample date of 8/21/70. The intake amount and date* ***could not be adjusted*** *to align the two points (8/81 & 9/11) but* ***it was adjusted so that*** *the second point was less than the detection limit*. [Emphasis added.]

Intake #5 through Intake #13: . . . *With no second point to help determine the timing of the intakes, the midpoint between samples* ***was assumed*** *as a starting point. With this date the amount of the intake* ***could not be adjusted*** *to keep samples on 8/15/71 & 11/26/71 below the detection limit. The date and amount* ***were then adjusted to achieve this goal.*** [Emphasis added.]

Page 39 of 48:

Intake #15: . . . *At this point it was noted that the predicted value of the sample on 5/26/72 & 12/1/72 were considerably higher than the actual result. The date and quantity of intake #14 and #15* ***were adjusted to minimize these points but no acceptable combination could be found.*** *These intakes* ***were then modeled as chronic exposures using various intake dates and quantities. Eventually a suitable combination was found*** *that allowed the predicted result for 12/1/72 to drop below the detection limit, however, the sample on 5/26/72 was still above. Since the results of the sample on 5/26/72 was 0.0 pCi, it was* ***believed that the sample could be flawed and the results were rejected*** *The results of intake #14 and #15* ***were again changed*** *as a result of evaluating the next intake. The details are discussed under intake #16 . . . .* [Emphasis added.]

Intake #16, #17, and #18: *Intake #16 and #17 were then modeled using various combinations of acute and chronic exposures but all failed to reconcile with the sample on 12/1/72.* ***An additional exposure was then added*** *but it too failed to reconcile the difference.* ***At that point the sample on 12/1/72 was rejected.*** *Since this sample* ***led to several decisions*** *pertaining to intake #14 and #15, the analysis was redone starting with intake #14 but without the sample results for 12/1/72. This led to intakes #14 and #15* ***being reevaluated as acute exposures*** *with the final values listed above*. [Emphasis added.]

Intakes #16 and #17 were then evaluated simultaneously. Since the 12/1/72 sample was rejected, ***an attempt was made to model these intakes*** *so that the*

predicted value matched the actual value on 11/25/72. The final results indicated an acute exposure of 43000 pCi and 23000 pCi on 5/11/72 and 8/26/72 for intakes #16 and #17 respectively. ***This then required an additional intake (#18) to match the data*** *on 1/12/73 and 1/22/73. This was modeled as an acute intake on 12/30/72 in order for the predicted line to match both samples. The intake quantity was 17000 pCi.* [Emphasis added.]

Since the samples on 1/12/73 & 1/22/73 were only slightly higher than the sample on 11/25/72, it was realized that these three samples could actually represent statistical uncertainty of one predicted line. ***This scenario was explored by eliminating intake #18*** *and* ***adjusting the date and quantity of intakes*** *#16 and #17 in order to minimize the residuals of these three samples. This scenario resulted in no change to intake #16 while intake #17 was 40000 pCi on 8/24/72. Notice that this exactly matches the total of the original intake #17 and #18 (23000 + 17000).* [Emphasis added.]

In an attempt to further reduce the residuals by "flattening out" the predicted line through the three samples (11/25/72, 1/12/73, & 1/22/73), intake #16 ***was moved back as far as possible to the day of the previous sample*** *(3/31/72 since 5/26/72 was rejected). This resulted in intake #16 being a 53000 pCi intake. When only intake #17 was added the residuals were minimized when intake #17 occurred on 8/24/72 with 35000 pCi.* ***The last scenario to explore was to reconsider the two intakes*** *(#17 & #18) with intake #16 consisting of 53000 pCi on 3/31/72. This resulted in intake #17 being 23000 pCi on 8/26/72 with intake #18 being 13000 pCi on 12/30/72. . . . The dose reconstructor is left with subjective decisions to make and no clear, straightforward instructions on how to conduct the dose reconstruction.* [Emphasis added.]

In the sentences cited above, SC&A has emphasized those circumstances that may require subjective judgment and decisions. Subjective decisions are an inherent part of the interpretation of results for internal dose calculations. The dose reconstructor must not be mislead and should be informed clearly that professional judgment is necessary in many instances and that conclusions pertinent to one case may not be applicable to other cases.

The conclusion of this particular example (total intake is not sensitive to the actual intake date) is misleading, since it does not explicitly show that it is only pertinent to this special case and cannot be generalized. The following paragraphs were taken from Section 8.5, page 41 of 48, of OCAS-IG-002:

. . . This yielded a total of 36000 pCi (23000 + 13000) compared to 35000 pCi for the one intake scenario. This indicated that while it was not clear which scenario was correct, ***the final outcome was comparable****. Also note that the total intake from all four scenarios yielded results of intakes of 89000, 88000, 83000, and 83000 pCi. Even moving intake #16 back 41 days changed the total intake by <10%.* [Emphasis added.]

> ***This information implies that the total intake is not very sensitive to the actual intake date. The primary objective is to match data as closely as possible by some non-subjective means (such as residuals) regardless of the chosen scenario.*** [Emphasis in document.]

This conclusion contradicts Section 7.1, *Estimate of Intake Date*, page 26 of 48, of OCAS-IG-002:

> *The time of intake is an important parameter in assessing bioassay data. Based on one positive sample, the intake could have occurred anytime since the last non-detectable sample.* ***The difference in a calculated intake, based on assuming the intake occurred at either the beginning or the end of this period, can vary by orders of magnitude***. [Emphasis added.]

As stated in International Atomic Energy Agency (IAEA) Safety Report Series 37, *Methods for Assessing Occupational Radiation Doses due to Intakes of Radionuclides* (2004), a principal source of uncertainty in the interpretation of bioassay data is the determination of the time of intake. A reasonable estimate of the time of intake is vital for the proper interpretation of bioassay data.

This particular case relates to intakes of Pu, in a mixture of type M and type S solubility compounds. If the dose reconstructor were evaluating a uranium exposure case, for example, the conclusions would have been completely different:

- For a 30-day monitoring interval in the collection of urine samples from workers, assuming that a single intake of type M compounds occurred in the middle of the monitoring interval (day 15 of this monitoring period), a positive result will lead to a calculated intake 54 times higher than if it was assumed that exposure occurred 1 day before the date the sample was taken (day 29).
- For type F uranium compounds, the assumption that the intake occurred in the middle of the monitoring interval (day 15) will lead to a calculated intake 100 times higher than if it was assumed to have occurred 1 day before the date the sample was collected (day 29). For type F uranium compounds, the assumption that the exposure occurred in the middle of the monitoring interval (day 15) leads to a calculated intake that is 40% of the intake calculated, assuming that exposure occurred in the beginning of the monitoring interval (30 days before sampling).
- For chronic intakes, 5 days a week, 8 hours per day, the difference between collecting a urine sample before or after the weekend is very important.
- For type M uranium compounds, the daily intake calculated based on a result from a urine sample assumed to have been submitted on the last day of the weekend will be 75% higher than if it was assumed that the same activity concentration in urine was a result from a sample collected on the last day of the work week.

- For type F uranium compounds, the intake calculated assuming that the sample was taken after the weekend is approximately 4 times higher than when assuming that it was taken before the weekend for the same activity concentration in urine.

In addition, the instructions provided in Section 7.2, *Uncertainty*, provide no clear indication of the methodology for calculating internal dose estimate uncertainties. For example, the following two paragraphs are cited under OCAS-IG-002, Section 7.2, page 29:

> *It is important to note that, while the uncertainty of an internal dose estimate can be dominated by the uncertainty in determining the intake, this is not always the case. The intakes for individuals that submit many detectable bioassay samples may have their total intake calculated fairly accurately. However, this intake is based on a particular biokinetic model. Any inaccuracies or biases produced by this model must be considered.*
>
> *Uncertainties associated with the biokinetic models are difficult to assess. While some attempts have been made to evaluate the uncertainty of the overall models, (NCRP, 1998; Till et al., 2000), it is important to tailor the uncertainty assessment to the specific situation at hand.*

The International Commission on Radiological Protection (ICRP) does not recommend determining uncertainties based on its biokinetic models, which were developed for a reference individual. Independent of this ICRP recommendation, uncertainties in biokinetic models are very difficult to consider, and no straightforward instructions are given on this subject.

The example given in Section 8.7, *Uncertainty*, of OCAS-IG-002, demonstrates the lack of precise instructions in Section 7.2. The following paragraphs are cited from Section 8.7, page 45:

> *The error is relatively small as can be expected when a large number of detectable samples are submitted. This relative error is applicable to the intake amount only; it assumes the biokinetic model is accurate. With an intake error this low, it is necessary to assess the uncertainty of the biokinetic model in order to develop a realistic uncertainty for this individual's dose. . . .*
>
> *. . . In the case of probability of causation values less than 50%, a more detailed analysis will be required.* ***It may be necessary to reproduce the biokinetic model in a Monte Carlo calculation with known values given as constants. The results of this calculation can then be used to describe a detailed probability distribution of the organ dose.*** [Emphasis added.]

There are no clear instructions on how to assess the uncertainty. How should the dose reconstructor reproduce the biokinetic model? Which values should be used as constants? In the biokinetic models, more than 100 parameters may be modified. Which parameters are important? How do they relate to each specific case?

Review Objective 1.3

OCAS-IG-002 identifies the applicable ICRP publications that are needed to perform dose reconstruction involving internal exposure. However, the implementation guide is incomplete in the following areas:

(1) There is no specification on the treatment of daughter radionuclides. (A more detailed discussion is provided in Section 3.1.4 of this report.)

(2) The model to be used for Ca and Cm should be the updated to ICRP 71 (1995).

(3) The treatment of gases and vapors is not mentioned.

Review Objective 4.1

OCAS-IG-002 does not provide clear and unambiguous instructions for performing a preliminary internal dose estimate and the calculation of associated uncertainties, as described in Sections 6.0 and 7.0.

Review Objectives 6.1 and 6.2

Section 7.2 of OCAS-IG-002 discusses uncertainty associated with detailed (as opposed to preliminary) internal dose estimates. This section, however, only briefly addresses the issues surrounding uncertainty and does not provide adequate guidance for selecting probability distributions, random sampling, and other tasks.

3.1.4 Technical Issues

OCAS-IG-002 provides basic information on the methods to be employed in reconstructing internal dose. The end result of this internal dose reconstruction should be a claimant-favorable, reasonable estimate of the dose equivalent received by the worker, in individual calendar years, to the organ of interest, as well as the uncertainty associated with the dose. In order to comply with these directives, OCAS-IG-002 should provide more clarity in the following areas:

(1) Section 2.1, Figure 2, page 7: Figure 12 in Section 2.1, *General Models*, of this implementation guide depicts the ICRP 66 lung model with a description of the various lung regions. Within the extra thoracic region, ET_2 is described as consisting of the posterior nasal passages, pharynx, and larynx. The ET_2 portion of the extra thoracic region should also include the mouth. This is important in terms of the assignment of an ICRP organ to the primary cancer site.

(2) Section 2.2, page 9: Section 2.2, *Specific Models*, discusses biokinetic models of selected radionuclides that have been updated since the publication of ICRP 30. Table 1 in Section 2.2 specifies the ICRP model that is to be used for reconstructing energy employee dose. This section, however, does not specifically address the treatment of daughter radionuclides (independent kinetics from decay products formed within the body following the intake of radioisotopes of tellurium, radium, thorium, and uranium (as

specified in ICRP 71), and shared kinetics (same as parent) for decay products of other nuclides). This is important in terms of organ doses, especially in the treatment of the unspecified tissues (other tissues) for different chain members.

Table 1 of Section 2.2 should also include the models for Ca and Cm, which were updated in ICRP 71 (1995).

(3) Section 4.1.2, page 13:

Comment 1: Section 4.1.2, *Ingestion*, states the following: "Ingestion and clearance of insoluble compounds through the gastrointestinal (GI) tract delivers a dose for only a few days, and soluble compounds that are readily absorbed are eliminated fairly quickly." It is inaccurate to assume that soluble compounds that are readily absorbed are eliminated fairly quickly. Cesium, for example, always forms soluble compounds (type F for inhalation), f_1=1; thus, it is readily absorbed but not rapidly eliminated. In fact, organ doses associated with Cs-137 are in general higher for ingestion than from inhalation. Table 3.1-2 below, taken from the ICRP *Database of Dose Coefficients: Workers and Members of the Public*, available on CD-ROM, is used to compare 50-year committed equivalent organ dose coefficients from inhalation and ingestion of Cs-137.

Table 3.1-2. 50-Year Committed Equivalent Organ Dose Coefficients from Inhalation and Ingestion

	INHALATION AMAD 5 micron (Sv/Bq intake)	INGESTION f1=1 (Sv/Bq intake)
Time after Intake	**50 years**	**50 years**
Adrenals	6.70E-09	1.40E-08
Bladder Wall	6.90E-09	1.40E-08
Bone Surface	6.60E-09	1.40E-08
Brain	5.70E-09	1.20E-08
Breast	5.40E-09	1.10E-08
Esophagus	6.30E-09	1.30E-08
St Wall	6.30E-09	1.30E-08
SI Wall	6.70E-09	1.40E-08
ULI Wall	6.90E-09	1.40E-08
LLI Wall	8.00E-09	1.70E-08
Colon	7.40E-09	1.50E-08
Kidneys	6.50E-09	1.30E-08
Liver	6.50E-09	1.30E-08
Muscle	6.00E-09	1.20E-08
Ovaries	6.90E-09	1.40E-08
Pancreas	6.90E-09	1.40E-08
Red Marrow	6.30E-09	1.30E-08
ET Airways	1.30E-08	1.30E-08
Lungs	6.10E-09	1.30E-08
Skin	5.20E-09	1.10E-08
Spleen	6.50E-09	1.30E-08
Testes	6.00E-09	1.20E-08
Thymus	6.30E-09	1.30E-08
Thyroid	6.30E-09	1.30E-08
Uterus	6.90E-09	1.40E-08
Remainder	9.50E-09	1.20E-08
Effective dose	6.70E-09	1.30E-08

Depending on the number of years between exposure and the diagnosis of the cancer, a dose to the colon or to the lower large intestine (LLI) wall might be greater using the ingestion model, even for radionuclides for which f_1 does not equal 1.

Comment 2: In discussing the ingestion pathway, Section 4.1.2 states the following:

> *. . . While the fraction of material ingested often results in relatively minimal dose, it can produce bioassay data comparable to a larger inhalation dose. This implies that the erroneous assignment of a fraction of the bioassay data to ingestion can significantly bias the assigned dose. In some cases, this effect can result in doses that are several orders of magnitude low. Because of this, caution must be used before assuming any bioassay data is the result of ingestion. However, what appears to be conflicting bioassay data must be evaluated. For example, a fecal sample*

> *for Th-232 indicated a large dose when assumed to be the result of inhalation while an in vivo measurement indicated no detectable Th-232 in the lungs. If both samples are **valid**, and some evidence exists that indicates ingestion is possible, this dose can be assigned, at least in part, as ingestion since that is the only way to reconcile the two valid measurements.* [Emphasis added.]

This example is technically flawed when referring to ". . . an in vivo measurement [with] no detectable Th-232 in the lungs" as a "valid" sample. Th-232 is a pure alpha emitter, which is not readily detected by in vivo bioassay techniques. Therefore, the **absence** of a positive lung count can confirm neither the presence nor the absence of Th-232 in the lung. (Note: A positive in vivo bioassay could only result if Th-232 had been inhaled along with its radioactive decay daughter Ra-228 (half-life of 6.7 years) and gamma emitting radioactive daughter Ac-228 (half-life of 6.13 hours). In such a case, the question of pathways may be apparent if equilibrium is assumed and the exposure is high enough to exceed the detection limit of the in vivo method that was used.) In general, the detection limit of both excreta and in vivo monitoring techniques should be considered in the comparison of results.

The potential for ingestion should be investigated in relation to hygienic habits (existing rules for cigarette smoking, eating and drinking in the radiation area or radiation adjacent areas, placing contaminated hand or glove in the mouth).

(4) Section 4.3, page 15: Section 4.3, *Solubility Class*, indicates that the solubility of a radionuclide is one of the most important parameters in determining the internal radiation dose. In order to accurately determine the solubility class, this section also states:

> ***The most accurate means of evaluating the solubility class is by examining multiple bioassay samples after an intake. This has the potential of providing an accurate determination of solubility for the particular material.*** *However, inhaled material often exhibits more than one solubility class. A plot of multiple bioassay samples can produce a curve that appears to show a soluble compound when in fact it is only the soluble portion of the inhaled material that is actually being followed. The slowly changing insoluble portion may not be noticeable. Therefore, consideration must be given to the potential presence of more insoluble compounds whenever bioassay samples are used to determine solubility. Figure 4 demonstrates this effect. As can be seen, a mixture of solubility class S and M plutonium produces a clearance curve with virtually the same slope as that of pure class M material.* [Emphasis added.]

Determining the solubility type by multiple bioassay samples is a very complex process. When this method is used, the results may be misleading, as discussed in Section 4.3 and depicted in Figure 4 of OCAS-IG-002. This is one example in which the guide shows part of the problem but does not provide guidance on its resolution, yet states that **it is**

the most accurate means of evaluating the solubility class. OCAS-IG-002 omits the fact that the activity excreted on a daily basis varies significantly, often depending on the liquid or food ingested (as in the case of uranium), or on the daily exposure condition (differences in working condition or exposures from day to day).

Furthermore, OCAS-IG-002 does not mention that activities excreted in urine are also dependent on the individual metabolism, and that no worker is expected to behave like the standard man.

(5) Section 7.4, page 33: The last sentence in Section 7.4 of OCAS-IG-002 states, "Since the risk factors in NIOSH-IREP are based on WLMs, and a WLM is defined only for progeny, any exposure to Rn-222 gas (without its accompanying progeny) will have to be calculated as a dose and input into NIOSH-IREP as a dose instead of a WLM."

The guide does not explain how to calculate doses from Rn gas itself, without the daughters. ICRP does not recommend any strategy for this calculation.

3.2 ORAUT-PROC-0003 — INTERNAL DOSE RECONSTRUCTION

The review of ORAUT-PROC-0003, *Internal Dose Reconstruction*, Rev. 00, dated May 1, 2003, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

3.2.1 Purpose of Procedure

The stated purpose of this procedure is "to provide guidance in the performance of internal dose reconstructions under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). This procedure specifies steps taken to assure that internal dose reconstructions are sufficiently complete, correct and consistent for determining probability of causation of a covered employee's specified cancer(s)."

3.2.2 Review Protocol

SC&A's evaluation of ORAUT-PROC-0003 is summarized in Table 3.2-1 below. Table 3.2-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

3.2.3 General Comments

According to the scope of the procedure,

> "*This procedure applies to ORAU Team (ORAUT) personnel and contractors who are reconstructing and reviewing internal doses in support of the National*

Institute for Occupational Safety and Health (NIOSH) Office of Compensation Analysis and Support (OCAS).”

It defines responsibilities among the Principal Internal Dosimetrist, Internal Dosimetry Supervisor, Internal Dose Reconstructor, External Dose Reconstructor, Lead Dose Reconstructor, and Support Dose Reconstructor.

Table 3.2-1. Procedure Review Outline/Checklist

Document No.: ORAUT-PROC-0003	**Effective Date:** 05/01/2003
Document Title: Internal Dose Reconstruction	
Reviewer: Joyce Lipsztein	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	3	See Review Comments
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	3	See Review Comments
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)		It addresses generic data.
3.2.2	In vivo/In vitro bioassays		It addresses generic data.
3.2.3	Missing dosimetry data		It addresses generic data.
3.2.4	Unmonitored periods of exposure		It addresses generic data.
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	4	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?		See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?		See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?		See Review Comments
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	2	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	2	See Review Comments
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.2.4 Review Comments

Review Objectives 1.1 to 1.5

Objectives 1.1 to 1.5 were designed to determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.

Objective 1.3 seeks to determine if the procedure is complete in terms of required data. Appropriately, ORAUT-PROC-0003 refers to several other NIOSH documents. However, the references do not include ICRP 30, 56, 67, 69, 71, 72, and 78, although they are necessary to understand Table 1 of the procedure.

Objective 1.5 was designed to determine if the procedure is sufficiently prescriptive to minimize subjective decisionmaking and data interpretation. Dose reconstruction and data interpretation always depend on some subjective decisions. The note following item 6.5.4 on page 9 of ORAUT-PROC-0003 is an example of the need for subjective decisionmaking and data interpretation: "It may sometimes be possible to use the bioassay data to determine some of the parameter values, but there must be **sufficient** data of **good quality** in order to make this assertion. **A few positive results** are not sufficient." [Emphasis added.] The dose reconstructor must decide which results may be considered "sufficient data of good quality," and how many results are necessary to have useful data ("a few positive results are not sufficient").

The document provides some direction on making subjective decisions as an inherent part of the interpretation of results for internal dose calculations. On page 12, item 6.8.2, of ORAUT-PROC-0003, for example, the following advice is given: ". . . select possible values based on reasonable and scientific assumptions. If this yields multiple choices, select those representing the worst-case (claimant-favorable) assumptions."

Review Objectives 2.1 and 2.2

Objectives 2.1 and 2.2 were designed to determine whether the procedure provides adequate guidance to be efficient in cases in which a more detailed approach to dose reconstruction would not affect the outcome. ORAUT-PROC-0003 provides adequate guidance for identifying a potentially high probability of causation (POC) as part of the initial dose evaluation of a claim, as well as for claims with suspected cumulative low doses. The procedure also provides clear guidance in defining worst-case assumptions. However, certain problems with Table 1 may detract from this guidance (see Section 3.5.2, item 3).

Review Objective 4.1

Objective 4.1 was designed to determine whether the procedure supports a prescriptive approach to dose reconstruction. Since dose reconstruction and data interpretation require some subjective judgments, SC&A believes that the procedure is as prescriptive as can be expected given its objectives.

Review Objectives 5.1 to 5.3

Objectives 5.1, 5.2 and 5.3 were designed to assess whether procedure decisions are claimant favorable in cases of missing data, unknown parameters affecting dose estimates, and in which the claimant was not monitored. In general, those items are only addressed generically in the document. With regard to the assignment of a date for an intake, the approach recommended in ORAUT-PROC-0003 is not necessarily claimant favorable and requires further justification.

Review Objectives 6.1 and 6.2

Objectives 6.1 and 6.2 were designed to evaluate the procedure for its ability to adequately account for the uncertainty of dose estimates. Although the document recommends consulting OCAS-IG-002 to estimate intake and dose for likely noncompensable cases and advises that the Interactive RadioEpidemiological Program (IREP) should be run at regular intervals to determine if the POC is greater than 50%, it does not mention the issue of uncertainty.

3.2.5 Technical Issues

(1) Section 6.3.1.2, page 8 of 14: The last sentence should read, "The cancer will most likely be in an organ that does not concentrate the radionuclide(s) . . . ."

(2) Section 6.5.1, page 9 of 14: The usual approach for chronic intakes is to consider the whole period between the two samples:

> *For an acute intake, the use of the midpoint between the date of two consecutive monitoring results, to indicate the date of the intake, might lead to errors of several orders of magnitude, depending on the type of bioassay method used. Those errors are not claimant favorable.*

(3) Table 1, page 10 of 14: The deposition sites from Table 1 present some problems.

- The deposition sites are actually systemic deposition sites, and the table should refer to them as such.
- The soft tissues compartments are present in all new physiologically based biokinetic models (Sr, Ra, U, Th, Np, Pu, Am, Cm) and represent the compartments of the body that are not considered to be the main ones. It does not mean that all tissues of the body should be looked upon as special concentration sites for those radionuclides.
- The behavior of decay product nuclides produced in the body must be taken into consideration and may lead to the introduction of other compartments that may result in relatively high equivalent doses, such as the equivalent dose to the kidneys and spleen for Ra-226.
- The deposition sites contain several errors:

  The liver should be included for Ra.

The kidneys should be included for Th.
The kidneys and red bone marrow should be included for Np, Pu, and Am.
The gonads, kidneys, and red bone marrow should be included for Cm.

Table 1, which is very important for dose reconstruction, must be reviewed using the information that describes the behavior of the radionuclides, as given in the appropriate ICRP publications.

3.3 OCAS-TIB-008 — USE OF ICRP 66 TO CALCULATE RESPIRATORY TRACT DOSES

The review of OCAS-TIB-008, *Use of ICRP 66 to Calculate Respiratory Tract Doses*, Rev. 00, dated September 29, 2003, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

3.3.1 Purpose of Procedure

The stated purpose of this guide is to provide ". . .guidance on selecting an appropriate tissue to serve as the surrogate for the internal dose to specific organs/tissues associated with or near the respiratory tract."

The background section of OCAS-TIB-008 also states, ". . . This TIB attempts to designate the appropriate ICRP calculated organ/tissue dose to use for various ICD-9 coded cancers associated with the respiratory tract."

3.3.2 Review Protocol

SC&A's evaluation of OCAS-TIB-008 is summarized in Table 3.3-1 below. Table 3.3-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

3.3.3 General Comments

As stated in the purpose and background sections of OCAS-TIB-008, this document represents the primary source of technical support for ". . . selecting an appropriate tissue to serve as the surrogate for the internal dose to specific organs/tissues associated with or near the respiratory tract."

Table 3.3-1. Procedure Review Outline/Checklist

Document No.: OCAS-TIB-008	**Effective Date:** 09/29/2003
Document Title: Use of ICRP 66 to Calculate Respiratory Tract Dose	
Reviewer: Joyce Lipsztein	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	4	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	4	See Review Comments
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.3.4 Review Comments

Review Objectives 1.1, 1.3, and 1.5

Objectives 1.1, 1.3 and 1.5 were designed to assess whether a procedure is unambiguous and sufficiently prescriptive to minimize subjective decisions.

SC&A's review of this technical document has identified that the explanations on the use of certain organs as surrogates isare not always clear. For example, the explanation in Section 4.2, page 3, regarding the use of nonmodeled organs for the mouth, is complex but not clear.

Several paragraphs of ICRP 66 are referenced and discussed in the document, but the procedure is not always sufficiently prescriptive. In cases in which large differences exist among nonmodeled organs, the dose reconstructor must make subjective decisions on which organ to use, as specified on page 3, Section 4.1, of the document:

> *It is conceivable that a situation could arise where a photon emitting radionuclide causes a large difference in doses delivered to non-modeled organs. In accordance with the Internal Dose Reconstruction Implementation Guideline, it is acceptable in these situations to base the dose on an organ that is not the highest non-modeled organ. The choice in these cases should be based on the proximity of the surrogate organ to the organ of interest.*

Review Objective 4.1

Section 4.1, *Highest Non-Mmodeled Organ*, of OCAS-TIB-008, does not provide clear instructions on which organ to use in cases involving large differences among nonmodeled organs.

Review Objective 4.2

SC&A's review has identified that the procedure does not comply with the requirements in Title 42, Section 82.2, of the *Code of Federal Regulations* (42 CFR 82.2) to use the ICRP 66 model. In Section 4.2 of OCAS-OTIB-008, the following statement is made: ". . . As a result of this discussion, it is evident that the mouth was not considered in assessing the dose to the ET2 region and therefore should be treated as unmodeled tissue." The assignment of the mouth as the highest nonmodeled organ does not comply with ICRP 66 recommendations.

3.3.5 Technical Issues

In general, OCAS-TIB-008 is straightforward on the assignment of the appropriate tissue to serve as the surrogate when determining the internal dose to specific organs/tissues associated with or near the respiratory tract. However, the assignment of the mouth as the highest nonmodeled organ is not appropriate since the ICRP specifically lists the mouth as part of ET2.

3.4 ORAUT-PROC-0002 — USE OF INTEGRATED MODULES FOR BIOASSAY ANALYSIS

The review of ORAUT-PROC-002, *Use of Integrated Modules for Bioassay Analysis*, Rev. 01, dated August 14, 2003, was prepared by Kathleen Behling, and approved by John Mauro, PhD, CHP, on January 11, 2005.

3.4.1 Purpose of Procedure

The stated purpose of this procedure is ". . . to provide ORAU Team dose reconstructors an overview of running the IMBA (Integrated Modules for Bioassay Assessment) software and to specify IMBA documentation and file creation requirements for the NIOSH Dose Reconstruction Project."

3.4.2 Review Protocol

Our evaluation of ORAUT-PROC-002 is summarized in Table 3.4-1. Table 3.4-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

3.4.3 General Comments

The IMBA software program is designed to perform the complex calculations of estimating a worker's intake of radioactive materials and converting this intake to an annual dose to a designated target organ or tissue in a form suitable for input to the Interactive RadioEpidemiological Program (NIOSH-IREP).

The procedure describes the mechanics of running the IMBA software under routine or standard case evaluations (not when non-default assumptions are necessary) and specifies documentation requirements. The reader is cautioned that this procedure is neither designed to specify all operational steps necessary to use IMBA nor evaluate nonstandard internal dose reconstructions. Running the IMBA software will also require the use of information provided in the IMBA Expert user manual. In addition, this procedure does not provide guidance on performing a dose estimate. More detailed information for performing a dose estimate is provided in ORAUT-PROC-0003, *Performing Internal Dose Reconstructions*.

Table 3.4-1. Procedure Review Outline/Checklist

Document No.: ORAUT-PROC-0002	**Effective Date:** 8/14/2003
Document Title: Use of Integrated Modules for Bioassay Analysis (IMBA)	
Reviewer: Kathleen Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	5	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations:**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant:**		
5.1	Is the procedure claimant-favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant-favorable in instances of unknown parameters affecting dose estimates?	5	
5.3	Is the procedure claimant-favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	5	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.4.4 Review Comments

Review Objective 1.1

The IMBA software program is comprised of three primary screens: (1) the main screen, (2) the bioassay calculations screen, and (3) the dose calculations screen. Each of these screens or windows is further divided into functional portions (i.e., the intake scenario portion of the main screen) that allow for the input of required data. Due to the visual complexity of the IMBA

windows and amount of data that is required to be entered in each of the functional portions of the three screens, it is important that the procedure provide enough detail to point the reader to appropriate locations on the screen for entering necessary parameters and executing operations.

In a few instances, the procedure lacks clear descriptions for the locations of various functional buttons. For example, Section 6.2 describes the process for entering the host of data necessary for calculating intakes and/or predicting bioassay results in the Bioassay Calculations screen. This window is divided into three functional areas and requires entering data into table and graphic sub-screens. When all necessary data has been entered, the procedure simply states under Section 6.2.10: "Calculate intake by clicking Start Calculations." Due to the 'busy nature' of this window, it would be helpful to the user of IMBA to indicate that the 'Start Calculation' button is located in the center of the screen under the 'Calculation' area.

The clarity of the procedure could also be improved in Section 6.2.12. This section specifies: "Click on the first tool button under BIOASSAY QUANTITY once again to open the window containing bioassay data." However, based on previous procedural instructions, clicking on the tool button will actually open the 'graphic' tool window rather than the 'table' tool window. The user should be reminded to ensure that the 'table' radio button under the Bioassay Quantity portion of the screen is first selected.

Review Objective 1.3

Due to the complexity of running even routine evaluations using the IMBA software, ORAUT-PROC-0002 should provide some assistance to the user in evaluating results of the bioassay calculations. In Section 6.2, the procedure describes how to enter data into IMBA for estimating worker intakes and/or predicting bioassay results. However, the procedure does not provide any guidance on evaluating the fit of the data (Section 6.2.11) other than stating ". . . modify assumptions if necessary, in accordance with ORAUT-PROC-0003, Internal Dose Estimation." (It should be noted that the title of ORAUT-PROC-0003 is *Internal Dose Reconstruction*, not Internal Dose Estimation.) The SC&A reviewer read the entire recommended procedure (i.e., ORAUT-PROC-0003) and was unable to glean much additional useful information that specifically addressed modifying the IMBA assumptions in order to arrive at a better fit.

Review Objective 1.5

SC&A fully understands that, due to the complexity of internal dosimetry and the limitations and uncertainties surrounding bioassay measurements, subjective decisions are an inherent part of the interpretation of results for internal dose calculations. As was stated under Review Object 1.3 and is equally appropriate under this objective, the IMBA procedure could have provided the IMBA user with more guidance in areas requiring professional judgment, such as modifying bioassay input assumptions in order to establish a better fit of the data.

3.5 OCAS-TIB-002 — TRITIUM CALCULATION WITH IMBA

The review of OCAS-TIB-002, *Tritium Calculation with IMBA*, Rev. 00, dated April 22, 2003, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

3.5.1 Purpose of Procedure

The stated purpose of this technical information bulletin is to provide ". . . guidance on the use of IMBA to calculate tritium doses."

3.5.2 Review Protocol

SC&A's evaluation of OCAS-TIB-002 is summarized in Table 3.4-1 below. Table 3.4-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

3.5.3 General Comments

In the background section, this document provides a method to calculate internal doses due to exposure to various tritium compounds:

> *The ICRP has specified five different categories of tritium compounds. Many of these compounds are categorized as gases or vapors. While the IMBA program currently includes tritium, it does not yet handle gases and vapors. It is, however, possible to utilize IMBA to calculate doses for these compounds. This Technical Bulletin provides instructions for performing these calculations.*

Table 3.5-1. Procedure Review Outline/Checklist

Document No.: OCAS-TIB-002	**Effective Date:** 04//22/2003
Document Title: Tritium Calculation with IMBA	
Reviewer: Joyce Lipsztein	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	N/A	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.5.4 Review Comments

Review Objective 1.3

Objective 1.3 was designed to determine the degree to which the procedure is complete in terms of required data (i.e., does not reference other sources for additional data). SC&A's review has identified that ICRP 88 is listed as a reference but, although used, is not mentioned in the text. ICRP 30 and 66 are mentioned in the text but are not listed in the references. ICRP 71 is listed in the references but is not mentioned in the text.

3.5.5 Technical Issues

SC&A tested the instructions on bypassing problem with the integrated modules for bioassay analysis (IMBA) of not handling gases and vapors. SC&A compared the results obtained by following the instructions in OCAS-TIB-002 with those obtained using software that handles gases and vapors and calculates intakes and doses exactly as recommended by the ICRP. Results were similar. However, although the instructions are correct, it is cumbersome for the dose reconstructor to use this software for the following reasons:

(1) For tritiated water (HTO), the IMBA calculations window includes indicated activity per day instead of activity per liter. For both inhalation and ingestion routes of intake, the dose reconstructor should use injection.

(2) For **inhalation** of elemental tritium (HT), the dose reconstructor must specify inorganic tritium and **injection** as the route of intake. To calculate intake from a **bioassay result**, the dose reconstructor must divide the intake generated by IMBA by 10,000. **However, the doses calculated are correct**. If the dose reconstructor is calculating **dose from airborne concentrations,** he/she must divide the HT intake by 10,000 to obtain the correct dose.

(3) For **inhalation** of tritiated methane, the dose reconstructor must specify inorganic tritium and **injection** as the route of intake. To calculate intake from a bioassay result, the dose reconstructor must divide the intake generated by IMBA by 100. **However, the doses calculated are correct**. If the dose reconstructor is calculating **dose from airborne concentrations,** he/she must divide the tritiated methane intake by 100 to obtain the correct dose.

(4) For **inhalation** of organically bound tritium (OBT), the dose reconstructor must specify **injection** as the route of intake.

3.6 ORAUT-OTIB-0002 — MAXIMUM INTERNAL DOSE ESTIMATES FOR CERTAIN DOE COMPLEX CLAIMS

The review of ORAUT-OTIB-0002, *Maximum Internal Dose Estimates for Certain DOE Complex Claims*, Rev. 01, dated January 10, 2004, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

3.6.1 Purpose of Procedure

The stated purpose of this technical information bulletin (TIB) is to provide a method to facilitate timely processing of claims under EEOICPA which involve cancer to an organ with little or no reported internal dose from internally deposited radionuclides that might be associated with work at U.S. Department of Energy (DOE) complex sites.

3.6.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0002 is summarized in Table 3.6-1 below. Table 3.6-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

3.6.3 General Comments

In this document, the methods provided to assign internal doses are based upon the "largest reasonably possible value" of the source term comprised of radionuclides that are/were typically the more significant radionuclides (by either preponderance or by internal dose significance) on a site. This worst-case estimate of internal dose assumes that the covered employee had an acute inhalation intake of each of the radionuclides in the source term on the first day of the first year of employment.

Additional assumptions to develop this method are:

- All intakes are inhalations of standard 5 micrometer activity median aerodynamic diameter (AMAD), except for I-131, which is assumed to be in vapor form (class SR-1).
- The most soluble form of the radionuclide specified in ICRP 1994a was used to maximize dose to systemic organs, except as noted below; the dose to the lung is not germane to this exercise.
- Because maximum permissible body burdens (MPBBs) were the metric (actually uptake) for so many years, the assumed implausible uptake was based on a percent of the radionuclide-specific MPBB for soluble chemical forms, as defined by the National Committee on Radiation Protection and Measurements (NCRP 1959). It was assumed that an intake resulting in 10% of an MPBB would not likely occur to an unmonitored worker or would likely produce a readily noticeable bioassay result in a monitored worker, readily noticeable air sample, or other indicators of personnel contamination. In

other words, an event providing the possibility of an intake resulting in a body burden exceeding 10% of the MPBB would not have gone unnoticed, and there would be some sort of indication in the worker's records. This assumption applies to bona fide DOE sites and national laboratories with active radiation protection programs, not to Atomic Weapons Employers (AWEs). The current ICRP methodology is used to calculate doses from these implausible intakes.

- For type F and M materials, the associated derived intake (i.e., intake resulting in a 10% MPBB) was assumed to be 10 and 20 times the 10% MPBB, respectively. The factors of 10 and 20 come from the current ICRP models and the differences between an intake and the activity that is present in the body after the initial clearance of the short-term compartments. These factors are used to relate the historical quantity of control, body burden (which was based on ICRP 2 methods), to the present quantity of control, intake, (which is based on current ICRP methods).

Table 3.6-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0002	**Effective Date:** 01/10/2004
Document Title: Maximum Internal Dose Estimates for Certain DOE Complex Claims	
Reviewer: Joyce Lipsztein	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	2	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	3	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	2	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	2	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	2	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	3	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	3	See Review Comments
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	No mention of a statistical procedure
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	No mention of a statistical procedure
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	NA	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.6.4 Review Comments

Review Objectives 1.1 to 1.5

Objectives 1.1 to 1.5 were designed to determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.

SC&A's review has identified that, in several sections, the writing style is not clear and unambiguous and the information is not given in a logical sequence, making the document not easy to understand. It is difficult to accept the reasons to use 10 and 20 times the 10% MPBB as the maximum intakes. The logic behind the recommended procedures is also very challenging to follow and understand.

The procedure is not complete in terms of required data. The document references and uses data from documents that need to be known in order to understand the procedures described. The procedure is not consistent with all the others that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction. The standard procedures use new ICRP models for interpreting results. It is also not consistent with the procedure used in ORAUT-OTIB-0001.

The procedure is sufficiently prescriptive to minimize the need for subjective decisions. However, the technical derivation of the procedure is very difficult to understand and accept.

Review Objectives 4.1 and 4.2

The procedures described are difficult to understand and reproduce.

Review Objectives 5.1, 5.2, and 5.3

Objectives 5.1, 5.2, and 5.3 were designed to assess whether procedure decisions are claimant favorable in instances of missing data, unknown parameters effecting dose estimates, and in which the claimant was not monitored. The procedure is difficult to understand.

The assumption that the intakes are 10 to 20 times the 10% MPBB is not always justifiable in terms of the new ICRP models. For many nuclides, this is not a claimant-favorable approach. In addition, the method for choosing the solubility types is not always claimant favorable. These findings are exemplified in Section 3.6.5 of this review.

The procedure is designed to reconstruct doses for employees who were not included in a bioassay program. The design of the procedure is not always claimant favorable.

3.6.5 Technical Issues

Calculation of the Intake (pages 4 to 5 of 20, Section 3.1.1)

The TIB provides the following description as the basis for assigning an intake as the MPBB:

> *. . . It was assumed that an intake resulting in 10% of a MPBB would not have likely occurred to an unmonitored worker or would have likely resulted in a readily noticeable bioassay result in a monitored worker, readily noticeable air sample, or other indicators of personnel contamination. In other words, an event providing the possibility of an intake resulting in a body burden exceeding 10% of the MPBB would not have gone unnoticed and there would be some sort of indication in the worker's records.*
>
> *For type F and M materials, the associated derived intake (i.e., intake resulting in a 10% MPBB) was assumed to be 10 and 20 times the 10% MPBB, respectively. The factors of 10 and 20 come from the current ICRP models and the differences between an intake and the activity that is present in the body after the initial clearance of the short-term compartments. These factors were estimated from tables in the November 2002 issue of Health Physics that give the intake retention fraction (IRF) for the whole body (without the ET region) as a function of time after acute intake for different elements and inhalation types.*

The review identified the following specific issues:

- Instead of using an arbitrary number such as 10 or 20 times MPBB, the intake is more correctly estimated using IMBA or even the table from *Health Physics*, cited above, which was used to exemplify the derivation of the factors 10 and 20.
- The fractional retentions in Table 3.1.1-1 are incorrect. They are the fractional retention values from the tables in the November 2002 issue of *Health Physics*. Those fractions refer to the stable element. Each value must be corrected with a decay factor for the specific radionuclide in question. Depending on the radionuclide's half-life, the necessary correction could be significant.
- For example, if applied with the decay correction, the fractional retention in whole body for type M Nb-95 would be equal to 0.015 at 60 days and equal to 0.007 at 90 days. The corresponding factor to multiply the intake would be 67 (60 days) and 144 (90 days), not 20 as was used (Table 3.1.1-2).
- As another example, if applied with the decay correction, the fractional retention in whole body for type M Co-58 would be equal to 0.023 at 60 days and equal to 0.014 at 90 days. The corresponding factor to multiply the intake would be 43 (60 days) and 71 (90 days), not 20 as was used (Table 3.1.1-2). (As stated in Section 3.1.1, immediately after Table 3.1.1-1, "The assumption of type S for Co-58 and Co-60 is used . . . . the fractional retention in the whole body is similar for type M and type S at 60 and 90 days, so the derived intake is estimated as 20 times the 10% MPBB.")

- It is arbitrary to use 3-4 days post intake to calculate the fractional retention in whole body for inhalation type F and 60 and 90 days for type M to account for the rapid clearance components from the lung. (As stated in the last bullet before Table 3.1.1-1, "Because initial deposition in the lung was usually not considered by the ICRP (1959) to be part of the 'body burden,' the retention fractions used allowed some time for the rapid clearance components.")

Choice of the Solubility Types (page 5, Section 3.1.1)

The assignment of solubility types, based on the criterion of choosing the solubility type that produces the larger doses to systemic organs, is not correct for many nuclides. For example:

- As stated in Section 3.1.1, immediately after Table 3.1.1-1, "The assumption of type S for Co-58 and Co-60 is used because it results in larger doses to the systemic organs because of the high-energy photons." From the organs cited in Table 3.1.1-4, the application of type M instead of type S to Co-58 results in larger doses to the bladder wall, brain, uterus and stomach. From the organs cited in Table 3.1.1-4, the application of type M instead of type S to Co-60 results in larger doses to the bladder wall, brain, uterus, and colon.
- As stated in the third bullet after Table 3.1.1-1, "Mn-54 type M has a larger dose conversion factor for most organs/tissues and was generally more claimant favorable than type F." From the organs cited in Table 3.1.1-4, the application of type F instead of type M to Mn-54 results in larger doses to the adrenals, brain, colon, muscle, pancreas, skin, stomach, bladder wall, and uterus.

Minor Corrections

- Pages 8 and 14: The organs listed on page 14 include the thyroid, but it is not included in Table 3.1.1-4.
- Page 8 of 20, Section 4.0: Table 3.1.1-2 should be mentioned instead of Table 3.1.1-1.

3.7 ORAUT-OTIB-0005 — IMBA ORGAN, EXTERNAL DOSIMETRY ORGAN, AND IREP MODEL SELECTION BY ICD-9 CODE

The review of ORAUT-OTIB-0005, *IMBA Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code*, Rev. 01, dated January 23, 2004, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

3.7.1 Purpose of Procedure

The stated purpose of this TIB is to provide "guidance on selecting appropriate ICRP modeled organs/tissues in the Integrated Modules for Bioassay Analysis (IMBA) software program to estimate the internal dose for specific ICD-9 codes, the appropriate organs/tissues to estimate external dose, and the appropriate model in the Interactive RadioEpidemiological Program (IREP)."

3.7.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0005 is summarized in Table 3.7-1 below. Table 3.7-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

3.7.3 General Comments

This document provides a table for the correlation of "ICD-9 codes to the appropriate organ/tissue selection in IMBA, the appropriate organ/tissue selection for external dose estimate, and the appropriate IREP model," as stated in Section 3.0. Section 4.1 states, "The dose estimate for a number of tissues is based on the highest non-metabolic organ dose, designated as 'Highest non-met org/tiss' in the table. Metabolic organs are those that are specifically modeled by the ICRP for a particular element."

Table 3.7-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0005	**Effective Date:** 01/23/2004
Document Title: IMBA Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code	
Reviewer: Joyce Lipsztein	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	4	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	3	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	3	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	5	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	3	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.7.4 Review Comments

Review Objective 1.4

Objective 1.4 was designed to determine the degree to which the procedure is consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction.

SC&A's review has identified that this document is not consistent with ICRP 66. According to this publication, the oral cavity is part of the ET2 region of the respiratory tract. The IMBA applicable organs assigned for this organ are the highest nonmetabolic organ and tissue, instead of ET2. There is no reason to assign oral cavity as a nonmetabolic organ.

Review Objectives 1.5, 4.1, and 7.1

The procedure is not sufficiently prescriptive and requires levels of detail that cannot reasonably be accounted for by the dose reconstructor. Identification of the IMBA applicable organs for several types of cancers is missing and requires revision.

3.7.5 Technical Issues

Page 3 of 19 — ICD-9 (144 and 145)

The IMBA applicable organ assigned for the mouth should be ET2 (ICRP 66, 1993) instead of the highest nonmetabolic organ and tissue. According to ICRP 66, the oral cavity is part of the ET2. The epithelial layer of all compartments of ET2 is constantly renewed by cell division and differentiation, originating from stem cells located in the basal layer of the tissue. The mucous membrane of the oral cavity and pharynx is covered with a mucous layer produced by numerous salivary glands located in the submucosal connective tissue and is well supplied with nerves, blood, and lymph vessels. The oropharynx and larynx surfaces consist of the same tissue — stratified squamous epithelium. There is no reason to assign the oral cavity as a nonmetabolic organ.

3.8 ORAUT-OTIB-0001 — MAXIMUM INTERNAL DOSE ESTIMATES FOR SAVANNAH RIVER SITE (SRS) CLAIMS

The review of ORAUT-OTIB-0001, *Maximum Internal Dose Estimates for Savannah River Site (SRS) Claims*, Rev. 00, dated July 15, 2003, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

3.8.1 Purpose of Procedure

The stated purpose of this guide is to provide a method to be used in the assignment of internal doses to "employees who were monitored but had no detectable activity ('positive') in their

samples and to employees who were not included in the bioassay program, because there is some amount of intake and associated dose that is not detectable by an internal dosimetry program."

3.8.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0001 is summarized in Table 3.8-1 below. Table 3.8-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

3.8.3 General Comments

In this document, the method provided to assign internal doses is based upon a hypothetical intake with the following characteristics:

- *All radionuclides for which internal deposition by inhalation was calculated by the Savannah River Site were reviewed, except for tritium, which is addressed separately.*
- *The amount of inhalation intake for each radionuclide is the average (mean) of the five largest documented intakes, or the average of all intakes if there were fewer than five intakes reported for a radionuclide.*
- *An acute inhalation intake was assumed to have occurred on January 1 in the first year of employment.*
- *ICRP 66 and 68 modeling and default parameter values were used to determine dose.*
- *The material type resulting in the largest dose to the organ or tissue of interest was used. This was typically the most soluble form of the material because it would clear from the lung more rapidly than insoluble material, thus depositing in the organ or tissue sooner.*

. . . Intakes and doses at SRS were calculated using regulatory-prescribed ICRP 30 methodologies rather than the newer ICRP methodology prescribed for this dose reconstruction effort. The material classes used in the calculations were based on workplace source term information or the class that provided the best fit to the bioassay data; the most claimant favorable class was not necessarily selected.

Table 3.8-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0001	**Effective Date:** 07/15/2004
Document Title: Maximum Internal Dose Estimates for Savannah River Site Claims	
Reviewer: Joyce Lipsztein	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	2	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	2	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	2	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	2	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	2	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	NA	
3.1.4	Is the interview process sensitive to the claimant?	NA	
3.1.5	Does the interview process protect information as required under the Privacy Act?	NA	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	NA	
3.2.2	In vivo/In vitro bioassays	NA	
3.2.3	Missing dosimetry data	4	See Review Comments
3.2.4	Unmonitored periods of exposure	3	See Review Comments
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	3	See Review Comments
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	3	See Review Comments
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	3	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	2	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	2	See Review Comments
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	1	See Review Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	1	See Review Comments
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	2	See Review Comments
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	2	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). NA indicates not applicable.

3.8.4 Review Comments

Review Objectives 1.1 to 1.5

Objectives 1.1 to 1.5 were designed to determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction. SC&A's review has identified that, in several sections, the writing style is not clear and unambiguous. The document is not complete, and it is very difficult to understand. For example:

- Data for Tables 1 and 2 are not referenced, and it is impossible to verify or relate the data to specific jobs.
- There is insufficient information to reproduce the relative intakes in Tables 3 and 5.
- It is difficult to accept the reasons to use the ICRP 30 calculated intakes as the worst-case estimates when the procedure underestimates the ICRP 68 calculated intakes for several radionuclides.
- The calculation of annual organ doses from hypothetical intakes for Table 2 nuclides is not clear.
- The use of surrogate radionuclides is not well explained, including the use of type F nuclides as surrogates to types M and S. The choice of surrogate nuclides is very subjective, as are the comparisons on Tables 3 to 10.

The document is difficult to understand. For example, it does not mention that the Savannah River Site (SRS) doses were recalculated using ICRP 30 methodology in 1987 for active workers and in 1992 for inactive workers. This information is important for understanding the use of ICRP 30 methodologies to calculate the recorded intakes dating before the publication of ICRP 68. In addition, the procedure for the assignment of tritium dose should be complemented by the information contained in ORAUT-OTIB-0003.

The document is not consistent with other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction, specifically:

- The standard procedures in 42 CFR Part 82 and OCAS-IG-002 recommend the use of new ICRP models for interpreting bioassay; however, the document uses ICRP 30 models to calculate intakes.
- The approach for calculating maximum dose estimates is particular to SRS and differs from the approach recommended for other similar DOE facilities (ORAUT-OTIB-0002). For certain radionuclides, such as uranium, the maximum plausible intakes, based on a fraction of the MPBB, are 5,000 nCi of U-234 and 500 nCi of U-238, which are much higher than the values recommended in ORAUT-OTIB-0001 (i.e., 105.4 nCi of U-234 and 20.95 nCi of U-238).

Review Objectives 3.2.3 and 3.2.4

The document is relevant for employees who have no detectable activity in their monitoring results and for employees who were not included in the bioassay program. It does not explicitly refer to unmonitored periods of exposure and missing dosimetry data. For tritium, missing dosimetry data are addressed in ORAUT-OTIB-0003.

Review Objectives 4.1 and 4.2

The procedures described are confusing and difficult to understand and reproduce. There is no clear description of the data that were used to derive the hypothetical intakes. SC&A's review could not determine if the procedure adheres to the hierarchical process, as defined in 42 CFR 82.2. Based on Table 3-10, it appears that urine bioassay was used for assigning intakes for Pu, Am, U, Np, Cm, Sr and that in vivo methods were used for Co and Cs. There is no description of the method that was used to calculate intakes from Ce, Cf, Nb, Ru, Zn, and Zr.

Review Objectives 5.1, 5.2, and 5.3

Objectives 5.1, 5.2, and 5.3 were designed to assess whether procedure decisions are claimant favorable in instances of missing data, unknown parameters affecting dose estimates, and in which the claimant was not monitored. The procedure described in the document is not clear and does not apply the same claimant-favorable approach for all radionuclides. Specifically,

- The use of ICRP 30 models, instead of the current ICRP models, to calculate the hypothetical intakes is not claimant favorable for most radionuclides.
- The choice of the average of the five largest intakes is very subjective. Why were the five largest intakes chosen instead of the largest intake?
- The procedure recommended for the use of surrogate radionuclides is not claimant favorable.
- In addition, doses due to OBT are ignored.

Review Objectives 6.1 and 6.2

The document does not mention a statistical procedure to account for the uncertainty in dose estimates.

Review Objectives 7.1 and 7.2

The procedure does not provide the details needed to evaluate the degree to which the methods are scientifically valid and claimant favorable.

3.8.5 Technical Issues

ORAUT-OTIB-0001 provides basic information on the methods to be employed in assigning maximum internal dose estimates to SRS employees who were monitored but had no detectable activity ("positive") in their samples and to employees who were not included in the bioassay program.

SC&A's review of the document ORAUT-OTIB-0001 has identified some serious problems with the procedure used for establishing the maximum internal dose estimates, as follows:

(1) Hypothetical intakes (page 3, ORAUT-OTIB-0001): Hypothetical intakes were based on recorded intakes at SRS. There is no mention on the calculation of those intakes, upon which data they were based, and if they should be used indiscriminately for all SRS operations and facilities. In addition, there is no mention of chronic intakes, corresponding internal doses, and comparisons with the hypothetical intake doses.

(2) Use of ICRP 30 methodology to calculate hypothetical intakes (pages 3-8, ORAUT-OTIB-0001): Hypothetical intakes were calculated using ICRP 30 methodologies rather than the newer ICRP methodology prescribed for this dose reconstruction effort. The justification given by NIOSH for the use of these intakes is technically flawed; the use of ICRP 30 models do not produce intake values that are higher than the ones using the new ICRP models for the majority of the relevant nuclides cited in the document.

The following definition of the hypothetical intake is cited under ORAUT-OTIB-0001, page 3 of 14:

> *These hypothetical intakes were based on recorded internal doses at SRS and were assumed to be composed of the radionuclides contributing the majority of the recorded internal dose at the Savannah River Site, except for tritium (assignment of tritium dose is discussed at the end of this paper).*

The hypothetical intake internal dose was assigned based upon a hypothetical intake with the following characteristics:

- *All radionuclides for which internal deposition by inhalation was calculated by the Savannah River Site were reviewed, except for tritium, which is addressed separately.*
- *The amount of the inhalation intake for each radionuclide is the average (mean) of the five largest documented intakes, or the average of all intakes if there were fewer than five intakes reported for a radionuclide.*
- *An acute inhalation intake was assumed to have occurred on January 1 in the first year of employment.*

- ***ICRP 66 and 68 modeling and default parameter values were used to determine dose.*** [Emphasis added.]
- ***The material type resulting in the largest dose to the organ or tissue of interest was used. This was typically the most soluble form of the material because it would clear from the lung more rapidly than insoluble material, thus depositing in the organ or tissue sooner.*** [Emphasis added.]

The largest inhalation intakes reported by SRS are summarized in Tables 1 and 2, and include the material classes used in the SRS calculations. Several complicating factors arose in the use of the intake amounts to be applied to these cases. ***Intakes and doses at SRS were calculated using regulatory-prescribed ICRP 30 methodologies rather than the newer ICRP methodology prescribed for this dose reconstruction effort. The material classes used in the calculations were based on workplace source term information or the class that provided the best fit to the bioassay data; . . .*** [Emphasis added.]

Pages 5 to 8 provide a long explanation for using intakes calculated with ICRP 30 models instead of the new models, as prescribed in 42 CFR Part 82:

Because these values are being applied as a large overestimate of the dose likely received by the Covered Employee, ***it is not necessary to use the exact values determined by SRS but it must be shown that the values are indeed a likely overestimate.*** *To demonstrate this, the intake retention fractions (IRFs) for the radionuclides of interest from ICRP 30 and ICRP 68, for the applicable material classes/absorption types, are compared for several times following an intake. Tables 3 through 10 list the intake retention fractions for five specified times following an acute inhalation intake for the material type assumed here for dose reconstruction purposes and the material class(es) applied for the SRS-calculated intakes in Tables 1 and 2.* [Emphasis added.]

The solubility types in the comparisons were not paired by the same solubility (type F compared to class D, type M compared to class W, and type S compared to class Y). Instead, the ICRP 68 solubility types were chosen as "the most soluble form of the material because it would clear from the lung more rapidly than insoluble material, thus depositing in the organ or tissue sooner." The ICRP 30 classes, on the other hand, were chosen using "the material class(es) applied for the SRS-calculated intakes in Tables 1 and 2."

There is a fundamental problem with the comparisons of these IRFs from ICRP 30 and ICRP 68. In general, when intakes are used to calculate organ doses, the choice of the most soluble type is claimant favorable for doses calculated to systemic organs. When bioassay results are used to calculate organ doses, the assignment of the most insoluble material type often results in a higher dose for systemic organs, as illustrated by the following example:

- A 24-hour urine sample is collected five days after a single inhalation intake of Pu-238. The bioassay result is 1 becquerel (Bq) of Pu-238. Using the ICRP 67 model for Pu, the calculated intakes are:
  - For Pu-238, type S: intake of 2.2 E6 Bq (50y committed bone surface dose is 75 sieverts (Sv), 50y committed dose to colon is 0.053Sv, 1y committed dose to the colon is 0.006 Sv)
  - For Pu-238, type M: intake of 2.6 E4 Bq (50y committed bone surface dose is 24 Sv, 50y committed dose to colon is 0.042Sv, 1y committed dose to the colon is 0.002 Sv)

The use of Pu-238, type S, results in a higher intake than the use of type M Pu (and in higher doses to systemic organs):

- Using ICRP 30 IRF from Table 3, page 6, of ORAUT-OTIB-0001, the same bioassay result of 1 Bq of Pu-238 in a 24-hour urine sample, taken five days after a single intake, corresponds to intakes of:
  - For class Y: intake of 3.5 E5 Bq (ICRP30) (50y committed bone surface dose is 12 Sv, 50y committed dose to colon is 0.33Sv, 1y committed dose to the colon is 0.037 Sv)
  - For class W: intake of 1.9 E4 Bq (ICRP30) (50y committed bone surface dose is 17.5 Sv, 50y committed dose to colon is 0.03 Sv, 1y committed dose to the colon is 0.0015 Sv)

Thus, it is neither scientifically correct nor claimant favorable to compare the IRFs derived using the ICRP 68 most soluble form of material (material type) with those derived using the ICRP 30 methodology and the material classes applied for SRS calculated intakes. The relative intakes in Table 3, page 6, of ORAUT-OTIB-0001 would not have been obtained if type M were assigned to nuclides classified as class W and type S were assigned to nuclides classified as class Y. The use of ICRP 30 models for Pu-238 to calculate the intake **does not** result in an overestimate of the intake.

The tables below compare the relative intakes for all radionuclides listed in Tables 1 and 2, pages 4 and 5, of ORAUT-OTIB-0001 that are derived using ICRP 30 and ICRP 68 IRFs. Intakes were calculated assuming a constant bioassay monitoring result (e.g., unitary bioassay result) measured at different times after intake.

Table 3.8-2. Comparison of Pu Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from Urine Bioassay Data

Radionuclide: Pu-238

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	Type M ICRP68	Class W ICRP30	Intakes 30/68	IRF 30/68
Time (d) after intake	Urine IRF	Urine IRF		
1	2.30E-04	2.83E-04	8.13E-01	1.23E+00
5	3.90E-05	5.39E-05	7.24E-01	1.38E+00
10	1.50E-05	2.54E-05	5.91E-01	1.69E+00
50	8.50E-06	1.45E-05	5.86E-01	1.71E+00
100	6.80E-06	1.11E-05	6.13E-01	1.63E+00
180	5.60E-06	8.50E-06	6.59E-01	1.52E+00
200	5.10E-06	7.85E-06	6.50E-01	1.54E+00
300	4.20E-06	5.80E-06	7.24E-01	1.38E+00
360	3.85E-06	4.90E-06	7.86E-01	1.27E+00

The intakes from Pu, type M, are underestimated using ICRP 30 methodology.

Radionuclide: Pu-238, Pu-239, Pu-241

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	Type S ICRP68	Class Y ICRP30	Intakes 30/60	IRF 30/68
Time (d) after intake	Urine IRF	Urine IRF		
1	2.30E-06	1.55E-05	1.48E-01	6.74E+00
5	4.50E-07	2.87E-06	1.57E-01	6.38E+00
10	2.20E-07	1.29E-06	1.71E-01	5.86E+00
50	1.70E-07	7.56E-07	2.25E-01	4.45E+00
100	1.60E-07	6.97E-07	2.30E-01	4.36E+00
180	1.60E-07	7.25E-07	2.21E-01	4.53E+00
200	1.60E-07	7.34E-07	2.18E-01	4.59E+00
300	1.60E-07	7.75E-07	2.06E-01	4.84E+00
360	1.70E-07	7.80E-07	2.18E-01	4.59E+00

The intakes from Pu, type S, are underestimated using ICRP 30 methodology.

Table 3.8-3. Comparison of Am Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from Urine Bioassay Data

Radionuclide: Am-241
Intake: Inhalation
Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

Time (d) after intake	ICRP 68 Urine IRF	ICRP30 Urine IRF	Intakes 30/68	IRF 30/68
1	1.80E-03	6.66E-03	2.70E-01	3.70E+00
5	7.20E-05	5.24E-05	1.37E+00	7.28E-01
10	4.90E-05	4.97E-05	9.86E-01	1.01E+00
50	2.00E-05	3.48E-05	5.75E-01	1.74E+00
100	1.50E-05	2.22E-05	6.76E-01	1.48E+00
180	1.10E-05	1.25E-05	8.80E-01	1.14E+00
200	1.00E-05	9.70E-06	1.03E+00	9.70E-01
300	8.00E-06	5.47E-06	1.46E+00	6.84E-01
360	7.20E-06	4.50E-06	1.60E+00	6.25E-01

For Am, type M, ICRP 30 methodology may underestimate the intakes, depending on when samples are taken after the intake.

Radionuclide: Am-241
Intake: Inhalation
Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

Am-241 in matrix of Type S compounds of Pu Time (d) after intake	Type S ICRP 68 Urine IRF	Class Y ICRP30 Urine IRF	Intake 30/68	IRF 30/68
1	3.01E-05	3.76E-04	8.01E-02	1.25E+01
5	1.40E-06	2.21E-06	6.33E-01	1.58E+00
10	9.90E-07	1.87E-06	5.29E-01	1.89E+00
50	5.28E-07	1.91E-06	2.76E-01	3.62E+00
100	4.59E-07	1.97E-06	2.33E-01	4.29E+00
180	4.30E-07	2.04E-06	2.11E-01	4.74E+00
200	4.27E-07	2.06E-06	2.07E-01	4.82E+00
300	4.18E-07	2.13E-06	1.96E-01	5.10E+00
360	4.14E-07	2.15E-06	1.93E-01	5.19E+00

The intakes from Am, type S, are underestimated using ICRP 30 methodology.

Table 3.8-4. Comparison of U Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from Urine Bioassay Data

Radionuclide: U-234 - U-235 - U-238

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	Type F	Class D		
	ICRP68	ICRP30	Intakes 30/68	IRF 30/68
Time (d) after intake	Urine IRF	Urine IRF		
1	1.80E-01	1.87E-01	9.63E-01	1.04E+00
5	4.20E-03	1.31E-02	3.21E-01	3.12E+00
10	2.70E-03	7.26E-03	3.72E-01	2.69E+00
50	3.00E-04	6.67E-04	4.50E-01	2.22E+00
100	1.00E-04	1.11E-04	9.01E-01	1.11E+00
180	4.40E-05	4.40E-05	1.00E+00	1.00E+00
200	2.40E-05	5.15E-06	4.66E+00	2.15E-01
300	8.90E-06	1.80E-06	4.94E+00	2.02E-01
360	6.00E-06	1.70E-06	3.53E+00	2.83E-01

The intakes from U, type F, are underestimated using ICRP 30 methodology for samples taken up to 180 days after the intake. It is very unlikely that samples for type F are taken more than 180 days after exposure.

Radionuclide: U-234 - U-235 - U-238

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	Type M	Class W		
	ICRP68	ICRP30	Intakes 30/68	IRF 30/68
Time (d) after intake	Urine IRF	Urine IRF		
1	2.30E-02	4.13E-02	5.57E-01	1.80E+00
5	7.30E-04	2.69E-03	2.71E-01	3.68E+00
10	5.40E-04	1.75E-03	3.09E-01	3.24E+00
50	1.90E-04	4.80E-04	3.96E-01	2.53E+00
100	1.10E-04	2.43E-04	4.53E-01	2.21E+00
180	7.00E-05	7.00E-05	1.00E+00	1.00E+00
200	5.80E-05	7.49E-05	7.74E-01	1.29E+00
300	3.20E-05	2.33E-05	1.37E+00	7.28E-01
360	2.30E-05	1.00E-05	2.30E+00	4.35E-01

ICRP 30 underestimates U type M intakes for all reasonable times of collecting samples after an intake has occurred.

Radionuclide: U-234 - U-235 - U-238

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

Time (d) after intake	Type S ICRP68 Urine IRF	Class W ICRP30 Urine IRF	Intakes 30/68	IRF 30/68
1	7.00E-04	2.23E-03	3.14E-01	3.19E+00
5	2.20E-05	1.31E-04	1.68E-01	5.95E+00
10	1.60E-05	8.42E-05	1.90E-01	5.26E+00
50	5.70E-06	2.34E-05	2.44E-01	4.11E+00
100	4.10E-06	1.87E-05	2.19E-01	4.56E+00
180	3.45E-06	1.83E-05	1.89E-01	5.29E+00
200	3.20E-06	1.81E-05	1.77E-01	5.66E+00
300	2.80E-06	1.83E-05	1.53E-01	6.54E+00
360	2.68E-06	1.83E-05	1.47E-01	6.81E+00

The intakes from U, type S, are underestimated using ICRP 30 methodology.

Table 3.8-5. Comparison of Np Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from Urine Bioassay Data

Radionuclide: Np-237

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

Time (d) after intake	Type M ICRP68 Urine IRF	Type S ICRP30 Urine IRF	Intakes 30/68	IRF 30/68
1	6.20E-03	3.42E-03	1.81E+00	5.52E-01
5	3.40E-04	3.02E-05	1.13E+01	8.88E-02
10	1.30E-04	2.56E-05	5.08E+00	1.97E-01
50	6.20E-05	1.78E-05	3.48E+00	2.87E-01
100	4.20E-05	1.13E-05	3.72E+00	2.69E-01
180	2.75E-05	6.50E-06	4.23E+00	2.36E-01
200	2.40E-05	4.97E-06	4.83E+00	2.07E-01
300	1.60E-05	2.82E-06	5.67E+00	1.76E-01
360	1.30E-05	2.40E-06	5.42E+00	1.85E-01

The intakes from Np are underestimated using ICRP 68 methodology.

Table 3.8-6. Comparison of Cm-242 Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from Urine Bioassay Data

Radionuclide: Cm-242

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	Type M	Class W		
	ICRP 68	ICRP 30		
Time (d) after intake	Urine IRF	Urine IRF	Intakes 30/68	IRF 30/68
1	1.80E-03	6.63E-03	2.71E-01	3.68E+00
5	7.00E-05	5.13E-05	1.36E+00	7.33E-01
10	4.70E-05	4.77E-05	9.85E-01	1.01E+00
50	1.60E-05	2.81E-05	5.69E-01	1.76E+00
100	9.80E-06	1.45E-05	6.76E-01	1.48E+00
180	6.24E-06	7.20E-06	8.67E-01	1.15E+00
200	4.40E-06	4.15E-06	1.06E+00	9.43E-01
300	2.20E-06	1.53E-06	1.44E+00	6.95E-01
360	1.50E-06	1.53E-06	9.80E-01	1.02E+00

For Cm-242, type M, ICRP 30 methodology may underestimate the intakes, depending on when samples are taken after the intake.

Table 3.8-7. Comparison of Cm-244 Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from Urine Bioassay Data

Radionuclide: Cm-244

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	TYPE M	Class W		
	ICRP68	ICRP30	Intakes 30/68	IRF 30/68
Time (d) after intake	Urine IRF	Urine IRF		
1	1.77E-03	6.63E-03	2.67E-01	3.75E+00
5	7.17E-05	5.24E-05	1.37E+00	7.30E-01
10	4.85E-05	4.97E-05	9.75E-01	1.03E+00
50	2.02E-05	3.46E-05	5.84E-01	1.71E+00
100	1.48E-05	2.20E-05	6.74E-01	1.48E+00
180	1.08E-05	1.52E-05	7.11E-01	1.41E+00
360	6.80E-06	7.07E-06	9.62E-01	1.04E+00

For Cm-244, type M, ICRP 30 methodology underestimates the intakes most of the time.

Table 3.8-8. Comparison of Sr-90 Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from Urine Bioassay Data

Radionuclide: Sr-90
Intake: Inhalation
Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	Type F	Class D		
	ICRP68	ICRP30	Intakes 30/68	IRF 30/68
Time (d) after intake	Urine IRF	Urine IRF		
1	6.80E-02	8.57E-02	7.93E-01	1.26E+00
5	9.20E-03	2.45E-02	3.76E-01	2.66E+00
10	4.10E-03	1.04E-02	3.94E-01	2.54E+00
50	3.30E-04	1.94E-04	1.70E+00	5.88E-01
100	9.80E-05	1.26E-04	7.78E-01	1.29E+00
180	6.40E-05	8.40E-05	7.62E-01	1.31E+00
200	5.00E-05	7.42E-05	6.74E-01	1.48E+00
300	2.90E-05	5.04E-05	5.75E-01	1.74E+00
360	2.20E-05	4.02E-05	5.47E-01	1.83E+00
400	1.80E-05	3.71E-05	4.85E-01	2.06E+00

For Sr-90, type F, ICRP 30 methodology underestimates the intakes for most of the times that samples are taken.

Radionuclide: Sr-90
Intake: Inhalation
Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	Type S	Class W		
	ICRP68	ICRP30	Intakes 30/68	IRF 30/68
Time (d) after intake	Urine IRF	Urine IRF		
1	8.10E-04	1.34E-03	6.04E-01	1.65E+00
5	1.30E-04	4.22E-04	3.08E-01	3.25E+00
10	6.10E-05	1.87E-04	3.26E-01	3.07E+00
50	8.70E-06	1.62E-05	5.37E-01	1.86E+00
100	4.40E-06	1.55E-05	2.84E-01	3.52E+00
180	3.40E-06	1.51E-05	2.25E-01	4.44E+00
200	3.00E-06	1.50E-05	2.00E-01	5.00E+00
300	2.40E-06	1.48E-05	1.62E-01	6.17E+00
360	2.20E-06	4.65E-06	4.73E-01	2.11E+00

For Sr-90, type S, ICRP 30 methodology underestimates the intakes.

Table 3.8-9. Comparison of Co-60 Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from In Vivo Bioassay Data (Whole Body Counting)

Radionuclide: Co-60
Intake: Inhalation
Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	Type M	Class W		
	ICRP68	ICRP30	Intakes 30/68	IRF 30/68
Time (d) after intake	WB IRF	WB IRF		
1	4.90E-01	5.66E-01	8.66E-01	1.16E+00
5	9.10E-02	2.06E-01	4.42E-01	2.26E+00
10	7.20E-02	1.63E-01	4.42E-01	2.26E+00
50	4.40E-02	9.78E-02	4.50E-01	2.22E+00
100	3.10E-02	5.77E-02	5.37E-01	1.86E+00
180	2.30E-02	3.46E-02	6.65E-01	1.50E+00
200	1.90E-02	2.44E-02	7.79E-01	1.28E+00
300	1.30E-02	1.40E-02	9.29E-01	1.08E+00
360	1.06E-02	1.15E-02	9.22E-01	1.08E+00

For Co-60, type M, ICRP 30 methodology underestimates the intakes.

Table 3.8-10. Comparison of Cs-137 Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from In Vivo Bioassay Data (Whole Body Counting)

Radionuclide: Cs-137
Intake: Inhalation
Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	Type F	Type D		
	ICRP68	ICRP30	Intakes 30/68	IRF 30/68
Time after intake (d)	Tot. Body	Tot. Body		
1	6.00E-01	6.22E-01	9.65E-01	1.04E+00
5	4.30E-01	5.72E-01	7.52E-01	1.33E+00
10	4.10E-01	5.43E-01	7.55E-01	1.32E+00
50	3.20E-01	4.19E-01	7.64E-01	1.31E+00
100	2.30E-01	3.05E-01	7.54E-01	1.33E+00
200	1.20E-01	1.61E-01	7.45E-01	1.34E+00
300	6.40E-02	8.55E-02	7.49E-01	1.34E+00

The intakes from Cs-137 are underestimated using ICRP 30 methodology.

Table 3.8-11. Comparison of Ce-144 Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from In Vivo Bioassay Data (Whole Body Counting)

Radionuclide: Ce-144

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

Time (d) after intake	Type M ICRP68 WB IRF	Class W ICRP30 WB IRF	Intakes 30/68	IRF 30/68
1	4.96E-01	5.96E-01	8.32E-01	1.20E+00
5	9.30E-02	2.44E-01	3.81E-01	2.62E+00
10	7.97E-02	2.06E-01	3.87E-01	2.58E+00
50	6.19E-02	1.52E-01	4.07E-01	2.46E+00
100	5.08E-02	1.13E-01	4.50E-01	2.22E+00
200	3.78E-02	7.58E-02	4.99E-01	2.01E+00
300	2.87E-02	5.60E-02	5.13E-01	1.95E+00
400	2.20E-02	4.26E-02	5.16E-01	1.94E+00

The intakes from Ce-144 are underestimated using ICRP 30 methodology.

Table 3.8-12. Comparison of Cf-252 Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated From Urine Data

Radionuclide: Cf-252

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

Time (d) after intake	Type M ICRP68 Urine IRF	Class W ICRP30 Urine IRF	Intakes 30/68	IRF 30/68
1	1.30E-03	3.20E-03	4.06E-01	2.46E+00
5	1.42E-05	2.68E-05	5.30E-01	1.89E+00
10	1.32E-05	2.54E-05	5.20E-01	1.92E+00
50	8.43E-06	1.76E-05	4.79E-01	2.09E+00
100	5.75E-06	1.12E-05	5.13E-01	1.95E+00
180	3.72E-06	5.87E-06	6.34E-01	1.58E+00
360	1.86E-06	2.55E-06	7.29E-01	1.37E+00

The intakes from Cf-252, type M, are underestimated using ICRP 30 methodology.

Table 3.8-13. Comparison of Nb-95 Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from In Vivo Data (Whole Body Counting)

Radionuclide: Nb-95

Intake: Inhalation

Aerosol size: 5.0 micron AMAD(68) and 1.0 micron AMAD (30)

Time (d) after intake	Type M ICRP68 WB IRF	Class W ICRP 30 WB IRF	Intakes 30/68	IRF 30/68
1	4.90E-01	5.82E-01	8.42E-01	1.19E+00
5	8.30E-02	2.11E-01	3.93E-01	2.54E+00
10	6.10E-02	1.54E-01	3.96E-01	2.52E+00
50	1.90E-02	4.60E-02	4.13E-01	2.42E+00
100	5.50E-03	1.17E-02	4.70E-01	2.13E+00
200	5.20E-04	8.79E-04	5.92E-01	1.69E+00
300	5.10E-05	7.66E-05	6.66E-01	1.50E+00
400	5.10E-06	7.17E-06	7.11E-01	1.41E+00

The intakes from Nb-95, type M, are underestimated using ICRP 30 methodology.

Table 3.8-14. Comparison of Ru-106 Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from In Vivo Data (Whole Body Counting)

Radionuclide: Ru-106

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD(30)

Time (d) after intake	Type F ICRP68 WB IRF	Class D ICRP30 WB IRF	Intakes 30/68	IRF 30/68
1	5.10E-01	5.35E-01	9.53E-01	1.05E+00
5	2.10E-01	3.47E-01	6.05E-01	1.65E+00
10	1.70E-01	2.88E-01	5.91E-01	1.69E+00
50	8.30E-02	1.39E-01	5.97E-01	1.67E+00
100	5.50E-02	9.36E-02	5.87E-01	1.70E+00
180	4.00E-02	2.90E-02	1.38E+00	7.24E-01
200	3.60E-02	6.13E-02	5.87E-01	1.70E+00
300	2.70E-02	4.65E-02	5.80E-01	1.72E+00
360	2.30E-02	3.98E-02	5.78E-01	1.73E+00

The intakes from Ru-106, type F, are underestimated most of the time using ICRP 30 methodology.

Radionuclide: Ru-106

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

Time (d) after intake	Type M ICRP68 WB IRF	Class W ICRP30 WB IRF	Intakes 30/68	IRF 30/68
1	4.90E-01	5.84E-01	8.39E-01	1.19E+00
5	9.90E-02	2.36E-01	4.20E-01	2.38E+00
10	8.00E-02	1.91E-01	4.20E-01	2.38E+00
50	4.70E-02	1.09E-01	4.32E-01	2.31E+00
100	3.10E-02	6.31E-02	4.91E-01	2.04E+00
180	2.10E-02	1.52E-02	1.38E+00	7.24E-01
200	1.70E-02	2.75E-02	6.18E-01	1.62E+00
300	1.10E-02	1.64E-02	6.70E-01	1.49E+00
360	9.00E-03	1.31E-02	6.87E-01	1.46E+00

The intakes from Ru-106, type M, are underestimated using ICRP 30 methodology most of the time.

Radionuclide: Ru-106

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

Time (d) after intake	Type S ICRP68 WB IRF	Class Y ICRP30 WB IRF	Intakes 30/68	IRF 30/68
1	4.90E-01	5.85E-01	8.38E-01	1.19E+00
5	8.60E-02	1.98E-01	4.34E-01	2.30E+00
10	7.10E-02	1.63E-01	4.36E-01	2.30E+00
50	4.70E-02	1.39E-01	3.38E-01	2.96E+00
100	3.50E-02	1.19E-01	2.95E-01	3.39E+00
180	2.75E-02	8.69E-02	3.17E-01	3.16E+00
200	2.50E-02	8.93E-02	2.80E-01	3.57E+00
300	1.80E-02	6.83E-02	2.63E-01	3.80E+00
360	1.55E-02	5.76E-02	2.69E-01	3.72E+00

The intakes from Ru-106, type S, are underestimated using ICRP 30 methodology.

Table 3.8-15. Comparison of Zn-65 Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from In Vivo Data (Whole Body Counting)

Radionuclide: Zn-65

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	Type S	Class Y		
	ICRP68	ICRP30	Intakes 30/68	IRF 30/68
Time (d) after intake	WB IRF	WB IRF		
1	5.39E-01	6.05E-01	8.91E-01	1.12E+00
5	2.68E-01	3.96E-01	6.77E-01	1.48E+00
10	2.48E-01	3.66E-01	6.78E-01	1.48E+00
50	1.80E-01	2.85E-01	6.32E-01	1.58E+00
100	1.37E-01	2.27E-01	6.04E-01	1.66E+00
200	8.75E-02	1.50E-01	5.83E-01	1.71E+00
300	5.67E-02	1.00E-01	5.67E-01	1.76E+00
400	3.69E-02	6.72E-02	5.49E-01	1.82E+00

The intakes from Zn-65, type S, are underestimated using ICRP 30 methodology.

Table 3.8-16. Comparison of Zr-95 Relative Intakes (ICRP 30/ICRP 68), Assuming Intakes Were Calculated from In Vivo Data (Whole Body Counting)

Radionuclide: Zr-95

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	Type F	Class D		
	ICRP 68	ICRP 30	Intakes 30/68	IRF 30/68
Time (d) after intake	WB IRF	WB IRF		
1	5.40E-01	5.80E-01	9.31E-01	1.07E+00
5	2.30E-01	3.76E-01	6.12E-01	1.64E+00
10	1.80E-01	3.08E-01	5.85E-01	1.71E+00
50	8.20E-02	1.40E-01	5.85E-01	1.71E+00
100	4.70E-02	8.06E-02	5.83E-01	1.71E+00
180	2.10E-02	3.36E-02	6.25E-01	1.60E+00
200	1.60E-02	2.71E-02	5.91E-01	1.69E+00
300	5.40E-03	9.09E-03	5.94E-01	1.68E+00
400	1.80E-03	3.05E-03	5.90E-01	1.70E+00

The intakes from Zr-95, type F, are underestimated using ICRP 30 methodology.

Radionuclide: Zr-95

Intake: Inhalation

Aerosol size: 5.0 micron AMAD (68) and 1.0 micron AMAD (30)

	Type M ICRP68	Class W ICRP30	Intakes 30/68	IRF 30/68
Time (d) after intake	WB IRF	WB IRF		
1	4.90E-01	0.594	8.25E-01	1.21E+00
5	8.50E-02	2.03E-01	4.19E-01	2.38E+00
10	6.60E-02	1.69E-01	3.91E-01	2.56E+00
50	3.00E-02	7.51E-02	4.00E-01	2.50E+00
100	1.50E-02	3.24E-02	4.63E-01	2.16E+00
200	4.30E-03	7.97E-03	5.40E-01	1.85E+00
300	1.30E-03	2.41E-03	5.39E-01	1.86E+00
400	4.30E-04	7.85E-04	5.48E-01	1.83E+00

The intakes from Zr-95, type M, are underestimated using ICRP 30 methodology.

The ICRP 30 intake retention functions were taken from NUREG/CR-4884, except for Cf-252, which is not listed in the document. ICRP 68 intake retention functions were calculated using the software AIDE, and the intake retention function for Cf was calculated using ICRP 30 methodology.

From these tables, it is possible to conclude that intakes calculated using ICRP 30 methodologies were not a "likely overestimate," as written in page 5 of the document. Pu and Am are not "significantly overestimated," as stated in page 8 of the document. In fact, using the ICRP 30 methodology instead of the ICRP 68 biokinetic model underestimates the intakes from Zr-95, type M and type F; Zn-65, type S; Ru-106, type S; Nb-95, type M; Cf-252, type M; Ce-144; Cs-137; Co-60, type M; Sr-90, type S; U, type S; U, types F and M, for all reasonable times of collecting samples after an intake occurred; Pu, types M and S; and Am, type S. For Ru-106, types M and F, ICRP 30 methods underestimate the intake for most sampling times following intake. For Am, type M, ICRP 30 methodology may underestimate the intakes, depending on when samples are taken after intake.

Since the intakes listed in Tables 1 and 2 do not give additional information on the calculation of the largest intakes assigned at SRS, and since the ratio from ICRP 30 calculated intakes to the ones calculated using ICRP 68 methodology depends on the time samples were taken, the use of this document as a reference for dose reconstruction must be considered inappropriate, at least until intakes are recalculated using the recommended ICRP methodologies recommended in 42 CFR Part 82.

(3) Use of surrogate nuclides (pages 9 and 10, ORAUT-OTIB-0001): The calculation of annual organ doses from hypothetical intakes for Table 2 nuclides are not clear. The use

of surrogate radionuclide intake is not well explained, including the use of type F nuclides as a surrogate for types M and S.

The methods used to calculate organ doses described on pages 9 and 10 are not explained and are not claimant favorable. For example:

- For the intakes described in Table 12, the 50y committed equivalent dose to the adrenals due to the sum of Sr-90, type F; Ru-106, type M; Ce-144, type M; and Nb-95, type M is 7.07E-5 Sv.
- For the intakes described in Table 12, the 50y committed equivalent dose to the adrenals due to the sum of Sr-90, type F; Ru-106, type F; Ce-144, type M; and Nb-95, type M is 1.41E-4 Sv.
- Using the procedure described in the TIB, the 50y committed equivalent dose to the adrenals due to all four nuclides is 3.19E-5 Sv.

Thus, the example dose to the adrenals, using the correct ICRP dosimetric and biokinetic models for each nuclide, is higher than the dose using the procedure described in the document.

(4) Assignment of tritium dose (pages 10 and 11, ORAUT-OTIB-0001): Doses due to OBT are not included in the procedures for calculating tritium doses: "Organically bound tritium (OBT) historically has been ignored for occupational dose assessment . . ."

The effective dose per Bq intake of OBT is more than twice the effective dose per Bq intake of HTO. The urinary excretion rate is almost the same after the second day of exposure. One day after exposure, the activity concentration in urinary excretion for OBT is 57% of the HTO activity concentration in urine. As a consequence, for the same amount excreted in urine, the intake of OBT would be 77% higher in the first day than the one for HTO. Thus, the effective dose calculated for each Bq excreted in urine is four times higher because it is due to OBT instead of HTO. The procedure should provide methods for deriving doses for OBT and the types of operations where OBT may be an issue.

3.9 ORAUT-OTIB-0003 — SAVANNAH RIVER SITE TRITIUM DOSE ASSIGNMENT

The review of ORAUT-OTIB-0003, S*avannah River Site Tritium Dose Assignment*, Rev. 00, dated October 3, 2003, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

3.9.1 Purpose of Procedure

The stated purpose of this TIB is to provide "guidance on the assignment of tritium or H-3 dose for dose reconstructions at the Savannah River Site (SRS), and is based on information provided

in the Technical Basis Document for the Savannah River Site to be used for EEOICPA Dose Reconstructions, ORAUT-TKBS-0003 Rev. 01."

3.9.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0003 is summarized in Table 3.9-1 below. Table 3.9-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

3.9.3 General Comments

As stated in Section 3.0 of the TIB, "Flowcharts that provide the logic for the assignment of tritium dose are presented in Figures 1 and 2. These apply to dose reconstructions at the SRS for the periods of 1953 through 1983, and 1984 to the present, respectively. Decision criteria are provided to identify when it is appropriate to: use tritium doses as recorded in individual case records; assign tritium doses based on the potential missed dose (NIOSH 2002); or to evaluate the dose using recorded tritium bioassay results and internal dosimetry models."

Table 3.9-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0003	**Effective Date:** 10/03/2003
Document Title: Savannah River Site Tritium Dose Assignment	
Auditor: Joyce Lipsztein	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	2	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	It references other related NIOSH and ORAUT document, but this is not a problem.
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	5	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	5	
3.2.3	Missing dosimetry data	5	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	5	For HTO
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	5	For HTO
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	5	For HTO
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.9.4 Review Comments

Review Objectives 1.1 to 1.5

Objectives 1.1 to 1.5 were designed to determine if the procedure is written in a style that is clear and unambiguous. SC&A's review has identified that the flowcharts are not self- explanatory. This document describes an approach to assign the missed dose for H-3. ORAUT-OTIB-0001 describes another approach. It is difficult to distinguish the cases for which the dose reconstructor should use ORAUT-OTIB-0003 or ORAUT-OTIB-0001.

Review Objectives 5.1, 5.2, and 5.3

Objectives 5.1, 5.2, and 5.3 were designed to assess whether procedure decisions are claimant favorable in instances of missing data, unknown parameters affecting dose estimates, and in which the claimant was not monitored. Doses due to OBT are not included in the procedures for calculating tritium doses.

3.9.5 Technical Issues

The document assumes that workers were only exposed to HTO compounds. It does not mention exposures to OBT or metal tritides. The effective dose per Bq intake of OBT is more than twice the effective dose per Bq intake of HTO. The urinary excretion rate is almost the same after the second day of exposure. One day after exposure, the activity concentration in urinary excretion for OBT is 57% of the HTO activity concentration in urine. As a consequence, for the same amount excreted in urine, the intake of OBT would be 77% higher than the one for HTO ion the first day. Thus, the effective dose calculated for each Bq excreted in urine is four times higher since it is due to OBT instead of HTO.

3.10 ORAUT-OTIB-0004 — TECHNICAL BASIS FOR ESTIMATING THE MAXIMUM PLAUSIBLE DOSE TO WORKERS AT ATOMIC WEAPONS EMPLOYER FACILITIES

The review of ORAUT-OTIB-0004, *Technical Basis for Estimating the Maximum Plausible Dose to Workers at Atomic Weapons Employer Facilities,* Rev. 02, dated December 4, 2003, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

3.10.1 Purpose of Procedure

The purpose of this document is to provide guidance for estimating the maximum plausible dose to workers at AWEs. There were approximately 109 AWE facilities that handled only natural uranium in support of the atomic weapons program. The processes employed at these facilities included reduction, recasting, rolling, machining, and extruding of uranium; fuel element fabrication; scrap recovery; and recovery of uranium from phosphoric acid.

This document describes an efficient process that may be used to expedite the processing of claims requiring dose reconstruction under EEOICPA. The exposure matrix in this document is designed for estimating the maximum plausible annual dose in **all organs** with the **exception of the lung, skin, breast, eye, and testes, except when the testes dose is used as an analog for the prostate**.

3.10.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0004 is summarized in Table 3.10-1 below. Table 3.10-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

3.10.3 General Comments

As noted above, this procedure **excludes** the lung and several surficial tissues from consideration. Its chief purpose is to expedite the processing of AWE claims that may involve various metabolic cancers with POCs that are unlikely to be compensable even under assumptions of high uranium intakes and conservative biokinetic mode parameters.

Demonstration of noncompensability under worst-case (or highly conservative) assumptions is efficient, since it reduces the effort that would normally be required for a more realistic dose reconstruction. This approach to efficiency is also encouraged under 42 CFR 82.10(k)(2).

Table 3.10-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0004	**Effective Date:** 12/04/2003
Document Title: Technical Basis for Estimating the Maximum Plausible Dose to Workers at Atomic Weapons Employer Facilities	
Reviewer: Joyce Lipzstein	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	3	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	2	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	2	See Review Comments
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	2	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	2	See Review Comments
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal/lognormal)?	5	Constant Distribution
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	5	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	2	See Review Comments

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

3.10.4 Review Comments

Review Objectives 1.1 to 1.5

Objectives 1.1 to 1.5 were designed to determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.

SC&A's review has identified that, in several sections, the writing style is not clear. For example, the procedure is not explicit on how to add ingestion and inhalation doses.
The procedure is not complete in terms of required data. The adopted assumptions for maximum levels of exposure were derived based on data not provided in the document.

The procedure is not consistent with all others that are part of the hierarchy employed by NIOSH for dose reconstruction. It is not consistent with the procedures used in ORAUT-OTIB-0001, ORAUT-OTIB-0002, and ORAUT-OTIB-0005.

Review Objective 1.4

Table 5 of this TIB identifies annual organ doses due to the assumed annual diagnostic chest x-ray. These derived doses are high and inconsistent. Thus, for example, the lung and liver doses/examination are given as 133 mrem and 101 mrem, respectively, which is not consistent with data contained in ORAUT-OTIB-0006.

A minor inconsistency also exists with respect to statements contained in OCAS-PER-002, *Error in surrogate organ assignment resulting in an underestimate of x-ray dose in SRS dose reconstruction*. As previously noted in SC&A's review, Section 1.0 of OCAS-PER-002 states, "For organs not directly listed in ICRP 34, surrogate organs based on anatomical location are assigned for calculation of doses from collimated x-ray examinations. . . . the choice of surrogate organ for the **liver**, gall bladder, and spleen. . . . is the lung." [Emphasis added.]

For purpose of consistency with OCAS-PER-002, this TIB should have identified a maximum liver dose that was equal to the lung dose. It should be noted that SC&A fully recognizes the small difference in dose and its unlikely impact on POC values.

Review Objectives 5.1, 5.2, and 5.3

Objectives 5.1, 5.2, and 5.3 were designed to assess whether procedure decisions are claimant favorable in instances of missing data, unknown parameters affecting dose estimates, and in which the claimant was not monitored.

The adopted assumptions for maximum levels of exposure were derived based on data not provided in the document. Thus, it is not possible to judge if the exposure data is claimant favorable.

The procedure is not claimant favorable in instances of unknown parameters affecting dose estimates. The breathing rate used to evaluate the intake is not claimant favorable.

The procedure may be not claimant favorable in instances where the claimant was not monitored. The adopted assumptions for maximum levels of exposure were derived based on data not provided in the document. Thus, it is not possible to judge if the exposure data is claimant favorable.

Review Objective 5.2

For estimating exposure to residual contamination, ORAUT-OTIB-0004 assumes that normal/operational removal mechanisms reduce residual contamination at 1% per day. This value was not based on empirical study data and appears to be nonconservative/unrealistic. Studies pertaining to postoperational residual contamination at commercial nuclear power plant facilities could be used as surrogate data for a more defensible value.

Review Objective 7.2

It is difficult to judge the significance of the procedure with respect to the final dose estimate and its POC due to an inadequate description of the bases for the guidelines.

The adopted assumptions for maximum levels of exposure were derived from data not provided in the document. The rate and amount of air breathed through the nose versus the mouth should be better estimated. These details should be evaluated based on the workers' level of effort, according to the job and workplace temperature and humidity for each installation.

3.10.5 Technical Issues

(1) Page 2 of 13, Section 1.0: The document states the following:

> *The purpose of this document is to provide guidance for estimating the maximum plausible dose to workers at Atomic Weapons Employers (AWEs). The exposure matrix in this document is designed for estimating the maximum plausible annual dose in all organs with the exception of lung, skin, breast, eye, and testes except when the testes dose is used as an analog for the prostate. Because the current ICRP model does not calculate a dose to the prostate, the dose to the testes is reconstructed and used to determine the probability of causation for prostate cancer. This is considered a claimant-favorable approach.*

The use of the testes as an analog for the prostate is only recommended for external exposure in ORAUT-OTIB-0005.

(2) Page 3 of 13, Section 2.0: The choice of 100 as the maximum allowable concentration (MAC) is arbitrary. Of the facilities cited to justify the choice of 100 MAC, the Vulcan

Crucible (Aliquippa Forge) is the only AWE facility listed in the appendix and referenced in the text (second paragraph).

> *…surveys by the NYOO indicated that out of 648 exposed workers at these plants, 9% were exposed to uranium air concentrations greater than 125MAC (> 6250 μg/m3), 9% were exposed at 25-125 MAC (1250-6250 μg/m3), and 82% were exposed to less than 25 MAC (< 1250 μg/m3). . . .*
>
> *Vulcan Crucible (Aliquippa Forge) was a steel mill that contracted with the AEC to roll uranium billets into rods on a part-time basis from 1948 to 1949. The contract (AEC Contract No. AT-(30-1)-407) stated that the plant was to arrange to spend 'at least two consecutive weeks out of every five consecutive weeks' performing the AEC contract work. Four of the most exposed workers in the 1949 study were from this plant.*

Thus, without other information, such as the level of exposure at Vulcan Crucible (Aliquippa Forge), the choice of 100 MAC cannot necessarily be considered claimant favorable.

(3) Page 4 of 13, item 2.0: The choice of 1.2 m^3/h may not be justified. This breathing rate is characteristic of the ICRP-classified "light worker" (time budget distributed between 5.5h light exercise and 2.5h sitting). The rate and amount of air breathed through the nose versus the mouth should be better estimated. These details should be evaluated for the workers' level of effort, according to the job and workplace temperature and humidity for each installation.

(4) Page 5 of 13: The ingestion section should be updated according to OCAS-TIB-009, *Estimation of Ingestion Intakes*.

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4.0 INTERACTIVE RADIOEPIDEMIOLOGICAL PROGRAM (IREP) REQUIREMENTS/ISSUES

4.1 OCAS-TIB-001 — IREP ISSUES

The review of OCAS-TIB-001, *IREP Issues*, Rev. 0, dated March 4, 2003, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

4.1.1 Purpose of Procedure

The stated purpose of this Technical Information Bulletin (TIB) is to provide "clarification for three issues related to using the Interactive Radioepidemiological Program (IREP)."

4.1.2 Review Protocol

Our evaluation of OCAS-TIB-001, *IREP Issues,* is summarized in Table 4.1-1 below. Table 4.1-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

4.1.3 General Comments

In this document, three individual issues are discussed:

- Choice of "Exposure Type" for radon
- Leukemia and thyroid latency
- Correct use of the" Should alternate cancer be run" field.

Table 4.1-1. Procedure Review Outline/Checklist

Document No.: OCAS-TIB-001	**Effective Date:** 03/04/2003
Document Title: IREP Issues	
Reviewer: Joyce Lipsztein	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	5	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	5	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations:**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant:**		
5.1	Is the procedure claimant-favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant-favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant-favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

4.1.4 Review Comments

OCAS-TIB-001 is straightforward and relates to giving specific instructions in the use of IREP. SC&A has no significant review comments in behalf of this document.

4.2 OCAS-TIB-003 — INTERACTIVE RADIOEPIDEMIOLOGICAL PROGRAM REQUIREMENTS FOR MULTIPLE CANCERS

The review of OCAS-TIB-003, *Interactive Radioepidemiological Program Requirements For Multiple Cancers*, Rev. 0, dated April 30, 2003, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

4.2.1 Purpose of Procedure

The stated purpose of this TIB is to provide ". . . a summary of issues associated with multiple primary cancers, and cases in which no primary cancer is provided, including updated dose reconstruction (DR) requirements for various claim scenarios."

4.2.2 Review Protocol

Our evaluation of OCAS-TIB-003, *Interactive Radioepidemiological Program Requirements For Multiple Cancers,* is summarized in Table 4.2-1 below. Table 4.2-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

Table 4.2-1. Procedure Review Outline/Checklist

Document No.: OCAS-TIB-003	**Effective Date:** 04/30/2003
Document Title: IREP Requirements for Multiple Cancers	
Auditor: Joyce Lipsztein	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	5	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	5	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations:**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	5	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant:**		
5.1	Is the procedure claimant-favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant-favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant-favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

4.2.3 Review Comments

OCAS-TIB-003 is straightforward and relates to giving specific instructions in the use of IREP for cases involving multiple primary cancers. SC&A has no significant review comments in behalf of this document.

4.3 OCAS-TIB-005 — DOSE RECONSTRUCTION CANCER DATA REQUIREMENTS

The review of OCAS-TIB-005, *Dose Reconstruction Cancer Data Requirements*, Rev. 0, dated September 5, 2003, was prepared by Joyce Lipsztein, PhD, and U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on January 11, 2005.

4.3.1 Purpose of Procedure

The purpose of this TIB is to define ". . . the NIOSH OCAS Claims Tracking System (NOCTS) requirements and organizational business rules governing the cancer data required to perform dose reconstructions and conduct IREP runs at OCAS and ORAU. Cancer data requirements will ultimately apply to data management (i.e., entered and quality assured) in NOCTS, as well as general data requirements necessary to perform dose reconstructions and run IREP."

4.3.2 Review Protocol

Our evaluation of OCAS-TIB-005, *Dose Reconstruction Cancer Data Requirements*, is summarized in Table 4.3-1 below. Table 4.3-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

4.3.3 General Comments

In this document, information is given on Acceptable Dose Reconstruction Case Scenarios, Unacceptable Dose Reconstruction Case Scenarios, NOCTS Cancer Data System Requirements, and Dose Reconstruction Cancer Data Requirements. These cancer data requirements are identified in Sections 2 and 3 of the TIB. However, DOE has lead responsibility to identify and code cancers, which are only then forwarded to OCAS for dose reconstruction. Responsibilities assigned to OCAS (and possibly ORAU and its contractors) by this TIB are limited to notifying the DOE in instances of an obvious error that requires resolution by the DOL, as stated in Section 1.1 of the TIB:

> *Note: DOE has lead responsibility to identify and code cancers for purposes of adjudicating claims. Because of this, cancer data provided by DOE should not be reinterpreted by reviewing documents provided by DOL to OCAS upon receipt of the claim or claim supplement. Example documents include pathology reports or EE medical records. If an obvious error is detected (e.g., a cancer listed as secondary with a primary cancer code), these questions are to be forwarded to the appropriate OCAS PHA for DOL inquire and resolution.*

Because this TIB does not directly affect the dose reconstruction process, it has only limited relevance to SC&A's procedure review objectives.

Table 4.3-1. Procedure Review Outline/Checklist

Document No.: OCAS-TIB-005, Rev. 0	**Effective Date:** 09/05/2003
Document Title: Dose Reconstruction Cancer Data Requirements	
Reviewer: Joyce Lipsztein/U. Hans Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	5	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	NA	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	NA	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	NA	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	NA	
3.1.3	Does the interview process demonstrate objectivity and is it free of bias?	NA	
3.1.4	Is the interview process sensitive to the claimant?	NA	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). NA indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.1.5	Does the interview process protect information as required under the Privacy Act?	NA	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	NA	
3.2.2	In vivo/In vitro bioassays	NA	
3.2.3	Missing dosimetry data	NA	
3.2.4	Unmonitored periods of exposure	NA	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations:**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	NA	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	NA	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant:**		
5.1	Is the procedure claimant-favorable in instances of missing data?	NA	
5.2	Is the procedure claimant-favorable in instances of unknown parameters affecting dose estimates?	NA	
5.3	Is the procedure claimant-favorable in instances where claimant was not monitored?	NA	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal/lognormal)?	NA	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	NA	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	NA	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	NA	

4.3.4 Review Comments

None.

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). NA indicates not applicable.

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5.0 TELEPHONE INTERVIEWS

5.1 ORAUT-PROC-0004 — SCHEDULING TELEPHONE INTERVIEWS, ORAUT-PROC-0005 — PERFORMING TELEPHONE INTERVIEWS, AND ORAUT-PROC-0017 — REVIEWING TELEPHONE INTERVIEWS

The review of the following interview procedures and associated documents was prepared by Arjun Makhijani, PhD, and Kathryn Robertson-DeMers, CHP, and approved by John Mauro, PhD, CHP, on January 11, 2005: (1) ORAUT-PROC-0004, *Scheduling Telephone Interviews,* Rev. 00, November 5, 2003, (2) ORAU-PROC-0005, *Performing Telephone Interviews*, Rev. 00, November 6, 2003, (3) ORAUT-PROC-0017, *Reviewing Telephone Interviews*, Rev. 00, November 6, 2003, and (4) OMB-0920-0530, *CATI Interview Forms*, (Version 1 — employee version, and Version 2 — family member version), May 31, 2004.

5.1.1 Background Information: Interview Objectives

Title 42, Section 82.10(c), of the *Code of Federal Regulations* (42 CFR 82.10(c)) states the following requirements and objectives for the claimant interview process:

> *NIOSH will interview the claimant. The interview may be conducted in one or more sessions. The purpose of the interview is to:*
>
> *(1) Explain the dose reconstruction process;*
> *(2) Confirm elements of the employment history transmitted to NIOSH by DOL;*
> *(3) Identify any relevant information on employment history that may have been omitted;*
> *(4) Confirm or supplement monitoring information included in the initial radiation exposure record;*
> *(5) Develop detailed information on work tasks, production processes, radiologic protection and monitoring practices, and incidents that may have resulted in undocumented radiation exposures, as necessary;*
> *(6) Identify co-workers and other witnesses with information relevant to the radiation exposure of the covered worker to supplement or confirm information on work experiences, as necessary.*

The interview process allows claimants the opportunity to provide the National Institute for Occupational Safety and Health (NIOSH) with additional information relating to individual job responsibilities, the potential for exposure to various radionuclides and materials, the frequency of dosimeter changes, the methods and frequency of various types of bioassay monitoring of internal burdens of radionuclides, the type of workplace monitoring, such as air sampling, survey and area access controls, and involvement in incidents or unusual events. By design, the interview process is, therefore, an integral part of the dose reconstruction process.

To ensure completeness of the dose reconstruction process, NIOSH must also conduct a closing interview after a draft dose reconstruction has been reviewed by the claimant. The closing interview (which may be in one or more sessions) provides the claimant an opportunity to ask questions about the dose reconstruction and a final opportunity to provide additional information that may be pertinent to the claim. Key elements of the closing interview are specified in 42 CFR 82.10(l) and (m):

> *(l) After providing the claimant with a copy of a draft of the dose reconstruction report to be provided to DOL, NIOSH will conduct a closing interview with the claimant to review the dose reconstruction results and the basis upon which the results were calculated. This will be the final opportunity during the dose reconstruction process for the claimant to provide additional relevant information that may affect the dose reconstruction. The closing interview may require multiple sessions, if the claimant requires time to obtain and provide additional information, and to allow NIOSH time to integrate the new information into a new draft of the dose reconstruction report. NIOSH will determine whether to grant requests for time to provide additional information, based on whether the requests are reasonable and the claimant is actively seeking the information specified.*
>
> *(m) Subject to any additional information provided by the claimant and revision of the draft dose reconstruction report under § 82.10(l), the claimant is required to return form OCAS-1 to NIOSH, certifying that the claimant has completed providing information and that the record for dose reconstruction should be closed. Upon receipt of the form, NIOSH will forward a final dose reconstruction report to DOL, DOE, and to the claimant.*

5.1.2 Content and Organization

This portion of the Task 3 report is limited to the review of procedures pertaining to the interview of a worker claimant or a family member claimant. This review is represented below in Sections 5.2 through 5.8, which are followed by three attachments:

- Section 5.2 provides a brief description of the procedures under evaluation
- Section 5.3 identifies those elements of the procedure that SC&A considers positive strong points
- Section 5.4 consists of a summary review of findings (or checklist)
- Section 5.5 provides review comments regarding CATI Forms 1 and 2
- Section 5.6 describes significant findings pertaining to applicable procedures
- Section 5.7 provides summary conclusions
- Section 5.8 identifies suggestions for improvements
- Attachment 5-1 is an interview with Denise Brock

- Attachment 5-2 is an interview with Ed Walker
- Attachment 5-3 is an interview with ORAU Claimant Interview Staff

The format of the checklist in Section 5.4 and the scoring system follows the procedures for this task approved by the Advisory Board.

5.2 OVERVIEW OF PROCEDURES USED IN THE COMPUTER ASSISTED TELEPHONE INTERVIEW

To comply with the objectives specified in 42 CFR 82.10(c), NIOSH developed a formal step-by-step process for conducting a telephone interview, called the Computer Assisted Telephone Interview (CATI). The procedures set forth in ORAUT-PROC-0004, -0005, and -0017 have the objective of enabling the interviewer to capture a record of the interview on a computer form which becomes part of the documentation used to support the reconstruction of employee doses. There are also other opportunities for claimants to add to or amend interview records that are part of these procedures. Principal among these is the closing interview. Besides its designated function of eliciting information from claimants for the purpose of dose reconstruction, the CATI is a principal means of an extended interaction between NIOSH and claimants. It is therefore an important element in the relationship that NIOSH establishes with the public.

5.2.1 ORAUT-PROC-0004 — Purpose of Procedure: Scheduling Telephone Interviews

The purpose of ORAUT-PROC-0004 is to specify the process of scheduling the interview. Each claimant receives a letter informing him/her that he/she will be contacted by ORAU to schedule an interview (NIOSH Tracking No. 54). The letter includes a copy of the interview form. NIOSH and Oak Ridge Associated Universities (ORAU) use two different interview forms — one for worker-claimants and the other for family member claimants. For the claimant, the interview is voluntary. Since the purpose of the CATI is to provide input into the dose reconstruction process, both versions of the letter encourage claimant participation and inform the claimant of the following:

> *. . . if you choose not to be interviewed, this would hinder NIOSH in conducting the dose reconstruction for your claim. Choosing not to be interviewed may also result in a dose reconstruction that incompletely or inaccurately estimates the radiation dose to which the energy employee named in your claim may have been exposed.* [EEOICPA Interview Form, page 1]

(Note: The letter and ORAUT-PROC-0004 are audited together in this report.)

5.2.2 ORAUT-PROC-0005 — Purpose of Procedure: Performing Telephone Interviews

The purpose of ORAUT-PROC-0005 is to specify the process of conducting the interview. This procedure outlines a tightly prescriptive step-by-step process for conducting the interview. This procedure provides for updating the CATI so that the claimant has the opportunity to correct any information documented during the interview or to provide additional information. NIOSH has

two versions of the interview form, OMB-0920-0530, Versions 1 and 2, which are used for employee claimants and family member claimants, respectively.

5.2.3 ORAUT-PROC-0017 — Purpose of Procedure: Reviewing Telephone Interview

The purpose of ORAUT-PROC-0017 is to set forth an in-house NIOSH review of the CATI. This review process is intended to review the technical content of the CATI and to ensure its completeness, as well as to allow for updating the information in the interview.

5.2.4 Closing Interview

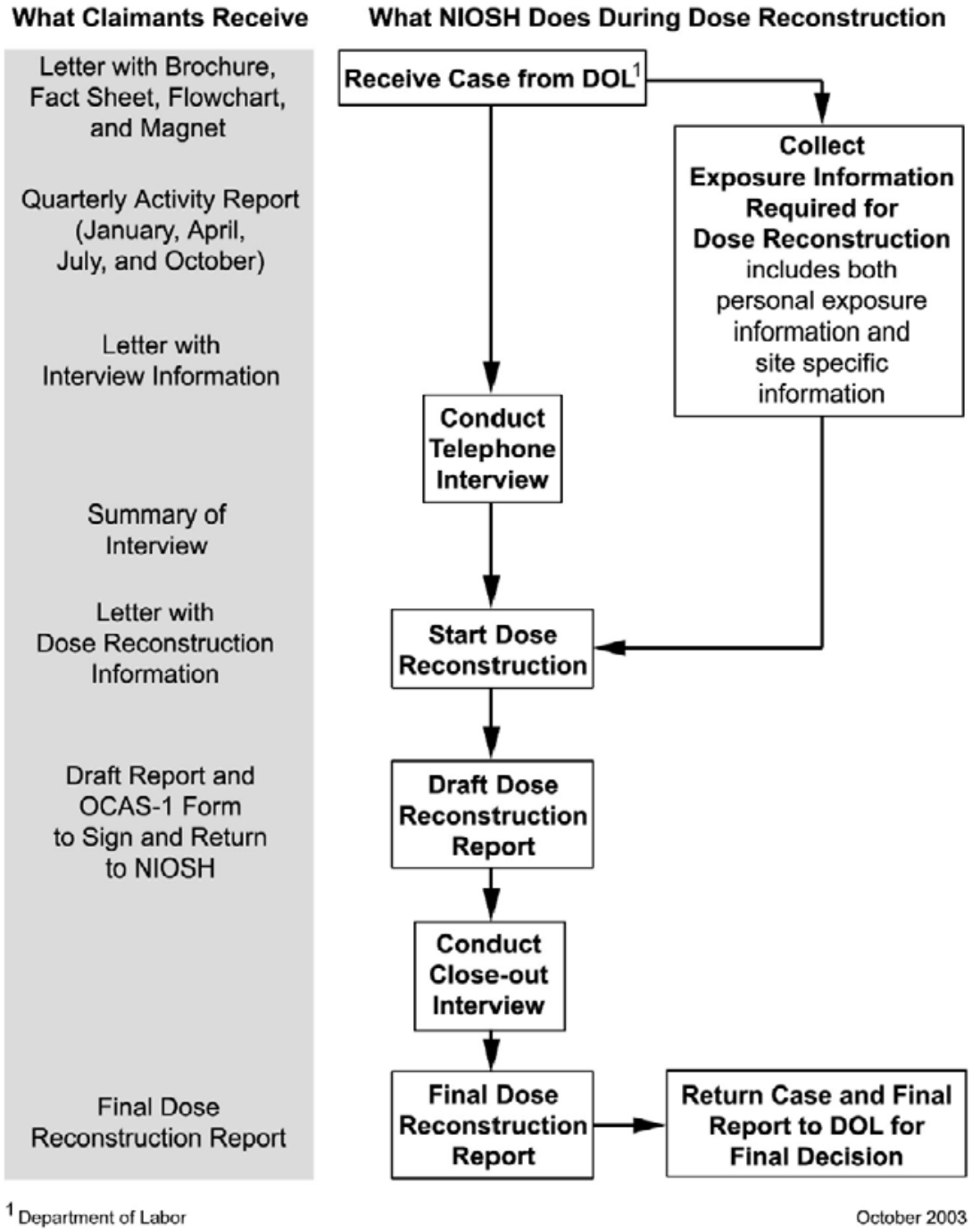
In spite of the regulatory requirements of 42 CFR 82 quoted above for conducting a closing interview, to date, NIOSH has not published a procedure for the closing interview. In the interim, an internal draft procedure is being used. This draft procedure may or may not incorporate suggestions made in this review to connect the closing interview to the CATI process. NIOSH has published a flowsheet of the dose reconstruction process on its Web site that shows where the closing interview fits into the process (see Figure 5.2-1). This review addresses the closing interview to the extent that it is pertinent to the review of the existing three CATI procedures and forms cited above.

5.2.5 Interviews Conducted by SC&A for this Report

Equally relevant to this review are two independent interviews conducted by Arjun Makhijani with a survivor-claimant and a worker-claimant, who have had extensive experience helping other claimants and who are, therefore, very familiar with the interview process. These interviews are presented in Attachments 5-1 and 5-2. Kathryn Robertson-DeMers also conducted an interview with a CATI interviewer with a Claimant Interview Supervisor present. SC&A requested an anonymous interview with a CATI interviewer [anonymous to NIOSH and ORAU] in order that the CATI interviewer could express themselves freely. However, an anonymous interview was not possible, as the ORAU team requested a supervisor be included in the interview. Because of their relevance to SC&A's review of procedures, the reader is strongly encouraged to carefully examine Attachments 5-1, 5-2, and 5-3.

Figure 5.2-1

What to Expect During the Dose Reconstruction Process



5.3 STRENGTHS OF ORAUT-PROC-0004, -0005, AND -0017, LETTER (NIOSH TRACKING NO. 54), AND CATI FORMS

The following strengths were noted in the three procedures, the associated letter, and the interview forms:[1]

- The logistical aspects of the scheduling process appear to be appropriately laid out (ORAUT-PROC-0004). For instance, a letter (NIOSH Tracking No. 54) is sent to the claimant informing him/her that an interviewer will call. The interview form is attached to the letter so that the claimant has an opportunity to review it.
- The scheduling and followup processes appear to be good. Privacy norms are specified as part of the scheduling process (ORAUT-PROC-0004).
- There is a specified procedure for capturing the information provided and recording it in a computer database (ORAUT-PROC-0005 and ORAUT-PROC-0017).
- Appropriate attention is paid to classification issues so far as enabling workers to have access to a face-to-face interview with a cleared interviewer (ORAUT-PROC-0005).
- Adequate Privacy Act protections are built into the interview process.
- Workers can contact ORAU both before and after the interview. There is a systematic way to record additional information and make corrections to the record that would be traceable. It appears possible for the well-informed worker to ensure that the information he/she has about working conditions, incidents, and other factors is incorporated into the dose record.
- The interviewer checks demographic information of the worker prior to the interview (ORAUT-PROC-0005).
- Having an interview form results in a systematic procedure for entering and updating the information, and provides a basis for achieving consistency in the types of information elicited from claimants.
- Provision is made for the review of the data and updates that claimants may provide (ORAUT-PROC-0017).

5.4 SUMMARY REVIEW FINDINGS

SC&A's evaluation of ORAUT-PROC-0004, ORAUT-PROC-0005, and ORAUT-PROC-0017 is summarized below in Tables 5.4-1, 5.4-2, and 5.4-3, respectively. The tables contain a checklist of objectives that SC&A designed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process.

[1] Comments apply to all three procedures, the letter, and the CATI forms, unless otherwise specified.

Table 5.4-1. ORAUT-PROC-0004 Procedure Review Outline/Checklist

Document No.: ORAUT-PROC-0004; letter (Tracking No. 54)	**Effective Date:** 11/05/2003
Document Title: Scheduling Telephone Interviews, accompanying letter has no title	
Reviewer: Arjun Makhijani	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	Interview letter sent out without adequate dose reconstruction information (See Finding 2).
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	4	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	N/A	
3.1.1	Is scope of information sufficiently comprehensive?	See Comment	Letter lacking in essential content especially for family member claimants. Score = 4 for employee claimants, Score = 2 for family member claimants.
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable. Alternative interpretation 1=Poor, 2=Borderline Unacceptable, 3=Moderate, 4=Good, 5=Excellent.

No.	Description of Objective	Rating 1-5*	Comments
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?	2	Procedure is objective in that same letter is sent to all claimants. However, it has an implicit bias in the case of family member claimants, who likely need more preparation prior to receiving interview letter.
3.1.4	Is the interview process sensitive to the claimant?	3	Request for telephone interview without better claimant preparation.
3.1.5	Does the interview process protect information as required under the Privacy Act?	5	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	N/A	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable. Alternative interpretation 1=Poor, 2=Borderline Unacceptable, 3=Moderate, 4=Good, 5=Excellent.

Table 5.4-2. Procedure Review Outline/Checklist

Document No.: ORAUT-PROC-0005, OMB-0920-0530 Versions 1 and 2	**Effective Date:** 11/06/2003
Document Title: Performing Telephone Interviews, and accompanying CATI forms (Versions 1 and 2)	
Reviewer: Arjun Makhijani	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	4	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	3	No reference to Site Profile or closing interview.
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	3	No procedure or requirement for coworker interview or explanation if coworkers not interviewed.
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	See Comment	Procedure is better for employee claimants (score = 4) than family member claimants (score = 2, coworker interviews more important).
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	2	Interviewer not required to have incident list, job category list, familiarity with facility.
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	2	Same as 2.1.
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	4	Data sought are relevant and appropriate (see row below).
3.1.1	Is scope of information sufficiently comprehensive?	See Comment	Score = 3 for employee claimant, score = 2 for family member claimant.

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable. Alternative interpretation 1=Poor, 2=Borderline Unacceptable, 3=Moderate, 4=Good, 5=Excellent.

No.	Description of Objective	Rating 1-5*	Comments
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	2	Interviewer not required to have knowledge of facility though some may have it.
3.1.3	Does the interview process demonstrate objectivity and is it free of bias?	See comment	Score = 4 for employee claimant, score = 2 for family member claimant Procedure is formally objective but is implicitly biased in case of family member claimants due to deficiencies discussed below (e.g. no coworker interview requirement before denial). This deficiency is procedural and exists despite sensitivity of interviewers to claimants at a personal level.
3.1.4	Is the interview process sensitive to the claimant?	3	Interviewers are trained to be sensitive but procedure does not require facility knowledge. This can produce apprehension that procedure does not address.
3.1.5	Does the interview process protect information as required under the Privacy Act?	5	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	3	Procedure does not require interviewer training to elicit site-specific data.
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	4	
3.2.2	In vivo/In vitro bioassays	3	In vivo question missing
3.2.3	Missing dosimetry data	2	Interview contains many gaps (see Section 5).
3.2.4	Unmonitored periods of exposure	2	Interview contains many gaps (see Section 5).

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable. Alternative interpretation 1=Poor, 2=Borderline Unacceptable, 3=Moderate, 4=Good, 5=Excellent.

No.	Description of Objective	Rating 1-5*	Comments
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	See Comment	Procedure does not provide for explanation if information is not used; Score = 3 for employee claimant, score = 2 for family member claimant due to coworker interview issue.
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	4	DOE file not required to be with interviewer during interview.
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	See comment	Score = 4 for employee claimant, score = 2 for family member claimant Procedure is not claimant favorable for family member claimants in the absence of preparation and requirement for coworker interview or detailed explanation of failure to interview.
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	See comment	Score = 2 for employee claimant, score = 1 for family member claimant Interviewer training appears to be insufficient, at least in some cases. CATI has many gaps.
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	See comment	Score = 3 for employee claimant, score = 1 for family member claimant; see 5.2 comment. No coworker interview requirement or explanation.
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable. Alternative interpretation 1=Poor, 2=Borderline Unacceptable, 3=Moderate, 4=Good, 5=Excellent.

No.	Description of Objective	Rating 1-5*	Comments
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	See Comments	Some aspects elicit detail while others do not; Score = 3 for employee claimant, score = 2 for family member claimant.
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable. Alternative interpretation 1=Poor, 2=Borderline Unacceptable, 3=Moderate, 4=Good, 5=Excellent.

Table 5.4-3. ORAUT-PROC-0017 — Procedure Review Outline/Checklist

Document No.: ORAUT-PROC-0017	**Effective Date:** 11/06/2003
Document Title: Reviewing Telephone Interviews	
Reviewer: Arjun Makhijani	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	2	Definitions and scope of key terms "completeness" and "technical content" not given.
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	N/A	
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	2	No reference to Site Profile or closing interview, no reference to dose file of claimant.
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	3	No explicit connection to review of information in closing interview is provided.
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	1	No definition of key terms "completeness" and "technical content." This can introduce arbitrariness and inconsistency.
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	3	Reviewer qualifications are not specified in the procedure; reviewer not required to review claimant dose file; coworker interviews or explanations for not interviewing not required and therefore not reviewed.
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable. Alternative interpretation 1=Poor, 2=Borderline Unacceptable, 3=Moderate, 4=Good, 5=Excellent.

No.	Description of Objective	Rating 1-5*	Comments
3.1.3	Does the interview process demonstrate objectivity and is it free of bias?	2	Process is implicitly biased against family member claimants because the standard of completeness is implicitly lower. This is largely because no specifications relate to coworker interviews, and there is no definition of "completeness" or "technical content." A CATI review process that approaches all CATIs without these definitions or coworker interviews does not recognize greater gaps likely to be present in family member claimant interviews.
3.1.4	Is the interview process sensitive to the claimant?	4	Review requirement is sound but incomplete.
3.1.5	Does the interview process protect information as required under the Privacy Act?	5	
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	2	Reviewer not required to know Site Profile or claimant dose records. Basis for judging completeness and technical content of interview is not specified.
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations.**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	1	Procedure does not specify scope of terms "completeness" and "technical content."
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	3	Reviewer not required to review claimant DOE file.
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant.**		
5.1	Is the procedure claimant favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable. Alternative interpretation 1=Poor, 2=Borderline Unacceptable, 3=Moderate, 4=Good, 5=Excellent.

No.	Description of Objective	Rating 1-5*	Comments
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating system of 1 through 5 corresponds to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable. Alternative interpretation 1=Poor, 2=Borderline Unacceptable, 3=Moderate, 4=Good, 5=Excellent.

5.5 COMMENTS REGARDING CATI FORMS[2]

SC&A has evaluated each question identified in the CATI form for its importance in relation to the dose reconstruction. Some gaps were identified in the interview questions, which could hinder the complete elicitation of information from workers. The implications for improvement of the questionnaires are understood. Only the questions on which there are comments are shown on Tables 5.5-1 and 5.5-2 below. The other questions are acceptable in their present form.

Table 5.5-1. Reviewer Comments Pertaining to CATI Form — Worker-Claimant (OMB-0920-0530, Version 1)

Question #	Question Topic	Comment and Recommendations
2	Work hours per week	There is no question about overtime.
5	Eight-part question on routine work duties	In the early years of operations, employees may not have been told what radionuclides were present in their workplaces. Employees may also have only a partial idea of the radionuclides, since they may not be aware of decay chains or contaminants in the material processed. The question contains no provision for helping the employee remember which of the radionuclides in the list might be relevant, such as directing them to the Site Profile Review. "Radiation-generating device" is a technical and specific term and may not be understandable to some claimants. The question does not provide examples, such as portable x-ray units, electron beam welders, radiography sources, etc. Workers are often more familiar with the terms Radiological Work Permit (RWP) or Special Work Permit (SWP). Facilities also use work packages, which are not mentioned in the CATI form. Workers often have to sign security logs to access certain areas. Reference to such forms is missing even though such areas are likely to have radioactive material stored and under guard.
7	Internal radiation dose	This question left out *in vivo* analysis. There is no question regarding details about bioassay frequency. This is a serious gap. Employee information on monitoring frequency could confirm completeness of a dose record or else indicate gaps in it that could be crucial in the dose reconstruction process.
8	Copies of dosimeter and bioassay records	The question does not include annual worker radiation reports.
9	Routine frisking survey	Incomplete question, since a Radiological Control Technician is responsible for the frisking at some facilities. Inadequate followup to a yes answer. For instance, there is no question asking whether the claimant ever had items of clothing or shoes confiscated due to contamination discovered during a frisking.

[2] This section was initially drafted by and prepared in collaboration with Kathryn Robertson-DeMers, CHP.

Question #	Question Topic	Comment and Recommendations
10	Area rad monitoring	Merge questions 10 and 11 to ask what types of workplace radiological measurements were taken. It does not provide a list asking yes or no questions on job-specific air samples, lapel air samples, general area air samples, environmental air samples, job coverage, contamination surveys, and radiation surveys. Also, the worker is not asked about the presence of continuous air monitors and area radiation monitors. These are an indication of high potential airborne concentrations and high radiation levels in the area.
11	Rad surveys	No details are elicited except for radon at certain facilities. See questions 10 and 12.
12	Radon monitoring	Technically, all air samples measure ambient radon and thoron daughters. When counting air samples, an immediate count and a decayed count are performed. The immediate count includes contributions from short-lived radon and thoron daughters. The decay count (several days later) represents the air concentrations of the source term of interest (e.g., plutonium, strontium, cesium). The question does not ask about unapproved practices that could lead to high radon exposure: This may be relevant for some sites like Fernald and Mallinckrodt Chemical Works.
13	Was worker ever restricted from job?	There is no followup if worker responds affirmatively. This is a gap in eliciting information. This is the place where abnormal practices, such as workers not turning in badges when their doses are near the administrative exposure limit could be detected. Zero doses were sometimes recorded in such cases.[3] Hence, the questionnaire fails to address potentially systemic problems in dosimetry practices.
14	Sixteen-part question about incidents	This question is likely to miss critical information. For instance, no specific question asks if a nasal smear was taken, which would be an indication of suspected internal inhalation exposure. No questions ask whether real-time monitors alarmed or whether the employee may be aware of an incident report.
15	Three-part question about medical x-rays	No followup regarding photofluorography in case of an affirmative answer.
18	Coworker information	No commitment to inform employee whether the coworkers identified were interviewed and, if not, why not.

Overall, the employee questionnaire is well structured. However, several important areas have gaps with the potential to significantly affect dose reconstruction and/or dose estimates. See below for further specific discussion.

[3] Makhijani, Hu, and Yih, eds. 2000, page. 263. See also Attachment 5-1 to this report.

Table 5.5-2. Reviewer Comments Pertaining to CATI Form — Family Member Claimant (OMB-0920-0530, Version 2)

Question #	Question Topic	Comment and Recommendations
2	Weekly work hours	There is no question about overtime.
3	Work buildings or locations	This information could be very useful, if available. However, it is likely to be difficult for the survivor claimant to remember building names or numbers, if he/she ever knew them. No descriptive questions solicit information about the kinds of activities at work or processes (PUREX) employees may have worked on or names of machines (e.g., Rockwell furnaces or N-reactor), or nicknames of buildings such as "igloos" (used for plutonium storage at Pantex).
5	Blank	There is no question 5 on the interview.
6	External rad monitoring	There is no preliminary explanation of the information sought. The question is therefore unlikely to elicit useful information in many cases, since many people outside the field are not familiar with terms such as "radiation dosimetry badge."
7	Internal rad monitoring	This question is also unlikely to elicit useful information in most cases unless prior information or an explanation is provided. The letter and form do not contain any explanation of terms such as "biological radiation monitoring program." Again, the question fails to ask about *in vivo* counts.
9	Was employee restricted from job?	Other indicators, such as change of assigned job, may more readily elicit the needed information.
10	Seven-part question on incidents	This question is too complex to elicit useful information in most cases without a considerable amount of preparation. For instance family member claimants are unlikely to know what chelation therapy is (see Attachment 5-1). There are no general questions, such as whether employees were sent home or received medical examinations due to incidents, or whether coworkers who visited the claimant socially ever mentioned any incidents. Evidence regarding any advice to drink lots of water or beer after tritium exposure is not reflected in this question. The numbers 10.4 and 10.5 are repeated in labeling questions. This could lead to problems in logging information. The last two parts should be labeled 10.6 and 10.7.
15	Coworker information	This could be the most important question on the interview for many or most family member claimants. Coworkers and supervisors are likely to know more information on the exposure conditions of the covered employee than the family. Despite that there is no requirement to inform claimants and provide information about coworker interviews or reasons if coworkers not interviewed.

See also Finding 8.

5.5.1 Gaps in the CATI Forms

SC&A's review identified a number of potential gaps in the questionnaires. The first seven items listed below are for all claimants. The rest pertain only to the employee questionnaire. (Note: All 14 items would also be pertinent in modified form for the coworker questionnaire, if one were to be developed.)

(1) There is no question about food. Workers often ate in contaminated places and may have stored their food in contaminated places.

(2) There is no question about overtime.

(3) There is no question about bringing home contaminated clothing or vehicles and how regularly this may have occurred.

(4) There are no questions that relate to exposure from visits to other facilities or from subcontractor or construction activities. These records may or may not be available in the home facility's radiation exposure records.

(5) There is no requirement to connect the closing interview to the CATI in the CATI procedures.

(6) There is no commitment to respond to the claimant regarding the status of coworker interviews (results, if interviewed, or reasons for not interviewing, if that is the case).

(7) There is no interview form specific to coworkers.

(8) There is no question about control and/or handling of badges (i.e., taking badges home or offsite). This could affect badge readings. There is also no question that would elicit information about off normal or systemic data logging problems, or about what Denise Brock calls "inattentiveness on the part of the company" regarding data. (See Question 13 in Table 5.5-1 and Attachment 5-1)

(9) The questions about badges imply that a worker would have worn only one badge (except to some extent in that the question asks the respondent to identify the part of the body on which the badge was worn). Some workers regularly wore more than one badge, for example, when ring and/or wrist badges were used to complement the badge normally worn on the pocket of the coveralls.

(10) There is no question about bioassay monitoring frequency.

(11) The reference to monitoring of "breath" is too vague to elicit data on breathing zone air contamination measurements. Many workers wore portable air samplers. The interview form asks the question about monitoring "breath" in the context of biological monitoring, such as occurs after an inhalation of radionuclides. This may cause a worker to miss mentioning breathing zone measurements, which are not a bioassay measurement as such. Breathing zone data could be crucial in determining internal dose in some cases, especially where biological monitoring documentation is missing.

(12) The questions may not reveal the specific ways in which the particular worker may have come into contact with radioactive material. For example, workers who stamped uranium ingots at Fernald sat on ingots. Hence, the external dose to the gonads can be expected to be far higher than recorded on any of the dosimeters worn by the worker.

(13) The only question about neutrons relates to neutron-generating facilities. This omits neutrons from the spontaneous fission of various isotopes, notably Pu-240, which is important for workers at several large facilities.

(14) There is no question about in vivo monitoring.

5.6 SIGNIFICANT FINDINGS PERTAINING TO PROCEDURES

Finding 1: Procedures do not require the CATI interviewer to be knowledgeable about the facilities, job descriptions, or the main substantive aspects of the claim for which the interview is done.

The interviewers are only required to check the demographic data for the person and to have looked at the application. The interviewers are not required to have knowledge about the facility where the worker was employed. The interviewers are not required to read the portion of the Site Profile relating to the description of the specific facility or facilities where the claimant worked before calling the claimant. Some interviewers may become knowledgeable over time, for example, if they happen to interview many employees from the same facility, or if they have worked at the facility, but facility knowledge is not a requirement of the procedures.

Deficiencies in CATI qualifications are of even greater concern when worker claimants do not have knowledge of radionuclides at the facility (see below). Many atomic weapons workers were not told that they were working with radioactive materials. Many employees may be unaware of decay chains of radionuclides, like U-238 or Th-232, or about the contaminants in recycled uranium. They may, therefore, be insufficiently knowledgeable and at a loss as to what information to provide.

Family member claimants are at an even greater disadvantage because of the lack of a requirement in the procedure for the interviewer to have facility knowledge. They are unlikely to be aware of incidents, let alone to have substantive information that can be used in dose reconstructions. The interview with Ed Walker (Attachment 5-2) indicates that many claimants may not know what a radiation dosimetry badge is. Even when claimants or family members of the claimants do have some knowledge, the lack of knowledge on the part of some interviewers may constitute a significant barrier to eliciting information that is as reliable and as complete as possible under the circumstances.

Neither ORAUT-PROC-0004 nor ORAUT-PROC-0005 requires the CATI interviewer to review work history, plant data, plant processes, incident databases, working conditions, or any other matter that pertains to radiological conditions that may be relevant to the claimant's dose reconstruction. SC&A's interview with Denise Brock, family member of an AWE employee who has helped many family member claimants, provides examples of interviewers who were not familiar with radionuclide lists, indicating inadequate technical training (see Attachments 5-1 and 5-3). This is most likely not true of all interviewers (see Attachment 5-3). The point here is that the procedure does not require adequate understanding of relevant technical issues and operational practices. Evidence suggests that at least some interviewers may not be well enough prepared to take additional information in the open-ended questions or to guide claimants when they are trying to recall information (see Attachments 5-1 and 5-2). This makes it likely that less information is obtained than if the interviewer were more knowledgeable.

The flowsheet (see Figure 5.2-1 on page 5-5) indicates that dose records are collected in parallel with the interviews. Hence, no connection appears to exist between the two steps. Further,

ORAUT-PROC-0005 does not require interviewer knowledge of the U.S. Department of Energy (DOE) dose record. It only requires that the interviewer have opened the claimant file and that he/she is familiar with the claimant demographics. This is insufficient to elicit information in questions relating to dosimetry practices, administrative restrictions on workers, and incidents.

Finding 2: Neither NIOSH's form letter to the claimant nor ORAUT-PROC-0004 and ORAUT-PROC-0005 contain provisions that would prepare the interviewee for specific questions. This is especially true with regard to family member claimants.

While the letter informing the claimant about the interview is correct and formal and states that the interview is voluntary, it also states that refusal of the interview

> *. . . would hinder NIOSH in conducting the dose reconstruction for your claim. Choosing not to be interviewed may also result in a dose reconstruction that incompletely or inaccurately estimates the radiation dose to which you may have been exposed.*

If refusal to take part in the interview process would hinder dose reconstruction, then this statement clearly implies that NIOSH places a great deal of value on the answers in the dose reconstruction process.

In the absence of better preparation, there is an implicit element of compulsion that is not consistent with the statement that the interview is voluntary (see Attachments 5-1 and 5-2). The words quoted above clearly set up an expectation that the goal is to estimate a complete and accurate dose, and that the interview is an important part of the estimation procedure. This is not in accord with many of the dose reconstructions as they are actually done. Specifically, the form letter does not describe the minimum and maximum efficiency procedures that are used in many dose reconstructions. This omission can lead to misunderstandings. The element of implicit compulsion can be reduced greatly if the interview procedures, especially ORAUT-PROC-0004, which sets up the interview, were accompanied by a document that briefly informs the claimants or their representatives about the reconstruction process (including efficiency procedures), the nature of the facility, and the nature of questions they will be asked.

NIOSH has created a fact sheet for the claimant, entitled *What a Claimant Should Know about Radiation Dose Reconstruction*. However, the fact sheet does not give any indication of the types of procedures employed in dose reconstruction.

Finding 3: The interview procedure does not take adequate account of the stressful nature of the interview or recognize the high stakes that many claimants feel are involved in their answers.

SC&A's evaluation of responses by interviewees (i.e., claimants or their representatives) suggests that CATI interviewers are "kind and considerate." In rare instances to the contrary, NIOSH appears to take corrective action promptly (See Attachment 5-1). This is a commendable and necessary component of the interview process. However, the lack of

preparation of claimants creates frustration that CATI interviews and interview procedures do not address. Even employee claimants often need preparation. For instance, Denise Brock (the daughter of a family member claimant and spokesperson for other claimants) recounted the following during SC&A's interview with her (Attachment 5-1):

> *Then a worker came to me with the questionnaire. He began to cry and he said "I don't know what I am going to do with this list [of radionuclides]." I said "Please let me help you and see if I can find it [the information about radionuclides]." I made 600 copies of the answers and handed them out.*

NIOSH has no procedure to undertake comparable outreach work in the affected communities related to the interviews. In the absence of preparation and outreach by someone who is knowledgeable, the interview process may make many claimants, especially family member claimants, but also employee claimants, ill-at-ease and very stressed (see Attachments 5-1 and 5-2). Unless the claimant knows the answers to rather complex questions, it will be very difficult for the claimant to assess the extent to which his/her specific answers help or hinder dose reconstruction. For instance, claimants are not in a position to assess the significance of providing "don't know" as a frequent answer.

Finding 4: Lack of procedural guidance regarding coworker interviews leaves open the possibility of arbitrariness, unevenness in claimant records, and inconsistency. It also suggests a lack of accountability to the claimant who provided the information.

Many claimants are able to provide coworker contact information. Sometimes this may require a considerable effort on the part of claimants or those who are assisting them (see Attachments 5-1 and 5-2). Such information can be especially important to family member claimants because coworkers may be able to provide at least some of the information on work assignments and hazards, as well as on incidents for which family member claimants may not have information. The interview form does inform claimants that coworkers may or may not be interviewed. 42 CFR 82.10(c)(6) only requires identification and interviews of coworkers when "necessary." The procedures for CATIs contain no elaboration of this term and therefore no guidelines as to when coworker interviews must be carried out. This can lead to arbitrariness and, therefore, to unevenness in the kinds of information that are collected. In addition, the procedures and forms related to the interviews do not require coworkers to be contacted or even to provide an explanation to the claimants if they are not contacted. A failure to contact coworkers after eliciting their identity can undermine confidence in the dose reconstruction process, especially for family member claimants. There are indications that this may have occurred (see Attachments 5-1 and 5-2). It also suggests a lack of accountability to the claimant. Only about one dozen interviews have been conducted so far, although NIOSH reports on their web site (January 10, 2005) that 6,216 of dose reconstructions have been completed (See Attachment 5-3).

Finding 5: There is no formal published procedure or form for the closing interview. The current closing interview process has been in use for only one year (see Attachment 5-3). This may have resulted in unevenness and arbitrariness in the closing procedure over time and in the connection of the closing interview to the CATI process.

The closing interview complements the initial telephone interview process because it gives the claimant a last opportunity to correct error(s) or to provide more information about the case. At this time, the claimant has a draft of the dose reconstruction and can ask questions about it. The moment also provides an opportunity for NIOSH to explain how the information in the CATI was used in the dose reconstruction process.

There is no published procedure for the closing interview or even for logging the interview. There is no closing interview form. A review of the draft procedure was not part of this task; however, the closing interview is connected in a technical sense to the CATI, in that it is supposed to elicit information relevant to dose reconstruction. This finding is related to the connection between the closing interview and the CATI.

The procedures do not require the interviewers to be trained/qualified to explain the highly technical contents of the claimant's draft dose reconstruction, despite the requirements of 42 CFR 82.10(l) that NIOSH should "review the dose reconstruction results and the basis upon which the results were calculated" during the closing interview. It appears that no health physicist is required to be available in real time. SC&A understands that one is supposed to be available, but anecdotal evidence indicates that the application of this internal requirement may be less than satisfactory in at least some cases. This is indicated by SC&A's interview with Denise Brock (Attachment 5-1):

> *Denise Brock: No, there is no form or letter for the closeout interview. You get the results of the dose reconstruction, with a form, OCAS-1. There is a lot of information in the dose reconstruction, including a lot of numbers indicating dose estimates. Then there is a phone call asking if you've read and understood the material and if you are ready to sign OCAS-1.*
>
> *The person who calls seems like the same type who did the interview. I know someone who refused to sign and they said a health physicist will call you. That was weeks ago and no one has called yet. I think she should sign because they will close out her case if she does not.*

SC&A's experience in auditing individual dose reconstructions indicates that, at best, the standard dose reconstruction report requires a good deal of time and effort even for a well-qualified expert to review it and understand the results, especially in denial cases (where dose reconstructions tend to be more complex). This is especially true of the first time a case relating to a facility is considered, which is of course automatically true of almost every worker (except for family members or employee claimants like Denise Brock and Ed Walker who help other claimants and become very familiar with a facility). While many employee claimants would have the advantage of knowing the details of their own activities, the details of the draft dose

reconstruction are likely to be essentially incomprehensible to most employee claimants or family representatives. The lack of a procedural requirement (in ORAUT-PROC-0005) for a qualified health physicist to be available during the interview process (both in the CATI and closing interview) is likely to be a special problem for most family member claimants. A health physicist should be required to be available for consultation during the closing interview to explain the draft dose reconstruction.

Finally, the fact that the closing interview in its present form has apparently been done for only 1 year (see Attachment 5-3) raises the issue of consistency between recent CATIs and those done before the present draft procedure was instituted. An evaluation of various aspects of the closing interview including compliance with 42 CFR 82.10(l) is beyond the scope of this review.

Finding 6: The procedures governing the interview contain no element connecting the CATI with the stated purpose of 42 CFR 82.10(l), which governs the closing interview.

The closing interview provides the last opportunity for the claimant to provide information relevant to the dose reconstruction:

> *(l) After providing the claimant with a copy of a draft of the dose reconstruction report to be provided to DOL, NIOSH will conduct a closing interview with the claimant… This will be the final opportunity during the dose reconstruction process for the claimant to provide additional relevant information that may affect the dose reconstruction. The closing interview may require multiple sessions, if the claimant requires time to obtain and provide additional information, and to allow NIOSH time to integrate the new information into a new draft of the dose reconstruction report.*

It is evident that 42 CFR 82.10(l) requires any substantive information provided to be connected to the dose reconstruction process. In the absence of information to the contrary, it is presumed that any data provided during closing interviews would be used to revise the dose reconstruction report as specified above. In the present context, SC&A is only commenting on the lack of a published procedure to connect substantive information provided by the claimant at this stage to the CATI process. This point is especially important in light of the example provided by Denise Brock, quoted above, regarding lack of responsiveness in the closing interview process. 42 CFR 82.10(l) does not require a formal connection with the CATI process. Therefore, this item has been listed under the heading "findings" rather than "procedural and regulatory issues."

Finding 7: ORAUT-PROC-0017 does not contain any criteria or checklist for the reviewer of the CATI to assess the completeness or technical content of the CATI.

ORAUT-PROC-0017 contains no definitions of the terms "completeness" and "technical content" or a checklist against which the NIOSH in-house reviewer might be guided in his/her evaluation. Many claimants may answer "don't know" to some important questions, with a greater likelihood for the family member claimant. Conversely, some claimants may, in fact, be able to provide detailed information on these same points. This can lead to inconsistencies

between claimants both with regard to completeness of the data and how CATIs are evaluated by the in-house NIOSH reviewers. Without a checklist, one reviewer may overlook some gaps, while another may address them. Or there may be gaps, such as those discussed in Section 5, that simply remain unaddressed even though they may be important for specific claimants.

Finding 8: The deficiencies in the procedures for the interview process are considerably greater for family member claimants than for employee claimants.

The analysis and findings above lead to the conclusion that the interview procedures are much less likely to elicit information useful for dose reconstruction from family member claimants than employee claimants. Information such as job categories, special hazards, incidents, and examples of a lack of monitoring is more likely to be missed. The following factors contribute to this finding:

- The lack of preparation for the interview regarding facility operations, job categories, etc. would likely hinder family member claimants more that employee claimants since the former are less likely to know the needed details.
- Lack of a procedural requirement for the interviewer to have knowledge of the facility job descriptions and radionuclide list is likely to hinder the ability of family member claimants in particular to provide their input in a way that may be useful for dose reconstruction.
- Due to the complexity of work assignments or, in some cases, classified work assignments or locations, family member claimants may not know what the employee did. Lack of scientific understanding and lack of sufficient communication with claimant in advance of the interview, and difficulty in recollection may compound these problems in many cases.
- Family member claimants are unlikely to have the same type of details about incidents and job types as employee claimants. There is no procedure to judge if the gaps are important in any particular case, since the CATI reviewer has no checklist. Questions that might trigger relevant memories, such as if an employee's job was changed because of overexposure or if he/she was sent for medical examinations for the same reason, are not in the family member claimant interview form. (See Table 5.2 above.)
- NIOSH is not required to contact coworkers to provide information on behalf of the claimant or, if the coworker interviews are not performed, to explain why. This gap in the procedure especially affects family member claimants because the survivor CATI form is (necessarily) less detailed, and coworker data are therefore more essential to complement the worker data in the DOE file or the data in the Site Profile. In practice NIOSH vary rarely contacts coworkers (See Attachment 5-1, 5-2, and 5-3).
- There appears to be no requirement for a health physicist to be present during the closing interview so that the dose reconstruction can be explained in a manner that could elicit additional data. This gap is also likely to disproportionately impact family member claimants, since they are less likely to be able to understand the draft dose reconstruction.

They are thus less likely to know what kinds of information might be helpful in a re-draft of the dose reconstruction. Employee claimants are also adversely impacted by this gap.

These factors are also more likely to contribute to heightened anxiety for family member claimants, resulting in greater frustration, despite the kindness and politeness of the interviewers to claimants. Considerations similar to the ones above are also likely to apply to those employee claimants who are too ill to answer questions or who simply cannot recall most relevant details, necessitating family members to stand in for them.

Finding 9: ORAUT-PROC-0017 does not require the reviewer of the CATI to be a health physicist.

ORAUT-PROC-0017 requires the reviewer to examine the CATI for "completeness" and "technical content" (page 5). This requires a reviewer who is qualified in health physics, a need that is accentuated by the lack of sufficient technical training of interviewers regarding sites and elements of dose reconstruction. NIOSH has indicated that the "Health Physics Team" is responsible for the review. This indicates that the reviewer is qualified in Health Physics. This should be made an explicit requirement in ORAUT-PROC-0017.

5.7 SUMMARY AND CONCLUSIONS

NIOSH procedures, which provide guidance and define the scope of the interview process with claimants, can be regarded as functionally adequate overall when (1) the interviewee is the employee, (2) the employee has some understanding of radiological issues that characterize his/her employment period, and (3) the CATI interviewer and/or the CATI report reviewer are knowledgeable enough to elicit the needed information. Even so, there are important gaps in the interview form and process that need to be filled.. Conversely, based on the procedures under review, the adequacy of the interview process is adversely affected and compromised when the claimant is a family member or when the energy employee is not the interviewee, for example because the employee is too ill to be interviewed. Lastly, the potential problems in the interview process, as an integral part of the dose reconstruction process especially for family member claimants, are complicated by the current absence of a published procedure that specifically addresses the closing interview and the failure to involve the claim's dose reconstructor (or a qualified health physicist) in the closing interview in real-time.

The stated objectives of 42 CFR 82.10(c) regarding the interview are to:

(1) Explain the dose reconstruction process;
(2) Confirm elements of the employment history transmitted to NIOSH by DOL;
(3) Identify any relevant information on employment history that may have been omitted;
(4) Confirm or supplement monitoring information included in the initial radiation exposure record;

(5) Develop detailed information on work tasks, production processes, radiologic protection and monitoring practices, and incidents that may have resulted in undocumented radiation exposures, as necessary.
(6) Identify co-workers and other witnesses with information relevant to the radiation exposure of the covered worker to supplement or confirm information on work experiences, as necessary.

The ability of ORAUT-PROC-0004, ORAUT-PROC-0005, and the interview forms to consistently satisfy the objectives given in 42 CFR Part 82 is questionable with regard to items (1), (4), and (5) for employee claimants due to gaps in the interview forms and other issues detailed above.

For family member claimants, the procedures are unlikely to satisfy any of the six objectives of 42 CFR 82.10(c). With regard to item (6), the deficiency is largely related to the lack of a requirement for coworker interviews in the case of family member claimants or a careful technical justification if such interviews are not done, especially when claims are denied.

The procedures reviewed here are also silent on (1) the training of interviewers, especially regarding facility knowledge, (2) when coworker interviews should be performed, (3) the participation of a health physicist at the time of the closing interview, and (4) integration of the closing interview with the CATI, as necessary. As summarized in Section 5.8 below, a substantial modification of the procedures and interview forms would be required for a consistent and systematic fulfillment of 42 CFR 82.10(c).

5.8 SUGGESTIONS FOR IMPROVEMENT

(1) Prior to the interview, claimants should be given selected information about the site that would prepare them for the interview. For instance, NIOSH can prepare an easy-to-understand booklet about the site and processes for distribution to claimants. The Site Profiles on the NIOSH Web site are far too complex for this purpose. This booklet can be included with the letter informing the claimant that someone will call to schedule an interview. The booklet could also contain site maps and names of major facilities (including informal site names) for the claimant's reference.

(2) NIOSH should hold meetings with groups of claimants/workers before the start of dose reconstruction at a given site, if possible. This will allow employees and family members to jog one another's memories about the operations at the facility and other details. This could be done as part of NIOSH's information gathering for revisions of Site Profiles. SC&A recognizes, of course, that the dose reconstruction process is well underway. This makes it important that the procedures be revised as soon as possible to include such meetings and to develop the booklets discussed in recommendation (1) above.

(3) Knowledgeable/informed third-party contacts should be appointed to serve as liaisons between NIOSH and claimants (see Attachments 5-1 and 5-2). This is especially important for family member claimants, or employee claimants who are very ill. This

addition to the CATI process could be connected to the NIOSH outreach program that has already been established.

(4) ORAU personnel who interview claimants should be required to have an adequate understanding pertaining to (1) site-specific facility operations, (2) the nature of radionuclides/radioactivity, (3) exposure pathways, (4) radiation monitoring practices, and (5) fundamentals in radiation protection. Evidence indicates that present training is insufficient in at least some cases to elicit critical information (see Attachment 5-1, 5-2, and 5-3).

(5) There should be a formal requirement in ORAUT-PROC-0017 that the reviewer who is responsible for evaluating/determining the completeness and technical content of the CATI report be a health physicist. The procedure should also have a checklist regarding completeness and technical content. Such a checklist would help the reviewer to identify potential deficiencies in the CATI report.

(6) There should be a formal requirement for a health physicist (possibly the dose reconstructor) to be available during the closing interview. It is not necessary for the health physicist to be on the line, but to be available during the call, if needed.

(7) NIOSH should create a form specifically for coworker interviews. The present use of the employee interview form (See Attachment 5-3) is problematic. For instance, it does not contain questions relating to the knowledge that the coworker has about the covered employee, or the details of the working relationships between them. NIOSH should also amend its CATI procedures to require information derived from coworker interviews to be communicated to claimants. If coworker interviews are not performed, the reasons should be provided to the claimant, especially in cases where the claim is denied. This could be done at the time of the closing interview.

(8) The CATI procedures, ORAUT-PROC-0005 and ORAUT-PROC-0017, should be modified in order to ensure that any additional data provided during the closing interview relevant to dose reconstruction is incorporated into the CATI.

(9) The CATI forms should be modified to fill in the gaps and amend the deficiencies discussed in Section 5.0 above. NIOSH should take a longer view of the Paperwork Reduction Act with regard to the interview process, since loss of confidence in the process on the part of the claimants may produce more paperwork than obtaining all of the relevant information in the first place.

The adoption of these suggestions would benefit the dose reconstruction program by helping to improve the quality and quantity of relevant information gathered. It may also help to reduce the anxieties and frustration with the process felt by many claimants, especially family member claimants.

REFERENCES

42 CFR Part 82, "Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule," May 2, 2002.

EEOICPA Dose Reconstruction Telephone Interview, CATI Form OMB-0920-0530, Version 1 (employee claimant) and Version 2 (family member claimant)

Makhijani, Hu, and Yih, eds. 2000. Arjun Makhijani, Howard Hu, and Katherine Yih, eds., *Nuclear Wastelands: A Global Guide to Nuclear Weapons Production and Its Health and Environmental Effects*. Cambridge, MA: MIT Press, 2000.

NIOSH Tracking No. 54, Sample letter to claimant, addressed to John Doe, dated September 16, 2004, with an attachment consisting of the telephone interview form in two versions – worker-claimant and survivor-claimant.

OMB, 2004, Office of Management and Budget, CATI Interview Forms, *OMB-0920-0530,* Washington, DC.

ORAUT-PROC-0005, *Performing Telephone Interviews*, Rev. 00, November 6, 2003.

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ATTACHMENT 5-1: AN INTERVIEW WITH DENISE BROCK (Daughter of an MCW Worker and Community Activist Helping Other Claimants)

Presented below is an interview with Denise Brock on September 18, 2004, by Arjun Makhijani, SC&A. This interview is further supplemented by a second interview on September 25, 2004, which was amended by phone, finalized, and sent to Denise Brock on September 26, 2004.

Note: This is not a verbatim transcript but paraphrases the conversation in the form of questions (denoted below as Q) and answers (denoted below as A), along with a report of the substance of what was said. Denise Brock also granted written permission for this interview to be published in an e-mail of September 22, 2004, as reproduced at the end of this interview record. References to Denise's third parties have been deleted for privacy reasons. Ms. Brock was interviewed primarily because she has helped other claimants.

Q. Arjun Makhijani: Have you helped workers fill out claimant forms?

A. Denise Brock: Yes, both families and workers. I've also helped with telephone interviews.

Q. Arjun Makhijani: Do you think workers are able to get their information out during the interviews?

A. Denise Brock: With guidance, they can do that. What I do is guide them. I started when my mother was sent a questionnaire. Especially as a family member for something that was considered as top secret, you look at it and say "my god I don't know any of that!" I did research and helped my mother answer the questions. I obtained enough documents so I could do that to the best of my ability.

Then a worker came to me with the questionnaire. He began to cry and he said, "I don't know what I am going to with this list [of radionuclides]." I said, "Please let me help you and see if I can find it [the information about radionuclides]." I made 600 copies of the answers and handed them out. I sit there with them during the interviews. I prepare them prior to the interview. Sometimes they are nervous during the interview. For the most part the workers are able to get out everything that they need to say.

Q. Arjun Makhijani: Let's focus on the workers first and then go on to families and survivors. How many workers have you helped by being right there with them when they are answering the questions for the CATI?

A. Denise Brock: Sitting there with them? Probably about 20.

Q. Arjun Makhijani: How many times during the interview typically does a worker stop to ask you to help?

A. Denise Brock: They don't stop during the interview. They are prepared beforehand. If a worker were to look at that form and not have anyone say to him regarding the radionuclide list, they could not tell you. They get nervous and have to say "I don't know" and "I don't know" again and again. So if I can't be there I have done everything I can to help them about things beforehand, like what radionuclides were there in the building [where they worked]. Job descriptions they do wonderfully.

Q. Arjun Makhijani: Can they describe incidents?

A. Denise Brock: Yes, they do well with that part of it.

Q. Arjun Makhijani: How about monitoring history?

A. Denise Brock: They seem like they can give a really good feedback.

Q. Arjun Makhijani: Do you feel the questionnaire is complete?

A. Denise Brock: I think it is a good questionnaire. The only thing I would like to make sure is that workers feel like they can add to it. I know they are asked "have we missed anything?" by the interviewer. A lot of them are talkative.

Q. Arjun Makhijani: Do interviewers come across as knowledgeable about the facilities?

A. Denise Brock: No. They are kind 98 or 99 percent of the time — kind and courteous but when you talk about facilities… For instance, if you have a survivor of a worker and the questionnaire asks about isotopes. My survivors would answer with the isotope list [that I prepared for them]. They read the list to the interviewers and typically CATIs are shocked. They [the interviewers] sometimes say they don't have room on the form for the list – but I know they can add pages. Or they may need help spelling the radionuclide names.

Q. Arjun Makhijani: Workers are asked whether they have dose data. Do they have it and if they do they give it or withhold it?

A. Denise Brock: No workers don't have dose data. They were never given results of bioassay. They will say "I have worn a badge." But no one I have seen has any sort of information. No, they were never told anything. I have seen people say they would drop a badge into orange oxide and the badge would be exposed they would turn it in and no one would say anything

[about a high exposure]. One guy would come up red hot and one would come up with nothing though they were next to each other. They were never told they were hot or given results for anything.

Q. Arjun Makhijani: Have workers communicated this kind of discrepancy during interviews?

A. Denise Brock: No, because it is not really a question [in the questionnaire]. They are asked "Do you have copies of your dose information?" and they say "no." I tell them to add information [that they know].

Q. Arjun Makhijani: During some of the interviews where you've been present have they said things like the badges were not properly read?

A. Denise Brock: They say things like badges only read external and did not take into account internal doses. Workers would say one was hot and one would come up with nothing, so how do the workers know what the dose was? They have no way of knowing. At least nobody I've seen knows. Sometimes, workers would not be allowed to resume a job. I know of a case like that when he was not allowed to go back. Sometimes the badge would turn up colored and he assumed his badge was hot. Sometimes they were told to go to another area for a few days. They were not given readings, but the guy next to him would be fine even though he did the same thing….

Q. Arjun Makhijani: Has any worker told NIOSH that badge readings may be tampered with, like the orange oxide item?

A. Denise Brock: I have told them. During my mother's phone interview, during other interviews, during Advisory Board meetings. I have broached subject with them several times. I have sent this in to NIOSH.

(Denise reading a document.) Exposure printout cards are incorrect, internal, external. 0.00 is used where there are no records of exposure whereas in many cases no tests were made, etc.

I said that if NIOSH is using zeros, then that is incorrect. I have 8,000 documents of my own beyond what others have. I have another one that talks about a dust study.

Q. Arjun Makhijani: Could you please send me a few documents, such as the one showing that doses were not properly recorded and that zeros were entered when there were no tests made and others like it? This observation about zeros is similar to GAO testimony during a 1994 Congressional hearing.

A. Denise Brock: Yes. Also there was no isotopic monitoring for protactinium and actinium.

Q. Arjun Makhijani: Do you think NIOSH is getting information regarding bad data and possibly fraudulent data entry practices that workers may have in these interviews?

A. Denise Brock: No. I think several things. For one, workers, from what I gather talking with them, felt that if there would have been something wrong that surely the company would have told them. They assumed that everything was okay. Not everyone realized that there was inattentiveness on the part of the company.

There were a few workers who became suspicious, like the one who put his badge in orange oxide to see if anyone would notice the high exposure, and the foreman who turned his badge in from a high rad area and did not hear anything about it. There was the thorium bag bursting and there was the terrible explosion. In the explosion case the company paid them off. The workers were never told of anything appearing on their urinalysis or badge readings. They were just issued a new badge.

There is no question that is asked during the interview that would jog the workers' mind that they may be looking for instances of bad data. Workers are extremely nervous during the interview even though it's not adversarial. But they are uncomfortable. They have never heard of chelation therapy. They know that everything that they say — there is $150,000 riding on that. They are offended they have to go through the process. All they know is that they are sick and their coworkers are deceased. They can see that the numbers [of deceased workers] are adding up and they answer the questions as they are asked.

There is nothing in the interview that leads to a worker commenting on inattentiveness on the part of the company. For example, I have a lot of stuff about unreliability of radon measurements in the breath. I just don't think that anything like that would ever come out unless they were asked, "Were you ever told of your readings?" or something like that. Then the interview could go down that line of thinking.

Q. Arjun Makhijani: Now I'd like to turn to the family interview process. Tell me about how family members give information to the interviewer.

A. Denise Brock: You are talking about many years ago. Spouses are elderly, in their 70s and 80s. That's a lot of years later to try to remember. Then again the men were secretive because they did not know or they were told not to discuss this stuff. Survivors are not aware of what the workers did or what

were exposed to. It is very difficult to go through this interview. So I try to keep a list of jobs: maintenance, electricians, operators in a particular job and they can tell from that if they have the same job descriptions. What I did was prepare folders for them and I take a copy of my mom's interview. It was the first I think that came out of Mallinckrodt so it's a little different. I put a copy of that in there; I put an incident report by Leo Goodman. I almost sit there and go over it with them before they actually have the interview. For someone that doesn't have help it is very difficult.

[Description of rude interview] ….And we could hear a snicker and the lady was just hateful. When that happens the workers feel defeated and their face is red and I have to remove myself and cry. It is like they are being deposed [in a lawsuit]. I think they are humiliated. I don't know why they feel that way but they feel humiliated.

Q. Arjun Makhijani: Is there a way of lodging a compliant?

A. Denise Brock: Yes and I do it and they take care of it. That's part of how the process works. I don't know what you could do to make it better. I think the interviews are a good thing because it gives workers the opportunity to interact and comment on their work.

Q. Arjun Makhijani: You've made lists of job categories to help survivors?

A. Denise Brock: Yes

Q. Arjun Makhijani: And you prep them? How do you find out what job they did?

A. Denise Brock: If they don't know anything I can't. That happens. But then I call living workers to see if they know the person. They can give me a description sometimes and I ask them for information or ask them to call the wife and tell them about the work that her husband did. I know there was one worker who came during the interview to help a wife and I put him on a speaker phone. In one case I had six people here and there were two claimants and there was someone with the same job description to help with incidents and occurrences that the family could not remember or know about.

A lot of this happens at our house or office. I live in a mobile home and we drag chairs and sit on the bed and so on. It got crowded and friends of mine now let me use their office.

Q. Arjun Makhijani: How central is the helper role in the family interview?

A. Denise Brock: My role makes them more relaxed. It also helps with chemicals and radioisotopes. I make them relaxed and hold their hand and they do everything else.

Q. Arjun Makhijani: Are you being modest and minimizing your role? For example, when you prep them does it jog their memory? Have you talked to family members who have gone through process without help?

A. Denise Brock: I don't know. I am sure I have but if I am not there, I have given them a folder. I can't think of any names.

Q. Arjun Makhijani: Does NIOSH call coworkers in cases of survivor applicants?

A. Denise Brock: Not that I know of. But this is because in most cases they are dead. Whether the living ones get called I don't know.

Q. Arjun Makhijani: Is this the correct procedure, since they ask the names of coworkers?

A. Denise Brock: I would assume that NIOSH talked to maintenance men and chemical operators and would assume they have a list in their computer of all the job descriptions. That's what I try to do and I assume that NIOSH does it too.

Q. Arjun Makhijani: If you can think of someone who hasn't had help, it would be helpful to have a comparison of how they did, to get an idea of your role.

A. Denise Brock: Now I can think of one and I will talk to her. I think she may have done it by herself.

Q. Arjun Makhijani: Do you think it would make a different if the interviewer were more scientifically qualified?

A. Denise Brock: No.

Q. Arjun Makhijani: Why?

A. Denise Brock: The worker might get more intimidated. The thing I thought would help if you had someone familiar with the site itself. They could help trigger memory and they could help ask leading question that would help people remember. For an interviewer to know all the radionuclides and how to spell them, I don't think that that would help.

Q. Arjun Makhijani: So someone more like you?

A. Denise Brock: I doubt seriously they would hire me. I love doing this and would do it anyway. It would nice for them to pay me to do this though.

Q. Arjun Makhijani: What else should NIOSH do regarding the interview?

A. Denise Brock: The one thing I wish they would do prior to the interview would be to come in here and do what SC&A did. Group the workers and get as many living workers and let them come and talk about their work environment and let them do that as a group so that they can trigger each other's memories. That way, they can feel not intimidated or that the $150,000 depends on that interview. I know it is not that way but the workers feel that way. The Site Profile was done without worker input. Things like not monitoring for all radionuclides. They [workers] know about stuff on their faces and blowouts and explosions and mobility of workers between facilities. Someone should have come in and have those descriptions from workers. Weldon Springs is not yet done. They can do it there. They deserve to be heard and this is a situation that they are nervous. If you put them together they are eager to share with one another — that can provide more information. Coupled with the phone interview — it would make sense to do them both.

Q. Arjun Makhijani: Do you think if they did this and give applicants copies of the results of the group meetings before the interviews, it would help the interview process?

A. Denise Brock: Yes, definitely and it would definitely help survivors. When we did my mom's interview I did not know very much. Now I have met people who knew my dad and it would have helped. We practiced for that interview for two weeks; she was a nervous wreck when she was going to do that interview. They're not adversaries. But workers feel it is an integral part of their dose reconstruction and without briefing before it is scary for them.

Q. Arjun Makhijani: Thanks so much for helping me like this. We will follow up regarding that person you said you would contact. Is that okay?

A. Denise Brock: Yes.

End

Second Interview with Denise Brock on September 25, 2004
Discussion Topic: Closeout Interviews

Q. Arjun Makhijani: Did you have a closeout interview?

A. Denise Brock: Yes.

Q. Arjun Makhijani: Did they send you a letter or form relating to this interview?

A. Denise Brock: No, there is no form or letter for the closeout interview. You get the results of the dose reconstruction, with a form, OCAS-1. There is a lot of information in the dose reconstruction, including a lot of numbers indicating dose estimates. Then there is a phone call asking if you've read and understood the material and if you are ready to sign OCAS-1.

The person who calls seems like the same type who did the interview. I know someone who refused to sign and they said a health physicist will call you. That was weeks ago and no one has called yet. I think she should sign because they will close out her case if she does not.

End

Permission from Denise Brock; e-mail of September 22, 2004:

Hi Arjun!

Yes, you have my written permission to use my name. Could you please give me a call though, I would like to clarify or answer some of the questions that you have asked in the interview draft?

[Call made on September 26, 2004, and corrections incorporated].

ATTACHMENT 5-2: INTERVIEW WITH ED WALKER ON SEPTEMBER 26, 2004 (Former Bethlehem Steel Employee and Community Activist Helping Other Claimants)

Presented below is an interview with Ed Walker, September 26, 2004, by Arjun Makhijani, SC&A, supplemented by a brief interview September 27, 2004. Note: This is not a verbatim transcript but paraphrases a conversation in the form of questions (denoted below as Q) and answers (denoted below as A). These statements were reviewed, corrected, and approved by Ed Walker by fax, November 23, 2004. Permission to print this interview with his name on it was granted by Ed Walker by fax on November 23, 2004 (reproduced at the end of this attachment). Specific references to third parties, including their names, have been deleted for privacy reasons.

Mr. Walker was interviewed mainly because he has helped other claimants.

Q. Arjun Makhijani: Have you helped workers fill out claimant forms?

A. Ed Walker: Yes, I have.

Q. Arjun Makhijani: About how many?

A. Ed Walker: Ten or twelve.

Q. Arjun Makhijani: Were they employees or survivors?

A. Ed Walker: They were all survivors. I don't believe I've helped any worker claimants.

Q. Arjun Makhijani: Have you helped workers also in some way? I am reviewing both the worker interview procedure and the survivor interview procedure. Let's focus on the workers first and then go on to families and survivors. For instance, have you helped workers by being right there with them during the interview when they are answering the questions for the CATI?

A. Ed Walker: Partially I did.

Q. Arjun Makhijani: You hesitated. Why?

A. Ed Walker: At the time I did my application, we did not have much information. We knew that we had worked with uranium, but we did not know much about the compensation program. I just looked at that form [again] preparing for your call. When I first looked at the questionnaire I was able to tell my work experience. Where it asked for your experience I felt at the time of that questionnaire, I was able to give them enough information when I was interviewed. I felt after my interview that there was no question that I

would be compensated. So I felt that I got out the information that I wanted to.

Q. Arjun Makhijani: Did they ask you about incidents and unusual work that you did?

A. Ed Walker: Yes. But I was not able to give them data on incidents. I did not know what incidents were. It is only recently, in the last few months, as I have looked at declassified documents that it dawned on me what it meant. At that time, I did not have a clue what they were talking about.

Q. Arjun Makhijani: Do you feel questionnaire is complete in terms of the kinds of information it asks you for?

A. Ed Walker: I think the questionnaire itself is complete if the claimant would be more informed. Well, as a claimant and survivor — you were aware that they send you a letter. On the second page they tell you that you have a very important role in the process [of dose reconstruction]. A lot of people read that, and they understand it but they don't have the information. So they [NIOSH] tell them it's important, but the claimants don't know the information. So they get a little scared. And they are a little tense. Obviously, the elderly ones, many don't have the schooling, and they are afraid to say the wrong thing. That's why I thought for myself, I could handle that part of it.

Q. Arjun Makhijani: In retrospect you felt that you missed giving information that might have been useful to your case?

A. Ed Walker: Yes. With the lack of knowledge about what incidents meant, I could not give them that information.

Q. Arjun Makhijani: Are there other things that you did not say because you did not know enough?

A. Ed Walker: If I had redone it today, I would have stated some things differently, but as I know now it would not have made any difference. I would have mentioned some of the things that as you know we went through during the workers meeting at Hamburg [organized by NIOSH on July 1, 2004].

Q. Arjun Makhijani: Let's talk about the survivors you've helped. How did you help them?

A. Ed Walker: In a lot of cases, I go to their house. They say "I can't locate anyone who worked with my husband, he's been dead for 20 or 30 years. I don't understand this." Mostly, it would be the questionnaire. I go and try and help them locate someone [who knew the employee] and go and find what department he worked for. Or I might locate a friend he talked about to

her [the survivor claimant] if she can tell me the name, and then I try to trace back the information [about his work] that way.

As far as the questions about work were concerned they [the survivor claimants] don't really know and I could not help them. If they knew the job their husbands did, then I could tell them what they did [specifically]. Like if they say "electrical," I can tell them that he likely worked all around the plant. My brother worked there and assigned people to work around the plant. So I could tell them what the normal procedure for that kind of work meant. In some cases, they were able to locate a relative to find out what type of work he [the employee] did.

Q. Arjun Makhijani: Did you find coworkers in all cases?

A. Ed Walker: No. We found coworkers in most cases but could not find coworkers in a few cases. Someone would call later after my calls and give us information.

Q. Arjun Makhijani: Were you present during the interviews with some of the survivors? Many?

A. Ed Walker: I have attended three or four interviews besides my own.

Q. Arjun Makhijani: How do you prepare the claimant-survivors for the interviews?

A. Ed Walker: I tell them to be honest and say what they know. So I encourage them not to just say they were in the bar mill but to say what they know and the truth.

One person I know got confused, and I had to interrupt during her interview because she was missing things. She would get emotional and lose her train of thought. Another person also lost her train of thought because the interview triggers memories. It's hard for them to bring out the information. The agent doing the interview was good. When people get emotional, I get tied up with it too, and it's very hard to continue. The interviewers are good in such situations. People know the interviewers have a job to do, and I don't feel they can do much about it. They were there to listen. They seem to be kind. This last one was exceptionally so. They were all kind. I've had people tell me that they had cold interviewers, but I haven't seen that.

Q. Arjun Makhijani: Do interviewers come across as knowing about the facilities?

A. Ed Walker: Not really. It's hard to say. I felt they were not fully aware about the facts that went on [at the plants]. Like I went over the notes from the Hamburg

meeting today. I felt there is an awful lot that they did not know. If I was going to handle the interview department, the interviewers would have been briefed about the situation. It may have made a difference during the interview.

Q. Arjun Makhijani: What do you mean situation?

A. Ed Walker: I mean the situation at Bethlehem Steel and what the people went through. Had they been briefed about the facility, whether it would have made any difference to the analysis of the dose reconstructions, I don't know. But they have to go through the procedure and do what the law tells them. It is a complaint that not many people know what went on here at Bethlehem Steel. I really think as hard as I've worked, there are a few people who really know, and I have a job to do to educate elected officials and others. But they do listen.

For the presidential advisory board, one member came up to me and he was unaware that we were unaware [at the time of the rollings] that there was uranium there. The people have to be informed and that's my job is.

Q. Arjun Makhijani: Workers and family members are asked whether they have dose data. Do they have it and if they do they give it or withhold it?

A. Ed Walker: No one here has dose data. A lot of the claimants had questions about film badges. We finally explained it to them. They kept mentioning badges, and I did not know what a film badge was. People would say I kept my dad's badge. But it was a security badge.

Q. Arjun Makhijani: Interviewers don't explain what badge they are referring to?

A. Ed Walker: It may say film badge but it means nothing to us unless you worked in a facility that used them. And children even know less than the wives. They were all little. In a lot of cases, their mothers have also passed away.

Q. Arjun Makhijani: What kind of preparation do you think survivors need to answer the questions? Is what you did sufficient? In the cases where you did not find coworkers, what happened?

A. Ed Walker: They went alone. They said, "I wish you would have gone." They wish they would have thought of the answers. Then they would ask me. Some took attorneys, which is not much help. So they can't answer the questions. They felt that it wasn't going to make a difference. These are people who did not ask for help and then commented to me about the interview.

I got two calls yesterday; they did not even know about our group. One said, "I went to a hearing, and I did not know anything about uranium." People who do not know about us go to the interviews on their own. Maybe our group should explain more. As you know, you can explain something and people can get wrong information. Maybe our group should push to have more of a process to educate people more.

Q. Arjun Makhijani: Do you think there should have been an official role for a group like yours in the interview?

A. Ed Walker: Oh yeah. Someone that is going to stand up and be honest and understand what is going on.

Q. Arjun Makhijani: How should that work?

A. Ed Walker: I would have to give some thought to that, to sleep on it. Give me a minute to write that down.

Q. Arjun Makhijani: Can we talk tonight? This interview process is supposed to feed dose reconstruction. How can the imbalance in family and worker claims be rectified to some extent?

A. Ed Walker: One idea is: If NIOSH and ORAU would take one person who is knowledgeable about the site. If they [NIOSH] would interview this person and make a summary or booklet or something simple that claimants can read, it would help a great deal. It would have information like what people from my group would know and the booklet would be mailed to the [survivor] claimants. So they would have some idea of what their husbands did. Some of them come up to me and say "how did this [uranium] get there?" and "What did they do with it?" If they just had an outline of what the workers were doing of different types. Like millwrights, engineers, office workers. If they put that in a packet and send it before the interview, say with the letter.

Q. Arjun Makhijani: Do you think the person who does the interview should know about the facility?

A. Ed Walker: Definitely. If NIOSH and ORAU is going to act on it [the information], they should. I will do some more thinking about ways to get people better prepared and talk to you later.

Q. Arjun Makhijani: Can I call you later tonight?

A. Ed Walker: At nine would be good.

Q. Arjun Makhijani: Do you know people who have complained about the process?

A. Ed Walker: Almost everyone.

Q. Arjun Makhijani: What kind of complaints have there been?

A. Ed Walker: Basically they feel, it does not mean anything – it's just a procedure.

Q. Arjun Makhijani: Can you explain that to me a little more?

A. Ed Walker: Most cases they feel that it is just a government bureaucracy, a waste of money and a waste of time, and [that the interview] is really not needed for dose reconstruction. They feel it's just a paper to give them another process to go through to procrastinate on paying their claims. Most of them feel if they spent the money paying the claims they would save money.

Q. Arjun Makhijani: Do you see a difference between the cases where you have helped and those where you have not?

A. Ed Walker: Definitely. They feel better about doing the interview, and if they did not get compensation, they are not surprised. Mostly, they don't feel that the interview affects the outcome. One person did get his award, but he does not say anything about the interview. He did have a review of his dose reconstruction, and we like to think we made a difference. But I don't think they [the claimants] think it [the interview] makes a difference.

Q. Arjun Makhijani: Does NIOSH call coworkers in case of survivor applicants?

A. Ed Walker: To date, I have not heard of a single witness [i.e., coworker] that has been interviewed.

Q. Arjun Makhijani: How many names have you supplied [of] witnesses [coworkers]?

A. Ed Walker: A lot of them. I told people where to find them. I would tell them how to find them, and they would tell me we found them. I would say put them down for interviews. I think we identified 15 or 20 coworkers. But it has been brought out that they have not interviewed witnesses [coworkers]. I myself had furnished four coworker witnesses on April 23, 2003. And to date, November 23, 2004, not one of them has been contacted by NIOSH. We have discussed this in meetings. We have 100 to 200 people in meetings, and I have never heard one of them say they that they [NIOSH/ORAU] interviewed a witness.

Q. Arjun Makhijani: Do you think it would make a difference if the interviewer were more scientifically qualified?

A. Ed Walker: I don't think interviewers are scientifically qualified. They are there to take the story. When they start the interview, we are told they will not answer any questions about the dose reconstruction methodology — that they are not allowed to talk about it.

Q. Arjun Makhijani: Can you repeat that? I want to make sure I got it right.

A. Ed Walker: They say they are not allowed to talk about methodology and that we are not allowed to challenge that. That's the way they put it. I don't remember them telling me that in my case. But now they seem to be doing it. First time I heard about it was in February [2004]. Someone also brought this out at a meeting of our group [Bethlehem Steel Action Group].

Q. Arjun Makhijani: Do you think it would help if the interviewers were qualified scientifically?

A. Ed Walker: No.

Q. Arjun Makhijani: Why?

A. Ed Walker: I don't think so because what they could do was argue. If they are just taking notes, it wouldn't make any difference. They send us a letter with the qualifications of the person who does the dose reconstruction. But that doesn't do much. How would we know how to pick [a dose reconstructor] or know whether they had the right qualifications?

Q. Arjun Makhijani: But if they were willing to tell you about how dose reconstruction works? Would it help?

A. Ed Walker: No, because most people won't understand it. I listened to it for two days down in Cincinnati. I told Larry Eliot I will tell the group what I learned from the dose reconstruction seminar for two days, and it will be very condensed. I do understand it better, but I don't want to give a class on it in the near future!

Q. Arjun Makhijani: Anything else for now?

A. Ed Walker: No.

Q. Arjun Makhijani: Let's talk again later.

Interview Followup on September 27, 2004, with Ed Walker
Discussion Topic: Other Ways to Improve the Process

Ed Walker: The way they presented the applications can be improved. The information that there was a compensation program was on the news and people filled out the applications, and they did not have information about the program. They should place someone in the community with knowledge of the site so that they can help claimants fill out the forms properly from the site. The person can be from the community or from the government. They would be there to answer questions from the people.

Arjun Makhijani: This is helpful. Thanks so much.

End of interview.

Permission to publish interview, provided by Ed Walker by fax, November 23, 2004, was as follows:

I Edwin Walker give Mr. Arjun Makhijani full permission to publish this interview and the use of my name as he pleases.

Signed

Edwin Walker

ATTACHMENT 5-3: INTERVIEW WITH ORAU CLAIMANT INTERVIEW STAFF ON JANUARY 7, 2005

Presented below is an interview with ORAU Team Claimant Interviewer conducted by Kathryn Robertson-DeMers, SC&A, on January 7, 2005, in the presence of a Claimant Interview Supervisor. This interview was performed to assess the implementation of the claimant interview procedures and verify training.

Note: This is not a verbatim transcript but paraphrases the conversation in the form of questions (denoted as Q) and answers (denotes as A), along with a report of the substance of what was said. The Claimant Interviewer who participated in this discussion was selected randomly from a list of five. A Claimant Interview Supervisor participated in the interview to answer general questions about the program. The names of the individuals participating in this interview have been deleted to protect their privacy.

Q. Kathryn Robertson-DeMers: What is your educational background?

A. ORAU Staff: The Staff member interviewed held a B.S. in Science. This is typical of all the interviewers.

Q. Kathryn Robertson-DeMers: What is your employment background? Have you ever worked at a DOE facility or a facility where radioactive material was handled? Is your background typical of other interviewers?

A. ORAU Staff: The Staff member interviewed indicated that she had previously worked at the Fernald site. Seven of the 12 claimant interviewers had worked at DOE sites, with an average of 15 years worked at DOE sites per interviewer.

Q. Kathryn Robertson-DeMers: What training is provided to you? Does this training include radiation protection principles and information on the dose reconstruction process?

A. ORAU Staff: ORAU provides interviewers with extensive training, including classes in the following topics.

- Freedom of Information Act
- Privacy Act
- Radiological Contamination Regulations and Protection Principles (basic principles of radiation and radiological regulations)
- Radiological Protection Fundamental and Protection Concepts
- Effective Communication
- Effective Telephone Communication

- EEOICPA NIOSH Project Overview
- Biological Effects of Radiation Exposure
- Methods of Radiation Contamination Measurements
- Occupational and Environmental Radiation Protection

Some of those who worked at DOE sites have also completed Radiological Worker Training at the DOE site.

Q. Kathryn Robertson-DeMers: Have terms and phrases such as chelation therapy, incident, dosimeter, and radiation-generating equipment been defined for you? If so, are you able to define these terms for the claimant?

A. ORAU Staff These terms are defined for the Claimant Interview Staff in the training provided to them by ORAU. There are occasions where the claimant is not familiar with these terms. In general, DOE employees know these terms. Approximately half of the AWE employees are familiar with these terms. The survivor claimants have difficulty with some of these terms and the interviewer has to explain them in layman's terms.

Q. Kathryn Robertson-DeMers: Are you allowed to ask additional questions outside those on the claimant interview forms? If so, are there limitations to these questions?

A. ORAU Staff The interviewer is allowed to ask clarifying or verification questions. For example, if the claimant answers yes to Question 13, "Were you ever restricted from the workplace or certain job duties because you had reached a radiation dose limit?," the interviewer may follow up on this question by asking if the energy employee was involved in an incident. Typically, the interviewers strictly follow the script. There are some questions that they are not allowed to ask, such as about an individual's smoking history.

Q. Kathryn Robertson-DeMers: Is the claimant work history record available during the interview? Is the radiation exposure record available during the interview? What other records are made available to you for the interview?

A. ORAU Staff The interviewer has access to the Department of Labor initial case file and any correspondence to date. Radiological records are available to the interviewer if they have been uploaded into the NOCTS system.

Q. Kathryn Robertson-DeMers:	Do you perform coworker interviews? Is there a procedure for coworker interviews? How are coworker interviews documented?
A. ORAU Staff	They have completed approximately twelve coworker interviews. NIOSH requested all but one of the coworker interviews. The other was requested by a Health Physicist. Version 1 (covered employee) of the interview is modified for the purposes of coworker interviews by putting the interview in third person. All coworker interviews completed to date have been done on behalf of a survivor.
Q. Kathryn Robertson-DeMers:	Do you perform closing interviews following completion of the dose reconstruction? If yes, how are these interviews documented? If no, are others responsible for these interviews?
A. ORAU Staff	After the claimant receives a copy of the completed dose reconstruction, a Closing Interview is performed. There is a new draft procedure for this process. The Closing Interview process is relatively new and has been implemented within the last year. In general, the interviewer uses the dose reconstruction report as a guide to conduct these interviews. These interviews vary in length depending on the number of questions the claimant has.
Q. Kathryn Robertson-DeMers:	Do Health Physicists routinely review interviews? Are interviews returned to the interviewers by the Health Physicists for correction and/or follow up? What other quality assurance is in place to insure consistency, accuracy and completeness of interviews?
A. ORAU Staff:	The Health Physics review team is responsible for providing quality assurance. The documented interview is provided to review team upon completion. This team reviews the interview for completeness, accuracy, and editorial error. Usually the interviews are referred back to the interviewer due to editorial errors. Occasionally there will be a clarification question. For example, the Health Physicist will want the interviewer to delineate between a direct quote and a paraphrased statement. This process is completed prior to sending the interview to the claimant for review and comment.

Q. Kathryn Robertson-DeMers: What percentage of claimants decline the interview? Is this primarily energy employees or survivors?

A. ORAU Staff: Approximately 1% of the energy employees and 7% of the survivors decline the interview. These numbers include those who initially decline, then later decide they want to participate in an interview. For some claimants, the process is too emotional. In other instances, survivors do not know what the energy employee did as a part of their job.

Q. Kathryn Robertson-DeMers: Tell me about the 1-800 number and what service it provides.

A. ORAU Staff: There are two staff members that man the 1-800 numbers. Voice mail is available for claimants who are not able to get through to ORAU staff immediately. The staff responds to these messages as soon as possible. Phone calls are documented in the NOCTS phone log.

Overall the CATI program is felt to be very consistent.

6.0 QUALITY ASSURANCE PLANS

6.1 ORAUT-PLAN-0001 — QUALITY ASSURANCE PROGRAM PLAN

The review of ORAUT-PLAN-0001, *Quality Assurance Program Plan*, Rev. 0, dated January 30, 2003, was prepared by Steve Ostrow, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

6.1.1 Purpose of Plan

The stated purpose of this document is ". . . to provide guidelines to assure quality of program activities associated with the ORAU Team NIOSH Dose Reconstruction Project."

6.1.2 Review Protocol

Our evaluation of ORAUT-PLAN-0001, *Quality Assurance Program Plan*, is summarized in Table 6.1-1 below. Table 6.1-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

6.1.3 General Comments

The Quality Assurance Program Plan (QAPP) applies to all corporate and individual participants and all aspects of the ORAU-team dose reconstruction project. The QAPP contains sections on purpose, project description, scope, references, objectives, organization, responsibilities, qualifications, training, document control, non-conformance and corrective action, and management assessment and audits. The ORAU QAPP meets the standards for such a document.

Table 6.1-1 QA Document Compliance Checklist

Document No.: ORAUT-PLAN-0001, Rev. 0	**Effective Date:** 1/30/03
Document Title: Quality Assurance Program Plan	
Reviewer: Stephen Ostrow	

No.	Question	Y/N	Comments
1.0	**Quality Assurance Program Plan (QAPP)**		
1.1	Have the organizations originating the procedures and related documents established a QA program appearing in a Quality Assurance Program Plan (QAPP), and do the implementing documents reflect higher-level regulatory and project requirements and nuclear industry good practices?	Y	This document is the ORAU Team QAPP. Regulatory & guidance documents are referenced in Section 4.
1.2	When more than one organization is involved in the execution of activities, are the responsibilities and authorities of each organization clearly established in the QAPP to the extent necessary to smoothly perform the activities?	Y	The QAPP identifies team members, applies to the entire team, and discusses organization in Section 6.
1.3	Does the QAPP identify the management position responsible for QA development, implementation, assessment, and improvement?	Y	Quality Assurance Manager (Section 7.2) and individual task managers (Sections 7.3-7.8)
1.3.1	Are there adequate procedures for assuring that personnel performing project tasks have proper levels of experience and education?	Y	Section 8 covers personnel qualifications.
1.4	Are there adequate procedures for training of project personnel?	Y	Section 8 covers personnel training.
1.4.1	Have staff training requirements been identified?	Y	Section 8 covers personnel training.
1.4.2	Has staff received general orientation training?	?	Section 8.7.1 requires such training. However, compliance has not been verified.
1.4.3	Has staff received training in the requirements of the Privacy Act of 1974 and the Freedom of Information Act?	?	Section 8.7.2 requires such training. However, compliance has not been verified.
1.4.4	Has staff received training in the provisions of the QAPP?	?	Section 8.7.3 requires such training. However, compliance has not been verified.
1.4.5	Is a master record of staff training maintained in project files?	?	Section 8.5 requires such documentation. However, compliance has not been verified.

No.	Question	Y/N	Comments
1.5	Are there adequate procedures for Management and QA surveillance, inspection, and audit of work products and processes to achieve continuous quality improvement?	Y	Section 18 lists management assessments and audit procedures.
1.6	Do procedures provide for adequate corrective action for identified deficiencies and non-conformances in work products and processes?	Y	Section 16 covers non-conformance and corrective action.
1.7	Is there an adequate procedure for the maintenance of project QA records in identifiable, legible, and retrievable condition?	Y	Section 17 covers QA records.
1.8	Are there procedures covering all work activities of the project?	Y	Section 3 lists the processes governed by the QAPP.
2.0	**Individual Procedures and Documents**		
2.1	Is the procedure or document properly identified by title, document number, revision number, and date?	Y	
2.2	Do the title, document number, revision number, page number, and date appear on each page?	N	Title appears only on first page; however, the other items unambiguously identify the document.
2.3	Has the procedure been reviewed and approved by an independent reviewer familiar with the subject matter?	Y	Reviewed and approved by Project Director and OCAS Administrator.
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	Y	
2.5	Are revisions clearly indicated on affected pages?	N/A	This document is Rev. 0.
2.6	Are all abbreviations, acronyms, and technical terms, which may not be generally known by the average reader, adequately defined in the text or in a separate section?	Y	In text.
2.7	Are all scientific and engineering constants, values, equations, and assumptions, which may not be known by the average reader, clearly presented and referenced?	N/A	Not in QAPP.

6.1.4 Review Comments

The following observations are made about the QAPP:

(1) Section 4.8: The Privacy Act is incorrectly referenced. The correct citation is "5 U.S.C. 552a, as amended."

(2) Section 4.9: The Freedom of Information Act is incorrectly referenced. The correct citation is "5 U.S.C. 552, as amended."

(3) Since the QAPP is a high-level procedure, perhaps it should include a list of specific implementing procedures that it covers. Section 3 of the QAPP mentions processes covered by the QAPP, but not the specific procedures. The list could be included as an attachment, which could be revised as required.

(4) Checklist questions 1.4.2 through 1.4.5 relate to training. The ORAU QAPP covers training adequately in Section 8, but the checklist questions ask about implementation of the procedures. Answers to these questions would require an audit/inspection of the ORAU records, which is not in the scope of this review.

6.2 ORAUT-PLAN-0002 — INTERNAL MANAGEMENT REVIEW PLAN

The review of ORAUT-PLAN-0002, *Internal Management Review Plan*, Rev. 01, dated March 6, 2003, was prepared by Steve Ostrow, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

6.2.1 Purpose of Plan

The stated purpose of this document is ". . . to provide guidance for the conduct of internal management reviews of activities associated with the ORAU Team Dose Reconstruction Project for NIOSH and to serve as a charter for the project's Internal Management Review Team."

6.2.2 Review Protocol

Our evaluation of ORAUT-PLAN-0002, *Internal Management Review Plan*, is summarized in Table 6.2-1 below. Table 6.2-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

6.2.3 General Comments

The Internal Management Review Plan provides guidance for conducting semiannual internal management reviews, scheduled 1 month in advance of the NIOSH-OCAS semiannual project performance reviews. The Plan provides adequate guidance to the review team regarding purpose, scope, references, responsibilities, review team membership, meetings, reviews, records, and applicable documents. The Plan also includes a four-page checklist, providing guidance for internal management reviews. The checklist covers many of the areas of the QAPP.

It contains sections on organizational structure, staffing, facilities, equipment, safety management, polices and procedures, training, financial management, conflict of interest management, privacy act and confidentiality, quality assurance, production, and follow-up of previous findings.

Table 6.2-1 QA Document Compliance Checklist

Document No.: ORAUT-PLAN-0002, Rev. 01	**Effective Date:** 3/6/03
Document Title: Internal Management Review Plan	
Reviewer: Stephen Ostrow	

No.	Question	Y/N	Comments
1.0	**Quality Assurance Program Plan (QAPP)**		
1.1	Have the organizations originating the procedures and related documents established a QA program appearing in a Quality Assurance Program Plan (QAPP), and do the implementing documents reflect higher-level regulatory and project requirements and nuclear industry good practices?	N/A	
1.2	When more than one organization is involved in the execution of activities, are the responsibilities and authorities of each organization clearly established in the QAPP to the extent necessary to smoothly perform the activities?	N/A	
1.3	Does the QAPP identify the management position responsible for QA development, implementation, assessment, and improvement?	N/A	
1.3.1	Are there adequate procedures for assuring that personnel performing project tasks have proper levels of experience and education?	N/A	
1.4	Are there adequate procedures for training of project personnel?	N/A	
1.4.1	Have staff training requirements been identified?	N/A	
1.4.2	Has staff received general orientation training?	N/A	
1.4.3	Has staff received training in the requirements of the Privacy Act of 1974 and the Freedom of Information Act?	N/A	
1.4.4	Has staff received training in the provisions of the QAPP?	N/A	
1.4.5	Is a master record of staff training maintained in project files?	N/A	
1.5	Are there adequate procedures for Management and QA surveillance, inspection, and audit of work products and processes to achieve continuous quality improvement?	N/A	

No.	Question	Y/N	Comments
1.6	Do procedures provide for adequate corrective action for identified deficiencies and non-conformances in work products and processes?	N/A	
1.7	Is there an adequate procedure for the maintenance of project QA records in identifiable, legible, and retrievable condition?	N/A	
2.0	**Individual Procedures and Documents**		
2.1	Is the procedure or document properly identified by title, document number, revision number, and date?	Y	
2.2	Do the title, document number, revision number, page number, and date appear on each page?	N	Title appears only on first page; however, the other items unambiguously identify the document.
2.3	Has the procedure been reviewed and approved by an independent reviewer familiar with the subject matter?	Y	Reviewed and approved by Project Director and OCAS Administrator.
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	Y	
2.5	Are revisions clearly indicated on affected pages?	N/A	Revision log notes that Rev. 01 is the first approved issue.
2.6	Are all abbreviations, acronyms, and technical terms, which may not be generally known by the average reader, adequately defined in the text or in a separate section?	Y	In text.
2.7	Are all scientific and engineering constants, values, equations, and assumptions, which may not be known by the average reader, clearly presented and referenced?	N/A	

6.2.4 Review Comments

The Internal Management Review Plan provides adequate guidance for the conduct of such reviews.

6.3 ORAUT-PLAN-0003 — INFORMATION SYSTEMS QUALITY ASSURANCE PLAN

The review of ORAUT-PLAN-0003, *Information Systems Quality Assurance Plan*, Rev. 00, dated October 30, 2003, was prepared by Steve Ostrow, PhD, and approved by John Mauro, PhD, CHP, on January 11, 2005.

6.3.1 Purpose of Plan

The stated purpose of this document is ". . . to provide a framework for attesting to the quality of data and information management practices used in activities associated with the ORAU (Oak Ridge Associated Universities) Team NIOSH (National Institute of Occupational Safety and Health) Dose Reconstruction Project."

6.3.2 Review Protocol

Our evaluation of ORAUT-PLAN-0003, *Information Systems Quality Assurance Plan*, is summarized in Table 6.3-1 below. Table 6.3-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

6.3.3 General Comments

The Information Systems Quality Assurance Plan (IS QA Plan) provides guidance for the development of information management practices and procedures to maintain quality of data throughout the project processes and to assure that calculations are performed accurately and consistently. The plan contains sections on purpose, scope, information systems QA program objectives, organization, responsibilities, audits, qualifications and training, QA reports, corrective actions, references, and applicable documents. The IS QA Plan provides adequate guidance on how to design an effective system of information management.

Table 6.3-1 QA Document Compliance Checklist

Document No.: ORAUT-PLAN-0003, Rev. 00	**Effective Date:** 10/30/03
Document Title: Information System Quality Assurance Plan	
Reviewer: Stephen Ostrow	

No.	Question	Y/N	Comments
1.0	**Quality Assurance Program Plan (QAPP)**		
1.1	Have the organizations originating the procedures and related documents established a QA program appearing in a Quality Assurance Program Plan (QAPP), and do the implementing documents reflect higher-level regulatory and project requirements and nuclear industry good practices?	N/A	
1.2	When more than one organization is involved in the execution of activities, are the responsibilities and authorities of each organization clearly established in the QAPP to the extent necessary to smoothly perform the activities?	N/A	
1.3	Does the QAPP identify the management position responsible for QA development, implementation, assessment, and improvement?	N/A	
1.3.1	Are there adequate procedures for assuring that personnel performing project tasks have proper levels of experience and education?	N/A	
1.4	Are there adequate procedures for training of project personnel?	N/A	
1.4.1	Have staff training requirements been identified?	N/A	
1.4.2	Has staff received general orientation training?	N/A	
1.4.3	Has staff received training in the requirements of the Privacy Act of 1974 and the Freedom of Information Act?	N/A	
1.4.4	Has staff received training in the provisions of the QAPP?	N/A	
1.4.5	Is a master record of staff training maintained in project files?	N/A	
1.5	Are there adequate procedures for Management and QA surveillance, inspection, and audit of work products and processes to achieve continuous quality improvement?	N/A	
1.6	Do procedures provide for adequate corrective action for identified deficiencies and non-conformances in work products and processes?	N/A	
1.7	Is there an adequate procedure for the maintenance of project QA records in identifiable, legible, and retrievable condition?	N/A	

No.	Question	Y/N	Comments
1.8	Are there procedures covering all work activities of the project?	N/A	
2.0	**Individual Procedures and Documents**		
2.1	Is the procedure or document properly identified by title, document number, revision number, and date?	Y	
2.2	Do the title, document number, revision number, page number, and date appear on each page?	N	Title appears only on first page; however, the other items unambiguously identify the document.
2.3	Has the procedure been reviewed and approved by an independent reviewer familiar with the subject matter?	Y	Reviewed and approved by Project Director and OCAS Administrator.
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	Y	
2.5	Are revisions clearly indicated on affected pages?	N/A	Revision log notes that Rev. 0 is the first approved issue.
2.6	Are all abbreviations, acronyms, and technical terms, which may not be generally known by the average reader, adequately defined in the text or in a separate section?	Y	In text.
2.7	Are all scientific and engineering constants, values, equations, and assumptions, which may not be known by the average reader, clearly presented and referenced?	N/A	

6.3.4 Review Comments

The following observation is made about the IS QA Plan:

Section 5.1: It is not clear whom the position "Quality Assurance Analyst" refers to. The QAPP refers to a "QA Manager." Are the "Quality Assurance Analyst" and the "QA Manager" the same person? If so, the title should be amended in the IS QA Plan, and, if not, an explanation should be provided.

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7.0 DOCUMENTATION/RECORDS MANAGEMENT

7.1 OCAS-TIB-004 — NAMING CONVENTIONS

The review of OCAS-TIB-004, *Naming Conventions*, Rev. 1, dated October 3, 2003, was prepared by Kathleen Behling, and approved by John Mauro, PhD, CHP, on January 11, 2005.

7.1.1 Purpose of Technical Information Bulletin

The stated purpose of the Technical Information Bulletin (TIB) entitled *Naming Conventions*, OCAS-TIB-004, Rev. 1, is to define ". . . the naming conventions for documents used to create the Administrative Record (AR)."

7.1.2 Review Protocol

Our evaluation of OCAS-TIB-004, *Naming Conventions,* is summarized in Table 7.1-1 below. Table 7.1-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

7.1.3 General Comments

Naming conventions are used to create a unique identifier for grouping and sorting large quantities of information. The primary goal of adopting a naming convention is to easily identify the type and purpose of the information, which is typically stored in a database. A practical, logical, unambiguous, and consistent set of rules should, therefore, be established for producing names for these database elements. In the case of this TIB, naming conventions are required for tracking the various types of documents used to create a claimant's Administrative Record.

The types of documents included in the Administrative Record (AR) have been categorized into five directories: (1) Dose Reconstruction (DR) Files, (2) Correspondence, (3) DOE Files, (4) DOL Files, and (5) Appeal Files. Each directory consists of at least one sub-directory, as specified below:

- Dose Reconstruction Files
  - Living Energy Employee
  - Survivor to the Energy Employee
  - Survivor to the Energy Employee with Authorized Representative or Power of Attorney (POA)
  - Energy Employee with Authorized Representative or Power of Attorney
  - Modification of IEP Files

- Correspondence
  - Living Energy Employee
  - Survivor to the Energy Employee
  - Survivor to the Energy Employee with Authorized Representative or Power of Attorney (POA)
  - Energy Employee with Authorized Representative or Power of Attorney

- DOE Files
  - All Claims

- DOL Files
  - Living Energy Employee

- Appeal Files
  - All Case Types

Section 1.0 of the *Naming Conventions* TIB includes definitions and information on abbreviations, formatting, version numbers, and dose reconstruction drafts. Section 2.0 defines the naming requirements. The remaining sections (3.0 through 6.0) provide examples of names that have been assigned to documents included in the AR under the Correspondence, DOE Files, DOL Files, and Appeal Files directories.

Table 7.1-1. Procedure Review Outline/Checklist

Document No.: OCAS-TIB-004	**Effective Date:** 10/03/2003
Document Title: Naming Conventions	
Reviewer: Kathleen Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	4	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	4	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	N/A	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	4	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations:**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant:**		
5.1	Is the procedure claimant-favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant-favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant-favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

7.1.4 Review Comments

The only objectives that are applicable to OCAS-TIB-004 *Naming Conventions* correspond to four of the five questions identified under Section 1.0 of the Table 7.1-1 checklist. Section 1.0 objectives are designed to "determine the degree to which the procedures support a process that is expeditious and timely for dose reconstruction." Comments associated with the rating of applicable questions are presented below:

Review Objective 1.1

This technical information bulletin is generally written in a concise, clear format. However, it was given a rating of 4 (frequently), because it was noted that an acronym identified in the Correspondence directory, "PHA," is not defined under the abbreviations. In addition, the "Energy Employee with Authorized Representative or POA" sub-directory is given a "survivor identification number," which does not appear to be necessary and is not used in the naming convention.

Review Objective 1.2

The TIB establishes the requirements for naming applicable AR documents in a manner that follows a logical sequence and was given the highest rating of 5 (Always or Yes).

Review Objective 1.3

The TIB contains all necessary basic information for the reader to establish a logical, unique document name for each of the AR sub-directory elements. However, Objective 1.3 was given a rating of 4 (Frequently), since (as mentioned in Objective 1.1) the data was incomplete in the area of providing all necessary abbreviations, namely "PHA."

Review Objective 1.5

Although a TIB is not designed to be as prescriptive as other types of documents, such as a procedure, the *Naming Conventions* TIB contained very limited discussions/descriptions regarding its purpose and the examples presented. Therefore, Objective 1.5 was given a rating of 4 (Frequently), since data interpretation could have been improved by providing a more descriptive purpose and a brief opening statement prior to presenting naming convention examples.

7.2 ORAUT-PLAN-004 — RECORDS AND INFORMATION MANAGEMENT PLAN

The review of ORAUT-PLAN-004, *Records and Information Management Plan,* Rev. 00, dated January 6, 2004, was prepared by Kathleen Behling, and approved by John Mauro, PhD, CHP, on January 11, 2005.

7.2.1 Purpose of Plan

Section 1.0 of ORAUT-PLAN-0004 presents the purpose of this document as follows:

> *The purpose of the ORAU Team Dose Reconstruction and Project Records and Information Management Plan is to provide the requirements and responsibilities for a functional records and information management system with the ORAU Team Dose Reconstruction Project. Through implementing procedures, this system will govern the functions necessary to identify, collect, receive, process, control, retain, protect, and disposition all project records and project documents.*

7.2.2 Review Protocol

Our evaluation of ORAUT-PLAN-0004, *Records and Information Management Plan,* is summarized in Table 7.2-1. Table 7.2-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

7.2.3 General Comments

The *Records and Information Management Plan* is an upper-tier document that clearly states the objectives, organization, responsibilities, and general requirements for managing project records. The plan presents all elements necessary for establishing a functional and comprehensive information management system, as summarized below:

- Scope – The records management system will ensure that (1) appropriate records are preserved, (2) appropriate records are retained and records that do not require retention are disposed of, (3) records are protected from damage, loss, and unauthorized disclosure, (4) the distribution of records is controlled, (5) project commitments are tracked and monitored, (6) a centralized location is established for maintaining records, (7) personnel are trained on records and information management policies and procedures, and (8) records are reviewed for compliance with policies and procedures. The plan applies to all project records, documents, controlled documents, official correspondence generated or received, and commitments to the client.

- Objectives –To accomplish the goals of the Records Management Program, the plan identifies five objectives, summarized as follows:

  (1) Control and protect information that has administrative, legal, research, operational, and historical value

  (2) Provide for an effective Records Management Program through personnel orientation and training

(3) Establish and maintain systems to carry out an effective and efficient Records Management Program

(4) Provide a process for initiation, preparation, review and approval, distribution, receipt, revision, and use of controlled project documents

(5) Ensure that established deliverables and commitments are properly monitored and managed

- Organization – The plan provides an organizational chart consisting of personnel within the Records Management Program.
- Responsibilities – The plan presents a comprehensive list of responsibilities for the Project Director, Project Records Manager, Task Managers, Quality Assurance Manager, Records Custodians, Project Personnel, and Cincinnati Operations Center (COC) Records Center.
- General Requirements – Requirements are identified for establishing and documenting all aspects of the records management system, such as document identification, retention, protection, and disposition; personnel training; records safeguards, etc.
- Applicable Documents – A comprehensive list of applicable Code of Federal Regulations and United States Codes is provided.
- Definitions and Acronyms – Definitions of key terminology and acronyms are presented in this section.

Table 7.2-1. Procedure Review Outline/Checklist

Document No.: ORAUT-PLAN-0004	**Effective Date:** 01/06/2004
Document Title: Records and Information Management Plan	
Reviewer: Kathleen Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	See Checklist Comments Section
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	See Checklist Comments Section
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	See Checklist Comments Section
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	N/A	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	See Checklist Comments Section
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations:**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant:**		
5.1	Is the procedure claimant-favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant-favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant-favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

7.2.4 Review Comments

The only checklist objectives that are applicable to ORAU's *Records and Information Management Plan* are those listed under Section 1.0 of Table 7.2-1. Objectives addressed in Section 1.0 are designed to evaluate the style, clarity, logical sequence, and prescriptive nature of the plan. In each of these areas, the plan received the highest rating of 5 (Yes or Always). Our review concluded that the plan archives, in a clear and comprehensive manner, the objectives, organization, responsibilities, and general requirements for a functional records and information management system.

7.3 ORAUT-PROC-0001 — DOCUMENT PROGRAM

The review of ORAUT-PROC-001, *Document Program*, Rev. 01, dated October 6, 2003, was prepared by Kathleen Behling, and approved by John Mauro, PhD, CHP, on January 11, 2005.

7.3.1 Purpose Of Procedure

The stated purpose of this procedure is ". . . to provide the process for the development, revision, cancellation, and control of documents generated by the ORAUT Team Dose Reconstruction Project for NIOSH." Documents included in the scope of this procedure include plans, procedures, technical basis documents, implementation guides, forms, tables and figures, training materials, and reports. The procedure does not apply to the NIOSH Report of Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) or the NIOSH EEOICPA Dose Reconstruction Telephone Interview report.

7.3.2 Review Protocol

Our evaluation of ORAUT-PROC-001, *Document Program,* is summarized in Table 7.3-1 below. Table 7.3-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

7.3.3 General Comments

As defined within the scope of *Document Program,* procedures are ". . . comprehensive step-by-step requirements for accomplishing work activities that typically are well defined." This procedure provides an example of a comprehensive step-by-step set of instructions for completing a specific activity, namely the development, revision, cancellation, and control of key documents used in the dose reconstruction process.

To ensure that documents are created, modified, reviewed, and retired in a consistent and controlled manner, the procedure addresses the following key elements:

- Scope – Definitions are provided for the primary types of documents addressed in this procedure (i.e., plans, project operating documents, procedures, technical basis

documents, implementation guides, forms, tables and figures, reports). This section also discusses how to handle documents that have been approved prior to the issuing of this procedure.

- Responsibilities - Four individuals with the functional title of Document Owner, Document Coordinator, Subject Expert, and NIOSH Quality Assurance Technical Contact are identified as being responsible for meeting the requirements of the *Document Program* procedure.
- Procedural Instructions – Responsible individuals are given step-by-step instructions for the following activities:
  - Establishing a New Document Identification
  - Development of a New Document
  - Revision of an Existing Document
  - Reviewing a Document
  - Resolution of Document Comments
  - Document Approval Process and Issue Preparation
  - Cancellation of a Document
  - Preparation of Document Issue/Revision/Cancellation Notice
  - Conducting Biennial Reviews
- Records and Applicable Documents – The procedure identifies all documents that are relevant to requirements of this procedure, as well as records and standardized forms that may be generated as a result of document processes presented in the procedure.
- Definitions – Definitions are provided for key terminology and functional organizational positions (e.g., document coordinator) who are responsible for implementing this procedure.
- Attachments – Four attachments are included in the procedures, which provide responsible individuals with (1) a definitive description of the document format for procedures, (2) an example of ORAU Team procedures, (3) step-by-step instructions for a page change notice, and (4) an example of a page change notice.

Table 7.3-1. Procedure Review Outline/Checklist

Document No.: ORAUT-PROC-0001	**Effective Date:** 10/06/2003
Document Title: Document Program	
Reviewer: Kathleen Behling	

No.	Description of Objective	Rating 1-5*	Comments
1.0	**Determine the degree to which the procedure supports a process that is expeditious and timely for dose reconstruction.**		
1.1	Is the procedure written in a style that is clear and unambiguous?	5	See Review Comments
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	5	See Review Comments
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	5	See Review Comments
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	N/A	
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	5	See Review Comments
2.0	**Determine whether the procedure provides adequate guidance to be efficient in instances where a more detailed approach to dose reconstruction would not affect the outcome.**		
2.1	Does the procedure provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim?	N/A	
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	N/A	
3.0	**Assess the extent to which the procedure accounts for all potential exposures and ensures that resultant doses are complete and based on adequate data in instances where the POC is not evidently clear.**		
3.1	Assess quality of data sought via interview:	----	
3.1.1	Is scope of information sufficiently comprehensive?	N/A	
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?	N/A	
3.1.3	Does the interview process demonstrate objectivity and is it free of bias?	N/A	
3.1.4	Is the interview process sensitive to the claimant?	N/A	
3.1.5	Does the interview process protect information as required under the Privacy Act?	N/A	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

No.	Description of Objective	Rating 1-5*	Comments
3.2	Assess whether the procedure adequately addresses generic as well as site-specific data pertaining to:	----	
3.2.1	Personal dosimeters (e.g., film, TLD, PICs)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	N/A	
3.2.4	Unmonitored periods of exposure	N/A	
4.0	**Assess procedure for providing a consistent approach to dose reconstruction regardless of claimants' exposures by time and employment locations:**		
4.1	Does the procedure support a prescriptive approach to dose reconstruction?	N/A	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	N/A	
5.0	**Evaluate procedure with regard to fairness and giving the benefit of the doubt to the claimant:**		
5.1	Is the procedure claimant-favorable in instances of missing data?	N/A	
5.2	Is the procedure claimant-favorable in instances of unknown parameters affecting dose estimates?	N/A	
5.3	Is the procedure claimant-favorable in instances where claimant was not monitored?	N/A	
6.0	**Evaluate procedure for its ability to adequately account for the uncertainty of dose estimates.**		
6.1	Does the procedure provide adequate guidance for selecting the types of probability distributions (i.e., normal, lognormal)?	N/A	
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	N/A	
7.0	**Assess procedure for striking a balance between the need for technical precision and process efficiency.**		
7.1	Does the procedure require levels of detail that can reasonably be accounted for by the dose reconstructor?	N/A	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	N/A	

* Rating System of 1 through 5 correspond to the following: 1=No (Never), 2=Infrequently, 3=Sometimes, 4=Frequently, 5=Yes (Always). N/A indicates not applicable.

7.3.4 Review Comments

The only objectives that are applicable to ORAU's *Program Document* procedure are those listed under Section 1.0 of Table 7.3-1. Objectives addressed in Section 1.0 are designed to evaluate the style, clarity, logical sequence, and prescriptive nature of the procedure. In each of these areas, the procedure received the highest rating of 5 (Yes or Always). Our review concluded that the procedure provides clear, concise, comprehensive, and definitive instructions to those individuals responsible for the development, revision, cancellation, review, and tracking of key documents generated in behalf of the dose reconstruction process.

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