SC&A S. COHEN & ASSOCIATES
AN EMPLOYEE-OWNED COMPANY

June 8, 2006

Mr. David Staudt
Centers for Disease Control and Prevention
Acquisition and Assistance Field Branch
Post Office Box 18070
626 Cochrans Mill Road – B-140
Pittsburgh, PA 15236-0295

Subject: Contract No. 200-2004-03805**,** Task Order 3: The Review of NIOSH/ORAU Procedures and Methods Used for Dose Reconstruction

Dear Mr. Staudt:

SC&A is please to submit to NIOSH and the Board the enclosed draft supplemental report entitled, *The Review of NIOSH/ORAU Procedures and Methods Used for Dose Reconstruction, Supplement 1*. This report fulfills, in part, the scope of work for Task Order 3 as authorized by the Board in Modification No. 6, dated August 30, 2005. This report presents a review of 30 procedures. Not included in the report are the reviews of two procedures dealing with Computer Assisted Telephone Interviews (i.e., ORAUT-OTIB-0090 and ORAUT-OTIB-0092). A review of those procedures will be provided as a supplement within a few weeks. Included in the review of the procedures are the reviews of three workbooks. We are currently working on a separate deliverable dedicated to the review of workbooks, as required by Modification No.6. That deliverable will include the review of the full suite of workbooks, along with the three workbooks included in the enclosed deliverable.

SC&A will be prepared to provide the Board with a summary of the enclosed report at the upcoming full Board meeting in Washington, DC, and begin the issues-closeout process, as directed by the working group. I would like to point out that the vast majority of the reviews are favorable, and I believe the closeout process should be able to proceed expeditiously.

Sincerely,

John Mauro, PhD, CHP
Project Manager

cc: P. Ziemer, PhD, Board Chairperson
Advisory Board Members
L. Wade, PhD, NIOSH
L. Elliott, NIOSH
J. Neton, PhD, NIOSH
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K. Behling. SC&A
Project File (ANIOS/003)

Draft Report

NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH

ADVISORY BOARD ON RADIATION AND WORKER HEALTH

TASK 3

REVIEW OF NIOSH/ORAUT PROCEDURES AND METHODS USED FOR DOSE RECONSTRUCTION
Supplement 1

Contract No. 200-2004-03805

Prepared by

S. Cohen & Associates
6858 Old Dominion Drive, Suite 301
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June 8, 2006

S. Cohen & Associates: ***Technical Support for the Advisory Board on Radiation and Worker Health Review of NIOSH Dose Reconstruction Program***	Document No. SCA-TR-TASK3 Supplement 1 Effective Date: Draft – June 8, 2006, Supplement 1 Revision No. 0
REVIEW OF NIOSH/ORAUT PROCEDURES AND METHODS USED FOR DOSE RECONSTRUCTION	Page 2 of 194
Task Manager: _____ Date: _____ U. Hans Behling, PhD, MPH Project Manager: _____ Date: _____ John Mauro, PhD, CHP	Supersedes: N/A

TABLE OF CONTENTS

LIST OF TABLES

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 on Radiation and Worker Health (Advisory Board or Board), S. Cohen & Associates (SC&A) has been charged under Task 3 to support the Advisory Board in this effort by completing the following three 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 Advisory Board in April 2004.

(2) **Conduct a Critical Review of Methods and Procedures Used by NIOSH for Dose Reconstruction:** Under Modifications Nos. 2 through 5 (initially authorized on June 24, 2004), the Advisory Board approved SC&A's proposal of work to perform a review of a total of 33 procedural documents that included implementation guidelines, procedures, technical information bulletins (TIBs), and plans. This review was completed and a draft report delivered to NIOSH and the Advisory Board on January 17, 2005, entitled *Task 3: The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, SCA-TR-Task3, Rev 0, Final Draft, January 17, 2005. This document and its findings are the subject of an issues resolution process that is currently underway under the direction of an Advisory Board working group.

(3) **Conduct a Supplemental Critical Review of Methods and Procedures Used by NIOSH for Dose Reconstruction:** Under Modification No. 6 (authorized on August 30, 2005), NIOSH and the Advisory Board authorized SC&A to proceed with the scope of work delineated in SC&A's proposal of work entitled *Task Order 3 Proposal for FY 2006, Review Dose Reconstruction Procedures and Methods*, dated August 16, 2005. Modification No. 6 adds an additional set of 32 OCAS and ORAU procedures and 13 generic workbooks to the review process, and provides the resources and mandate to continue with the issues resolution process that was initiated in FY 2005 to address the findings provided in our January 17, 2005, report cited above. The draft work product presented herein is provided in partial fulfillment of Modification No. 6 to this work

assignment, in that it is limited to the review of the supplemental set of 32[1] procedures listed in SC&A's August 16, 2005, proposal of work.

SUMMARY FINDINGS

The 32 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. These documents were created in 2004 and 2005 by the Office of Compensation Analysis and Support (OCAS) and the Oak Ridge Associated Universities Team (ORAUT), and reflect a maturation of the dose reconstruction program that began in 2000, and the first set of guidelines issued in 2002. Unlike our previous Task 3 procedures review report issued in January 2005, this report reveals an integration of the generic OCAS and ORAUT guidelines with the site profiles to the extent feasible. We believe this aspect of the guidelines will help to avoid inconsistencies between the procedures and the site profiles.

It is equally important to note that some of the 32 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. However, the latter issue is less of a concern for the procedures reviewed in this supplement because of the concerted effort made by NIOSH to cross-reference site profiles.

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. Our review of this set of procedures revealed that most were concise, well organized, and provided generally complete and unambiguous guidance. Unlike many of the procedures we reviewed in our January 2005 report, the procedures reviewed in this report do not

[1] As described in subsequent sections of this report, the specific procedures reviewed herein changed over time as it became apparent that some of the procedures originally identified for review did not require a review, while other procedures not identified in our original proposal were identified for review or were reviewed at the request of the Board.

require the dose reconstructor to read through voluminous and frequently irrelevant background information.

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. As in our January 2005 report, we found that 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. However, we have come to believe that it is not always possible to provide explicit guidance on making these judgments, and that it is best to leave these judgments to the dose reconstructor working within a QA/QC framework that ensures consistency in these judgments. However, we have also found that, when it was possible to assist the dose reconstructor in making these judgments, such guidance was provided. For example, many of the guides are highly explicit regarding the assumptions that should be employed for reconstructing doses at specific facilities and for specific time frames. A good example is ORAUT-OTIB-0033. However, for some guidelines, such as ORAUT-OTIB-0020, *Use of Coworker Dosimetry for External Dose Assignment*, a great deal of judgment is left 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 Evident

This objective 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. We found that, to a large extent, a concerted effort was made in these procedures to take into consideration site-specific and time-dependent factors, with appropriate cross-references to site profiles.

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, though some of the procedures tend to overlap, which presents the dose reconstructor with multiple options, an effort was made to help the dose reconstructor navigate his way through multiple overlapping guides. For example, ORAUT-OTIB-0033 attempts to guide the dose reconstructor through the appropriate selection and use of ORAUT-OTIB-0002,

-0014, and -0018. However, we uncovered some inconsistencies between the guidance provided in ORAUT-OTIB-0023 regarding missed neutron dose and that provided in OCAS-IG-001.

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 the doubt when there are **unknowns**, and (2) defining uncertainties for measured data and selecting the 99th percentile value of a Monte Carlo distribution when determining the POC.

With few exceptions, the guidelines reviewed in this report give the benefit of the doubt to the claimant. Some exceptions include the procedure for reconstructing occupational medical doses where the full range of potential uncertainties are not addressed (ORAUT-PROC-61), and the procedures for reconstructing ingestion doses (OCAS-TIB-009) where, under some circumstances, the procedures could underestimate the dose.

Objective 6: Evaluate Procedure for its Ability to Adequately Account for the Uncertainty of Dose Estimates

With few exceptions, the procedures reviewed in this report adequately address uncertainties, with the possible exception of ORAUT-PROC-61 dealing with medical x-ray exposures.

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. Some of the areas where we identified technical inadequacies include the methods used to (1) derive ingestion doses, (2) quantify uncertainty in deriving medical x-ray exposure, (3) address exposure to non-penetrating radiation, (4) adjust film badge readings for glovebox workers, and (5) derive neutron doses associated with alpha,n reactions. These deficiencies were found to be minor, however, and most of our independent technical evaluations found the methodologies to be scientifically correct.

Tables ES-1 and ES-2 present a roll-up of the findings of the results of SC&A's review of the 19 procedures dealing with internal and external dosimetry and the 11 procedures dealing with quality assurance issues. As indicated by the number of "fives" that were assigned to individual criteria, it is evident that most procedures received very high scores. However, there are a few procedures that were assigned a "one" for some of the criteria that should be mentioned, as follows:

- In the review of ORAUT-OTIB-0020 (Use of Coworker Dosimetry Data for External Dose Assignment, Table 2.3.1), item No. 4.1 was assigned a score of 1, indicating that the procedure does not support a prescriptive approach to dose reconstruction. The reason for the low score for this item is that the procedure directs the dose reconstructor to make a quantitative determination of what corresponds to "reasonable" upper exposures that the unmonitored person may have received. Such an approach requires considerable judgment and is not considered prescriptive.

- In the review of ORAUT-OTIB-0017 (*Interpretation of Dosimetry Data for Assignment of Shallow Dose*, Table 2.5.1), item No. 2.1 does not provide adequate guidance for identifying a potentially high probability of causation as part of an initial dose evaluation of a claim. The concern is that in many circumstances, a negative reading on a film badge is not a reliable indicator that a person has not experienced localized skin exposures due to either localized contamination of the skin or exposure to a beta source located at some distance from the location of the dosimeter. Beta dosimetry is useful when it reveals a positive result, but a negative result does not necessarily mean that the individual experienced no localized beta exposure.

- In the review of ORAUT-OTIB-0024 (Estimation of Neutron Dose Rates from Alpha-Neutron Reactions in Uranium and Thorium Compounds, Table 2.6-1), items No. 2.1, 5.1, 5.2, and 5.3 (all dealing with claimant favorability) were assigned a score of 1, because the procedure neglects the neutron contribution to dose due to fissioning. In addition, item 7.3 was assigned a score of 1 because the fundamental methodologies used to derive the neutron flux associated with alpha,n reactions are technically deficient.

With regard to the quality assurance procedures reviewed in this report, Table ES-2 indicates that a few items were assigned a score of "no." In these circumstances, the procedures could have done a better job in establishing the overall quality assurance framework within which the given procedure applies. In addition, there were a number of places where the procedures were not properly labeled with regard to document number, revision number, etc.

Table ES-1. Roll-up of Findings of the Review of the 6 External and 13 Internal Dosimetry Procedures

No.	Description of Objective	5	4	3	2	1	N/A
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?	16		3			
1.2	Is the procedure written in a manner that presents the data in a logical sequence?	16	1	2			
1.3	Is the procedure complete in terms of required data (i.e., does not reference other sources that are needed for additional data)?	15	1	1	1		1
1.4	Is the procedure consistent with all other procedures that are part of the hierarchy of procedures employed by NIOSH for dose reconstruction?	16	1	1	1		
1.5	Is the procedure sufficiently prescriptive in order to minimize the need for subjective decisions and data interpretation?	12	5	1	1		
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?	11	2	1		2	3
2.2	Conversely, for claims with suspected cumulative low doses, does the procedure provide clear guidance in defining worst-case assumptions?	12		1			6
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?						19
3.1.2	Is the interview process sufficiently flexible to permit unforeseen lines of inquiry?						19
3.1.3	Does the interview process demonstrate objectivity, and is it free of bias?						19
3.1.4	Is the interview process sensitive to the claimant?						19
3.1.5	Does the interview process protect information as required under the Privacy Act?						19
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)	4					15
3.2.2	In vivo/In vitro bioassays	8					11
3.2.3	Missing dosimetry data	10		1			8
3.2.4	Unmonitored periods of exposure	9	1	1			8

No.	Description of Objective	5	4	3	2	1	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?	16	1			1	1
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	15	2	1			1
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?	11	1	3		1	3
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	11	1	4		1	2
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	10	1	3		1	4
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)?	12		1			6
6.2	Does the procedure give appropriate guidance in the use of random sampling in developing a final distribution?	7					12
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?	17		2			
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	17		1			1
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses?	9	4	3	2	1	

Table ES-2. Roll-up of the Findings of the Review of the 11 Quality Assurance Procedures

No.	Question	Yes	No	N/A
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?			11
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?			11
1.3	Does the QAPP identify the management position responsible for QA development, implementation, assessment, and improvement?			11
1.3.1	Are there adequate procedures for assuring that personnel performing project tasks have proper levels of experience and education?			11
1.4	Are there adequate procedures for training of project personnel?			11
1.4.1	Have staff training requirements been identified?			11
1.4.2	Has staff received general orientation training?			11
1.4.3	Has staff received training in the requirements of the Privacy Act of 1974 and the Freedom of Information Act?			11
1.4.4	Has staff received training in the provisions of the QAPP?			11
1.4.5	Is a master record of staff training maintained in project files?			11
1.5	Are there adequate procedures for Management and QA surveillance, inspection, and audit of work products and processes to achieve continuous quality improvement?			11
1.6	Do procedures provide for adequate corrective action for identified deficiencies and non-conformances in work products and processes?			11
1.7	Is there an adequate procedure for the maintenance of project QA records in identifiable, legible, and retrievable condition?			11
1.8	Are there procedures covering all work activities of the project?		1	10

No.	Question	Yes	No	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?	11		
2.2	Do the title, document number, revision number, page number, and date appear on each page?		11	
2.3	Has the procedure been reviewed and approved by an independent reviewer familiar with the subject matter?	11		
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	11		
2.5	Are revisions clearly indicated on affected pages?	1	2	8
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?	11		
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?			11

1.0 INTRODUCTION

1.1 STATEMENT OF PURPOSE

The purpose of this draft report is to assist the Advisory Board on Radiation and Worker Health (Advisory Board or 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:

> *. . . 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 Advisory Board, as stated in the following:

> *As described above under the discussion of statutory provisions related to the rule, EEOICPA requires the Advisory Board to conduct an independent review of a sample of NIOSH dose reconstructions. 42 U.S.C. 7348 n(d). Since this review is specified to be independent, the Advisory* ***Board****, rather than HHS, must determine the procedures for the Advisory* ***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

In its proposal of work dated August 16, 2005, which was approved by NIOSH and the Advisory Board in Modification No. 6, dated August 30, 2005, SC&A identified a list of OCAS/ORAUT dose reconstruction-related procedures, technical information bulletins (TIBs), and workbooks for review. That list included 7 OCAS documents, 13 ORAU Team procedures, 12 ORAU Team TIBs, and 13 complex-wide workbooks. This list was obtained from ORAU's Controlled Document list that was on the web as of August 3, 2005. As acknowledged in our August 16, 2005, proposal of work, these lists of documents and workbooks are continually being revised and expanded. In appreciation of the fluid nature of the various procedures and other tools in use by OCAS and ORAU, such as workbooks, Table 1 presents a complete list of all documents and workbooks that were on ORAU's Controlled Document list as of December 7, 2005. The documents designated as "authorized for review" are within SC&A's scope of work for this assignment. Some of the documents are designated as "authorized for review under Task 1." These documents are currently authorized for review in FY 2006, but are being reviewed under

Task Order 1. Some documents are designated as "previously reviewed." These documents have already been reviewed, and the review reports have already been delivered to NIOSH and the Advisory Board under this work assignment or other work assignments in FY 2005. Some documents are designated as "out of scope." This means that SC&A has not yet been requested to perform a review of those documents. In addition, documents highlighted in yellow identify procedures that (1) SC&A recommends for review as replacements for other procedures that, on close inspection, require no reviews, or (2) are included in the list requiring review as a result of direction provided by the Advisory Board at the meeting held in Oak Ridge, Tennessee, on January 24–26, 2006. These include the latest revisions of ORAUT-OTIB-0004 and ORAUT-PROC-0092.

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APPROVED OCAS CONTROLLED DOCUMENTS					
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					DR Tool
APPROVED OCAS CONTROLLED DOCUMENTS (Continued)					
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ORAU TEAM TECHNICAL INFORMATION BULLETINS (TIBs)					
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ORAU TEAM TECHNICAL INFORMATION BULLETINS (Continued)					
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ORAU TEAM TECHNICAL BASIS DOCUMENTS					
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ORAU TEAM TECHNICAL BASIS DOCUMENTS (Continued)					
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-					No
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	-				No
					No
-					No
-					No
-	-				No
-					No
-					No
-					No
-					No
-					No
-					No
-					No
-					No
-					No

					DR Tool
ORAU TEAM TECHNICAL BASIS DOCUMENTS (Continued)					
-					No
-					No
-		-			No
-		-			No
-		-			No
-		-			No
-					No
-					No
-					No
-					No
-					No
-					No
					No
					No
	-				No
					No
	-				No
-	-				No
-	-				No
-	-				Yes

					DR Tool
ORAU TEAM TECHNICAL BASIS DOCUMENTS (Continued)					
-					Yes
-		-			Yes
-					Yes
-					No
ORAU TEAM PLANS					
					No
	-				No
	-				No
					No
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					No
					No
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					No

1.2.1 OCAS Procedures

The following are the OCAS procedures authorized for review. Nore that some of the procedures were deleted from consideration and replaced with other procedures.

OCAS-COT-0007: OCAS *Asessment Report: Efficiency of the Dose Reconstruction Process,* Rev. 00, July 20, 2004 (deleted and replaced)

This report presents the results of an assessment of the performance of ORAU with respect to the efficiency of the dose reconstruction process. This document was deleted from the list of documents for review by SC&A because it is not within the intended scope of work for Task Order 3. The review of this report was replaced with a review of *Guidance on Wound Modeling for Internal Dose Reconstruction*, ORAUT-OTIB-021, Rev. 00, November 18, 2005, which is described below.

OCAS-PR-004: *Internal Procedures for the Evaluation of Special Exposure Cohort Petitions,* Rev. 00, September 23, 2004 (deleted and replaced)

This document sets forth NIOSH's procedures for evaluating Special Exposure Cohort (SEC) petitions in accordance with the requirements of the EEOICPA and its implementation regulation as set forth in 42 CFR part 83. This NIOSH procedure is not reviewed in this SC&A report because it was reviewed as part of SC&A Task 5. SC&A's draft review of this NIOSH procedure was delivered to NIOSH and the Advisory Board on November 23, 2005. The draft report is entitled *Review of NIOSH/ORAU Special Exposure Cohort Evaluation Procedures,* Task 5, Subtask 1, SCA-TR-TASK5-0001, November 23, 2005.

The review of OCAS-PR-004 was replaced with the review of ORAUT-PROC-0060, *External On-Site Ambient Dose Reconstruction,* Rev. 00, March 7, 2005. This ORAU Team procedure provides direction to dose reconstructors on how to reconstruct external onsite ambient doses to workers.

OCAS-PR-005: *Conduct of Assessments,* Rev. 00, December 3, 2004

This procedure provides guidance to OCAS personnel involved in the assessments of the performance of contractor, contractor personnel, and self-assessments in all matters related to NIOSH's scope of reponsibility under the EEOICPA. It is part of the quality assurance and quality control procedures employed by NIOSH.

OCAS-PR-007: *Dose Reconstruction Review,* Rev. 01, April 18, 2005

This procedure provides guidance to OCAS personnel involved in the assessments of the performance of contractor, contractor personnel, and self-assessments in matters specifically related to dose reconstruction under 42 CFR Part 82. It is part of the quality assurance and quality control procedures employed by NIOSH.

OCAS-TIB-009: ***Estimation of Ingestion Intakes,*** **Rev. 00, April 13, 2004**

This TIB provides guidance to be used for estimating intakes of radioactive material through inadvertent ingestion of paticulate material that may be deposited directly onto food items and drinks or onto work-area surfaces and inadvertently ingested by hand-to-mouth behaviors. It does not address the ingestion of material that is deposited in the upper respiratory tract from inhalation and then ingested due to muco-ciliary clearance. That mode of "ingestion" is evaluated as part of the inhahation dosimetry protocols incorporated into IMBA.

OCAS-TIB-010: ***Special Dose Reconstruction Consideration for Glovebox Workers,*** **Rev. 01, May 18, 2005**

This TIB provides guidance on performing minimum and maximum dose calculations for workers that may have experienced external exposures while working in the vicinity of a glovebox (or dry box, as it was referred to in the early years). Procedures for performing realistic dose estimates for this exposure scenario are (or will be) provided in a separate guideline.

OCAS-TIB-011: ***Lung Dose Conversion Factor for Thoron WLM,*** **Rev. 01, April 15, 2005**

This TIB provides the dose conversion factors for calculating lung dose from radon-220 decay products in working-level months (WLMs). The guide was prepared because, though considerable guidance has been developed for estimating the doses to lungs from radon progeny, expressed in working levels (WL), less attention has been given to guidance on deriving exposures to thoron progeny, the concentrations of which are also often expressed in terms of WL. However, the lung dose rate per WL of radon progeny is different than the lung dose rate per WL of thoron progeny. This guide presents a method for converting thoron progeny exposure expressed in units of WL to lung dose rate.

1.2.2 ORAU Team Technical Information Bulletins

ORAUT-OTIB-0004: ***Estimating the Maximum Plausible Dose to Workers at Atomic Weapons Employers Facilities,*** **Rev 03, PC-1, November 18, 2005 (authorized for review at the January 26, 2006, Board meeting)**

The stated purpose of this document "is to provide guidance for estimating the maximum plausible dose at Atomic Weapons Employers (AWEs). This document may also be used to estimate doses at Department of Energy facilities when exposures would be adequately estimated by the methods in this document… This document describes an efficiency process that may be used to expedite the processing of claims requiring dose reconstruction under the EEOICPA."

ORAUT-OTIB-0011: ***Tritium Calculated and Missed Dose Estimates,*** **Rev. 00, June 29, 2004**

This OTIB provides a method for estimating the effective dose from tritium in the body from urine data, where a complete set of urine data may not be available and extrapolation methods

are required to fill in the missing dose, taking into consideration the minimum detectable activity (MDA) of the urinalysis.

ORAUT-OTIB-0012: ***Monte Carlo Methods for Dose Uncertainty Calculations,*** **Rev. 00, February 14, 2005**

This OTIB presents an efficiency method applied to Monte Carlo methods, which yield best-estimate organ doses. Implementation of this method allows the generation of site-specific reference tables for use in best-estimate dose reconstructions without requiring individual Monte Carlo simulations.

ORAUT-OTIB-0014: ***Assessment of Environmental Internal Doses for Employees Not Exposed to Airborne Radionuclides,*** **Rev. 00, June 22, 2004**

This OTIB provides guidance on the methods for assigning environmental internal doses to workers who may have experienced such doses, and when such doses could have the potential to contribute significantly to internal doses relative to the doses that may have been experienced by the workers in the workplace.

ORAUT-OTIB-0017: ***Interpretation of Dosimeter Data for Assessment of Shallow Dose,*** **Rev. 01, October 11, 2005**

This OTIB provides guidance for assigning shallow doses to the skin, testes, and breast from non-penetrating radiation, including beta exposures and exposures to low-energy photons.

ORAUT-OTIB-0018: ***Internal Overdose Estimates for Facilities with Air Sampling Programs,*** **Rev. 01, August 9, 2005**

This OTIB provides guidance for assigning upper-end doses using site-specific air-sampling data. It is designed to be used as an alternative, less conservative, method for deriving high-end internal doses than that provided in ORAUT-OTIB-0002.

ORAUT-OTIB-0019: ***Analysis of Coworker Dosimetry Data for Internal Dose Assignment,*** **Rev. 01, October 7, 2005**

This OTIB provides guidance for assigning internal doses to workers using co-worker bioassay data for workers who do not have bioassay data, but the possibility exists that the worker may have experienced internal exposures.

ORAUT-OTIB-0020: ***Use of Coworker Dosimetry Data for External Dose Assignment,*** **Rev. 01, October 7, 2005**

This OTIB provides guidance for assigning external doses to workers using co-worker data for workers who have no or inadequate external dosimetry data for use in dose reconstruction and the possibility exists that the worker may have experienced external exposures.

ORAUT-OTIB-0022: ***Guidance on Wound Modeling for Internal Dose Reconstruction,*** **Rev. 00, November 18, 2005** (not in original scope but was added as a replacement for a procedure that was deleted from the original list of procedures authorized for review)

This OTIB provides guidance for assigning internal doses from plutonium and other radionuclides associated with contaminated wounds.

ORAUT-OTIB-0023: ***Assignment of Missed Neutron Doses Based on Dosimeter records,*** **Rev. 00, March 7, 2005**

This OTIB provides guidance for assigning neutron doses to workers using the LOD/2 method for cases where the neutron dosimetry records are considered reliable.

ORAUT-OTIB-0024: ***Estimation of Neutron Dose Rates from Alpha-Neutron Reactions in Uranium and Thorium Compounds,*** **Rev. 00, April 7, 2005**

This OTIB provides a quick method for assigning neutron doses at sites that processed uranium and thorium compounds, did not perform neutron monitoring, and the potential existed for alpha particle collisions with low atomic number materials at the site, thereby creating the potential for neutron exposures.

ORAUT-OTIB-0025: ***Estimation of Ra-226 Activity in the Body from Breath Radon-222 Measurements,*** **Rev. 00, April 5, 2005**

This OTIB provides guidance for assigning the Ra-226 body burden, and associated organ doses, of individuals based on radon breath analysis.

ORAUT-OTIB-0028: ***Validation of Thorium Annual Dose Conversion Factors,*** **Rev. 01, March 7, 2005**

This OTIB verifies the annual dose conversion factors used for the assessment of Th-232 and Th-228 doses. This verification was needed because IMBA does not explicitly model the dosimetry of these radionuclides and the independent kinetics of their progeny chain. As a result, a separate set of dose conversion factors were developed for these radionuclides, which are verified in this document.

ORAUT-OTIB-0033: ***Application of Internal Doses Based on Claimant-Favorable Assumptions for Processing as Best Estimates,*** **Rev. 00, April 20, 2005**

This OTIB supplements ORAUT-OTIB-0018, titled *Internal Dose Overestimates for Facilities with Air Sampling Programs*, which is intended to be used to deliberately overestimate inhalation exposures for workers with no significant intakes. This OTIB provides guidance for performing more realistic dose reconstructions, taking into consideration time period of employment, process knowledge, job location and category, and any available bioassay data.

1.2.3 ORAU Team Procedures

ORAUT-PROC-0022: ***Additional Requests for DOE Information,*** **Rev. 00, March 15, 2005**

The purpose of this procedure is to outline the methods for requesting additional energy employee information from various DOE sites for the purpose of dose reconstruction for specific energy employees, and not in support of the preparation of site profile reviews.

ORAUT-PROC-0031: ***DOE Site Profile Development, Review, and Approval Process,*** **Rev. 00 PC-1, March 15, 2005**

The purpose of this procedure is to document and describe the process used to develop site profiles.

ORAUT-PROC-0042: ***Accounting for Incomplete Personal Monitoring Data on Penetrating Gamma-Ray Doses to Workers in Radiation Areas at the Oak Ridge Y-12 Plant Prior to 1961,*** **Rev 00, September 9, 2004 (deleted since it is part of the Y-12 Site profile review process)**

The purpose of this procedure is to provide dose reconstructors with guidance they can use to account for incomplete monitoring of penetrating gamma doses to workers in radiation areas at Oak Ridge Y-12 plant prior to 1961. Since this procedure was reviewed as part of the site profile and SEC petition review process, it was deleted from review under this task and replaced with another procedure.

ORAUT-PROC-0060: ***External On-Site Ambient Dose Reconstruction,*** **Rev. 00, March 7, 2005 (not in the original set of procedures authorized for review, but is included as a replacement for one of the previously authorized procedures that were deleted)**

The purpose of this procedure is to provide guidance to dose reconstructors regarding the assignment of external doses from onsite ambient radiation. This guide supersedes ORAUT-PROC-0006.

ORAUT-PROC-0061: ***Occupational X-Ray Dose Reconstruction for DOE Sites,*** **Rev. 00, December 1, 2004**

The purpose of this procedure is to provide guidance to dose reconstructors regarding the assignment of organ dose from medical x-ray exams that were required as a condition of employment. This guide supersedes the guidance on this subject provided in ORAUT-PROC-0006.

ORAUT-PROC-0065: ***Internal Finding and Corrective Action to Prevent Recurrence,*** **Rev. 00 PC-1, November 3, 2005**

The purpose of this procedure is to provide guidance for initiating and documenting internal findings, determining the root cause, developing corrective actions to rectify existing conditions and to prevent recurrence, monitoring and implementing corrective actions to completions, and

verifying complete corrective actions. This procedure addresses findings and observations identified during ORAU quality assurance audits, and not those of NIOSH or other organizations external to ORAU.

ORAUT-PROC-0066: ***Quality Assurance Records Management,*** **Rev. 00, September 3, 2004**

The purpose of this procedure is to describe the activities and responsibilities necessary for the identification, control, storage, retrieval, and disposition of ORAU quality assurance audits.

ORAUT-PROC-0067: ***Conduct of Quality Assurance Surveillances,*** **Rev. 00, September 14, 2004**

The purpose of this procedure is to describe the process and responsibilities for administering and conducting surveillances of the ORAU dose reconstruction project, as performed by ORAU.

ORAUT-PROC-0069: ***External Nonconformance and Corrective Action to Prevent Recurrence,*** **Rev. 00, September 9, 2004**

This procedure establishes the process for responding to nonconformances issued by external auditors, and instructions for identifying the root cause, developing corrective actions, and preventing recurrences.

ORAUT-PROC-0077: ***Dose Reconstruction Error Tracking and Reporting,*** **Rev. 00, March 28, 2005**

This procedure provides the process for review, disposition, correction, tracking, and trending of dose reconstruction errors and comments received by ORAU.

ORAUT-PROC-0080: ***Conduct of Quality Assurance Audits,*** **Rev. 00, September 9, 2004**

The purpose of this procedure is to establish the process and responsibilities for the administration and performance of formal independent quality assurance audits and assessments of activities performed by ORAU dose reconstructors.

ORAUT-PROC-0090: ***Computer Assisted Telephone Interview Process,*** **Rev. 00, June 21, 2005**

This purpose of this procedure is to provide the process for the scheduling, performance, and review of computer-assisted telephone interviews (CATIs).

ORAUT-PROC-0091: ***Dose Reconstruction Submittal,*** **Rev. 00, June 29, 2005**

This procedure establishes the process for the receipt, modification, and submittal of draft dose reconstruction reports.

ORAUT-PROC-0092: ***Close-Out Interview Process,*** **Rev. 00, August 17, 2007**

The purpose of this procedure is to provide the process for the scheduling, performance, and follow-up of a closeout interview. (Not in the original set of procedures authorized for review, but is included as a replacement for one of the previously authorized procedures that were deleted.)

1.3 SC&A'S APPROACH FOR TASK 3

The approach used to perform the reviews contained in this report follows the SC&A procedures provided in *A Protocol for the Review of Procedures and Methods Employed by NIOSH for Dose Reconstruction* (SCA-PR-Task3, Rev 1, Final, April 29, 2004). In the original 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 procedures 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 questionnaires used for work history telephone interviews (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 reconstructions

* Note: This element was excluded from the review process for this task order because it is being addressed under Task Order 1 and Task Order 5.

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

In addition to technical elements, SC&A also recognized that the review of methods and procedures must also address non-technical 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, by regulation, the establishment of 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 non-technical 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 Advisory 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**.

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 doesn't 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 1.4.1 below identifies the Procedure Review Outline/Checklist that is used in this report to assess the degree to which a given procedure meets the seven objectives, as applicable to the procedure. This table is slightly different than the table

used in our original Task 3 report (dated January 17, 2005), in that it includes item 7.3, which explicitly addresses the scientific validity of the methodology employed in the procedure to perform or support dose reconstruction.

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, Quality Assurance 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 affecting 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?		
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses.		

* 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-TIB-0010: BEST ESTIMATE EXTERNAL DOSE RECONSTRUCTION FOR GLOVEBOX WORKERS

2.1.1 Purpose of Procedure

The stated purpose of this procedure "…is to provide guidance on dose reconstructions for glovebox workers. This TIB discusses the special exposure characteristics that may be encountered by energy employees who work with gloveboxes and provides special dose correction factors or modifiers that should be applied to affected energy employee's dose."

2.1.2 Review Protocol

Our evaluation of OCAS-TIB-0010: *Best Estimate External Dose Reconstruction for Glovebox Workers,* is summarized in Table 2.1-1 below. This table presents a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether a 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.: ORAUT-OTIB-0010	**Effective Date:** 04/20/2005
Document Title: Best Estimate External Dose Reconstruction for Glovebox Workers	
Auditor: Robert Anigstein, PhD	

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)?	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?	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)	5	
3.2.2	In vivo/In vitro bioassays	N/A	
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	
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)?	5	
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?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	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.

2.1.3 General Comments

This document presents the results of an analysis designed to determine the degree to which the external dose to organs in the lower torso could be underestimated "if the energy employee wore his/her dosimeter on the lapel and not the center area of the chest or on the waist." The analysis

calculates the particle[2] flux rates from a radioactive source inside a glovebox at 30 locations on the surface of an anthropomorphic phantom, using the ATTILA computer code, which solves the 3D multi-group transport equations for neutrons, charged particles, and infrared radiation on an unstructured tetrahedral mesh. Ratios of flux rates at randomly selected locations on the lower torso to those at randomly selected locations on the upper torso were calculated using Crystal Ball, a Monte Carlo sampling program. The resulting distribution appears to be lognormal, with a geometric mean of 2.3 and a geometric standard deviation (GSD) of 1.13.

We performed our own analysis to verify these results, using the MCNP5 computer code (LANL 2004) to calculate $H_p(10)$ dose rates at two hypothetical locations; one corresponding to a dosimeter worn on the waist along a horizontal line centered on the radiation source, and another corresponding to a dosimeter worn just outside the clavicle, approximately the level of the lapel. We utilized a detailed MCNP model constructed by Crawford (2006). Crawford (2004) describes gloveboxes used at the Los Alamos National Laboratory (LANL) for handling plutonium, as well as at other facilities. The LANL gloveboxes, in use since the 1970s and believed to be based on still earlier designs, were the basis of Crawford's model. The radiation source, which is the same as was used in the NIOSH analysis (Macievic 2006), has the same composition as the generic objects containing weapons-grade plutonium described by Traub et al. (2005). We utilized the photon spectrum presented by Traub et al., but calculated the neutron spectrum independently, using the SOURCES-4C computer code (LANL 2002), a code system that determines neutron production rates and spectra from (alpha,n) reactions, spontaneous fission, and delayed neutron emission due to radionuclide decay. Our calculated neutron yield matched that of Traub et al.

The results of our analysis showed that the total $H_p(10)$ dose rate at the dosimeter location on the waist was about 2.1 times the dose rate for the lapel location. This is consistent with the results of the NIOSH analysis.

2.1.4 Review Comments

Review Objective 1.1

The first issue is the lack of transparency of the OTIB analysis. Figure 7 of the OTIB shows a diagram of the side view of the exposure geometry. Neither the exact dimensions, the exact location of the source, nor the thickness of the walls are presented.[3] More importantly, the radioactive source[4] is not identified. This lack of detailed information required extensive private communications with the author of the OTIB to enable us to understand and confirm the analysis.

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[2] Erroneously referred to as “photon flux” in the TIB. See discussion in Section 2.1.4.

[3] Curiously, the anthropomorphic phantom depicted in the diagram seems to be suspended in air.

[4] The TIB variously referred to a “radiological source” or a “radiation source”—“radiation source” is the term listed in the NRC's “Glossary of Nuclear Terms” (NRC n/d), while the term “radioactive source” is widely used in health physics.

Review Objective 7.3

Although we concur with the correction factor for a dosimeter worn on the lapel, we nevertheless find a number of issues with this OTIB.

The first issue is the design of the analysis. NIOSH/OCAS has procedures for translating personal dosimeter readings into organ doses. We therefore question the design of the analysis that compares the particle flux over locations on the upper and lower torso, rather than modeling the variation of dosimeter response with location. If the purpose of the analysis is to develop a correction factor for dosimeters worn on the lapel when the source is at the level of the waist, those are the locations that should be analyzed. Furthermore, since a dosimeter—by definition—registers dose, not particle flux, that is the quantity that should have been analyzed. As stated earlier, our analysis of the comparison of dose rates happens to produce results that fall into the range of the OTIB analysis. That does not, however, validate the methodology used in the OTIB.

A second issue is the design of the glovebox. The OTIB presents a general description of gloveboxes, including illustrations of gloveboxes at various plutonium processing facilities. The actual analysis, however, utilized the engineering design drawings of a glovebox from Innovative Technology (n/d) (Crawford 2006). That glovebox was designed for inert atmosphere applications, such as the manufacture of light bulbs. More important, the OTIB glovebox has walls of steel and Lexan that are over 4 cm thick (Crawford 2006). Such a thickness, based on an apparent misinterpretation of the Innovative Technology engineering drawings, is unrealistic. By contrast, the LANL glovebox has walls that are about 4.8 mm thick. The choice of Lexan for the OTIB model is questionable (Innovative Technology does not specify the material of the viewing window). Lexan is a relatively new plastic—large-scale production of Lexan sheets did not start until 1972 (GE 2004). Curiously, the OTIB states that the view window is made of Lucite, the DuPont trade name for poly(methyl methacrylate), which has a different composition than Lexan, the General Electric trade name for its polycarbonate resin. The LANL glovebox has glass view windows. Although the OTIB glovebox design does not significantly alter the relative particle flux over the torso of the anthropomorphic phantom, it calls into question the credibility of the analysis.

A third issue is the use of an anatomical illustration of a human torso as a basis for the anthropomorphic phantom used in the OTIB analysis. ORNL has developed a series of anthropomorphic phantoms (e.g., Eckerman et al. 1996) based on the ICRP Reference Man (ICRP 1975). These phantoms form the basis of most external dose simulations and would be more appropriate for the OTIB analysis.

A fourth issue is the use of the Attila software. Attila is a discrete ordinate code, which solves radiation transport problems deterministically. Discrete ordinate codes treat the spatial domain, the energies, and the angles as discrete variables. The accuracy of such codes need not be limited by spatial resolution, since the mesh in principle could be made as fine as desired, depending on limitations on computer memory. However, the energy discretization is an issue for neutron transport, as neutron cross-sections often feature resonance structure that is typically approximated by a single group in a multi-group cross-section approximation. Scattering-angle

discretization is also an issue. This can lead to non-physical results, called "ray effects," along the boundaries between angle bins. In contrast, MCNP5 samples from continuous energy cross-section tables, preserving the full accuracy of the original evaluations.

A discrete ordinate code can offer some advantages in execution time for complex geometries; furthermore, Attila offers an advantage in efficiency of the user's time by allowing direct import of the output of a computer-aided design (CAD) program. In the present case, however, the glovebox geometry used in the OTIB analysis is extremely simple; a rectangular box with one sloping face, uniform thickness, and only two materials, as well as an anthropomorphic phantom made up of water. Our MCNP calculations required two runs (one for photons and another one for neutrons) of 90 minutes each on a desktop computer with a 1.7 GHz Pentium IV processor running under Windows XP. The statistical uncertainties in these results indicate that a precision of "0.1% could have been achieved by running for less than 10 minutes. Although we did have the advantage of a detailed MCNP model of the glovebox that had already been constructed at LANL, we could have replicated the simple model used in the OTIB analysis in a relatively brief time.

Another objection to the use of Attila in the OTIB analysis is related to the issue of transparency. The Attila code is not well known and not widely available. A prospective user has to acquire a license from Transpire, Inc., and the license must be renewed annually at a substantial fee. By contrast, MCNP is well known and widely used. It is readily available from the Radiation Safety Information Computational Center (RSICC) at Oak Ridge National Laboratory.

Finally, the OTIB refers to the calculation of photon flux, whereas the analysis actually calculated the particle flux (photons plus neutrons).

In an appendix to the OTIB, NIOSH reports an attempt to validate the use of the calculational model used in the OTIB, based on the Attila code, by comparing the model predictions to the ratios of wrist-to-whole body exposures of Rocky Flats workers. These data were apparently the deep-dose components of doses recorded by dosimeters worn on the wrist, as well as by dosimeters worn elsewhere on the body. The ratios of wrist-to-whole body doses, as calculated from the dosimetry data on both glovebox and nonglovebox workers, were compared to the ratios of the fluxes over the wrist area and the upper torso, presumably using the same phantom and glovebox geometry.

The distributions of wrist-to-whole body ratio dosimetry data had geometric means ranging from 2.24 to 3.08, depending on which data set was being analyzed. The corresponding GSDs ranged from 2.14 to 2.68. The Attila model yielded ratios with a geometric mean of 2.64 and a GDS of 3.13.

Although the geometric mean of the ratios calculated by the Attila model falls within the range of the distributions of the ratios of the dosimetry data, the Attila GSD is significantly higher than those calculated from the dosimetry data.

The Rocky Flats data is based on glovebox and nonglovebox workers. Therefore, it is questionable how well these data represent the situation that is modeled by Attila. Furthermore,

the Attila model is used to calculate the ratio of particle flux (neutron plus photon) to the upper torso, while the dosimetry data represents dose to the whole body. Absent specific knowledge of where the whole-body dosimeters were worn (the whole point of the OTIB), the comparison of the model to the measured data is questionable.

Further issues regarding the use of the Rocky Flats dosimetry data concern lack of information about the radiation sources; the Attila model utilizes the neutron and photon spectra from a plutonium weapon, while the Rocky Flats workers were exposed to both uranium and plutonium in various configurations and stages of purification.

Finally, the appendix suffers from the same lack of transparency as does the main body of the OTIB. One issue is the lack of detail regarding the Rocky Flats dosimetry data. Much more data should be presented than just the geometric means and the GSDs of six classes of workers. The reader cannot deduce how the dosimetry data were selected, what criteria were used for including or excluding individual readings (e.g., did the < 30 mrem and <100 mrem exclusions apply to the wrist or the whole-body dose, or to both?), and how the neutron dose corrections were applied to individual workers. If the purpose is to validate the model using real-world data, what is the reason for selecting the maximum value of the annual, quarter, and cycle data?

It is implied, although not clearly stated, that the same model geometry used in the main body of the OTIB was utilized in the analysis described in the appendix.

In conclusion, the OTIB accomplishes its stated purpose in that it provides guidance for reconstructing doses from external exposures of glovebox workers. The correction factors to dosimeter readings are consistent with the results of our own analyses. However, the methodology of the analysis presented in the OTIB is not transparent. Furthermore, the methods, assumptions, and parameters used in the analysis should be revised to more appropriately address the problem at hand.

The use of the Rocky Flats dosimetry data, which do not necessarily represent the exposure conditions embodied in the Attila model, calls the model validation into question. Absent better correspondence between the Rocky Flats exposures and the model, the partial agreement between the model predictions and the dosimetry data can only be termed fortuitous.

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2.2 ORAUT-PROC-0061: OCCUPATIONAL X-RAY DOSE RECONSTRUCTION FOR DOE SITES

The review of ORAUT-PROC-0061, *Occupational X-ray Dose Reconstruction for DOE Sites*, Rev. 00, dated December 1, 2004, was prepared by Harry Pettingill, PhD, and approved by John Mauro, PhD, CHP, on March 22, 2006.

2.2.1 Purpose of Procedure

The stated purpose of this procedure is to provide guidance "…for the assignment of organ dose from medical x-ray exams that were required as a condition of employment. This procedure relies upon information contained in the Technical Basis Documents (TBDs), and it supersedes the instructions pertaining to x-ray dose reconstruction in ORAUT-PTOC-0006 Rev. 00."

2.2.2 Review Protocol

SC&A's evaluation of ORAUT-PROC-0061 is summarized in Table 2.2-1 below. Table 2.2-1 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 2.2-1. Procedure Review Outline/Checklist

Document No.: ORAUT-PROC-0061	**Effective Date:** 12/01/2004
Document Title: Occupational Dose reconstruction for DOE Sites, Rev. 00	
Auditor: Harry Pettengill	

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	It references other related NIOSH and ORAUT documents, 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?	4	See Review Comments
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?	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?	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)?	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	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	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.

2.2.3 General Comments

The procedure is intended to guide dose reconstructors on a methodology for estimating the occupational medical dose to claimants. Notably, the procedure is based upon 17 separate references of which the first 12 are references to the 12 separate site profile medical TBDs completed as of the date of this procedure. The most recent TBD is for the Portsmouth site, dated July 19, 2004. A number of site TBDs have been completed or revised after this date, but

the procedure has not been updated accordingly. We suggest that NIOSH implement a system that updates all references in any procedure where it is cited.

The procedure correctly advises the dose constructor to use the latest TBD revision; however, failure to do this automatically could lead to confusion and unnecessary rework of dose constructions. Of the five remaining references, it appears that only two are pertinent to the procedure; *NIOSH (2002) External Dose Reconstruction Implementation Guideline* and the *Technical Information Bulletin: Dose Reconstruction from Occupationally Related Diagnostic X-ray Procedures*. Unfortunately, both are dated and require that a new revision be cited. This is of importance, because information in both documents can appreciably affect claimant dose. This is particularly true of ORAUT-OTIB-0006, which is currently in Revision 3, while Revision 2 is being cited. The remaining three references add little value, with the possible exception of the *Handbook of Health Physics and Radiological Health*. Notably missing in the reference list are both *ICRP Publication 34* and *NCRP Report 102*, upon which most of the TBDs rely quite heavily.

The most important comment relates to the very first sentence in this section. It states that, "…doses from occupational x-ray procedures provided to employees that are required as a condition of employment must be included." It further states that doses must rely on information provided in site TBDs and the TIBs. However, it appears that dose reconstructors and subject matter experts who write the TBDs are being unduly restrictive as to what constitutes, "required as a condition of employment." More times than not, the only exams considered are a pre-employment x-ray and any annual chest x-rays taken as part of the physical. Therefore, exams from injury or incidents, special monitoring and surveys, etc., are mostly not included in the dose estimate to the disadvantage of the claimant. We have pointed out this important gap to NIOSH on prior site TBD reviews and shown that it is not consistent with guidelines in the subject OTIB.

The section also provides guidance to dose constructors regarding how to estimate medical dose, based upon a presumed probability of causation. Instructions are provided regarding when to use the Maximizing, Best Estimate, or Minimizing approach. In the case of using the Maximizing approach, the dose constructor is told to use all x-rays in the record, and/or prescribed in the TBD. However, the TBD often declares that only chest x-rays are of importance; thus, it is not necessarily a maximum approach.

In the case of the Best Estimate approach, the guide instructs the dose reconstructor to use only "potentially-required x-rays," which means that the dose constructor may use only chest or lumbar spine x-rays to assess dose. The guide is silent on the use of the TBD.

In the case of the Minimizing approach, the dose reconstructor is directed to assume that the only x-ray exposures experienced by the worker are those that are explicitly required for employment. The dose reconstructor may not use assumptions from TBDs, and must rely on claimant records only. This strategy is appropriate for a minimizing approach.

In the case of assessing the presumed probability of causation for skin cancer, the protocol states that backscatter included in ESE measurements would overestimate the dose and is therefore

appropriate for a maximizing approach, but is not appropriate for best estimate and minimizing approaches. It suggests using an alternative organ dose that is proximal to the site of the skin cancer for a best estimate or minimizing approach. This strategy is considered reasonable.

2.2.4 Review Comments

Review Objectives 2.1, 5.1, 5.2, and 5.3

The procedure allows for consideration of exposures in excess of those delineated in the procedure if the case records indicate that the worker received additional x-ray examinations, or if the TBD indicates that additional examinations were performed at the site. Also, the procedure recommends multiplying the TBD derived doses by 1.3 to account for uncertainty. However, the dose reconstructor is not advised to make corrections for retakes or additional exposures due to poor technique or processing. Most TBDs viewed to date do not account for this important component of estimating dose. It would seem that using this procedure for *"maximizing"* dose may not be claimant favorable.

2.3 ORAUT-OTIB-0020: USE OF COWORKER DOSIMETRY DATA FOR EXTERNAL DOSE ASSIGNMENT

The review of ORAUT-OTIB-0020, Revision 01, dated October 7, 2005, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on March 31, 2006.

2.3.1 Purpose of Procedure

The purpose of this OTIB is to provide general information to the dose reconstructor for assigning external doses to workers at DOE sites with little or no personal monitoring data. Dose reconstruction in behalf of such individuals is to be based on site co-worker external dosimetry data. Thus, guidance provided in this OTIB is to be used in conjunction with other TIBs or approved documents that provide site-specific external co-worker data.

2.3.2 Review Protocol

The evaluation of ORAUT-OTIB-0020 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 directed by the EEOICPA and defined under 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).

Table 2.3-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0020, Rev 01	**Effective Date:** 10/07/2005
Document Title: Use of Coworker Dosimetry Data for External Dose Assignment	
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)?	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?	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?	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)	N/A	
3.2.2	In vivo/In vitro bioassays	N/A	
3.2.3	Missing dosimetry data	3	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?	1	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)?	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?	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	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses.	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.

2.3.3 General Comments

In order to facilitate the evaluation of this procedure, select portions of ORAUT-OTIB-0020 are reproduced here verbatim. Statements contained therein will be critically evaluated in context with SC&A's Review Objectives.

The following statements/guidance are the focus of this review. Line numbers are assigned to the quoted material because the commentary that follows refers back to specific line numbers in the quotes.

From Section 2.0, Background

. . . For the purpose of this document, coworkers are considered to be workers at a site (potentially grouped by work location, job description, or other appropriate category) whose measured doses are considered representative of those received by one or more claimants with no individual monitoring data.

Cases without individual external monitoring data may fall into one of several categories, including:

- *the worker was unmonitored and, even by today's standards, did not need to be monitored (e.g., a non-radiological worker).*
- *the worker was unmonitored, but by today's standards would have been monitored.*
- *the worker may have been monitored but the data are not available to the dose reconstructor.*
- *the worker may have partial information, but the available information is insufficient to facilitate a dose reconstruction.*

Some cases with little or no individual monitoring data can be processed in the absence of completed coworker studies, most notably those falling under the first category listed above. For example, nonradiological workers with no potential for workplace radiation exposures may be assigned on-site ambient doses. Even some cases falling under the second and third categories above do not require coworker studies, e.g., radiological workers who may in some cases be assigned reasonable upper limits provided that the total probability of causation (POC) is less than 45%. Regarding the last category above, if sufficient information is available, a prorated dose could be assigned in certain circumstances.

From Section 3.0, General Approach

The general approach to applying coworker data for cases with little or no individual external monitoring data is to assign either 50th or 95th percentile doses with the intent that the doses assigned represent, but do not underestimate, the doses that would be assigned had the employee been monitored. As described in Section 6.0, the percentile doses include consideration of missed dose. This is necessary because the coworker data are intended to represent the results for

unmonitored workers had they been monitored, and missed doses are assigned to null monitoring results for monitored workers.

Site-specific coworker data sets containing 50th and 95th percentile penetrating and non-penetrating doses are provided in separate, site-specific TIBs. In general, the 50th percentile dose may be used as a best estimate of a worker's dose when professional judgment indicates the worker was likely exposed to intermittent low levels of external radiation. The 50th percentile dose should not be used for workers who were routinely exposed. For routinely exposed workers (i.e., workers who were expected to have been monitored), the 95th percentile dose should be applied. For workers who are unlikely to have been exposed, external on-site ambient dose should be used rather than co-worker doses. The site-specific TIBs also provide information on the sources of the site data, validation of the data, and conversion of the data into annual doses to be applied in dose reconstructions.

The coworker doses presented in the site-specific TIBs shall be treated as constant values. However, they do not include all factors that must be applied by the dose reconstructor in order to assign doses. Specifically, site-specific adjustments based on technical considerations (e.g., dosimeter bias) must be incorporated by the dose reconstructor based on the site Technical Basis Documents (TBDs). Additionally, organ dose conversion factors based on OCAS-IG-001 must be applied; for likely compensable or likely non-compensable cases, they shall be applied in the same manner in which they are applied for monitored employees, and otherwise they shall be applied as a triangular distribution.

From Section 4.0 Applications and Limitations

In parallel with the development of site-specific TIBs that document the external coworker data sets to be used in dose reconstructions, cases not yet completed are screened to identify those cases requiring external coworker data to facilitate case processing. As described previously, some cases with little or no individual monitoring data have been processed using methods not dependent on coworker data. Cases identified as requiring coworker data shall be processed as described in Section 7.0.

Some workers are concerned that their dose records are not accurate because they were encouraged or instructed by a supervisor not to wear their badges (dosimeters), or they were not given badges while doing jobs that could have resulted in exposures sufficient to exceed an administrative or regulatory dose limit. If this concern is expressed by a claimant verbally in the CATI interview or in written correspondence, the dose reconstructor should try to determine if this could have happened by examining the dose records and considering the workplace conditions, potential source terms, and incident reports. In cases in which the dose reconstructor believes this could have happened, it may be necessary to modify the dose reconstruction and/or perform additional research.

2.3.4 Review Comments

Review Objectives 1.1, 1.2, 1.3, and 1.5

This procedure lacks clarity and repeatedly demands the dose reconstructor's opinion and/or subjective interpretation of information. For example, under Section 2.0, lines 9, 10, 12, and 13 require the dose reconstructor to make a highly subjective comparison between present monitoring requirements/standards and those that may extend over a long period of time (and as far back as the 1940s). Moreover, the absence of available monitoring records may equally be due to the loss of records of a monitored worker.

Equally perplexing is the applicability (or need for) ORAUT-OTIB-0020, as given in Section 2.0, lines 21 through 29. For each of the "four categories" of workers for whom OCAS-OTIB-0020 **may apply**, reasons are provided as to why the ORAUT-OTIB-0020 co-worker dose may **not** apply or may not be needed for dose reconstruction.

In brief, the applicability of ORAUT-OTIB-0020 lacks clarity and prescriptive guidance.

Review Objectives 2.1, 2.2, 3.2.3, and 3.2.4

Section 2.0, lines 26 through 29, stipulate that site-specific **co-worker** data, as defined in ORAUT-OTIB-0020, may **not** be necessary for dose reconstruction. Thus, in lieu of site-specific co-worker data, the dose reconstructor may select ". . . reasonable upper limits, provided that the total probability of causation (POC) is less than 45%."

Side-stepping the use of ORAUT-OTIB-0020 and co-worker data, however, requires the dose reconstructor to make a quantitative determination of what corresponds to "reasonable" upper exposures that the **un**monitored person may have received.

Review Objective 4.1

See discussion that references Review Objectives 2.1, 2.2, 2.3, 3.2.3, and 3.2.4 above.

Review Objectives 5.1, 5.2, and 5.3

If, in fact, the dose reconstructor elects to employ site-specific co-worker data for dose reconstruction, a decision must be made whether to use the 50^{th} or the 95^{th} percentile dose of a representative co-worker population.

Section 3.0, lines 1 through 21, contain guidance for selecting the 50^{th} and 95^{th} percentile values. Again, the dose reconstructor is placed into a situation where "professional judgment" must be made whether (1) the **un**monitored worker was exposed only **intermittently** or routinely and/or (2) the assigned dose is to represent a "best estimate" or a bounding value.

It is SC&A's opinion that data needed for these decisions are unlikely to be available to the dose reconstructor.

Review Objective 6.1

Lines 23 and 25 of Section 3.0 state that co-worker data (which SC&A assumes to include the 50th percentile value) will be treated as a constant (i.e., without any estimate of uncertainty). While SC&A concurs with the use of a 95th percentile value as a constant, SC&A considers the 50% percentile constant value as one that is without scientific basis and not claimant favorable.

Review Objective 7.1

As already discussed above, there are multiple elements described in the guidance/use of this OTIB that require the dose reconstructor to make subjective decisions or require information that is not likely to be available.

In addition to previously cited examples, Section 4.0, lines 9 through 19, prompts the dose reconstructor to resolve complex issues involving work practices, radiological incidents, etc. Resolution of such complex issues will require a great deal of judgment by dose reconstructors, and these judgments may not be made in a consistent manner among different dose reconstructors.

2.4 ORAUT-OTIB-0023: ASSIGNMENT OF MISSED NEUTRON DOSES BASED ON DOSIMETER RECORDS

The review of ORAUT-OTIB-0023, Rev. 00, dated March 7, 2005, was prepared by U. Hans Behling, PhD, MPH, and approved by John Mauro, PhD, CHP, on March 31, 2006.

2.4.1 Purpose of Procedure

The purpose of this OTIB is to provide information to allow ORAU Team dose reconstructors to determine when it is appropriate to assign missed neutron doses at DOE sites using the *n*LOD/2 method or an "alternative" method. Use of the "alternative" method should be applied when the missed neutron central estimate (i.e., *n*LOD/2) exceeds 75% of the assigned photon dose (i.e., from recorded dosimeter dose + missed dose). A description of the alternative method is provided below in behalf of Review Objective 1.4.

2.4.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0023 is summarized in Table 2.4-1 below. Table 2.4-1 is a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether the procedures adequately support the dose reconstruction process as directed under the EEOICPA and defined in 42 CFR Part 82.

Table 2.4-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0023, Rev. 00	**Effective Date:** 03/07/2005
Document Title: Assignment of Missed Neutron Doses Based on Dosimeter Records	
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)?	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?	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). 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?	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)?	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
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses.	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.

2.4.3 Review Comments

Review Objectives 1.1 and 1.2

The procedure lacks clarity by failing to provide clear definition(s), and is inconsistent in its terminology. References/descriptions pertaining to neutron monitoring in Section 2.0,

Background, that relate to *"unreliable"* neutron dosimeters are not only irrelevant to the OTIB, but introduce unnecessary confusion, since this OTIB is intended only for accurate neutron monitoring data that are considered the "dose of record."

Review Objective 1.3

For the alternative method (when *n*LOD/2 is not used), detailed information is required that will **not** be readily available to the dose reconstructor. (For a more detailed explanation, see Review Objectives 7.1, 7.2, and 7.3 below.)

Review Objective 1.4

ORAUT-OTIB-0023 references OCAS-IG-001 as the basis for its guidance. Guidance contained in ORAUT-OTIB-0023 and OCAS-IG-001, however, is inconsistent. The key discrepancies are as follows:

(1) Reference to the dosimeter data that reflect **reliable** versus **un**reliable neutron dosimeters differs between the two guidance documents.

(2) The need for use of neutron survey data and stay times when missed neutron doses exceed 75% of photon doses is **only** prescribed in OCAS-IG-001.

(3) The same 75% condition in ORAUT-OTIB-0023, however, is only invoked in combination with a second condition in order to **avoid** the assignment of missed neutron dose altogether. Thus, if the second condition is **not** met, ORAUT-OTIB-0023 provides no guidance for assigning missed neutron dose.

The following provides a more detailed description of these discrepancies:

- OCAS-IG-001, Section 2.2.2.2.1, provides the following guidance:

  An exception to the method is needed for unreasonably high neutron missed doses. Generally the neutron dose is significantly less than the photon dose. Therefore ***when the neutron missed dose central estimate (nLOD/2) exceeds 75% of the photon dose*** *(dosimeter dose + missed dose), the exposure should be treated as an unmonitored exposure and radiation survey data combined with stay times (frequency of exposure) should be used to estimate the missed dose. The reason for this deviation is that early monitoring of neutrons was* ***sufficiently poor*** *that the missed dose was virtually an unmonitored exposure. With accurate stay time information and numerous neutron measurements, a reasonable estimate of exposure can be derived for recorded exposures below the limit of detection.* [Emphasis added.]

  In summary, OCAS-IG-001 cites the 75% photon criteria in behalf of neutron dosimeters judged to be **un**reliable, and proposes to use "radiation survey data

combined with stay times" as the alternative method for estimating missed neutron doses.

- ORAUT-OTIB-0023, Section 3.0, Applications and Limitations, provides the following:

  *The guidance in this TIB applies to cases in which the neutron monitoring devices in use at the site produced results that were **considered the dose of record**. It does **not** apply to periods during which the monitoring was **unreliable** and some method other than the monitoring data (e.g., neutron-gamma ratios) is normally used to assign neutron dose based on information in the site TBD or other reliable source.* [Emphasis added.]

  And,

- ORAUT-OTIB-0023, Section 6.0, Guidance, provides the following:

  *Workers who were monitored for neutrons using **reliable** dosimeters should generally be assigned missed doses in accordance with OCAS-IG-001 (i.e., using the LOD/2) method for any null results. As described in the IG, however, an exception to the method is needed for unreasonably high neutron doses.*

  ***Missed neutron doses do not need to be assigned if both of the following conditions are met**:*

  1. *The neutron missed dose central estimate (nLOD/2) would exceed 75% of the photon dose (dosimeter dose + missed dose).*

  2. *Based on the employee's work location(s) and relevant information in the site TBD or other documentation (e.g., neutron source term information, neutron survey results, and the potential for neutron exposures), the dose reconstructor determines that the employee's neutron dose was zero or incidental relative to the external dose assigned.*

  *If **both of the above conditions are met**, dose reconstructors should include appropriate explanatory language in the dose reconstruction (DR) report. This should include a discussion in the DR report of the available information regarding work locations and the rationale for the conclusion that neutron doses could not have exceeded **incidental** levels.* [Emphasis added.]

Review Objective 1.5

For the dose reconstructor, potentially subjective decisions may include (1) the determination of neutron dosimeters as being reliable or unreliable, and (2) the need to assign a quantitative value to the term "incidental levels" of neutron exposures. (Note: SC&A assumes that this OTIB is intended for dose reconstructions that are classified as "best estimates"). It is questionable

whether dose reconstructors are in a position or have the information to make such judgments. In addition, when such judgments are made, there is a high potential for different dose reconstructors to come to different judgments; i.e., by its very nature, it is unlikely that the OTIB can be implemented in a consistent manner.

Review Objective 4.2

ORAUT-OTIB-0023 defers to OCAS-IG-001 with regard to the technical basis for its guidance. However, a comparison between the two documents identifies significant differences as described under Review Objective 1.4 above.

Review Objective 7.1

At this time, it is uncertain whether guidance contained in OCAS-IG-001 (which requires the assignment of neutron doses based on neutron survey data and worker stay times) applies to ORAUT-OTIB-0023 in instances when only condition #1 is met.

If the answer is yes, then the reconstruction of missed neutron doses from ". . . **numerous** neutron measurements and **accurate** time information" [emphasis added] can only be regarded as unrealistic.

Review Objective 7.2

SC&A interprets the current guidance in ORAUT-OTIB-0023 as providing two options:

- Option #1. Missed neutron doses are assigned for "reliable neutron dosimeters" on the basis of *n*LOD/2. Since NTA film at most facilities is not considered reliable, LOD values for TLNDs are generally given at 10 or 20 mrem. For TLND, common exchange cycles involve quarterly or monthly exchange periods and would result in *n*LOD/2 missed neutron doses of as little as (4)(10)/2 or 20 mrem per year to (12)(20)/2 or 120 mrem per year.

- Option #2. When both conditions are met, missed neutron doses may be ignored altogether and a zero dose is assigned.

Thus, the difference between Option #1 and Option #2 may vary between 20 mrem per year to 120 mrem per year. Given these trivial doses and the need to provide compelling rationale/ explanation for selecting Option #2, the regulatory recommendation for "striking a balance between the need for technical precision and process efficiency" has clearly been ignored.

Review Objective 7.3

A key element in ORAUT-OTIB-0023 (as well as in OCAS-IG-001) is the unsupported assumption that when the missed neutron dose exceeds 75% of recorded + missed photon dose, such a missed neutron dose must be regarded as inflated/unrealistic.

A review of several TBDs identifies multiple locations where the neutron-to-photon ratios exceed 0.75. For example, ORAUT-TKBS-0014-6 identifies several locations at Y-12 with neutron-to-photon ratios well in excess of 1:1 and as high as 25:1. Thus, the generic assumption of a neutron-to-photon ratio of 0.75:1 as a limiting value for the application of *n*LOD/2 is neither technically defensible nor claimant favorable.

2.5 ORAUT-OTIB-0017: INTERPRETATION OF DOSIMETRY DATA FOR ASSIGNMENT OF SHALLOW DOSE

The review of OCAS-OTIB-0017, *Interpretation of Dosimetry Data for Assignment of Shallow Dose*, Rev. 01, dated October 11, 2005, was prepared by John Hunt, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006.

2.5.1 Purpose of Procedure

This OTIB provides guidance for assigning shallow doses to the skin, testes, and breast from non-penetrating radition, including beta exposures and exposures to low-energy photons.

2.5.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0017 is summarized in Table 2.5-1 below. Table 2.5-1 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 2.5-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0017	**Effective Date:** 10/11/2005
Document Title: Interpretation of Dosimetry Data For Assignment of Shallow Dose, Rev. 01	
Auditor: John Hunt, PhD	

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?	4	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	It references other related NIOSH and ORAUT documents, 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?	1	See Review Comments
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)	5	
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?	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	
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)?	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	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses.	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.

2.5.3 General Comments

ORAUT-OTIB-0017 presents a comprehensive and thoughtful discourse on the challenges associated with reconstructing shallow doses from soft photons and beta emitters. It provides detailed and comprehensive guidance regarding the difficulties in interpreting external dosimetry data for several target tissues and organs and for a range of facilities and times periods, considering their different monitoring techniques and reporting practices. However, we would like to offer the following observations and suggestions that we believe would further improve

the document. The format used here is to first quote the statement made in the guide (the statement in italics) followed by our comment(s).

Page 6, item 3: Assign the non-penetrating dose as electrons >15 keV (corrected for attenuation where applicable) or photons < 30 keV if the employee worked in a plutonium facility.
It is suggested that the dose reconstructor should check whether the site was reporting dose due to electrons or photons, and whether the dosimetry system had been calibrated for that type of radiation. For example, consider an employee that worked with plutonium. If his individual dosimeter had been calibrated for beta radiation, the result would have been reported as 40 mrem (due to beta radiation). It is not procedurally correct to now say that he was exposed to 40 mrem of low-energy photon radiation. If the above-mentioned employee had, in fact, been exposed to low-energy photon radiation and not beta radiation, then the case is more complicated.
Unless a calibration factor that would convert the beta dose into a low-energy photon dose can be calculated, then it could be stated that the dosimetry system at the time was not capable of measuring low-energy photons, and therefore, the employee's dose due to low-energy photons is unknown.

Electron attenuation
Page 7: An acceptable minimizing approach is to assume a transmission of 0.6.
The protective clothing used for each case was known in the great majority of the cases. The transmission factors for this clothing should be used.

Exposure geometry
Page 7: The nature of beta particles suggests that some recorded doses may significantly overestimate or underestimate the actual dose to the skin at the cancer diagnosis location.
Unless there were fundamental mistakes in the calibration of the dosimeters, the beta dose will never have been overestimated. However, we agree that the recorded dose can and will significantly underestimate the real beta dose. It is SC&A's opinion, from a practical occupational exposure point of view, that individual monitoring for beta particles only works on a "yes there was a beta dose/no there was no beta dose" basis. Consider the following examples, which cover most, if not all, working place geometries:

(1) Directly handling uranium, as in the OCAS-IG-001 example, or directly handling other beta/gamma emitters (hopefully with thick gloves). Dose to dosimeter less than 1% of the dose to the skin of the hand or forearm.

(2) Hot particle or evenly distributed skin contamination, to the lip or to the shoulder as in the OCAS-IG-001 example – dose to dosimeter less than 1% of the skin dose.

(3) Working in a confined contaminated space, such as pipe, vessel, or duct, or lying face down on a contaminated surface – in this case, the beta dose to the dosimeter approximates the dose to skin if the beta energy spectrum is similar to the beta calibration spectrum. The front of the dosimeter has to be facing the contaminated surface.

(4) Standing, sitting, kneeling, or on all fours on a contaminated surface – beta dose to dosimeter less than 10% of the overall skin beta dose and less than 1% of the dose to the

skin in contact with the surface. The dosimeter held perpendicular to the contaminated surface considerably reduces the response.

(5) Standing facing a contaminated surface – if the distance to the surface is lower than around 50 cm, the dose to dosimeter approximates the dose to skin if the beta energy spectrum experienced by the worker is the same as that used for calibration. If the distance from the dosimeter to the contaminated surface is higher than around 50 cm, the dose is too low to be relevant for POC calculations. For any other relative position, the dose to the dosimeter is less than 1% of the skin dose.

Looking at the five irradiation geometries above suggests that, unless the employee spent most of his day doing maintenance work in confined spaces or supervising a contaminated control panel, the beta dose to his or her dosimeter (basically zero) will have no relation to the real beta skin dose.

For dosimeters that discriminate beta radiation (with a true OW and a plastic filter for the betas), and if it is clear that the dosimeter has been exposed to beta radiation, it is a good practice to make a workplace survey with portable equipment to determine the location and count rate (which can then be used to approximate dose rate) of the beta-gamma radiation fields. Once located, the beta-gamma contamination should be removed or reduced. Loose beta-gamma contamination poses a greater hazard from the point of view of internal contamination than as an external hazard. As part of the site profile and dose reconstruction, an attempt should be made to determine whether these practices were employed if beta exposures are of concern for particular facilities and claimants.

Film dosimeters are also useful to detect loose beta-gamma contamination in the workplace; a particle or dust deposited on the outside of the film badge holder will leave a distinctive circular black mark on the film. The film is a very sensitive detector of a beta-gamma emitter on the film badge, as the source is almost in contact with the film, and the film integrates the dose over the interval between the contamination and the film change. This was also the way that radioactivity was discovered in the first place. It is not possible, of course, to estimate the shallow dose; only to give a yes/no beta contamination indication.

The particle may be deposited on the film badge as dust or by holding the film badge with contaminated hands. If there was sufficient removable beta-gamma contamination in the workplace to produce a relevant beta dose, then there is a high probability that this would have been seen directly on a few of the film badges over a number of the dosimeter changes. From our experience, for each month of monitoring a NPP, we would see on average one film with a characteristic mark of beta-gamma contamination on the film badge. The dose report would then contain the observation, “Film badge holder contaminated, please change.” The nuclear medicine clinics were worse; the incidence rate of beta-gamma contamination marks was higher.

If this film badge contamination was not seen, it could be concluded that beta radiation fields from open beta-gamma contamination were not an occupational radiation protection problem for the specific DOE facility operation.

Non-uniform exposure of the skin

Page 8: If it is known that the cancer occurred in an area not within the area for contamination or partial-body irradiation, no dose should be assigned to that cancer location.

As discussed in the item on exposure geometry, it is possible to state definitely where the cancer site is, but not where the contamination was, if film or TLD dosimetry were the only detection methods available.

Page 8: For example, a hot particle skin exposure for 1cm^2 in accordance with OCAS-IG-001 should be modified to account for total skin area…

As stated previously, a skin dose due to hot particle exposure will not be detected by individual dosimetry because of the localized nature of the exposure. There is a high probability that employees were exposed to hot particles if their activities included entering workplaces where the following may have existed:

- Particles from damaged and used fuel elements
- Fission products from nuclear device testing or a criticality accident
- Fission products in hot-labs, canyons, or hot-cells (maintenance work)
- Particle releases from facility stacks (Hanford)

The employees were normally "frisked" out of the control area, but the success of detection of hot particles is not 100%. Normally, only the hands, shoes, and possibly hair are "frisked." It would help the dose reconstructors if a "reference hot-particle skin dose" could be calculated that would establish (1) a "standard hot particle," (2) the time expected before "frisking" and removal of the contamination, (3) the calculation of the dose, due to the hot particle placed on the skin or placed on protective clothing, and (4) the uncertainties due to the non-uniform exposure of the skin. This "standard hot-particle exposure" would then be used for the cases of skin cancer for employees whose jobs included the above-mentioned activities. However, using the example and the procedure given in the OTIB, the skin dose due to a "hot particle" will not generate a POC higher than around 30%. Specifically, the case given in the OTIB (skin – basal cell cancer, electrons > 15 keV – acute, GM = 0.01 rem, GSD = 14, birth 1925, exposure 1945, diagnosis 1980) gives a POC of 27%.

The mathematics of probability can be used to show that if 1,000 such employees suffered skin doses due to hot particles, with the above POC, around 270 of them would develop skin – basal cell cancers, and not zero, as calculated through the IREP methodology.

There is also the question of how many hot-particle irradiations per person should be considered for the dose reconstruction. Exposure to three of the OTIB hot particles will give a POC above 50%.

Over-response of film to low-energy photons

Page 9: …..by factors of 8.5-12 and 14-19.

We assume that these factors represent over-response of film to low energy photons relative to exposure to photons with energies greater than 250 keV photons. This should be made clear in the document.

Page 9: …a factor of 0.6 is prescribed….
Considering the order-of-magnitude factors given above, a factor of 0.6 is very claimant favorable.

Page 9: Missed doses assigned as < 30 keV photons should also include this correction factor (0.6)…
If a dosimetry service recorded, for example, 30 mrem as the LOD for OW and S dose, then this value (30 mrem) should be used as the basis for the missed dose calculation.

Attachment A
Page 15: The thickness of each garment is 2 mm, giving a total of 4 mm….
It is not claimant favorable to consider that the employee had 4 mm of clothing thickness. Our own measurements made with a micrometer determined the thickness of a number of items of clothing, such as a laboratory overcoat (0.4 mm), a thin sweater (0.8 mm), and a thick shirt (0.6 mm). We would suggest checking the basis for the 4 mm assumption (or 5 mm assumption on page 17), and recalculating the shielding and correction factors accordingly.

Page 17: The source was modeled as a 10-cm2 infinitely thin disk source located 2 cm away from the skin.
For the breast area, the film dosimeter would give a reasonable dose estimate. If the source was near the testicles, the film dosimeter would not measure anything.

Page 17: Tables A-1 and A-2
In almost all real cases, it is not possible to state that the beta dose was due to Ru/Rh-106, Sr/Y-90, Nb-95, and so on. All that can be said is that "the beta dose was due to a mixture of fission products" or "the beta dose was due to decay products of U-238 and U-235." Therefore, this table and the other tables should include correction factors for a "standard" fission product mix and for uranium series decay products in equilibrium.

Page 18:…a significant fraction of the X-rays being absorbed by the 1 cm thick shield (on the film dosimeter).
The correct thickness of the shield should be given.

Page 18:…sensitive issues
Should read, "sensitive tissues."

Page 18: …is more notable for the low energy beta sources, especially those with maximum energies below 500 keV.
As indicated in the Portsmouth TKBS (ORAUT-TKBS-0015-6), for low-energy beta radiation, the dosimeters were likely incapable of furnishing accurate doses in terms of Hp(0.07).

Attachments B and C
Pages 21 and 24…
It is not clear why the two tables of examples give the recommendation to assign a 30-250 keV for missed dose to the skin for 0 "OW reading" and 0 "S reading," as this does not follow the general logic of the table, and this energy range is not claimant favorable.

Attachment D

Page 25…..in general, the contribution to skin dose at GDPs from low energy photons is extremely small compared to the contribution from beta particles.

It is likely that the beta doses to the skin (mainly the hands) of employees doing maintenance or decontamination work at the GPDs will be higher than the low-energy photon doses. However, considering the arguments in this report, it is also likely that the dosimeters used did not record this beta dose, only the low-energy photon dose. The employees in operation areas with closed systems with UF_6 or other uranium compounds would be more exposed to low-energy photons ($E < 30$ keV) than beta particles. In any case, the photon dose rate would be low.

2.5.4 Review Comments

Review Comments 1.2:

The title of the OTIB, *Interpretation of Dosimetry Data for the Assignment of Shallow Dose*, does not correspond to the content of the OTIB, as the assignment of both shallow and penetrating doses are discussed. A more correct title would be *Interpretation of Dosimetry Data for the Assignment of Dose to the Skin and Other Shallow Organs*. The logical order of the information in Chapter 3: General Approach could be improved.

Review Comments 2.1

The OTIB does not identify any cases where a possibly high POC can be determined early in the investigation. It does identify assumptions to be made to minimize the POC in likely compensable cases.

Review Comment 5.2

The procedure is not claimant favorable in instances of unknown parameters effecting dose estimates. In summary, due to the localized form of beta irradiation, the beta dose as measured on the thorax or extremity dosimeter has no relationship to the worker's skin dose at the point of cancer incidence. There are two exceptions to this general rule:

(a) Immersion in a cloud of beta-gamma emitters
(b) Skin cancer on the wrist for a wrist extremity dosimeter or on the chest for a thorax dosimeter

It is convenient to say "the beta dose was as measured on the dosimeter." However, the dosimeter will give at best a "yes, there was a beta radiation field" or "no, there was no beta radiation field." In almost all cases, the dosimeter dose will substantially underestimate the beta dose. This substantial underestimation by the dosimeter is mentioned in the OTIB, but not dealt with in any way.

Review Comment 7.3

The procedure does not employ scientifically valid protocols for reconstructing doses, as follows:

(a) Page 6, item 3 of the OTIB states, "Assign the non-penetrating dose as electrons >15 keV (corrected for attenuation where applicable) or photons < 30 keV if the employee worked in a plutonium facility." Either the dose was originally calculated as being due to electrons using the dosimeter calibration factor for betas, or the equivalent calculation was made for photons. It is not possible to change a beta dose to a photon dose and visa-versa.

(b) The assumption of 4 mm thickness of clothing for beta radiation shielding is not claimant favorable.

(c) The treatment of hot spots is not adequate. There is not enough information to allow the POC to be calculated. Open points are the beta energies, the dose to the skin, and the number of hot spots per worker that could be considered as reasonable.

2.6 ORAUT-OTIB-0024 (REV. 00, APRIL 7, 2005): ESTIMATION OF NEUTRON DOSE RATES FROM ALPHA-NEUTRON REACTIONS IN URANIUM AND THORIUM COMPOUNDS

2.6.1 Purpose of Procedure

The stated purpose of this document ". . . is to provide a quick estimate of neutron doses from alpha particle collisions with low atomic number materials. This document provides an estimate of neutron doses at sites that processed thorium and uranium compounds with low atomic number components, but did not perform neutron measurements" (Hysong et al. 2005).

2.6.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0024: *Estimation of Neutron Dose Rates from Alpha-Neutron Reactions in Uranium and Thorium Compounds*, is summarized in Table 2.6-1 below. This table presents a checklist containing objectives that SC&A developed under the first phase of Task 3 to evaluate whether a procedure adequately supports the dose reconstruction process, as described in the introduction to this report.

Table 2.6-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0024	**Effective Date: 04/07/2005**
Document Title: Estimation of Neutron Dose Rates from Alpha-Neutron Reactions in Uranium and Thorium Compounds	
Reviewer: Robert Anigstein, PhD	

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?	1	See Review Comments
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	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?	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?	1	See Review Comments
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	1	See Review Comments
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	1	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?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses.	1	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.

2.6.3 General Comments

Summary of Document

This document aims to ". . . estimate neutron production and dose rates from the alpha-neutron reaction in uranium and thorium compounds. The chemical forms of uranium considered were

UF_4 and UF_6, as well as the uranium oxide forms (UO_2, UO_3, U_3O_8) and "soda salt" ($Na_2U_2O_7$) (Hysong et al. 2005). These estimates are based on a review of published results of experimental measurements, and involve interpolating and, in some cases, extrapolating the published data.

Published data on the average and maximum energies of the spectra of neutrons produced by the (",n) reaction for "-particle energies of 4.0–5.5 MeV incident on oxygen and fluorine targets are extrapolated to " energies of 6.0–8.8 MeV, based on "scaling" the published data. Only one datum is listed for a sodium target; the maximum energy of neutrons produced by bombardment by P-239 " rays. Based on these values, Hysong et al. conclude that the average energy of neutrons produced by the (",n) reaction is 2.0 MeV.

Next, the authors present tables of the neutron yield from the isotopes in natural uranium and from Th-232 mixed with oxygen, fluorine, and sodium, respectively. These tables are based on values from three sources; DOE Standard –1136 (DOE 2000), Salmon and Hermann (1992), and Auguston and Reilly (1974). These references are secondary sources. DOE 2000 cites data from Reilly et al. (1991), which itself is a reference manual that cites other sources. Salmon and Hermann (1992, Table 3) present a table of neutron yields vs. " energies, which are interpolated from data published in other reports. Auguston and Reilly (1991, Table 7.1) list neutron yields for different light elements bombarded by " particles from Po-210, while Table 7.2 lists neutron yields for beryllium bombarded by " particles from various actinides. Hysong et al. combined the data in these two tables and attributed their results to Auguston and Reilly. After comparing data derived from these three sources, Hysong et al. selected the Salmon and Hermann data to use in estimating the neutron yields from compounds of uranium and thorium.

The yield from each radionuclide was derived on the basis of its average "-particle energy by interpolating the Salmon and Hermann data, which are themselves interpolations of data published between 1960 and 1982. The neutron yields of compounds of separated natural uranium and separated natural thorium, as well as of compounds of uranium and thorium in secular equilibrium with their progenies, are calculated by summing the contributions of " particles from each isotope in the mixture.

The dose from each mixture of "-emitting nuclides and light elements is then estimated by calculating the neutron flux at distances of 1 ft and 3 ft from a point source and multiplying these fluxes by a conversion factor of 1.3×10^{-4} rem/h per neutron cm^{-2} s^{-1}.

Independent Verification of Neutron Doses

SC&A independently calculated the dose rates from neutrons emitted by compounds of separated natural uranium, as well as by compounds of natural uranium in secular equilibrium with its entire radioactive progeny. The neutron yields and energy spectra were calculated by use of the SOURCES-4C computer code (LANL 2002), a code system that determines neutron production rates and spectra from (",n) reactions, spontaneous fission, and delayed neutron emission due to radionuclide decay.

The SOURCES-4C code package includes a data file with (",n) reaction cross-sections for 19 target isotopes of various light elements. Each data set encompasses a range of " energies;

the maxima of these energy ranges vary from 6.5 to 11.5 MeV, depending on the target nuclide. These data sets can enable the calculation of neutron yields from the (",n) reaction with each of the target nuclei over the corresponding range of " energies.

The energy spectrum of the neutrons produced by the (",n) reaction depends on the target nucleus, the energy of the incident " particle, and the energy level of the excited state of the nucleus produced by the reaction. As an example, if the target nuclide is O-18, a naturally occurring isotope of oxygen, the reaction is written as $^{18}O(",n)^{21}Ne$. The product nuclide, Ne-21, is left in an excited state. Calculating the energy spectrum of the neutrons requires knowledge of the branching fractions of the excited-state energy levels of the product nuclide. SOURCES-4C includes energy level branching fractions for 16 of the 19 nuclides for which cross-section data are provided. The maxima of the "-particle energy ranges in these 16 data sets vary from 6.0 to 12 MeV.

The SOURCES-4C code includes decay data on 107 source nuclides. In principle, the user can specify any combination of these nuclides. However, in its current release, the code will not execute if any source nuclide emits any " particles with an energy, $E_" > 6.5$ MeV.

Our calculations of the neutron energy spectra omitted the contributions of source nuclides with $E_"$ greater than the range of " energies in the branching fraction data for each target nuclide. The maximum value of $E_"$ for a F-19 target (the only stable isotope of fluorine) is 6.0 MeV; it is 6.5 MeV for all other target nuclides in our analysis. In calculating the uranium oxide neutron energy spectra, we omitted Po-214, which would be in secular equilibrium with U-238, and Rn-219, Po-215, and Bi-211, which are in equilibrium with U-235. In the case of uranium fluorides, we also omitted Po-218, which would also be in secular equilibrium with U-238, and Th-227, part of the U-235 progeny. We then used the MCNP5 computer code (LANL 2004) to calculate effective doses based on these spectra, utilizing the fluence-to-dose coefficients for the anterioposterior (AP) exposure geometry listed in ICRP Publication 74 (ICRP 1996). Table 2.1-2 presents the results of our calculations and compares them to values presented by Hysong et al. It should be noted that our results are listed in terms of 1 g of compound, while the OTIB values are for 1 g of uranium. In calculating the comparisons in the last column, the dose rates are renormalized to a common basis.

In the case of uranium compounds with progenies, we calculated the dose rate at 1 ft by multiplying the average dose per neutron (based on the neutron spectra without high-$E_"$ isotopes) by the neutron yield for the entire decay chain.[5] For example, the row "Progeny: < 6.5 MeV" lists the doses from the compound in equilibrium with all daughters except for high-energy alpha emitters, while the rows "Progeny: all" lists the dose rate that is the product of the neutron yield from the entire decay chains and the average dose per neutron in the previous row. All neutron spectra and yields include neutrons from the spontaneous fission of the uranium isotopes and their progenies. Except for spontaneous fission, we omitted decay modes with an effective

[5] We calculated the neutron yield for target nuclides and values of E_a for which the appropriate cross-section data were included in the data file. This was accomplished by deleting the lines of the SOURCES-4C Fortran source code that prevented the calculation of neutron yields for $E_" > 6.5$ MeV. This is consistent with modifications that had been made by one of the authors of the code for a similar purpose (Shores 2006).

branching ratio—the product of the branching ratio and the activity fraction of the parent nuclide in natural uranium—of ~0.01% or less.

Table 2.6-2. Dose Rates from Neutrons at 1 Foot from Point Sources of Various Uranium Compounds

Compound		U Decay Series	Ave. Dose (pSv/neutron)	Yield (n/s)	Dose (rem h^{-1} g^{-1})		Δ[a]
Formula	%U				Calculated[b]	OTIB[c]	
$Na_2U_2O_7$	75.1%	Separated[d]	2.64E-02	1.11E-02	1.06E-10	2.89E-11	-79%
UCL_4	62.7%	Separated	2.69E-02	8.54E-03	8.26E-11	6.62E-10	403%
UF_4	75.8%	Separated	2.45E-02	3.89E-02	3.43E-10	6.62E-10	46%
		Progeny: < 6.0 MeV[e]	2.50E-02	1.68E-01	1.51E-09		
		Progeny: all[f]		4.87E-01	4.38E-09	1.19E-8	106%
UF_6	67.6%	Separated	2.44E-02	4.01E-02	3.51E-10	6.62E-10	27%
		Progeny: < 6.0 MeV	2.50E-02	1.79E-01	1.61E-09		
		Progeny: all		5.25E-01	4.72E-09	1.19E-8	70%
UO_2	88.2%	Separated	2.71E-02	1.22E-02	1.19E-10	7.91E-12	-94%
		Progeny: < 6.5 MeV[g]	2.76E-02	1.33E-02	1.32E-10		
		Progeny: all		1.40E-02	1.39E-10	1.04E-10	-34%
UO_3	83.2%	Separated	2.71E-02	1.15E-02	1.13E-10	7.91E-12	-94%
		Progeny: < 6.5 MeV	2.78E-02	1.31E-02	1.31E-10		
		Progeny: all		1.41E-02	1.41E-10	1.04E-10	-39%

Note: Due to limitations in the cross-section data, we did not calculate the doses from $Na_2U_2O_7$ and UCl_4 in the presence of the entire uranium decay chains.

[a] Difference between dose rates in previous two columns, renormalized to 1 g of uranium.

[b] Dose rate at 1 ft calculated using SOURCES-4C, per gram of compound (see text).

[c] Dose rate presented by Hysong et al. 2005, per gram of uranium. A single dose rate is assigned to every oxide, regardless of chemical composition. The same is done for fluorides; the fluoride dose rates are also assigned to chlorides.

[d] Uranium isotopes in ratios of natural abundance, separated from "-emitting progeny.

[e] Uranium isotopes in secular equilibrium with entire decay chain, omitting nuclides with $E_{"} < 6.0$ MeV.

[f] Uranium isotopes in secular equilibrium with all members of decay chain.

[g] Uranium isotopes in secular equilibrium with entire decay chain, omitting nuclides with $E_{"} < 6.5$ MeV.

2.6.4 Review Comments

Issues

The overriding issue with the OTIB is its reliance on outdated experimental results collected from secondary or even tertiary sources, and that it overlooks a current computer code, SOURCES-4C, which is readily available, easy to use, and has been extensively benchmarked.

A second issue is that the OTIB limits the neutron generation to the (alpha,n) reaction. Although this limitation is stated in the text, the brunt of the OTIB, and of the Excel workbook that embodies the calculated results (see Section 2.1.5), would be to cause the dose reconstructor to rely on these results for estimating the neutron dose from compounds containing separated uranium, and overlook the much larger contribution of the neutrons from spontaneous fission of the uranium isotopes. This leads to understating the dose rate by 94% in the case of UO_2 and UO_3, and by 79% for $Na_2U_2O_7$.

The third issue is the listing of doses from uranium decay chains that are truncated at Ra-226 for the U-238 decay series, and at Ra-223 for the U-235 decay series. The use of such truncated uranium decay chains in dose reconstruction implies that all of the Rn-222, the next member of the U-238 decay chain, has escaped during the previous 200 or more years (the time that it would take for Pb-210, the longest-lived member of the Rn-222 decay chain, to come to secular equilibrium). Such an assumption is non-conservative and not scientifically supported. There are few conditions under which all (or almost all) of the radon escapes from a solid matrix. The emanation fraction (the fraction of Rn-222 that escapes the granules of a divided matrix, such as soil) has a range of .05–.7 in soil, with a typical value of .25 used for environmental assessments (Sextro et al. 1987). Even then, not all of the radon that leaves the matrix completely escapes the matrix within which it is contained; some of it decays before it escapes to the atmosphere. Therefore, most of the radon remains with the uranium, and its progeny contributes to the neutron yield. This is also true of Rn-219 (the next member after Ra-223 in the U-235 decay chain), which has a 4-second half-life. Similar observations apply to the doses from the Th-232 decay chain that are truncated at Ra-224; the next member is Rn-220, which has a half-life of less than 1 minute.

Still another issue is expressing the dose rates per gram of source isotopes, rather than per gram of compound. This requires the dose reconstructor, who is more likely to have data on the total mass of the material, to do an additional calculation to determine the mass of uranium or thorium in each compound, adding a needless level of complexity and increasing the opportunity for errors.

The remaining issues concern the details of the neutron dose calculations and the scientific validity of these calculations. Table 3-3 of the OTIB presents average and maximum energies of the neutron spectra from oxygen and fluorine for alpha particle energies of 4.0–8.8 MeV. The neutron energies for alpha energies of 4.0–5.5 MeV are based on published data; the values corresponding to higher alpha energies are based on "scaling" that is not further explained. Any such extrapolation ignores the complex nature of the (alpha,n) reaction, which is strongly dependent on the energy of the alpha emitter. These tabulated results are not scientifically valid.

Table 3-4 of the OTIB lists quality factors and fluence per unit dose equivalent for a range of neutron energies, based in part on a 1971 NCRP report. Use of these values is contrary to NIOSH policy as stated in 42 CFR 82, which requires the use of the latest scientific data. ICRP Publication 74 (1996, Table A.41) lists a more recent set of neutron fluence-to-dose coefficients. For 0.5 MeV neutrons in the AP exposure geometry, the ICRP 74 coefficient is 188 pSv cm^2 (1.88×10^{-8} rem cm^2), in contrast to 2.6×10^{-8} rem listed in Table 3-4. For 5.0 MeV neutrons, the ICRP value is equivalent to 4.74×10^{-8} rem cm^2 vs. 4.3×10^{-8} rem cm^2, listed in Table 3-4.

In the end, the OTIB adopts a value of 1.3×10^{-4} rem/h per neutron cm^{-2} s^{-1}, which is equivalent to ~360 pSv cm^2, whereas the ICRP 74 coefficient for 2 MeV neutrons is 383 pSv cm^2. While the difference is not large, the failure to use current ICRP data undermines the scientific validity of the OTIB.

Tables 4-1 and 4-2 of the OTIB present neutron yields for oxygen, fluorine, and sodium in contact with uranium isotopes and with Th-232, and include data attributed to Auguston and Reilly (1974, Tables 7.1 and 7.2). In fact, Table 7.1 lists neutron yields for various light elements, including beryllium, bombarded by alpha particles from Po-210, while Table 7.2 lists the yields from beryllium bombarded by alpha particles emitted by various other nuclides. Hysong et al. combined these two disparate sets of data, based on the unstated assumption that the ratio of the neutron yield of beryllium to that of other light elements is independent of the energy of the incident alpha particles. As with the extrapolation of average and maximum neutron energies in Table 3-3, such an assumption is not scientifically valid. Although these results are not used in the dose calculations, their inclusion undermines the scientific validity of the OTIB.

Table 4-3 of the OTIB presents neutron yields for the members of U-238 decay series. These data are interpolated from Salmon and Hermann (1992, Table 3), which itself is based on interpolations of published data. Table 4-3 lists At-218 with an alpha-emission abundance of 100%. While this is technically correct in one sense—the branching ratio for alpha decay of this nuclide is 99.9%—At-218 is produced by the beta decay of Po-218. The branching ratio for that decay mode is only 0.02%; thus, the relative activity of At-218 in the U-238 decay chain is 0.02%, not 100%, as presented in the table and used in the calculations. Similar errors are found in Table 4-4, which lists neutron yields for the U-235 decay series. Th-227 is given an alpha emission abundance of 100%; in fact, although 100% of the disintegration are by alpha decay, its abundance is 98.62%, which is the branching ratio of the beta decay of its parent, ^{227}Ac-227. More important, At-215 is also listed with an alpha emission abundance of 100%, while its relative activity is only 2.3×10^{-4} %, the branching ratio for beta decay of its parent, Po-215. Likewise, Po-211 is given an abundance of 98.9%. In fact, it undergoes alpha decay in 100% of the disintegrations; however, its activity relative to U-235 is only 0.276%, the branching ratio of its parent, Bi-211. Finally, Table 4-5, which presents neutron yields for the Th-232 decay series, lists Po-212 as being 100% abundant, whereas the correct value is 64.06%. These errors cause significant overestimates of the doses and further undermine the scientific validity of the OTIB.

Conclusions

Limiting the scope of the OTIB to doses from neutrons produced by the (alpha,n) reaction while omitting neutrons from spontaneous fission could lead dose reconstructors to understate the neutron dose from uranium oxides and $Na_2U_2O_7$ by as much as 94% in the case of separated uranium, as shown in Table 2.1-2 of the present review. The alternative would be for NIOSH to issue separate guidance on neutron doses from spontaneous fission; the preferable solution would be to expand the scope of this OTIB to include spontaneous fission. The risk of understating these doses is magnified by the use of the Excel workbook, which embodies the calculations in the OTIB but does not require dose reconstructors to read the OTIB and understand its limitations.

Save for the omission of spontaneous fission, the doses from all uranium compounds would have been overstated. This is evident in the case of the uranium fluorides, where the spontaneous fission plays a much smaller role, due to the much larger yield from the (alpha,n) reaction on fluorine. Here, the dose rate is overstated by over 100% in the case of UF_4 in equilibrium with the uranium progenies.

We also have reservations about presenting dose rates at 1 ft and 3 ft from a point source. Such a situation does not appear to be a realistic representation of actual working conditions. It would be more useful to calculate the ratios of neutron-to-photon doses for uranium and thorium compounds in various generic configurations (e.g., small objects, 55-gal drums, large piles, etc.) The best solution would be to present dose reconstructors with a methodology (e.g., a suite of computer codes) which can be applied to specific situations.

The SOURCES-4C code is, to the best of our knowledge, the state-of-the-art methodology for calculating neutron spectra and yields. In the publicly distributed version, the code is limited to source nuclides with $E\alpha < 6.5$ MeV. NIOSH might consider contacting LANL to develop a customized version of the code that could be used as an aid to dose reconstruction.[6] The spectra produced by the SOURCES code can be directly imported into MCNP5, providing an efficient way of applying the entire set of ICRP Publication 74 fluence-to-dose coefficients to the entire neutron spectrum, rather than applying a single value to an assumed average neutron energy.

One limitation to the calculated doses presented in Table 2.1-2 is the use of the average dose per neutron, calculated from a neutron spectrum that does not embody source nuclides with $E\alpha$ greater than the maxima in the level branching data for the given target nuclide, to calculate the neutron dose from the entire uranium decay chain. The neutrons from the entire decay chain would have somewhat higher energies, which leads to an increase in the dose due to the slightly higher values of the fluence-to-dose coefficients. This effect would increase the discrepancy between our calculations and the OTIB values for uranium oxides with progenies, while somewhat reducing the discrepancy with the corresponding calculation for fluorides.

2.6.5 Review of Workbook

We have reviewed the Excel workbook, ORAUT-OTIB-0024Rev00-Calphaneutrondose.xls, which is furnished to dose reconstructors as a tool for utilizing the results of the OTIB. We start the discussion with the second sheet of the workbook, entitled "Alphan." This sheet embodies the calculations presented in Tables 5-1 – 6-3 of the OTIB. Since we have reviewed these calculations in the preceding sections of the present report, they will not be discussed further at this time. The first sheet of the workbook, "AlphanCalcs," contains 13 blocks of data formatted as tables—an example is illustrated in Table 2.6-3.

[6] Data for the (",n) reaction for " energies up to 15 MeV have recently been calculated by the Japan Atomic Energy Agency (JAEA 2006). It is likely that these data, suitably formatted, could be imported into the SOURCES-4C data files.

Table 2.6-3. User Input Field in ORAU Workbook

Natural Uranium in $UO_2/UO_3/U_3O_8$ (No Progeny)		
ENTER Mass (grams) of U_{nat}		1
NEUTRON DOSE RATES (rem/h)		
1 ft from source	7.91E-12	
3 ft from source	8.79E-13	

Each table corresponds to natural uranium isotopes, or natural thorium, in the form of different chemical compounds, as described in the OTIB. Each table contains a cell, highlighted in yellow, in which the user enters the mass of uranium or thorium (not the mass of the oxide or other compound—see discussion earlier in this review). The neutron dose rates at distances of 1 ft and 3 ft from the point source that contains the mass of uranium or thorium entered by the user are displayed in the table. The cells displaying these doses are linked to the dose rates, per gram of uranium or thorium, calculated in the worksheet Alphan; the cells in the table multiply the mass of uranium (or thorium, as the case may be) input by the user by the dose rate in worksheet Alphan. The multiplication is performed correctly. The only additional findings concerning this workbook are errors in the text in AlphanCalcs!F9 and AlphanCalcs!K9. The legend in AlphanCalcs!F9 is incorrectly formatted: "$Na_2/U_2/O_7$" should be "$Na_2U_2O_7$," as in AlphanCalcs!A9, where it is entered correctly. In AlphanCalcs!K9, the material is incorrectly listed as $UO_2/UO_3/U_3O_8$, whereas the dose rates are those for $Na_2U_2O_7$.

Other than the above comments, the workbook embodies the calculations in the OTIB. The issues raised regarding the dose calculation in the OTIB in Sections 2.6.3 and 2.6.4 of this review apply equally to this workbook.

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3.0 INTERNAL DOSIMETRY PROCEDURES/DOCUMENTS

3.1 OCAS-TIB-009 (REVISION NO. 0, APRIL 13, 2004): ESTIMATION OF INGESTION INTAKES

The review of OCAS-TIB-009, *Estimation of Ingestion Intakes*, Rev. 0, dated April 13, 2004, was prepared by John Mauro, PhD, CHP, and approved by Hans Behling, MPH, PhD, on May 30, 2006.

3.1.1 Purpose of Procedure

This TIB provides guidance to be used for estimating intakes of radioactive material through inadvertent ingestion of particulate material that may have been deposited directly onto food items and drinks, or deposited onto work-area surfaces and inadvertently ingested by hand-to-mouth behaviors. The procedure is to be used when bioassay data are not available, and it is necessary to estimate ingestion dose based on information related to the airborne concentration of radioactive particles. The procedure does not adddress the ingestion of material that is deposited in the upper respiratory tract from inhalation and then ingested due to muco-ciliary clearance. That mode of "ingestion" is evaluated as part of the inhalation dosimetry protocols incorporated into IMBA.

3.1.2 Review Protocol

SC&A's evaluation of OCAS-TIB-009 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-TIB-009	**Effective Date:** April 13, 2004
Document Title: Estimation of Ingestion Intakes	
Reviewer: John Mauro	

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?	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?	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?	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	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?	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?	3	See comments below
5.2	Is the procedure claimant favorable in instances of unknown parameters affecting dose estimates?	3	See comments below
5.3	Is the procedure claimant favorable in instances where claimant was not monitored?	3	See comments below
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?	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?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	3	

* 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 5.1-5.3 and 7.2

As indicated in Table 3.1.1, all review criteria received a score of 5 except for criteria 5.1, 5.2, 5.3, and 7.3. These criteria were assigned a score of 3 because we believe that the fundamental

scientific approach to reconstructing ingestion exposures has certain flaws that could lead to an underestimate of ingestion doses under certain circumstances.

The method recommended in OCAS-TIB-009 is based on the assumption that the amount of radioactive material that may be inadvertently ingested by a worker is directly proportional to the airborne concentration and settling velocity of the radionuclide. NIOSH assumed that ingestion involves two modes. The first mode involves the transfer of surface contamination to the hand and subsequently from the hand to the mouth. The fundamental assumptions are as follows:

- Airborne radionuclides deposit onto surfaces continually with a deposition velocity of 0.00075 m/sec. This is the settling velocity of particles with an AMAD of 5 microns. This deposition rate continues 24 hours after which an equilibrium is reached where the removal rate equals the deposition rate.

- The worker's hand, which has a surface area of 0.0155 m^2 (4 inches by 6 inches), is assumed to be contaminated at the same level as surfaces in the building after 365 days of continual deposition, and that 10% of the activity on the worker's hand is ingested per day.

- The fraction of the ingested radionuclides that is absorbed in the gastrointestinal (GI) tract is the same as the f_1 values for inhaled radionuclides.

The outcome of this calculation is that the daily ingestion rate is assumed to be 0.1 the airborne radionuclide concentration expressed in units of pCi/m^3. For example, if the airborne radionuclide concentration is 10 pCi/m^3, the inadvertent ingestion rate is 1 pCi/day. This is as compared to the daily inhalation rate, which would be 1.2 m^3/hr × 8 hrs/day × 10 pCi/m^3 = 96 pCi/day, or about 100 times the ingestion rate.

The second mode involves the 8-hour deposition of airborne contaminants into a drinking cup with a diameter of 3 inches. Using the same deposition velocity, a daily ingestion is derived that is also about 10% of the activity in a single cubit meter of air. In summary, TIB-009 assumes a total daily ingestion that is 20% of the activity contained in one cubic meter of air.

Model Limitations that are Likely to Results in Underestimates of Intakes

NIOSH's ingestion model is highly simplistic and is likely to yield intakes that are too low and unrealistic. Our concern centers primarily on mode 1, which firstly models the activity on surfaces and secondly models the transfer of surface contamination to the hand and subsequently to the mouth. This model suffers from the following deficiencies:

- Surface contamination levels are likely to be orders of magnitude higher than predicted by the settling velocity of airborne contaminants assumed at 5 microns. For example, at uranium rolling mills, airborne particulates are likely to represent a distribution of particles that range from a few microns to large/visible particles. For larger particles, settling velocities increase dramatically and while large particles limit internalization by inhalation, there are no limitations for their ingestion.

- Surface contamination is likely to build up over time that may extend to weeks/months or longer before reaching equilibrium. NIOSH's assumption that this equilibrium is reached in a 24-hour period is without scientific basis and highly nonconservative.

- For select processes, surface contamination may not be the result of settling, but may include liquid spills, or result from milling, grinding, cutting, welding, etc.

- The modeled transfer of surface contaminations to the mouth that assumes a 10% transfer from the surface area of one hand during a full workday appears unrealistic. In a hot/dusty work environment, a "radiologically uninformed/untrained" worker is likely to contact/wipe his/her face with both hands repeatedly over the course of a full workday.

- Ingestion may involve other modes such as direct deposition on lips, smoking of cigarettes, etc.

These and other issues related to the ingestion model were discussed with NIOSH as part of the issues resolution process for the Bethlehem Steel site profile review. NIOSH and SC&A agreed that many of fundamental assumptions used in the TIB model described above suffer from the above-described limitations. Based on these discussions, NIOSH has agreed to revise its approach to deriving radionuclide ingestion rates using empirical data relating the amount of radionuclides deposited on surfaces to the amount of radionuclides ingested. The revised strategy described by NIOSH in these conversations appears to be more scientifically valid and claimant favorable than the methods described in OCAS-TIB-009. SC&A recommends that the Advisory Board revisit this issue after NIOSH issues its revised procedures.

References:

EPA (Environmental Protection Agency) 1997. "Exposure Factors Handbook," EPA/600/P-95/002, August 1997.

NCRP (National Council on Radiation Protection and Measurement) 1996. "Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground." Report No. 123, January 22, 1996.

3.2 OCAS-TIB-011: LUNG DOSE CONVERSION FACTORS FOR THORON, WLM

The review of OCAS-TIB-011, *Lung Dose Conversion Factors for Thoron, WLM*, Rev 01, dated April 15, 2005, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on February 11, 2005.

3.2.1 Purpose of Procedure

This TIB provides the dose conversion factors for calculating lung dose from Rn-220 decay products in working level months (WLMs). The guide was prepared because, though considerable guidance has been developed for estimating exposures to lungs from radon progeny, expressed in WL, less attention has been given to guidance on deriving exposures to

thoron progeny, which are also often expressed in terms of WL. However, the lung dose per WLM of radon progeny is different than the lung dose per WLM of thoron progeny. This guide presents a method for converting thoron progeny exposure, expressed in units of WL, to lung dose.

3.2.2 Review Protocol

SC&A's evaluation of OCAS-TIB-011 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

The document provides an excellent description of why the dose rate per WL associated with radon progeny for a given time period is different than that associated with thoron progeny, even though they both are defined in terms of the amount of short-lived progeny in air that delivers 1.3E5 MeV alpha energy to the respiratory tract. As described in the TIB, the difference in dose rate per WL between 1 WL of radon progeny and 1 WL of thoron progeny is that thoron progeny have a much longer half-life than radon progeny. As a result, there is more time for the thoron progeny deposited in the lung to be redistributed to other regions in the respiratory tract, specifically the extrathoracic (ET) region of the respiratory tract, which includes the anterior nasal passages, nose, mouth, larynx, and pharynx. In addition, the longer half-life of the thoron progeny increases the amount of progeny that are attached to aerosols, thereby changing the particle size distribution and behavior of the inhaled progeny in the lungs.

Table 3.2-1. Procedure Review Outline/Checklist

Document No.: OCAS-TIB-011, Rev. 01	**Effective Date:** 04/15/2005
Document Title: Lung Dose Conversion Factor for Thoron, WLM	
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?	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?	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	
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)?	5	
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?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	4	See Comment Below

* 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.

In order to calculate the doses, some parameters were chosen for Rn-220 using literature data. SC&A agrees that those are reasonable choices, including the following:

- Absorption half-life of 10 hours for Pb-212 and Bi-212
- 2% unattached fraction for the working environment
- Median particle size of 0.25µm for the attached fraction and 0.0015 µm for the unattached fraction, with a GSD of 2.5, in accordance with ICRP 66
- Use of a range of equilibrium values (i.e., 0.2 to 0.8 for Bi-212 to Pb-212)

3.2.4 Review Comments

Review Objective 7.3

NIOSH should provide further clarification on how the values of Table 1 of the TBD were derived. We were not able to reproduce the values of Table 1, even using the same assumptions as the ones provided in the document. SC&A also does not agree with the following statement on page 5 of the TIB: "This causes Pb-212 to produce less lung dose per unit activity inhaled than that of Bi-212," because the lung dose per Bq intake of Pb-212 is about 4 times higher than the lung dose per Bq intake of Bi-212 for particle sizes of 0.25 µm and 0.0015 µm.

3.3 ORAUT-OTIB-0028: VALIDATION OF THORIUM ANNUAL DOSE CONVERSION FACTORS

The review of ORAUT-OTIB-0028, *Validation of Thorium Annual Dose Conversion Factors*, Rev 01, dated March 7, 2005, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on February 24, 2006.

3.3.1 Purpose of Procedure

This OTIB verifies the annual dose conversion factors used for the assessment of Th-232 and Th-228 doses. This verification was needed, because IMBA does not explicitly model the dosimetry of these radionucldes and the independent kinetics of their progeny chain. As a result, a separate set of dose conversion factors were developed for these radionuclides, which are verified in this document.

3.3.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0028 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.

Table 3.3-1. Procedure Review Outline/Checklist

Document No.: OCAS-TIB-0028	**Effective Date:** 03/07/2005
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?	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?	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?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	4	See Comments Below

* 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.

3.3.3 General Comments

The document is meant to validate the Tables of Annual Dose Conversion Factors for Th-232 and Th-228, generated by Dr. Keith Eckerman. The tables were validated by comparing committed equivalent dose coefficients (Sv/Bq) for Th-232 and Th-228, computed using ORNL's DCAL code system (apparently the code system used by Dr. Keith Eckerman) with

values tabulated by the ICRP. The document cites the files provided by Dr. Eckerman that should be used in dose calculations instead of the doses provided by IMBA, including the following:

- Th228AM5.INT - annual dose coefficient (Sv/Bq) for each year for Th-228, adult, Type M, AMAD 5µm, following an acute intake at time zero.

- Th228AS5.ANN - annual dose coefficient (Sv/Bq) for each year for Th-228, adult, Type S, AMAD 5µm, following chronic uniform intake of 1 Bq during year1.

- Th232AM5.INT - annual dose coefficient (Sv/Bq) for each year for Th-232, adult, Type M, AMAD 5µm, following an acute intake at time zero.

- Th232AM5.ANN - annual dose coefficient (Sv/Bq) for each year for Th-232, adult, Type M, AMAD 5µm, following chronic uniform intake of 1 Bq during year1.

It was not possible for SC&A to perform an independent verification of the dose conversion factors reported in this TIB. However, the methods employed appear to be in accordance with ICRP-approved protocols.

3.3.4 Review Comments

Review Objectives 4 and 7

The TIB refers to a number of files that are not provided and are required in order to independently verify the dose conversion factors presented in Table 1 of the document. In addition, the document is incomplete in terms of clarifying the following:

- What should be used when there is a chronic intake of Type M Th-232 or Th-228?
- What should be used when there is an acute intake of Type S Th-232 or Th-228?
- What should be used when there is an intake of Th-232 or Th-228, with AMAD different from 5µm?

3.4 ORAUT-OTIB-0022: GUIDANCE ON WOUND MODELING FOR INTERNAL DOSE RECONSTRUCTION

The review of ORAUT-OTIB-0022, *Guidance on Wound Modeling for Internal Dose Reconstruction*, dated November 18, 2005, was prepared by Joyce Lipsztein, PhD, and approved by John Mauro, PhD, CHP, on March 1, 2006.

3.4.1 Purpose of Procedure

The stated purpose of this procedure is to provide "information and guidance to dose reconstructors regarding the best estimate of internal dose from a contaminated wound."

3.4.2 Review Protocol

Our evaluation of ORAUT-OTIB-0022 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.

Table 3.4-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0022	**Effective Date:** 11/18/2005
Document Title: Guidance on Wound Modeling for Internal Dose Reconstruction	
Reviewer: Joyce Lipsztein, PhD	

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?	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	

* 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
3.1.2	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)	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?	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?	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?	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?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	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.

3.4.3 General Comments

The National Council on Radiation Protection and Measurements (NCRP) is currently working on a wound model, which will be adopted by the ICRP. The suggested wound model provided in this procedure for Pu absorbed from the wound site into the blood stream is a reasonable model to be used as a starting point for input of parameters into the IMBA wound model. The suggested wound model for other nuclides is not specific, but can be applied if there is sufficient bioassay data available. In summary, in the absence of an official NCRP/ICRP wound model, the suggested approach to wound modeling is a good interim alternative to calculate doses to the systemic organs, following an uptake via wound.

3.4.4 Review Comments

SC&A's review of this document produced no comments, and SC&A agrees with its contents and conclusions.

3.5 ORAUT-OTIB-0011: TRITIUM CALCULATED AND MISSED DOSE ESTIMATES

The review of ORAUT-OTIB-0011, *Tritium Calculated and Missed Dose Estimates*, Rev. 00, dated June 29, 2004, was prepared by Bruce Murray, and approved by John Mauro, PhD, CHP, on March 1, 2006.

3.5.1 Purpose of Procedure

The stated purpose of the OTIB is to provide "documentation of the method for estimating tritium missed and calculated doses from urine data. To facilitate entry of organ doses into the Interactive RadioEpidemiological Program (IREP) computer code, an Excel workbook (entitled "Tritium Doses from Urine Data Workbook.xls") was developed to create the IREP annual organ dose input data."

3.5.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0011 is summarized in Table 3.5-1 below. Table 3.5-1 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 3.5-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0011, Rev. 00	**Effective Date:** 06//29/2004
Document Title: Tritium Calculated and Missed Dose Estimates	
Reviewer: Bruce Murray	

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?	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)	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	4	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?	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	
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)?	5	
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?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	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.

3.5.3 General Comments

ORAUT-OTIB-0011 provides guidance for reconstructing doses for workers exposed to tritiated water using the results of either complete or incomplete bioassay programs. It also addresses special situations where two different bioassay measurements have the same bioassay date and time.

The algorithm described in ORAUT-OTIB-0011 is based on the assumption that dose to the whole body is proportional to the area under a urine concentration curve. The ORAUT-OTIB-

0011 algorithm is currently implemented in an EXCEL worksheet ("Tritium Doses from Urine Data Workbook.XLS"). The basic assumptions used in this OTIB are as follows:

- Tritiated water is assumed to be completely and instantly absorbed into the systemic circulation, whether taken in by inhalation, injection, or absorption by the intact skin.
- Tritiated water equilibrates with the body water, and therefore, all body fluids, including urine, are assumed to be equal.
- Instantaneous measurements of the concentration of tritium in urine can be used to directly estimate the effective dose from intakes of tritiated water.
- Urine measurements of tritium are considered to be in direct proportion to a body's water tritium concentration.
- The area under a urine concentration "curve" is directly proportional to effective dose.

Using these basic assumptions, a two-compartment biokinetic model is used to reconstruct the doses from urine data, and is in accordance with ICRP Publication 56, where 97% is incorporated as tritiated water and 3% as organically bound tritium (OBT). The dosimetry factors are as follows:

Radiological Half-Life	12.35 years	See footnote [7]
Biological Half-Life	9.7 days	ICRP 66 rounds to 10 days
HTO Dose Coefficient	1.8E-11 Sv/Bq	From ICRP Publication 68
Clearance Rate Constant (k)	7.14E-2 d-1	Discussed below as a note
Effective dose to decay value	1.5 E-15 rem/decay	

In addition, the OTIB algorithm uses as a "k" clearance constant of 7.14E-2 d^{-1} derived from a reference man removal of 3 liters/day of the 42 liters of body water (i.e., 1.4 L/day are removed as urine).

The algorithm in the workbook is designed to calculate the doses using sequential and comparative "If" statements. The comparative process uses sample data, time intervals, and sample sensitivity (Minimum Detectable Activity (MDA)). The OTIB provides a thorough description of the formulas used in the Excel workbook. The workbook presents simplified equations with graphic illustrations of the urine concentrations over sampling time intervals. The area under each curve representing each time interval is directly proportional to the dose delivered to internal organs over those time intervals.

[7] Radioactive decay is insignificant in this determination, because the biological clearance "… surpasses the physical half-time of 12 years" (PNNL–MA-860, Chapter 4).

3.5.4 Review Comments

Our review of the assumptions employed in the model reveals that, overall, they are consistent with the referenced and pertinent literature. SC&A finds that this document has been satisfactorily prepared; however, we have identified a few minor issues, as follows:

Review Objectives 1.3, 1.5, and 3.2.4

A full understanding of this OTIB requires a review of the workbook. In this regard, the OTIB is not entirely complete. It is not until the workbook is reviewed that the user is informed that an assumed tritium level can be input into the calculation for those time periods when no urine samples were taken, but there is reason to believe that the worker, in fact, could have experienced exposure to tritium. Section 4.1 of the OTIB would benefit from a discussion of the fact that the workbook provides for this contingency. In addition, some guidance is needed regarding when the dose reconstructor should take advantage of this feature of the workbook. For example, if 40 days have passed since the last urine sample, and there is reason to believe that the worker may have experienced continual exposure to tritium, the dose reconstructor should consider inputting a surrogate bioassay result for that time period. This situation could arise if the worker's job description remained unchanged and air sampling indicates that the worker likely continued to experience exposure to tritium.

Review Objective 7.3

ORAUT-OTIB-0011 is based on the assumption that tritiated water is instantaneously absorbed and distributed throughout body water. Our review of relevant literature (e.g., *Methods and Models of the Hanford Internal Dosimetry Program, Hanford Internal Dosimetry Technical Basis Manual*, PNNL-MA-860) indicates that absorption and distribution of tritium requires about 2 hours. This may be relevant for the special circumstance when multiple samples of urine are collected the same day, but have markedly different tritium concentrations. The document would benefit from a discussion of this matter as it applies to the special conditions discussed in Section 3 of the OTIB.

3.6 ORAUT-OTIB-0019: ANALYSIS OF COWORKER BIOASSAY DATA FOR INTERNAL DOSE ASSIGNMENT

The review of ORAUT-OTIB-0019, *Analysis of Coworker Bioassay Data for Internal Dose Assignment*, Rev 01, dated October 7, 2005, was prepared by Harry Chmelynski, PhD, and approved by John Mauro, PhD, CHP, on March 3, 2006.

3.6.1 Purpose of Procedure

This OTIB provides guidance for assigning internal doses to workers using co-worker bioassay data for workers who do not have bioasssay data, but the possibility exists that the worker may have experienced internal exposures.

3.6.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0019 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.

Table 3.6-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0019, Rev. 01	**Effective Date:** 10/07/2005
Document Title: Analysis of Coworker Bioassay Data for Internal Dose Assignment	
Reviewer: Harry Chmelynski, PhD	

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?	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.**		

* 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	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	
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	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?	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	
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?	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?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	4	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.

3.6.3 General Comments

The purpose of ORAUT-OTIB-0019 is to provide guidance for the use of bioassay data in the statistical analysis of worker intake rates. The recommended statistical methods are designed to provide estimates of lognormal distribution parameters based on minimal information. The proposed method has two components; (1) obtain estimates of the geometric mean and the GSD from the ranked observations, and (2) perform a regression analysis to verify that the lognormal distribution provides a good fit to the data. The recommended procedures are not necessarily the most efficient methods for estimating parameters of the lognormal distribution, but were designed to provide estimates of the lognormal parameters for a relatively large number of disparate data sets, many of which include recorded data entries that are below the minimum detectable level, or data entries that are recorded as zero or "less than x." The recommended statistical methods avoid many of the problems commonly encountered when fitting the lognormal distribution to censored data sets of this type.

Assuming the data are well fitted by a lognormal distribution, the 50^{th} percentile (i.e., the median) is used to estimate the geometric mean of the lognormal distribution. The OTIB recommends that an estimate of the GSD can be obtained from the ratio of the 84^{th} percentile to the 50^{th} percentile (see Strom and Stansbury 2000, Equation 7). The recommended procedures eliminate the need to define a minimum detectable activity (MDA) or amount that is appropriate for the measurements by basing all parameter estimates on the 50^{th} and 84^{th} percentiles. Hence, if no more than 50% of the measurements are below the MDA, no assumption concerning the MDA is necessary to obtain the lognormal parameter estimates.

The ORAUT-OTIB proposes that a determination of the goodness-of-fit of a lognormal distribution to a data set of size n is to be based on regression analysis. Specifically, the following recommendations are made in Section 3.4 of ORAUT-OTIB-0019:

> *Calculate the associated R^2 fit parameter. A value greater than 0.9 indicates a very good fit; however, values as low as 0.7 are acceptable, and even lower values may be acceptable if no better equation seems appropriate.*

3.6.4 Review Comments

Review Objective 7.3

It is difficult to determine the source and applicability of the OTIB recommendations regarding goodness of fit. Our concerns are based on the known dependencies that exist in the regression derived from ranked data.

The regression model addressed in this recommendation is written as follows:[8]

$$\ln(y_i) = a + b\, x_i$$

[8] It is far more common to use the symbol z_i for the normal score variate, but the use of x_i as the explanatory variable in a regression takes priority in this discussion.

where the independent variables y_i (i = 1, ... , m # n) denote the observed values, the explanatory variables x_i denotes the normal score of each observation, and *a* and *b* denote the intercept and slope of the regression line, respectively. If the data follow a lognormal distribution with parameters : and F, then a scatterplot of the points (x_i , $\ln(y_i)$) will lie on a straight line with slope *b* = F and intercept *a* = :.

Note that the regression method may be used not only to verify that the data follow a lognormal distribution, but also to provide alternative estimates for the parameters of the lognormal distribution when there are values in the data set below the MDA. Since the regression-based estimates are based on the entire set of data above the MDA, they may be preferred over the minimal information estimates currently recommended. This is particularly true for the estimate of the GSD, which is based on the ratio of the 84^{th} to the 50^{th} percentiles.

When the points in the scatterplot do not all lie on a straight line, it is recommended that the R^2 of the regression be examined to determine if the data is fitted approximately by a lognormal distribution. The authors fail to warn that the R^2 of this regression should be interpreted with care. Note that the data values in the scatterplot are not independent observations. Indeed, if x_i # x_j then it is known with certainty that y_i # y_j. This dependence among the observations violates the usual assumption of conditional independence of the y values in the regression, given the corresponding x values.

In general, the interpretation of R^2 when there is known conditional dependence and censored data is not a simple matter. As a result of the dependency, the observed R^2 value may be seriously over-inflated. The subject was explored long ago by Looney and Gulledge. Using a very similar scatterplot and regression-model approach to estimate the parameters of a normal distribution, they provide tables based on simulation studies that may be used to adjust the observed R^2 values to account for conditional dependence (with no censored data). Extrapolation to the censored data case does not appear to be a straightforward extension of their results.

The recommendations quoted above from Section 3.4 for interpreting the regression R^2 do not appear to take this deviation from the standard regression model assumptions into account. Note that the conditional dependence does not result in biased regression parameter estimates for : and F, only the interpretation of the R^2 value as a goodness-of-fit statistic. Hence, the regression estimates remain a valid "reality check" for the minimal information parameter estimates currently recommended.

References:

Looney, S.W. and T.R. Gulledge, Jr. 1985. "Use of the Correlation Coefficient with Normal Probability Plots," *American Statistician*, Vol. 39, No. 1, February 1985, pp. 75–79.

Strom, D.J., and P.S. Stansbury 2000, "Determining Parameters of Lognormal Distributions from Minimal Information." *American Industrial Hygiene Association Journal*, volume 82, pp. 877–880, eq. 7.

3.7 ORAUT-OTIB-0012: MONTE CARLO METHODS FOR DOSE UNCERTAINTY CALCULATIONS

The review of ORAUT-OTIB-0012, *Monte Carlo Methods for Dose Uncertainty Calculations,* Rev 00, dated February 14, 2005, was prepared by Harry Chmelynski, PhD, and approved by John Mauro, PhD, CHP, on March 3, 2006.

3.7.1 Purpose of Procedure

This OTIB presents an efficiency method applied to Monte Carlo methods which yields best estimate organ doses. Implementation of this method allows the generation of site-specific reference tables for use in best-estimate dose reconstructions without requiring individual Monte Carlo simulations.

3.7.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0012 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 ORAUT-OTIB presents a method for estimating doses by multiplying the annual dosimeter dose by an organ-specific dose conversion factor (DCF). Both quantities in this product have associated probability distributions, which reflect measurement error in the dosimeter readings and uncertainty in the DCF. The organ dose is thus a product of two random variables. NIOSH has assigned normal distributions for the dosimeter measurements and triangular distributions for the DCFs. Since the product of a normal variate times a triangular variate has no simple mathematical expression, the distribution of the products is simulated using a Monte Carlo simulation program, such as Crystal Ball.

The ORAUT-OTIB-0012 methodology provides a way to avoid the need for simulation by preparing tables that allow the user to approximate the distribution of the product doses for each organ. The approximation is derived by fitting normal distributions to samples of the organ dose products obtained for normal distributions with measurement errors ranging from 5% to 100%. The authors provide an example of the fitted normal distribution obtained for one organ and one level of measurement error.

Table 3.7-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0012, Rev. 00	**Effective Date:** 02/14/2005
Document Title: Monte Carlo Methods for Dose Uncertainty Calculations	
Reviewer: Harry Chmelynski	

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?	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	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?	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?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	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.

3.7.4 Review Comments

As part of this review, the Excel add-in program Crystal Ball 2000 was used to determine if the fitted normal distribution obtained in this example is appropriate. A set of 10,000 values was generated as the product of a normal random variable and an independent random variable with a triangular distribution. The normal random variable, which reflects the uncertainty in the

dosimeter reading, has a mean of zero and a standard deviation[9] of 0.10. The triangular distribution chosen as an example of the procedure reflects the error for the 30 to 250 keV photon DCF for the colon. The selected triangular distribution is one example of many such distributions used in the dose reconstruction modeling. The selected triangular distribution has parameter values of Min=0.23, Mode=0.75, and Max=0.80.

Crystal Ball was used to simulate 10,000 products of these two random variables. The batch-fit feature in Crystal Ball was used to fit a distribution to the 10,000 products. The Komolgorov-Smirnov (K-S) and the Anderson-Darling (A-D) test statistics were used as criteria to determine the best-fitting distribution. The K-S test is based on the maximum vertical distance between the empirical CDF of the 10,000 observations and the fitted distribution. The A-D test is similar to the K-S test, but more weight is given to the fit in the tails of the distribution. For both tests, the lowest value of the test statistic indicates the best fit.

The results, shown in Figure 3.7-1, indicate that the beta distribution was found to be the best-fitting distribution under both criteria. In both cases, the second-best fit was obtained using a Weibull distribution. The normal distribution ranks third when using the A-D criterion, and fourth when using the K-S criterion.

The parameters of the best-fitting beta and normal distributions were determined using the Crystal Ball distribution-fitting procedure. The best-fitting beta and normal distributions are shown in Figures 3.7-2 and 3.7-3. The beta distribution with the best fit has parameters alpha=6.981, beta=5.292, and scale=1.044. The best-fitting normal distribution has a mean of 0.594 and a standard deviation of 0.142. Note that the normal distribution parameter estimates exactly match those reported in Section 3.1 of ORAUT-OTIB-0012.

Two samples of size 10,000 were simulated in Crystal Ball 2000 using the fitted beta and normal distribution with parameters stated above. Despite the clearly better fit of the beta distribution based on the statistical tests, there is little difference in the statistics obtained from the two simulated data sets, as shown in Figure 3.7-4. This confirms that the best-fitting normal distribution provides a good approximation for the distribution of the product organ doses in the example selected. If the normal distributions for the dosimeter reading have a larger standard deviation than the 0.10 value in this example, it is likely that a normal distribution will continue to provide a good approximation to the distribution of the product's organ doses.

Care must be taken to ensure that the appropriate row in the tables is used, as determined by the estimated percent measurement error in the dosimeter readings for each case.

[9] In the second paragraph of ORAUT-OTIB-0012, Section 3.1, the standard deviation for the dosimeter readings in Table 1 is stated as 0.32 (32%). This appears to be a typographical error, perhaps one that remains from a previous version of the document. The referenced Table 1 shows that the standard deviation of the dosimeter readings is 0.10 (10%). Results obtained here using a 10% standard deviation agree with subsequent results quoted in the document.

Microsoft Excel - CB-Monte-Carlo2.xls

File Edit View Insert Format Tools Data Window Cell Run CBTools Help

Arial 10

G12 = =J11

	G	H	I	J	K	L	M	N	O	P
1	Best Fit to 10000 products:			Fitted Beta						
2	Beta		mean	0.594		**Data Series:**	1		**Data Series:**	1.00
3	0.594					**Kolmogorov-Smirnov:**	0.02180		**Anderson-Darling:**	9.00
4			alpha	6.981		**Distribution:**	0.00000		**Distribution:**	0.00
5			beta	5.292		**Best fit:**	Beta		**Best fit:**	Beta
6			scale	1.044						
7		**Kolmogorov-Smirnov:**		0.02180		Beta	0.02180		Beta	9.00
8						Weibull	0.03372		Weibull	22.26
9						Logistic	0.03498		Normal	27.97
10				Fitted Normal		Normal	0.03757		Extreme Value	35.57
11	Fited Normal		mean	0.594		Extreme Value	0.03774		Logistic	37.93
12	0.594					Gamma	0.04909		Gamma	48.52
13			mu	0.594		Lognormal	0.07975		Lognormal	133.62
14			sigma	0.142		Triangular	0.09359		Triangular	162.30
15		**Kolmogorov-Smirnov:**		0.03757		Uniform	0.21568		Uniform	977.91
16						Pareto	0.38889		Exponential	2640.07
17						Exponential	0.39259		Pareto	2734.59
18										
19										
20										
21										
22										
23										

Sheet1 DATA

Ready NUM

Figure 3.7-1. K-S and A-D Statistics for All Distributions Fitted to a Sample of 10,000 Products using Crystal Ball 2000 Batch-Fit Procedure

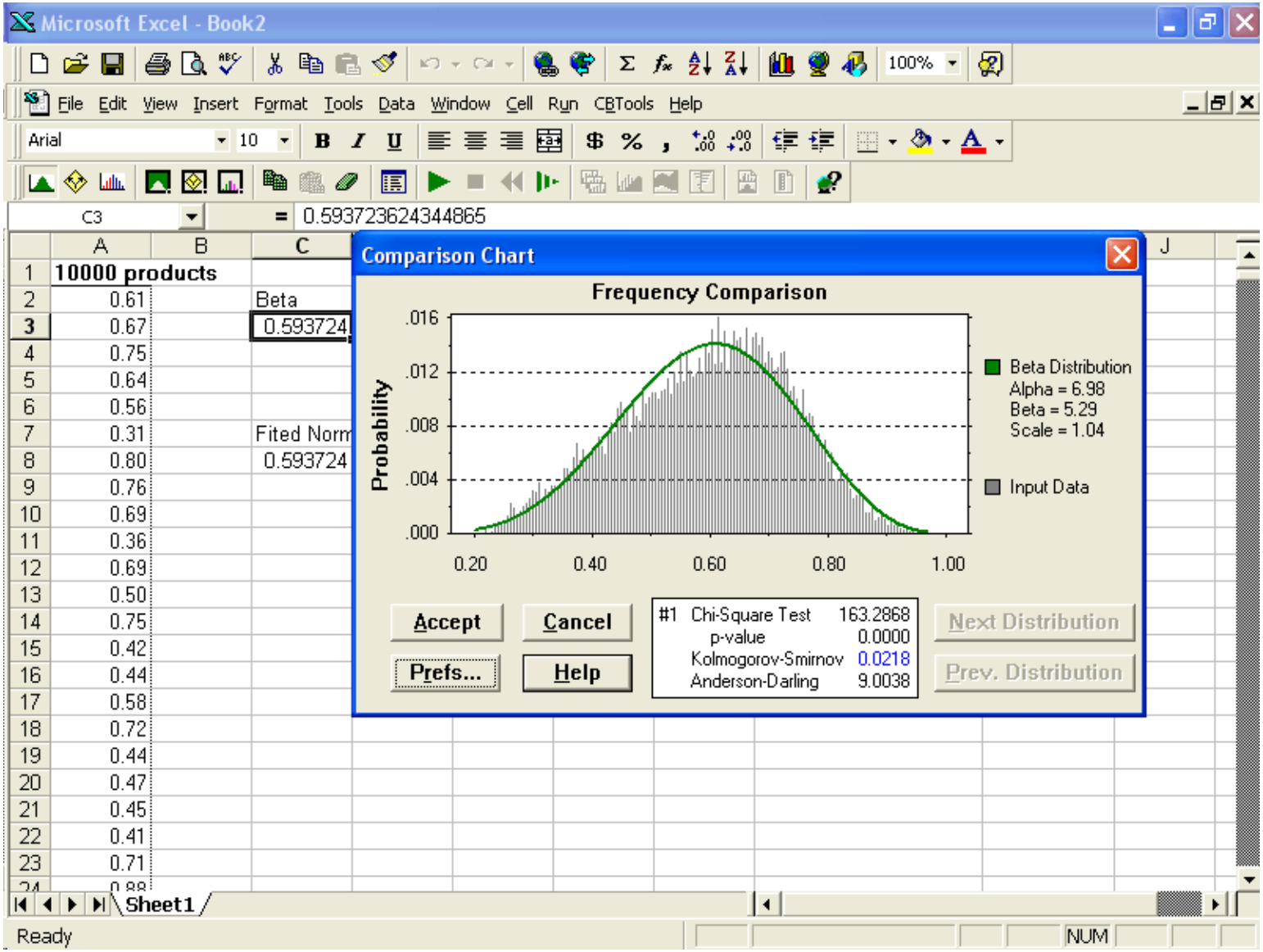

Figure 3.7-2. The Best-Fitting Beta Distribution, Fitted to the Sample of 10,000 Products

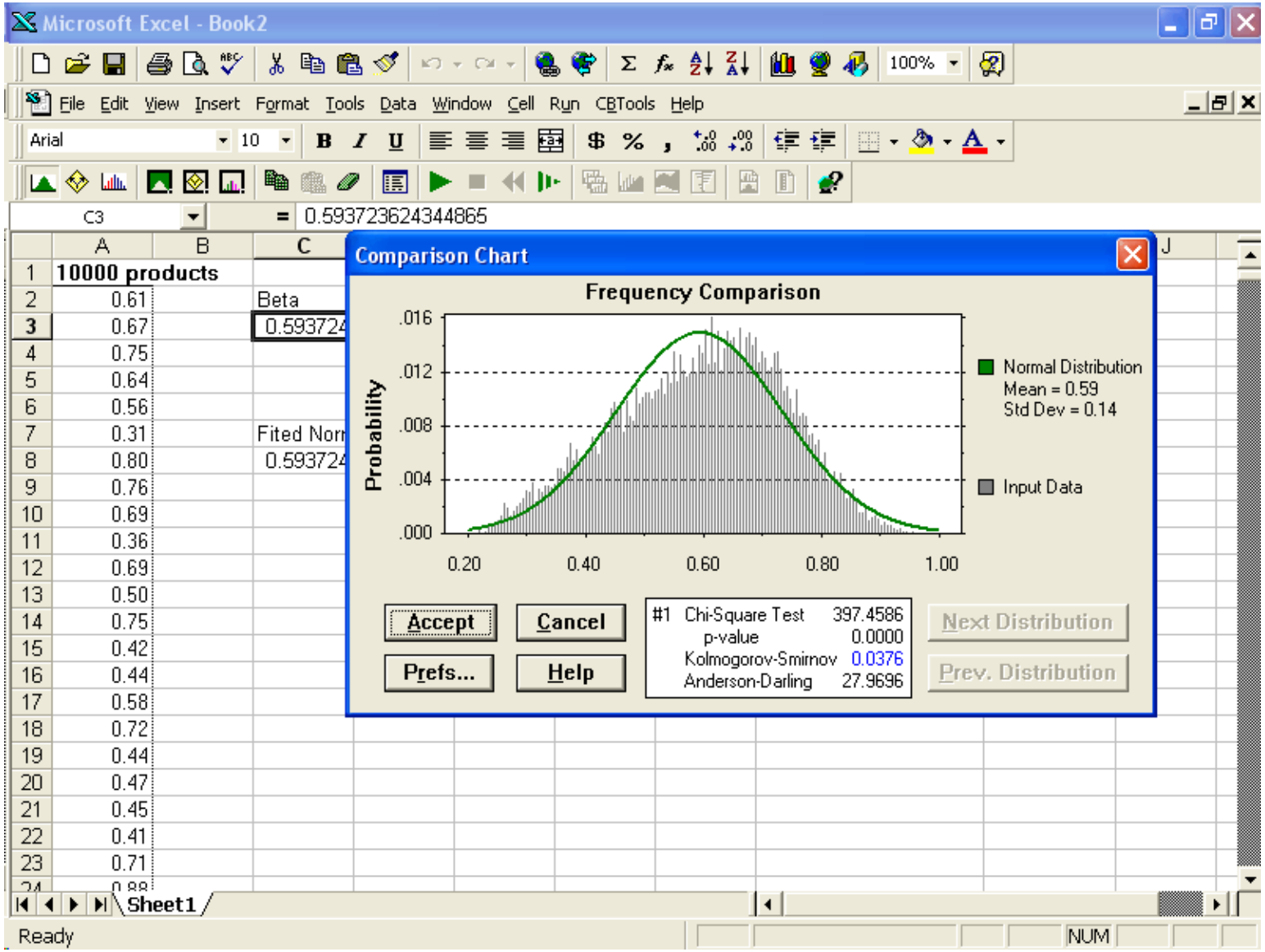

Figure 3.7-3. The Best-Fitting Normal Distribution, Fitted to the Sample of 10,000 Products

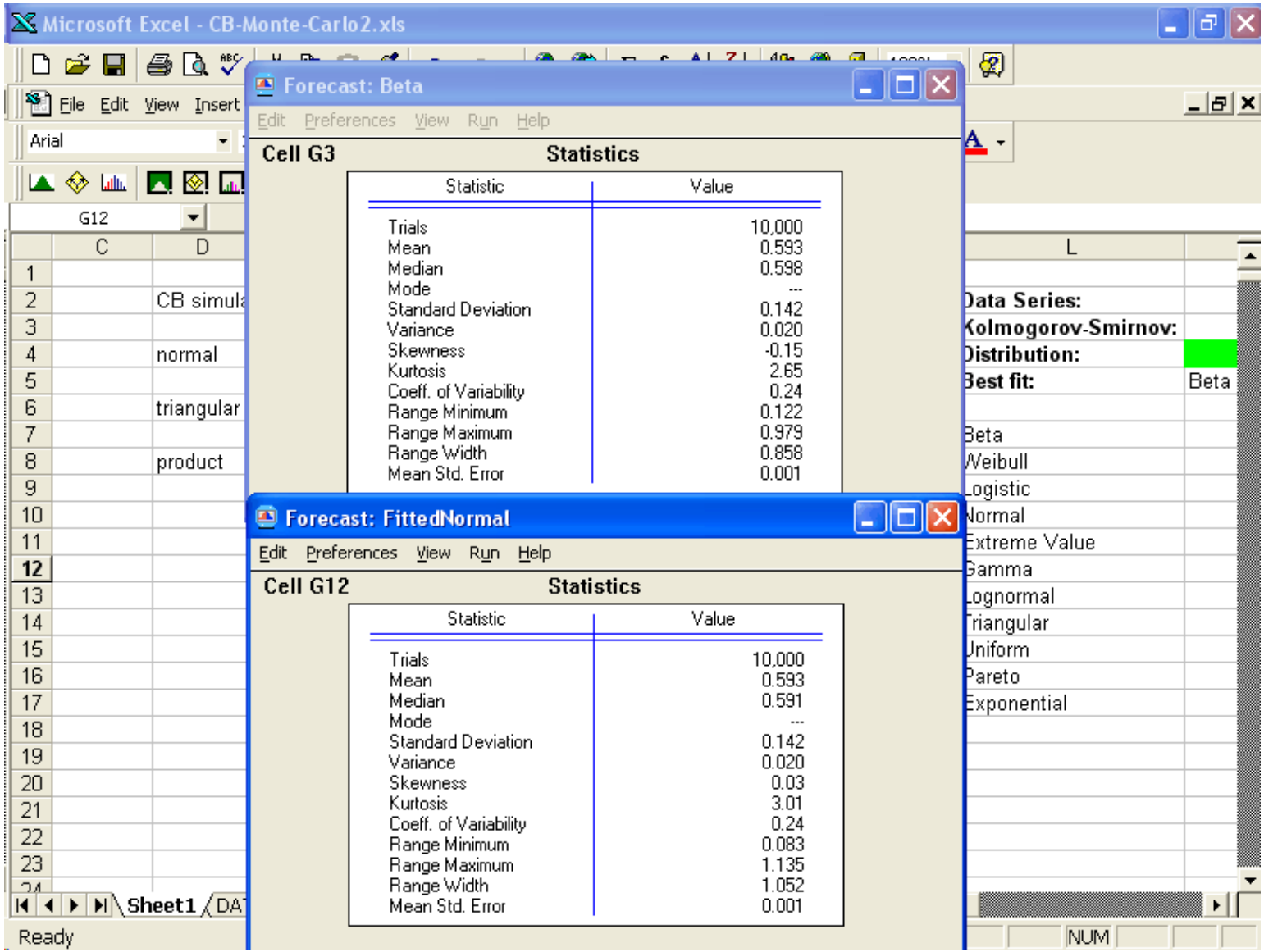

Figure 3.7-4. Comparison of Statistics Obtained from Samples of Size 10,000 from the Best-Fitting Beta Distribution and the Best-Fitting Normal Distribution

3.8 ORAUT-OTIB-0033: APPLICATION OF INTERNAL DOSES BASED ON CLAIMANT-FAVORABLE ASSUMPTIONS FOR PROCESSING BEST ESTIMATES

The review of ORAUT-OTIB-0033, *Application of Internal Doses Based on Claimant-Favorable Assumptions for Processing Best Estimates,* Rev. 00, dated April 20, 2005, was prepared by John Mauro, PhD, CHP, and approved by Hans Behling, PhD, on May 30, 2006.

Before proceeding with this review, it is important to point out that, during the preparation of this report, SC&A participated in the full Board meeting held in Denver, Colorado, on April 25–27, 2006. During that Board meeting, Knut Ringen, DrPH, MHA, MPH, Science Advisor to the Center to Protect Worker Rights, gave a presentation and provided handouts that contained a wealth of information pertinent to the reconstruction of doses to construction workers. In addition, Mr. Ringen provided SC&A with the names of experts on this subject. This OTIB could be considered especially relevant to construction workers because these workers often were not monitored, and the default protocols provided in this OTIB may appear to be appropriately applied to this class of workers, but, as indicated by Dr. Ringen, the potential for exposure of construction workers among sites and at different times and locations at a given site, were highly variable. Hence, this OTIB may have certain limitations as applied to some construction workers. In addition, it is SC&A's understanding that data and protocols specifically for the reconstruction of doses to construction workers are areas of active investigation at NIOSH. Given the complexity of the issues and the fact that it is an area of active investigation, SC&A believes that the findings of this review be used with caution as they apply to construction workers. This concern is especially pertinent to ORAUT-OTIB-0018, which is subsumed within this ORAUT-OTIB-0033.

3.8.1 Purpose of Procedure

The stated purpose of this OTIB is to provide the following:

> *…a graded approach to the application of overestimated internal doses in Oak Ridge Associated Universities (ORAU) Team TIB (ORAUT-OTIB) ORAUT-OTIB-0018, Internal Dose Overestimates for Facilities with Air Sampling Programs, for processing cases in the absence of complete information. ORAUT-OTIB-0018 was written to be applied as an overestimate for workers with no significant intakes of particulate radioactive material. Because it was intended to be used only as an overestimate, it did not consider additional factors that could limit the upper bound for certain types of workers.*
>
> *These factors include:*
>
> - *The period during which the energy employee worked,*
> - *The processes conducted at the site at which the energy employee worked,*
> - *The job category and work location of the energy employee, and*
> - *The results of bioassay measurements for the energy employee.*

These factors are addressed here to enable application of the values in ORAUT-OTIB-0018 in a graded manner as the best available estimate in the absence of specific site or individual information, when appropriate.

3.8.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0033 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

This OTIB is important because it represents the integration of several OTIBs (i.e., ORAUT-OTIB-0014, ORAUT-OTIB-0018, ORAUT-OTIB-0002, and ORAUT-OTIB-0033) in a manner that allows for a graded approach for reconstructing best estimates of internal doses in a claimant-favorable manner, and under a wide range of conditions where there may be limited bioassay data. In addition, since this OTIB is considered a realistic approach to dose reconstruction, it can be used to grant or deny claims. Though it is represented as being a realistic approach, it is also represented as claimant favorable for (1) a wide range of exposure settings, (2) conditions where bioassay and air sampling data are of limited availability, and (3) a wide range of job descriptions. In many respects, this OTIB establishes a framework for dose reconstructions for classes of workers that may be considered potential Special Exposure Cohort candidates. As such, the philosophy adopted in this OTIB, along with the strategy for implementing that philosophy, is fundamental to the reconstruction of doses for many classes of workers at virtually every facility, including construction workers.

This section describes the OTIB strategy for the reconstruction of internal doses (as understood by SC&A), and discusses the areas where we believe the approach may or may not be entirely scientifically sound and/or claimant favorable, and areas where considerable judgment is required by the dose reconstructor in order to implement this OTIB. This latter aspect of our review is considered important because, if a great deal of judgment is required to implement this OTIB, it raises concerns about the degree to which the OTIB can be implemented in a consistent manner. Before proceeding with the review, it is important to understand that ORAUT-OTIB-0033 is the culmination to date of a complex array of guidelines that have evolved over time as a means to complete the dose reconstruction process. As a result, in order to understand ORAUT-OTIB-0033 and its strengths and limitations, the role and strengths and limitations of ORAUT-OTIB-0002, ORAUT-OTIB-0014, and ORAUT-OTIB-0018 are needed. Hence, this review also addresses these OTIBs.

Table 3.8-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0033	**Effective Date:** 04/20/2005
Document Title: Application of Internal Doses Based on Claimant-Favorable Assumptions for Processing as Best Estimates	
Auditor: John Mauro	

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)?	3	It references other related NIOSH and ORAUT documents, 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?	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)	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	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?	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	
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)?	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	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	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.

ORAUT-OTIB-0033 uses a 3-dimensional matrix for identifying and reconstructing the internal doses to classes of workers, as follows:

By Exposure Potential

- Seldom exposed to airborne radionuclide concentrations above outdoor environmental levels

- Intermittently exposed above outdoor environmental levels
- Routinely exposed above outdoor environmental levels

By Time Period of Exposure

- Pre- vs. post-1989. This date demarcates the implementation of DOE Order 5480.11, *Radiation Protection for Occupational Workers*. Following this date, radiation protection programs became more robust, and there is a high degree of confidence that, if a worker entered an area where the airborne radionuclide concentrations exceed 10% of the derived air concentrations (DACs), that worker would wear respiratory protection and would be covered by a bioassay program.

By Bioassay Program

- A distinction is made between individuals who were routinely monitored versus unmonitored under a bioassay program.

For workers without routine bioassay, the dose reconstructor is instructed to place the worker into one of five categories based on exposure potential and time period of exposure. Category 1 is defined as all workers over all time periods that had very little potential for internal exposure. Under these conditions, the dose reconstructor is instructed to use ORAUT-OTIB-0014. ORAUT-OTIB-0014 assists the dose reconstructor in identifying workers with a low potential for internal exposure by providing a list of job categories and work locations with very limited potential for inhalation exposure. However, ORAUT-OTIB-0014 cautions the dose reconstructor that there will be exceptions to the general guidance provided. Once it is determined that the worker did, in fact, have very little potential for internal exposure, ORAUT-OTIB-0014 instructs the dose reconstructor to assume that the only source of internal exposure for that worker was to the radionuclide levels in the outdoor environment onsite. Under these circumstances, the dose reconstructor is directed to Part 4 of the site profile for that facility, which provides instruction on reconstructing outdoor environmental doses to workers at that site. This general strategy certainly appears reasonable, as long as there is a high level of assurance that the worker did not encounter any unusual conditions while working, including exposures resulting from incidents that are not addressed in the site profiles. In addition, during the early years of operations at a given facility, it may not be self-evident that the worker did not experience elevated levels of airborne radionuclides, notwithstanding his job category. Hence, in principal, the guidance is reasonable, but in practice it may be difficult to implement with a high degree of confidence, especially for the early years at a given facility. However, the OTIB acknowledges this limitation.

Unmonitored worker Categories 2 and 3 in ORAUT-OTIB-0033 consist of workers with only intermittent potential for internal exposure. Category 2 applies to pre-1989 workers, and Category 3 applies to post-1989 workers. For Category 2 workers, the dose reconstructor is instructed to assume that the worker was exposed to airborne particulates that are at 50% of the concentrations listed in ORAUT-OTIB-0018, while for post-1989 workers, 5% of the concentrations in ORAUT-OTIB-0018 are to be used.

ORAUT-OTIB-0018 is reviewed separately in this report. However, in order to place the role of ORAUT-OTIB-0018 into proper context in terms of its integration into ORAUT-OTIB-0033, a brief overview of ORAUT-OTIB-0018 is in order. ORAUT-OTIB-0018 is designed to be used to deliberately overestimate internal doses for unmonitored workers at facilities with airborne monitoring programs. It is intended to be used as an alternative to ORAUT-OTIB-0002. Hence, before discussing ORAUT-OTIB-0018, a brief overview of ORAUT-OTIB-0002 is needed.[10] ORAUT-OTIB-0002 is to be used as an efficiency tool for placing an unrealistic upper bound on the internal doses to workers who could not possibly have experienced organ doses that even approach a POC of 50%. This judgment could be based on data from air-sampling programs, bioassay data, job descriptions, and process knowledge, and with due consideration of the organ of concern. However, ORAUT-OTIB-0002 acknowledges that there could be undiscovered intakes that were missed by the monitoring programs. In light of this possibility, and in the interest of avoiding the investment of large amounts of time and resources that would be required to investigate such a possibility, ORAUT-OTIB-0002 simply postulates that the worker experienced an unrealistically high, one-time intake of radionuclides on the first day of the worker's employment at the facility. The postulated intake is based on multiples of the maximum permissible body burdens (MPBBs) for radionuclides, as listed in NCRP 1989. This fundamental approach is premised on the assumption that it is unlikely that a one time exposure of 10% of the MPBB would go unnoticed by an air sampling or bioassay program for radionuclides with low solubility. For radionuclides with higher solubility (i.e., Types M and F), a bioassay program could, in theory, miss such an exposure, because Types M and S materials are rapidly cleared from the body. For Types M and S radionuclides, the intakes are assumed to correspond to 1 times the MPBB and 2 times the MPBB, respectively. The ORAUT-OTIB also makes a distinction between reactor and non-reactor facilities in the list of radionuclides to be used in the calculation. ORAUT-OTIB-0002 also gives special consideration to tritium, radioiodines, and uranium; the employee's date of initial hire; the target organ; the extent of his bioassay program; and numerous other constraints and considerations described in the ORAUT-OTIB and reviewed in SC&A's January 2005 Task 3 report. A workbook that has been reviewed by SC&A implements the entire ORAUT-OTIB-0002 guideline. The bottom line is that ORAUT-OTIB-0002 is appropriate when used for its intended purposes and when there is assurance that unusual circumstances don't exist where the approach may not necessarily be bounding.

ORAUT-OTIB-0018 provides an alternative to ORAUT-OTIB-0002 as a means to overestimate internal doses with somewhat more realistic assumptions than those employed in ORAUT-OTIB-0002. ORAUT-OTIB-0018 goes a step further than ORAUT-OTIB-0002, because it describes and presents the limits on airborne radionuclide concentrations that were established at different times by standard-setting bodies and by regulation. The time period covered in ORAUT-OTIB-0018 begins with the NBS guidelines established in 1953 and goes up to limits established by DOE in 10 CFR Part 835, which were implemented in 1993. For some radionuclides, the standards became more restrictive over time, but for other radionuclides, the standards were actually slightly relaxed.

[10] Note that ORAUT-OTIB-0002 was reviewed as part of SC&A Task 3 report dated January 2005.

ORAUT-OTIB-0018 provides direction that takes into consideration the standards that were in place at a given point in time. This OTIB can be used for employment periods from 1953 to the present, and for workers who, in all likelihood, did not experience significant exposure to airborne particles. In addition, ORAUT-OTIB-0018 is only to be used for facilities that rigorously monitored airborne particulates, and met a number of other constraints and qualifications. Given the standards as a function of time, and the applicability and limitations of the guidance as specified in ORAUT-OTIB-0018, ORAUT-OTIB-0018 presents a recommended array of default airborne radionuclide concentrations that are recommended for dose reconstructions for different facilities and time periods of exposures, along with default breathing rates and exposure durations. Mr. Ringen makes specific reference to this OTIB and its assumptions as being inappropriate for at least some construction workers.

For facilities that handled recycled uranium, ORAUT-OTIB-0018 recommends default intakes of Pu-238, Np-237, Tc-99, Th-232, and Ru-106, expressed in terms of pCi of each radionuclide per pCi of U. For sites where the specific airborne radionuclides are not known because only gross alpha and gross beta/gamma counts were made, ORAUT-OTIB-0018 recommends assuming that the airborne activity is entirely comprised of the radionuclide and chemical forms with the highest dose conversion factors for the organs of concern. Finally, in light of the many uncertainties associated with characterizing the airborne radionuclide concentrations actually inhaled by a given worker, ORAUT-OTIB-0018 recommends assuming that each recommended default radionuclide concentration is the geometric means of lognormal distribution with a standard deviation of 3. Again, this assumption regarding the variability and uncertainty in the potential airborne exposures, as applied to construction workers, was criticized by Mr. Ringen.

Given the array of guidance provided in ORAUT-OTIB-0018, ORAUT-OTIB-0033 recommends using 50% of the ORAUT-OTIB-0018 default values for workers exposed before 1989, and 5% of the default values for those exposed following 1989. It is clear that these recommendations appear somewhat arbitrary. However, when one considers that these guidelines only apply to workers that were intermittently exposed, the guidance does not appear to be unreasonable.

ORAUT-OTIB-0033 defines unmonitored worker Category 4 and Category 5. Both categories apply to workers who routinely experienced exposures above environmental levels. Category 4 applies to pre-1989 workers and Category 5 applies to post-1989 workers. For Category 4, ORAUT-OTIB-0033 recommends using co-worker data to reconstruct doses, and, if these data are not available, it recommends using ORAUT-OTIB-0018. For post-1989 workers, ORAUT-OTIB-0033 recommends using co-worker data, and, if these data are not available, it recommends using 10% of ORAUT-OTIB-0018 default values.

This overall strategy for reconstructing the internal doses to unmonitored workers seems well considered and reasonable. It acknowledges the limitations of the methodologies and properly cautions the dose reconstructor to conditions where the default assumptions may not be claimant favorable. A limitation of the procedure is its heavy reliance on the judgment of the dose reconstructor in categorizing the workers and factoring in special circumstances. Also, no guidance is provided on how to use co-worker data. For example, should the dose reconstructor use the full distribution of the co-worker data, or the 95^{th} percentile value?

For all monitored workers and all time periods, if the results of bioassays are less than the MDAs (as defined in Table 7-1 of ORAUT-OTIB-0018), ORAUT-OTIB-0033 recommends using co-worker data. Again, no guidance is given regarding how this is accomplished.[11] If the co-worker data are judged to be inadequate, ORAUT-OTIB-0033 recommends using missed dose protocols. However, the OTIB is deficient, in that it neglects to refer the reader to the missed dose guidance. ORAUT-OTIB-0033 also provides the dose reconstructor with the option of defaulting to ORAUT-OTIB-0018 guidance as a third means of reconstructing the internal doses for workers whose bioassay results are below the MDAs. However, ORAUT-OTIB-0033 cautions the dose reconstructor not to default to ORAUT-OTIB-0018 under these circumstances if the POC is greater than 47%. If it is, a missed dose calculation should be employed. Again, no reference or guidance is provided on how to perform a missed dose calculation.

Finally, for all workers that have positive bioassay results, or are known to have been involved in incidents, ORAUT-OTIB-0033 recommends using IMBA to reconstruct internal doses. As an alternative, ORAUT-OTIB-0018 may be used, along with bioassay results, as long as the results are less than a POC of 47%. In referring to using IMBA as a means to reconstruct internal doses from bioassay data, which could reflect chronic, intermittent, or incident exposures, reference should be made to the guidance provided in OCAS-IG-002.

3.8.4 Review Comments

Review Objectives 1.5 and 7.1

A considerable amount of judgment is required by the reviewer in assigning workers to a given exposure category, and determining how best to go about using co-worker data and performing missed dose calculations.

Reference:

NCRP 1959, National Bureau of Standards, *Maximum Permissible Body Burdens and Maximum Permissible Concentrations in Air and Water for Occupational Exposures*. NBS Handbook 69 (also referred to as NCRP Publication 22), NBS, Washington, DC.

3.9 ORAUT-OTIB-0004, REVISION 3: ESTIMATING THE MAXIMUM PLAUSIBLE DOSE TO WORKERS AT ATOMIC WEAPONS EMPLOYER FACILITIES

The review of ORAUT-OTIB-0004, *Estimating the Maximum Plausible Dose to Workers at Atomic Weapons Employer Facilities*, Rev. 03 PC-1, dated November 18, 2005, was prepared by Nicole Briggs, John Mauro, and Robert Anigstein, and approved by John Mauro, PhD, CHP, on May 23, 2006.

[11] At the time of the preparation of this review, SC&A was informed that numerous initiatives are underway at NIOSH to develop guidance pertaining to the use of co-worker data.

3.9.1 Purpose of Procedure

The purpose of this document is to provide guidance for estimating the maximum plausible dose to workers at AWEs. 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**.

3.9.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0004 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.

Table 3.9-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0004, Rev. 03 PC-1	**Effective Date:** 11/18/2005
Document Title: Estimating the Maximum Plausible Dose to Workers at Atomic Weapons Employer Facilities	
Reviewer: Nicole Briggs, Robert Anigstein PhD, and John Mauro	

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	Reference is made to other documents, but it is appropriate
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?	4	See Review Comments
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	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?	5	
4.2	Does the procedure adhere to the hierarchical process as defined in 42 CFR 82.2?	4	
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)?	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	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	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.

3.9.3 General Comments

There were approximately 102 AWE facilities that handled 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 OTIB is intended to be used for AWE facilities that handled only uranium, including uranium metal, various forms of uranium associated with the uranium conversion and fuel fabrication process, enriched uranium, and recycled uranium that included trace amounts of activation and fission products and transuranics. This OTIB does

not address exposures from processing of thorium, radium, uranium ores, or other radioactive materials (except as recycled uranium contaminants).

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 model parameters.

Demonstration of non-compensability 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).

This review is organized according to the major topics addressed in ORAUT-OTIB-0004, including the following:

- Inhalation of airborne uranium oxide particulates
- Inhalation of other radionuclides associated with recycled uranium
- Ingestion of uranium
- Internal dose from depleted or enriched uranium
- External dose to penetrating radiation
- External dose to non-penetrating radiation
- Occupationally required medical exposures
- Exposure to residual radioactivity (i.e., the inhalation and inadvertent ingestion of uranium that has deposited on surfaces (floors, tables, equipment) in the workplace)

In the sections that follow, a brief description is provided of the guidance addressing each of these areas, including a discussion and analysis of the scientific validity and claimant favorability of the guidance.

3.9.3.1 Inhalation of Airborne Uranium Oxide

Inhalation of airborne uranium particles is the dominant pathway for AWE facilities and is, therefore, addressed in more detail than the other pathways.

ORAUT-OTIB-0004 recommends using a default airborne uranium dust loading of 100 MAC as a reasonable default upper bound for continuous inhalation exposures for workers at AWE facilities. ORAUT-OTIB-0004 cites air-sampling data compiled in a 1949 report prepared by the New York Operations Office (NYOO) of the Atomic Energy Commission as the basis for this guideline.

In 1949, the AEC's publication, *Health Hazards in NYOO Facilities Producing and Processing Uranium: A Status Report – April 1, 1949*, summarized the uranium dust concentration surveys performed to that date at seven uranium processing plants. All of the studies presented average daily exposures collected from the breathing zone and weighted for 8 hours of exposure per day. The data are presented as multiples of the preferred level (PL) of exposure of 70 alpha

disintegrations per minute per cubic meter of air. The methodology is described in Appendix II of AEC 1949 as follows:

> *Dust samples are then collected from the workers breathing zone and the general workroom air in such a way as to provide an estimate of the exposure for each job component. By properly weighting the samples with respect to time, we are then able to obtain the average daily concentrations to which the various employees are exposed.*

The following presents a summary of the data provided for each of these seven facilities.

Mallinckrodt Chemical Works

Mallinckroft operated two plants; #6, which was the refinery, and #4, which was the metal plant. Plant #6 produced brown oxide from pitchblend. Plant #4 converted the UF_4 to uranium metal. A dust survey was performed at these sites in 1948. The AEC 1949 report does indicate that the results were published, but the available copy did not contain those figures. A summary of the results is reproduced here in Table 3.9-4 toward the end of this section.

Harshaw Chemical Company

Harshaw employed 90 people and operated a uranium conversion process plant, which converted brown oxide to green salt, and green salt to UF_6. Dust concentration surveys were performed at this plant in September 1948. Of the seven plants included in this summary report, Harshaw had the largest number of workers exposed to high dust concentration levels for long periods of time. Of the 88 employees, 33 were exposed to dust concentration levels ranging from 140 to 370 MAC. Figure 11 of AEC 1949 indicates that 4 Brown Oxide Loaders were exposed to 140 MAC, another 4 Brown Oxide Loaders were exposed to 188 MAC, 1 Fume Recovery Room Operator was exposed to 216 MAC, and a total of 24 Hex Area Loaders were exposed to 374 MAC. In addition, these workers were exposed to these high dust concentration levels for extended periods of time. Table 3.9-2 is a reproduction of Table 5 of AEC 1949, which presents the exposure duration of the Harshaw employees as a function of dust concentration levels.

Table 3.9-2. Distribution of Employees by Length of Employment and Level of Dust Exposure at Harshaw Chemical Company

Multiple of Preferred Alpha Level	Number of Months of Exposure						
	0 - 6	6 - 12	12 - 24	24 – 36	36 - 48	> 48	Total
0 – 1	1	2	2	0	1	1	7
1 – 5	1	1	0	0	2	0	4
5 – 25	0	5	5	12	10	11	43
25 – 125	0	0	0	0	0	0	0
> 125	0	17	10	3	4	0	34
Total Personnel	2	25	17	15	17	12	88

Linde Air Products

The Linde plant converted brown oxide from Mallinckrodt to UF_4 for shipment to Electro-Metallurgical Company. Dust is dispersed in the plant through the transfer of "brown oxide to the weighing drums, scooping of oxide onto trays, and transfer of the trays to and from the green salt reactor." Dust concentration surveys were performed at this plant in October and November 1948. None of the 65 employees were exposed to dust concentration levels above 32 MAC.

Electro Metallurgical Company, Division of Union Carbide & Carbon Co.

Electro Metallurgical Company converted green salt from Linde to uranium metal billets. Dust concentration surveys were performed at this plant in November 1948. The majority of the plant's 50 employees were exposed to dust levels below 40 MAC. However, three Green Salt Room Operators involved in bomb concentration operations were exposed to dust levels of 557 MAC.

Simonds Saw & Steel

Uranium rolling processes at both Simonds Saw and Vulcan Crucible were described in AEC 1949 as the following:

> *Because of the pyrophoric character of uranium, this operation results in profuse atmospheric contamination. In addition to the fuming of the cherry-hot billets, continuous oxidation produces a scale which consistently spills from the billets. This material after falling to the floor is ground to dust by heavy floor traffic incidental to the rolling operation*.

Several dust concentration surveys were performed between 1948 and 1949, which are summarized here in Table 3.9-3.

Table 3.9-3. Summary of Weighted Daily Exposures at Simonds Saw & Steel

Operator	No. of Employees	Multiples of Preferred Level for Continuous Exposure		
		10/27/48*	12/1/48**	1/10/49***
Foreman	2	25	13	5
West Rollers	8	17	13	4
East Rollers	8	155	28	13
Quanoh and Stamp	6	25	10	28
Furnace Operator	4	8	4	1.4
Drag-down	2	9	10	1.6

* No dust control measures.
** Vacuum cleaner, and exhausts for rolls installed.
*** Exhaust for desoaler installed.

Table 3.9-3 reveals that prior to the use of dust control measures, eight employees at Simonds Saw were exposed to dust concentrations of 155 MAC.

Vulcan Crucible Steel Company

Uranium rolling processes at Vulcan were similar to those at Simonds Saw. Dust concentration surveys were performed at Vulcan in February 1949. The results indicate that one Hookman and three Roughing Rolls workers were exposed to over 5,000 MAC. AEC 1949 does indicate that all the data presented are time-weighted averages, but it does not seem possible that these employees could have been exposed to over 5,000 MAC for any extended period of time. All of the other employees had exposures below 40 MAC.

Vitro Manufacturing Company

The Vitro plant converted scrap materials to black oxide. The majority of the plant's 44 employees received dust concentration exposures below 40 MAC.

Summary

Table 3.9-4 summarizes the chronic uranium dust loading exposures of the 7 facilities investigated in the NYOO report. As can be seen, 100 MAC corresponds to about the upper 90th percentile level. The implications are that the use of 100 MAC as a default upper bound is reasonable, but certainly not overly conservative. In fact, it could be argued that it is not a truly bounding value.

Table 3.9-4. Summary of Average Daily Exposures to Alpha-Emitting Dust at Seven Uranium Plants

Uranium Plants	Multiples of PL*					
	0 – 1	1 – 5	5 - 25	25 - 125	125	Total
Mallinckrodt Chemical Works						
Plant #6	53 (31%)**	73 (43%)	24 (14%)	2 (1%)	18 (11%)	170
Plant #4	11 (14%)	7 (9%)	27 (35%)	30 (39%)	2 (3%)	77
Harshaw Chemical Company	9 (9%)	11 (11%)	45 (46%)	0	33 (34%)	98
Linde Air Products	119 (87%)	3 (2%)	0	15 (11%)	0	137
Electro-Metallurgical	19 (28%)	21 (31%)	21 (31%)	3 (5%)	3 (5%)	67
Simonds Saw & Steel (1/48)	0	16 (53%)	8 (27%)	6 (20%)	0	30
Vulcan Crucible Steel	0	4 (16%)	17 (68%)	0	4 (16%)	25
Vitro Manufacturing Company	23 (52%)	16 (36%)	4 (9%)	1 (3%)	0	44
Total	234 (36%)	151 (23%)	146 (23%)	57 (9%)	60 (9%)	648

* PL = Preferred Level for alpha emitting dust = 50 µg of uranium/m^3 = 70 d/m/m^3 on the average for an 8-hour workday.

** The first figure denotes the number of personnel. The second, in parenthesis, expresses the first as a percentage of the total in the last column.

Given a chronic uranium dust loading of 100 MAC, ORAUT-OTIB-0004 recommends assuming a breathing rate of 1.2 m^3/h, Absorption Type M or S (whichever gives the higher dose for the organ of concern), and an AMAD of 5 microns. These assumptions are generally scientifically valid and reasonable. The OTIB also recommends assuming that the radionuclide of concern is

entirely U-234. SC&A agrees with this simplifying assumption since U-238, U-234, and U-235 each have similar organ dose conversation factors when expressed in terms of Sv/Bq inhaled.

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 5.5 hours light exercise and 2.5 hours 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.

3.9.3.2 Inhalation of Other Radionuclides Associated with Recycled Uranium

Table 3-3 of the guide provides explicit instructions pertaining to the reconstruction of doses associated with the processing and handling of recycled uranium, which includes the presence of several radioactive fission impurities and transuranic elements (i.e., technetium-99, plutonium (Pu), and neptunium (Np)-237) in the recycled uranium feed or waste streams. A review of selected publications was performed as a check on the activity fractions recommended in Table 3-3. The DOE *Report of the Joint Task Force on Uranium Recycle Materials Processing* (DOE 1985) studied past practices at the Fernald, Y-12, and Ashtabula sites, and recognized that early practices regarding the processing of recycled material would have been improved with better understanding of contaminant levels in the feed material. Our review of this document revealed that the amount of fission products varies with the recycle uranium source and process. For example, the task force report indicates that 50% of Pu received at Fernald since plant startup (a period of 24 years) came in one shipment of Paducah ash in 1980. Another 32% is believed to have come from Hanford. The balance of the Pu received at Fernald was from SRS and West Valley. The report estimated that Pu-239 constituted an average of 6.7 parts per billion (uranium basis) in the recycled materials received between 1961 and 1985. Air sampling results at Fernald for Np-237, Pu-238, Pu-239, Th-228, and Th-232 were also presented, as were similar data for Paducah, Y-12, and other DOE sites.

In 2000, Idaho National Laboratory published a report (Lewis et al. 2000) demonstrating that the type of processing can influence the concentrations of the isotopic contaminants in recycled uranium. The concentrations of impurities vary in each waste stream as well. Additional information assessing data confidence and technical analysis of recycled uranium within the DOE complex was presented in DOE 2000 and DOE 2001.

Accordingly, and in reviewing Table 4.2 of ORAUT-OTIB-0018, SC&A was concerned that the empirical information and findings in the DOE Joint Task Force report (DOE 1985) and other documents (Lewis et al. 2000; DOE 2000 and 2001) were not considered and integrated in the development of the fission material concentrations in recycled uranium. This deficiency raises additional concerns about the sources of data regarding the radioactive contaminants in the recycled uranium, the calculation methods, and the bounding significance and uncertainties of the values presented. SC&A is also concerned that the uncertainties associated with these values would not allow us to give the benefit of the doubt to claimants. The procedures also ignored the relationships between the concentrations of the radioactive impurities and the recycled uranium process phases and associated waste streams. This section of the guide needs to be more thoroughly discussed, along with the rationale for the recommended values in Table 4.2.

3.9.3.3 Ingestion of Uranium

This ORAUT-OTIB adopts the procedure recommended in OCAS-TIB-009, Rev 0, *Estimation of Ingestion Intakes*, which is reviewed above in Section 3.1 of this report and is not repeated here. In brief, there are several aspects of the default procedure for estimating ingestion intakes that are not scientifically sound. Some aspects of the procedure are overly conservative, while other aspects are not claimant favorable. These matters have been discussed with NIOSH as part of the review of the Bethlehem Steel site profile, and NIOSH is in the process of revising the protocol.

3.9.3.4 Internal Dose from Depleted or Enriched Uranium

As discussed above, the primary objective of ORAUT-OTIB-0004, Rev. 3, is to provide guidance for deriving internal doses to uranium workers at AWE facilities when there is little or no reliable data upon which to base a dose reconstruction. The most important recommendation of the guide is the use of a default airborne uranium dust loading of 100 MAC (or 70,000 dpm/m^3). We have found this to be a reasonable upper-bound assumption. In addition, it can be used for facilities that work with natural, depleted, or enriched uranium, because the dose conversion factors for these different isotopes of natural uranium all have essentially the same dose conversion factor. However, the OTIB recognizes that there may be times when site-specific airborne samples or bioassay data are available, but they are provided in units of mg (e.g., mg/m^3 or mg/L). When the data were in this form, the isotopic mix is an extremely important consideration because of the widely different specific activities (i.e., Bq/mg) of U-234, U-235, and U-238).

In the case of depleted uranium, the OTIB recommends simply using the activity-to-mass ratio for natural uranium as a simplifying claimant-favorable assumption, because depleted uranium has a lower specific activity than natural uranium. SC&A considers this to be a reasonable and claimant-favorable assumption.

For enriched uranium, the OTIB provides multiplication factors to the intake of natural uranium that accounts for the greater specific activity of various degrees of enriched uranium if the workers actually experienced exposures to enriched uranium. For example, natural uranium has a specific activity of 0.68 pCi/ug, while highly enriched uranium (93.5%) has a specific activity of 68.11 pCi/ug. Hence, the ratio of the specific activity of highly enriched uranium to natural uranium is 99.7. This means that the lung dose from inhaling a mg of highly enriched uranium would be 99.7 times higher than inhaling a mg of natural uranium. We find that the recommended correction factors are scientifically sound.

3.9.3.5 External Dose to Penetrating Radiation

For the purpose of estimating default external exposures at AWE facilities, this OTIB recommends assuming a worker spends 2,000 hours per year 1 foot away from a pure natural uranium rectangular ingot with dimensions of 24 in long, 16 in wide, and 4 in high, with AP geometry. It is also assumed that the short-lived progeny of U-238 are in equilibrium. Using

MCNP, the OTIB estimates a dose rate of 4.16 rem/yr. SC&A concurs that this default external dose rate is scientifically sound and claimant favorable.

The OTIB also presents default values for external exposure to contaminated surfaces. The model adopted in this OTIB uses the same assumptions and models employed in OCAS-TIB-009 for estimating ingestion intakes, and suffers from the same deficiencies; i.e., it assumes that the contamination on surfaces is directly proportional to the airborne dust loading and does not take into consideration the possibility that surfaces at AWE facilities can become contaminated by the direct deposition of large flakes of uranium oxide. Since NIOSH is in the process of revising this generic methodology as part of its revisions to the Bethlehem Steel site profile, we assume that this deficiency in this OTIB will also be corrected.

3.9.3.6 External Dose to Non-Penetrating Radiation

SC&A is in accordance with the calculations in Section 3.2.2 for maximum shallow dose from handling of uranium metal. This matter was previously reviewed by SC&A in the context of the review of Rev. 01 of the Bethlehem Steel site profile. Hence, SC&A agrees that a dose rate of 0.126 rad per hour is an appropriate maximum dose rate to use for external shallow dose from uranium metal handling of various kinds. However, it is not appropriate to restrict this only to hands and forearms. Specifically, SC&A provided worker interview data in its site profile review that workers carried uranium rods against their bodies (Finding 8, SCA-TR-TASK1-0001, October 2004). Further, there is direct evidence from the Fernald plant that some workers sat on uranium ingots to stamp numbers on them (see Exhibit A photograph by Robert del Tredici, taken in 1987). In view of the foregoing, inclusion of male genitalia and other areas of skin could be exposed in broadly similar ways to the hands or forearms. This needs to be taken into account in a technical document that seeks to estimate "maximum plausible dose."

SC&A suggests that the dose of 252 rad per year be more broadly applied to male genitalia. It should also be applied to other parts of the skin as appropriate; for instance, stomach area of the skin, groin, thighs, and buttocks.

ORAUT-OTIB-0004 does not include a shallow dose component from contamination of clothing. NIOSH agreed as part of the comment resolution procedure for the Bethlehem Steel Site Profile that it would add a dose rate of 0.15 mrad/hour for this pathway (Bethlehem Steel Site Profile Review, Summary Matrix of Findings, November 28, 2005, Item 6).

Exhibit A: Fernald Uranium Meal Worker Stamping an ID Number on an Ingot Photo by Robert del Tredici, 1987, used with permission

3.9.3.7 Occupationally Required Medical Exposures

This OTIB adopts the procedures recommended in ORAUT-PROC-0061, *Occupational X-Ray Dose Reconstruction for DOE Sites*, and ORAUT-OTIB-0006, *Dose Reconstruction from Occupationally Related Diagnostic X-Ray Procedures*. A review of ORAUT-PROC-0061, along with ORAUT-OTIB-0006, is reviewed in Section 2.2 of this report and is not repeated here. In brief, we find that the only exams considered are a pre-employment and any annual chest x-rays taken as part of the physical. Therefore, exams from injury or incidents, special monitoring and surveys, etc., are mostly not included in the dose estimate to the disadvantage of the claimant. Also, the guidance instructs the dose reconstructor to multiply the doses by 1.3 to account for uncertainty. However, no guidance is provided for addressing uncertainties associated with poor technique or film processing. We believe these deficiencies also apply to this OTIB.

3.9.3.8 Exposure to Residual Radioactivity (i.e., the inhalation and inadvertent ingestion of uranium that has deposited on surfaces (floors, tables, equipment) in the workplace following termination of operations)

The OTIB assumes that the airborne activity in the working environment at a given AWE facility following termination of uranium operations is due to resuspension processes, and that resuspension processes are responsible for 50% of the airborne dust loading. As a result, immediately after termination of operations, the OTIB recommends assuming that the airborne dust loading from resuspension of uranium contamination on surfaces is 50 MAC (i.e., 3,500 dpm/m^3). This certainly appears to be a claimant-favorable assumption as an initial set of conditions.

The OTIB then recommends that the dust loading on surfaces and in the air gradually declines at a rate of 1% per day due to natural attenuation. When integrated over infinity, this assumption results in a total uranium intake from residual radioactivity that is 20% of the annual intake associated with uranium operations, where the dust loading is assumed to be 100 MAC. Intuitively, this appears to be a reasonable approach. However, NIOSH needs to provide a technical basis for the assumed 1% per day natural attenuation rate, or at least demonstrate that this is a claimant-favorable assumption. Alternatively, NIOSH may wish to make use of the data that are available for AWE facilities, such as the data from Simonds Saw, to estimate the amount of surface contamination during operations and how that activity declines as a function of time after the termination of operations, and/or employ an appropriately conservative set of assumptions regarding resuspension factors and building air turnover rates.

In order to evaluate the reasonableness of NIOSH's approach to evaluating doses to residual radioactivity, we performed a series of calculations using available data, and found that the approach adopted by NIOSH is scientifically sound and claimant favorable. Attachment A to this review presents the results of this analysis.

3.9.4 Review Comments

Review Objectives 2.1, 5.1, 5.2, 5.3, and 7.3

As discussed above, some default assumptions are employed that may not be claimant favorable (such as those dealing with breathing rate and medical exposures). In some cases, no technical basis is provided for the assumption (such as the assumed natural attenuation rate of 1% per day). In addition, some of the methods employed in this OTIB are undergoing revision (such as the inadvertent ingestion model). The OTIB should be revised, as appropriate, to take into consideration these findings.

Attachment A - Review of the ORAUT-OTIB-0004 Resuspension Model

We have examined the generic procedure used to estimate the exposure of workers to resuspended uranium dust after cessation of uranium operations at an AWE. The procedure recommends that the dose reconstructor assume a uranium dust concentration of 50 MAC immediately after the cessation of uranium operations, and an exponential decline of 1% per day.

The following presents scoping calculations as a means to verify these assumptions.

First, we define two commonly used measures of resuspension; the resuspension factor and the resuspension rate.

Resuspension Factor

The resuspension of radioactive material from contaminated surfaces is typically modeled by a resuspension factor or a resuspension rate. A resuspension factor "is the ratio of airborne contaminant concentration per unit air volume, P, divided by the contaminant surface concentration per unit area [S] . . ." (Sehmel 1984). Although the theoretical inadequacies of both the resuspension factor and the resuspension rate have been discussed in the literature (e.g., Healy 1971, Horst 1982), both are commonly used in assessments in the absence of more exact models. The following equations present the definition of the resuspension factor and its relationship to the resuspension rate:

$$F_r = \frac{\chi_i}{k_u S_i} = \frac{A R_r}{R_a V} \quad (1)$$

F_r = resuspension factor (m^{-1})

P_i = concentration of radionuclide *i* in ambient air (dpm/m^3)

k_u = units conversion factor
= 100

S_i = areal activity concentration of radionuclide *i* on contaminated surface (dpm per 100 cm^2)

A = area of residually radioactive surface (m^2)

R_r = resuspension rate (h^{-1})

V = volume of affected region (m^3)

R_a = air exchange rate (h^{-1})

Resuspension Rate

The resuspension rate is derived by solving Equation 1:

$$R_r = \frac{F_r R_a V}{A} \quad (2)$$

The depletion of the uranium available for resuspension is equal to the resuspension rate, R_r. To evaluate this rate, we first need an estimate of F_r, the resuspension factor. Although estimates of F_r span many orders of magnitude, the NIOSH assumption of an initial airborne activity concentration of 50 MAC (3,500 dpm/m^3) places a lower limit on this value. Table 3.9-5 presents the results of surface contamination measurements of the mill area at Simonds Saw &

Steel. The tabulated areal alpha activity concentrations span a range of 2,500 to 80,000 dpm per 100 cm^2. Using the highest of these values, an assumed airborne concentration of 50 MAC would correspond to F_r . 4.4 H 10^{-4} m^{-1}. To allow for possibly higher surface contamination levels at other facilities, we round down to $F_r = 10^{-4}$ m^{-1}.

Table 3.9-5. Alpha Radiation Measurements Taken at Simonds Saw (dpm/100 cm^2)

Location	Date		
	10/27/48	12/1/48	2/15/49
East Roller 1	50,000	12,000	12,000
East Center Line	25,000	16,000	18,000
East Bench	5,000	10,000	3,000
Desk	2,500	2,500	2,500
West Roller 2	15,000	11,000	8,000
West Roller 1	35,000	35,000	3,000
West Center Line	18,000	7,500	5,000
Furnace Area	50,000	80,000	10,000
Shear	30,000	25,000	6,000
West Bench	3,000	3,000	2,500

Source: AEC 1949, Table II

To evaluate the expression presented in Equation 2, we assume a nominal building air exchange rate of 1 h^{-1}, and a nominal height of 10 m. Assuming that all the contamination resides on the floor, $\frac{V}{A}$ = 10 m. Substituting these values into Equation 2 yields $R_r = 10^{-3}$ h^{-1}. To estimate the daily resuspension rate, we assume that the building ventilation system operates only when the building is occupied. Assuming a nominal occupation of 10 h/d, we obtain an air exchange rate of 10 d^{-1}, which yields a daily resuspension rate, $R_rN = 10^{-2}$ d^{-1}. Thus, a depletion rate of 1% per day, coupled with an initial airborne activity concentration of 50 MAC, is a plausible, claimant-favorable assumption.

We further observe that the integrated worker exposure over a long period of time is given by the following expression:

$$X_{int} = \frac{\chi_0}{R_r'}$$

X_{int} = Time-integrated exposure (0 < t < 4) (MACAd)

P_0 = Initial airborne activity concentration (MAC)

R_rN = Resuspension rate (d^{-1})

As we see, the integrated exposure rate depends on the ratio of the initial concentration to the resuspension rate. Since a lower resuspension rate would necessarily lead to a lower concentration, the time-integrated exposure is a more robust quantity than either the initial concentration or the resuspension rate.

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3.10 ORAUT-OTIB-0018: INTERNAL DOSE OVERESTIMATES FOR FACILITIES WITH AIR SAMPLING PROGRAMS

The review of ORAUT-OTIB-00018, *Internal Dose Overestimates for Facilities with Air Sampling Programs*, Rev 0, dated August 9, 2005, was prepared by Steven Schaffer, PhD, and approved by John Mauro, PhD, CHP, on March 20, 2006.

3.10.1 Purpose of Procedure

This document provides an alternative and less conservative method for determining radionuclide intake and internal doses when compared to the maximum exposure method used in ORAUT-OTIB-0002. Analysts may use this document when they need a more realistic but still claimant-favorable method to estimate internal dose, provided that the facility rigorously

sampled particulate air concentrations and rigorously controlled exposures based on air measurements.

3.10.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0018 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.

Table 3.10-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0018, Rev 0	**Effective Date:** 08/09/2005
Document Title: Internal Overdose estimates for Facilities with Air Sampling Programs	
Auditor: Steven Schaffer, PhD	

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	The guide should be revised to refer to ORAUT-OTIB-0033 for additional/more flexible guidance
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?	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?	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	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?	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	
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)?	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	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	4	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.

3.10.3 General Comments

ORAUT-OTIB-0018 describes and presents a generic methodology for placing a reasonable upper estimate on the inhalation of particulate radionuclides for workers who had no significant intakes, no bioassay measurement or bioassay results below the MDL, and at sites where the airborne radionuclide concentrations were rigorously monitored. The basic philosophy adopted by this guide is that individuals that meet the applicability criteria for this guide were unlikely to

have experienced exposures in excess of the maximum allowable airborne particulate concentration in effect at the time period and facility of concern.

Fundamental to the guideline are the limits on airborne radionuclide concentrations that were established at different times by standard-setting bodies and by regulation. The time periods covered in ORAUT-OTIB-0018 begin with the NBS guidelines established in 1953 and extend to the time period covered by the limits established by DOE in 10 CFR Part 835, which were implemented in 1993. As such, the guide is not to be used for time periods prior to 1953.

Given the standards as a function of time, and the applicability and limitations of the guidance, ORAUT-OTIB-0018 presents an array of default airborne radionuclide concentrations that are recommended for dose reconstructions for different facilities and time periods of exposures, along with default breathing rates and exposure durations. For facilities that handled recycled uranium, ORAUT-OTIB-0018 recommends default intakes of Pu-238, Np-237, Tc-99, Th-232, and Ru-106, expressed in terms of pCi of each radionuclide per pCi of U. For sites where the specific airborne radionuclides are not known, because only gross alpha and gross beta/gamma counts were made, ORAUT-OTIB-0018 recommends assuming that the airborne activity is entirely comprised of the radionuclide and chemical forms with the highest dose conversion factors for the organs of concern. Finally, in light of the many uncertainties associated with characterizing the airborne radionuclide concentrations actually inhaled by a given worker, ORAUT-OTIB-0018 recommends assuming that each recommended default radionuclide concentration is the geometric mean of a lognormal distribution with a standard deviation of 3.[12] The recommended approach seems to place a reasonable upper bound on inhalation exposures for the sites, time periods, conditions, and classes of workers for which it is applicable.

NIOSH may find it useful to add an attached example, so an analyst can see directly how the method is applied. In addition, the guide may benefit from some sort of computer-aided calculation tool to help implement the protocol. If one exists, it should be added to the example. If one does not exist, NIOSH may find it useful to develop one.

One of the limitations of the guide is that it does not explain the derivation of the activity fractions for recycled uranium in Table 4-2. Without this derivation, we don't know if the fractions are appropriate and tend to overestimate the dose. NIOSH should document the derivations of these fractions and provide evidence that they result in upper estimate doses.

Another possible limitation is that the guide adopts OCAS-TIB-009, *Estimation of Ingestion Intakes*, as the basis for deriving ingestion intakes. On this basis, this ORAUT-OTIB recommends assuming that the ingestion intake is 0.021 of the inhalation intake. The deficiencies associated with this approach are discussed in Section 3.1 of this report. However, in general, the recommended approach is likely appropriate for the facilities for which this guide applies, because the applicable facilities do not include AWE facilities, where the radionuclide intake rates via ingestion are not necessarily proportional to the radionuclide intake rates via inhalation.

[12] It is worth noting that ORAUT-OTIB-0033 recommends using 50% of the ORAUT-OTIB-0018 default values for workers exposed before 1989, and 5% of the default ORAUT-OTIB-0018 values for workers exposed following 1989. ORAUT-OTIB-0018 does not provide for this additional flexibility in reconstructing doses.

3.10.4 Review Comments

Review Objective 1.5

Though the OTIB is highly prescriptive, it is limited to workers and sites that meet specific criteria that may not be readily discernable by the dose reconstructor. For example, Sections 3.1 and 3.2 of the OTIB, Applicability and Limitations, require the dose reconstructor to make judgments regarding whether the site had a rigorous air particulate monitoring program; whether the worker was unlikely to have experienced significant exposure to airborne particultes; whether exposures were limited to only airborne particles and did not include iodines, C-14, radon, or H-3, and other conditions. Different dose reconstructors could easily come to different conclusions for the same worker regarding these matters. Such judgments may be especially difficult for construction and maintenance workers.

Review Objective 7.3

The OTIB would benefit from a more thorough explanation of the basis for the activity fractions for isotopes associated with recycled uranium, as prescribed in Table 4-2 of the guide.

3.11 ORAUT-OTIB-0060, REVISION 00: EXTERNAL ONSITE AMBIENT DOSE RECONSTRUCTION

The review of ORAUT-OTIB-0060, *External Onsite Ambient Dose Reconstruction*, Rev 00, dated March 7, 2005, was prepared by Steven Schaffer, PhD, and approved by John Mauro, PhD, CHP, on March 20, 2005.

3.11.1 Purpose of Procedure

This document provides specific instructions to a dose analyst on how to estimate external ambient doses. It provides specific instructions on how to determine if the ambient dose estimates are needed, how to estimate a maximizing dose to expedite cases that clearly will not result in compensation, how to perform a reasonably conservative analysis where ambient doses should be included for completeness, and how to perform a realistic analysis when ambient doses are important to the probability of causation.

3.11.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0060 is summarized in Table 3.11-1 below. Table 3.11-1 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 3.11-1. Procedure Review Outline/Checklist

Document No.: ORAUT-PROC-0060, Rev. 00	**Effective Date:** 03/07/2005
Document Title: External On-Site Ambient dose Reconstruction for DOE Sites	
Auditor: Steven Schaffer, PhD	

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	It references other related NIOSH and ORAUT documents, 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?	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?	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)	5	
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?	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	
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)?	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	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	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.

3.11.3 General Comments

The document explains the different procedures in a clear and concise manner. A comparison of the table of maximized ambient doses in Attachment B to site data supplied in selected site profiles suggests that the table values are, in fact, maximum. The method for calculating a conservative best-estimate ambient dose is reasonable.

3.11.4 Review Comments

Review Objective 1.5

The method for maximum doses should address what the analyst should do when there is no data in the table in Attachment B. For example, what should the analyst do for someone who was at the Nevada Test Site (NTS) prior to 1963? The table has no doses listed for this site for the years prior to 1963. Should the analyst use the best-estimate approach?

3.12 ORAUT-OTIB-0014, REVISION 00: ASSIGNMENT OF ENVIRONMENTAL INTERNAL DOSES FOR EMPLOYEES NOT EXPOSED TO AIRBORNE RADIONUCLDES IN THE WORKPLACE

The review of ORAUT-OTIB-0014, *Assignment of Environmental Internal Doses for Employees Not Exposed to Airborne Radionuclides in the Workplace,* Rev. 00, dated June 22, 2004, was prepared by Steven Schaffer, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006. 2005.

3.12.1 Purpose of Procedure

The stated purpose of this procedure "is to provide guidance to dose reconstructors on (1) when they can assign environmental internal doses rather than potential workplace exposures to workers, and (2) the methodology for asigning such doses."

3.12.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0014 is summarized in Table 3.12-1 below. Table 3.12-1 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 3.12-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0014, Rev. 00	**Effective Date:** 06/22/2004
Document Title: Assignment of Environmental Internal Doses for Employees Not Exposed to Airborne Radionuclides in the Workplace	
Auditor: Steven Schaffer, PhD	

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?	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)	5	
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?	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	
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?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	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.

3.12.3 General Comments

This is a very general guidance document that explains when a dose analyst should assign environmental internal doses rather than workplace exposures, and the methodology for assigning such doses. The approach to identifying who should be assigned environmental internal doses is reasonable and considers the important factors of job category, work location, time frames, monitoring data, and co-worker information. The attachment (A) presents a

reasonably comprehensive list of job categories with no, some, or probable potential for work place exposure.

The methodology for assigning environmental internal dose is left up to the dose analyst, but the document gives some generalized guidance on how to assign internal doses. This guidance seems reasonable and covers most types of situations that the analyst may encounter by referring the dose reconstructor to the appropriate sections of the site profiles. As is the case for many of the other procedures reviewed in this report, particular care must be taken when assigning a construction worker to a given category of exposures due to the highly diverse nature of the exposures that some construction workers experienced.

3.13 ORAUT-OTIB-0025, REVISION 00: ESTIMATION OF RADIUM-226 ACTIVITY IN THE BODY FROM BREATH RADON MEASUREMENTS

The review of ORAUT-OTIB-0025, *Estimation of Radium 226 Activity in the Body from Breath Radon Measurements,* Rev. 00, dated April 5, 2005, was prepared by Michael Thorne, PhD, and approved by John Mauro, PhD, CHP, on May 16, 2006.

3.13.1 Purpose of Procedure

The purpose of this procedure is to provide a methodology that can be used to estimate the Ra-226 body burden in an individual based on the amount of radon exhaled by that individual. The procedure was developed because of the existence of historical radon breath analyses for some workers, and that these data might be useful in estimating the Ra-226 body burden, thereby facilitating the reconstruction of their internal doses to Ra-226.

3.13.2 Review Protocol

SC&A's evaluation of ORAUT-OTIB-0025 is summarized in Table 3.13-1 below. Table 3.13-1 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 3.13-1. Procedure Review Outline/Checklist

Document No.: ORAUT-OTIB-0025, Rev. 00	**Effective Date:** 04/05/2005
Document Title: Estimation of Radium 226 Activity in the Body from Breath Radon Measurements	
Auditor: Michael Thorne, PhD	

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?	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	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?	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	
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?	5	
7.2	Does the procedure avoid levels of detail that have only limited significance to the final dose estimate and its POC?	5	
7.3	Does the procedure employ scientifically valid protocols for reconstructing doses	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.

3.13.3 General Comments

Summary of the OTIB

The OTIB presents a brief review of the literature and concludes that for every pCi/L of radon measured in breath, it can be assumed that the whole body contains 0.25 uCi and, of this, 0.13 uCi is in the bone. The equation used to derive this relationship is quite simple, as follows:

$$Q = (C_{Rn} \times I) / (\lambda_{Rn} \times f)$$

where:

Q = the quantity of Ra-226 present in the body (pCi)
I = the breathing rate of the subject (L/hr)
C_{Rn} = the concentration of Rn-222 in the breath sample (pCi/L)
λ_{Rn} = the decay constant of Rn-222 (per hr)

The procedure explains that the protocol must ensure that the breath sample is not contaminated by ambient radon by taking the sample in a low radon area and having the subject's breath as free as possible of ambient radon prior to collecting the sample (e.g., bottled oxygen prior to collecting the breath sample). In addition, the procedure recommends taking the breath sample on a Monday morning at least 2 hours after having breakfast. Taking the sample on Monday morning (after a work-free weekend) is recommended because it helps to minimize the presence of residual radon in breath due to ambient radon in the workplace. Delaying the collection of the breath sample until about 2 hours after breakfast is recommended because of evidence that the radon concentrations in breath samples taken immediately following a meal are temporarily elevated by a factor of about 2.

The procedure also recommends using an f value of 0.63, which is based on empirical data and is believed to result in a high-end estimate of the Ra-226. A breathing rate of 1.2 L/hr is recommended in the OTIB, since this is the default breathing rate for light activity recommended by the ICRP.

SC&A performed an independent review of the literature on this subject, and concurs with the OTIB's recommended relationship of 0.1 uCi of Ra-226 body burden per pCi/L of radon in breath.

The only observation we would like to make has to do with the fact that the higher the breathing rate, the lower the concentration of radon in exhaled air for a specified Ra-226 body burden. The implications are that, if the radon breath analysis records for a given worker are expressed in terms of radon concentration in breath (e.g., pCi/L of breath), then it may be preferable to derive the Ra-226 body burden assuming a resting level breathing rate (which is likely the condition under which the sample was originally collected). This will result in a more realistic (in this case lower) estimate of the Ra-226 body burden. Conversely, if the radon breath analysis record is expressed in units of radon expired per unit time, and no information is provided on the individual's breathing rate, then it would be preferable to derive the radon concentration in the exhaled air assuming a lower breathing rate, thereby deriving a slightly higher Ra-226 body burden.

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4.0 QUALITY ASSURANCE PLANS

4.1 OCAS-PR-005: CONDUCT OF ASSESSMENTS

This review of OCAS-PR-005, *Conduct of Assessments*, Rev. 0, December 3, 2004, was prepared by Stephen L. Ostrow, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006.

4.1.1 Purpose of Procedure

The stated purpose of this procedure is ". . . to provide the process for the conduct, documentation, and finalization of assessments performed by the Office of Compensation Analysis and Support (OCAS)" (Section 1.0).

4.1.2 Review Protocol

Since the OCAS procedure specifies the conduct of assessments, which is part of an OCAS quality assurance program, it is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Table 4.1-1, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review.

4.1.3 General Comments

The subject procedure applies to "OCAS personnel involved in conducting assessments of contractor performance and OCAS self-assessments" (Section 2.0). The procedure contains sections on purpose, project, scope, references, responsibilities, procedures, records, applicable documents, and definitions. It describes the overall process by which OCAS personnel conduct assessments; outlines the responsibilities and interactions of the OCAS Contract Oversight Team Leader, OCAS Assessor, office Automation Assistant, and Health Science Administrator; and describes the record generation process. The procedure also includes as attachments several checklists and report formats, which may be applicable depending on the circumstances of a particular review.

Table 4.1-1: QA-related Document Compliance Checklist

Document No.: OCAS-PR-005, Rev. 0	**Effective Date:** 12/3/04
Document Title: Conduct of Assessments	
Reviewer: Stephen L. Ostrow, PhD	

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	
1.8	Are there procedures covering all work activities of the project?	N	The procedure needs to refer to other QA

No.	Question	Y/N	Comments
			procedures.
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 the first page; however, the other items appear on each page and 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 the Health Science Administrator and the Associate Director for Science.
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	The 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	The procedure is "administrative," not "technical."

4.1.4 Review Comments

Review Objectives 1.8 and 2.2

The *Conduct of Assessments* procedure is clear and provides adequate guidance to OCAS for the conduct of such assessments. The following comments, observations, and suggestions are made to improve the procedure in future revisions:

(1) Section 3.0, References, does not contain any citations, although it is unlikely that this procedure is *sui generis*, without antecedents. It is expected that the subject procedure, which covers material that is customarily part of a quality assurance program, is an implementing procedure of a higher-level OCAS quality assurance plan; that plan, as well as any other related plans and procedures, should be referenced in Section 3.0, and, perhaps, referred to in other sections of the procedure as well. As now presented, the subject procedure stands without context related to how it fits into an overall quality program.

In addition, since assessments may consist of dose reconstruction reviews or blind dose reconstructions, the subject procedure should reference appropriate technical plans and procedures to perform these assessments; e.g., OCAS-PR-007 for dose reconstruction reviews.

(2) Although the responsibilities of various personnel (i.e., OCAS Contract Oversight Team Leader, OCAS Assessor, office Automation Assistant, and Health Science Administrator) are delineated in the procedure, the procedure does not mention any required qualification or training of these personnel. This deficiency may be particularly significant in some cases where the assessments are technical, such as for dose reconstructions. As we indicated earlier, these procedures should reference the overall quality program. If personnel training and qualifications considerations are treated elsewhere, the appropriate plans or procedures should be referenced in this document.

(3) It is not clear whether an Assessment Checklist is always required in an assessment, or whether use is at the discretion of the OCAS Assessor and whether the OCAS Assessor has the freedom to create his or her own checklist, appropriate for the conduct of a particular assessment.

Section 6.2.5 states that one of the responsibilities of the OCAS Assessor is to, "document the criteria to be assessed on an Assessment Checklist. Use the appropriate attachment for the checklist to be used during the assessment." This paragraph seems to require using one of the attached checklists. However, Section 6.2.3 states that the OCAS Assessor should "establish the criteria to be assessed through review of the pertinent requirements. Examples of checklists that may be used are included as Attachments 2 and 3." The use of the word "examples" in this paragraph seems to imply that other checklists may also be used. The subject procedure should clarify this apparent discrepancy and present the requirements related to an Assessment Checklist in a straightforward fashion.

(4) Attached assessment checklist examples and report formats all pertain to dose-related assessments and functions, such as for dose reconstruction reviews and blind dose reconstructions. We found that no similar attachments are provided for non-technical assessments that are covered in Section 5.1 of the procedures. If the subject procedures pertain only to dose-related assessments, the current document should be made clear; otherwise checklist examples and report formats should be provided as well.

4.2 OCAS-PR-007: DOSE RECONSTRUCTION REVIEW

This review of OCAS-PR-007, *Dose Reconstruction Review*, Rev. 1, dated April 18, 2005, was prepared by Stephen L. Ostrow, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006.

4.2.1 Purpose of Procedure

The stated purpose of this procedure is ". . . to provide the process for the conduct, documentation, and performance of dose reconstruction (DR) reviews performed by the Office of Compensation Analysis and Support (OCAS)" (Section 1.0).

4.2.2 Review Protocol

Since the OCAS procedure pertains to the dose reconstruction *review* process, rather than to the dose reconstruction *performance* process itself, the procedure is part of the OCAS quality assurance program, and is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Table 4.2-1, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review.

4.2.3 General Comments

The subject procedure applies to "OCAS personnel involved in reviewing DR [dose reconstruction] reports" (Section 2.0). The procedure contains sections on purpose, project, scope, references, responsibilities, procedure, records, applicable documents, and definitions. It describes the overall process by which OCAS personnel review dose reconstruction reports (using three different levels of review—Basic, Detailed, and Blind DR Verification), and outlines the responsibilities and interactions of the OCAS Health Science Administrator, OCAS HP Team Leader, Office of the Director, OCAS HP, and office Automation Assistant. The procedure also includes a sample Dose Reconstruction Review Checklist and a sample DR Review Form as attachments.

Table 4.2-1: QA-related Document Compliance Checklist

Document No.: OCAS-PR-007, Rev. 1	**Effective Date:** 4/18/05
Document Title: Dose Reconstruction Review	
Reviewer: Stephen L. Ostrow, PhD	

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	
1.8	Are there procedures covering all work activities of the project?	N/A	

No.	Question	Y/N	Comments
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 the first page; however, the other items appear on each page and 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 the Health Science Administrator and the Associate Director for Science.
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	(See 4.2-4(8))
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, but a separate section may be advisable (See 4.2-4(9)).
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	The procedure is "administrative," not "technical."

4.2.4 Review Comments

Review Objectives 2.2 and 2.5

The *Dose Reconstruction Review* procedure is, with a few exceptions noted below, generally clear, and provides adequate guidance to OCAS for the conduct of such reviews at three different levels of scrutiny; Basic, Detailed, and Blind DR Verification. The following comments, observations, and suggestions are made to improve the procedure in future revisions:

(1) The procedure needs to clarify the authority that establishes the frequency for performing the three different types of reviews. Section 5.1.2, discussing Detailed Reviews, states that "the minimum frequency of such reviews will be specified by the Contract Oversight Team Leader." No similar statement is made about this person specifying the frequency of Basic Reviews or Blind DR Verifications. The preceding statement also may contradict the one in Section 4.1.3, which states that the OCAS Health Science *Administrator* "establish[es] the frequency for each type of DR report review," which would imply that the OCAS Health Science Administrator would specify the frequency of Detailed Reviews. Perhaps the procedure is trying to make a distinction between the Contract Oversight Team Leader setting the *minimum* frequency of the Detailed Reviews

(why not also the minimum frequency of the other two types of reviews?), while the OCAS Health Physics Administrator establishes the *actual* frequency of all the reviews.

Further, Section 6.2 states the OCAS Health Science Administrator "establish[es] the frequency for performing DRRRC [Dose Reconstruction Report Review Checklist]" (Section 6.2.1) and "establish[es] the frequency for performing BDRV [Blind Dose Reconstruction Verification]" (Section 6.2.2). No mention is made of the frequency of performing the Basic Reviews. In addition, the usage of DRRRC in Section 6.2.1 does not appear to make sense; earlier in the procedure, DRRRC is given as an acronym for Dose Reconstruction Report Review Checklist. Section 6.2.1 probably means to refer instead to the Detailed Review, which uses the DRRRC as part of the process.

(2) The role of the Contract Oversight Team Leader should be delineated in Section 4.0 on Responsibilities, if, indeed, he or she has the responsibility of establishing the frequency of any of the three types of review.

(3) The procedure is not clear on how the cases are chosen for review. Are they chosen randomly from the entire cohort of dose reconstructions; chosen randomly, but in proportion to a stratification criterion (e.g., proportional representation by facility, cancer type, worker type, or time period); or according to some other scheme? Section 6.3.1 mentions that the OCAS HP "select[s] a DR report for review from the NIOSH OCAS Claims Tracking System (NOCTS) Review Queue or the Unassigned Queue," but does not say how a dose reconstruction report gets on these queues. The procedure should include details of the selection process or a reference to where such information can be found.

(4) The procedure mentions training for the Health Physics personnel reviewers in Section 6.1, but does not reference the procedure (if it exists) covering the "training process."

(5) Section 5.1.3, on Blind DR Verification, states that *"using the OCAS Conduct of Assessment procedure and other OCAS approved technical manuals and procedures as a guide [sic], perform an independent DR to compare with the ORAU DR,"* and Section 5.1.3.1 goes on to say that *"this [the dose review] should be documented as an assessment per the requirements of OCAS-PR-005 …"* The OCAS-PR-007 procedure, however, does not reference the OCAS Conduct of Assessment procedure (OCAS-PR-005) for Basic Reviews (Section 5.1.1) or for Detailed Reviews (Section 5.1.2). Since OCAS-PR-005 appears to cover all three types of reviews ("assessments"), why does OCAS-PR-007 cite that procedure for only one of the three types? The subject procedure should be corrected if this is only an oversight.

(6) Section 5.2.1.2 on accuracy of probability of causation consideration in dose reconstruction reviews states that, "for cases resulting in a probability of causation of 50% or greater, ensure that the dose assigned is not a significant overestimate of the dose potentially received considering all of the available information." The procedure should provide guidance on what is meant by a "significant overestimate," since the dose reconstructions are supposed to be claimant favorable.

(7) Section 5.2.2.2 defines "radiological worker" and subsequent sections discuss the likelihood of exposure of such a worker when no or incomplete records are available.

However, as seen in several site profile TBDs, in some cases, non-radiological workers, such as office personnel, may have been inadvertently exposed to radiation. Section 5.2.3.3 presents an example of an administrative office energy employee, who, in this case, received only minimal lifetime dose; such may not always be the case, however.

(8) As noted in Table 4.2-1, Item 2.5, the procedure does not indicate the details of the changes made from the original issue to the first revision, although the Record of Issue/Revisions makes the general statement, "Revision to incorporate improved method of DR review." An experienced reviewer using this procedure would have to do a paragraph-by-paragraph comparison of the two generations of the procedure to determine what has changed and how it affects the review process (a new reviewer would be coming to the procedure fresh, without any expectations or routines). It is suggested that the Record of Issue/Revisions provide more detailed information, and that revised sections are denoted.

(9) As noted in Table 4.2-1, Item 2.6, the procedure liberally sprinkles acronyms throughout the text. Although they are explained at first usage, it would be helpful to the reader to include an acronym section in the procedure to facilitate understanding and to minimize hunting through the procedure to find their first usage.

4.3 ORAUT-PROC-0022: ADDITIONAL REQUESTS FOR DOE INFORMATION

This review of ORAUT-PROC-0022, *Additional Requests for DOE Information*, Rev. 0, dated March 15, 2005, was prepared by Stephen L. Ostrow, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006.

4.3.1 Purpose of Procedure

The stated purpose of this procedure is as follows:

> *. . . to outline the method for requesting additional energy employee (EE) information from various U.S. Department of Energy (DOE) sites for purposes of dose reconstruction (DR) for the Oak Ridge Associated Universities (ORAU) Team Dose Reconstruction Project for the National Institute for Occupational Safety and Health (NIOSH)* (Section 1.0).

The designation "Energy Employee" can refer to a former or current employee of DOE, a DOE contractor or subcontractor, or an Atomic Weapons Employee (AWE).

4.3.2 Review Protocol

Since the procedure pertains to the gathering of information for dose reconstructions, rather than to the performance of dose reconstructions, it is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Furthermore, Section 8.1 of the procedure lists as one of the drivers, ORAUT-PLAN-

0001, *Quality Assurance Program Plan*. Table 4.3-1, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review.

Table 4.3-1: QA-related Document Compliance Checklist

Document No.: ORAUT-PROC-0022, Rev. 0	**Effective Date:** 3/15/05
Document Title: Additional Requests for DOE Information	
Reviewer: Stephen L. 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	

No.	Question	Y/N	Comments
1.7	Is there an adequate procedure for the maintenance of project QA records in identifiable, legible, and retrievable condition?	N/A	
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 the first page; however, the other items appear on each page and 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 the Task 2 Manager, Project Director, and Associate Director for Science.
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	The 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	Both in text and in a separate section (9.0).
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	The procedure is "administrative," not "technical."

4.3.3 General Comments

The subject procedure applies to "requests for radiation exposure information or records associated with an EE's employment from DOE" (Section 2.0). The procedure contains sections on purpose, scope, references, responsibilities, procedure, records, applicable documents, and definitions and acronyms. It describes the overall process by which ORAU personnel request additional radiation exposure information from DOE, necessary to complete a dose reconstruction. The procedure also includes an Additional Request Form as an attachment.

4.3.4 Review Comments

The *Additional Requests for DOE Information* procedure is generally clear with a few exceptions noted below, and provides adequate guidance to ORAU for requesting additional dosimetry information from DOE for individual energy employees. The following comments, observations, and suggestions are made to improve the procedure in future revisions:

(1) The subject procedure refers in several places (Sections 3.0, 5.7, and 6.1.5.2) to the ORAU procedure for complying with the Privacy Act (*The Privacy Act of 1974,* 5 U.S.C. § 552a – As Amended) requirements for safeguarding claimant personal information. Citations are not made consistently, as Section 3.0 refers to the procedure as *Protecting Privacy Act Data,* and Sections 5.7 and 6.1.5.2 as *Protecting Privacy Act Information*. More seriously, however, in all three citations, the subject procedure refers to ORAUT-PROC-0077 as the Privacy Act procedure, while examination of ORAUT-PROC-0077 reveals that it is entitled *Dose Reconstruction Error Tracking and Reporting*. This apparent discrepancy suggests that the subject procedure misidentified the ORAU Privacy Act procedure and should be revised.

(2) It is suggested that the subject procedure provide such an overview for requesting information as a guide for the reader. The subject procedure refers in several places to Task 2, Task 4, and Task 5, and assumes that the reader is familiar with the responsibilities of each task (the subject procedure appears to be part of Task 2) and their interrelationships. This assumption may confuse some staff who have to use the procedure without benefit of having an overview of the project task organization.

4.4 ORAUT-PROC-0031: DOE TECHNICAL BASIS DOCUMENT DEVELOPMENT, REVIEW, AND APPROVAL PROCESSS

This review of ORAUT-PROC-0031, *DOE Technical Basis Document Development, Review, and Approval Process,* Rev. 01, dated December 15, 2005, was prepared by Stephen L. Ostrow, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006.

4.4.1 Purpose of Procedure

The stated purpose of this procedure is to: "… document and describe the process used to develop site profile (SP) technical basis documents (TBDs) for the Oak Ridge Associated Universities (ORAU) Team Dose Reconstruction Project as implemented by the National Institute for Occupational Safety and Health (NIOSH)" (Section 1.0). As noted in Section 2.0, "this procedure applies to all SP TBDs developed for the U.S. Department of Energy (DOE) and Atomic Weapons Employee (AWE) Facilities," and "to all ORAU Team personnel who contribute to the development of TBDs and/or who are involved in the internal review and approval process for those documents, including the external review and approval by NIOSH" (Section 2.0).

4.4.2 Review Protocol

Since the subject procedure is procedural rather than technical, it is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Table 4.4-1, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review.

Table 4.4-1: QA-related Document Compliance Checklist

Document No.: ORAUT-PROC-0031, Rev. 01	**Effective Date:** December 15, 2005
Document Title: DOE Technical Basis Document Development, Review, and Approval Process	
Reviewer: Stephen L. Ostrow, PhD	

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	
1.8	Are there procedures covering all work activities of the project?	N/A	

No.	Question	Y/N	Comments
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 the first page; however, the other items appear on each page and 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 the Task 3 Manager, Project Director, and Project officer.
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	Revision log notes that Rev. 1 is a "total rewrite of the document."
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	Abbreviations and acronyms are explained as they occur in the text. In addition, Section 9 provides definitions of some key terms and acronyms.
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	The procedure is "administrative," not "technical."

4.4.3 General Comments

The subject procedure contains sections on purpose, scope, references, responsibilities, general matters, procedure, records, applicable documents, and definitions (which includes acronyms). It describes the responsibilities and interactions of various project personnel as they implement the different steps of the procedure. The procedure also includes five attachments, including (A) Examples of Tables for the Development of Technical Basis Documents, (B) Typical DOE Technical Basis Document Timeline, (C) Technical Basis Document Review and Approval Process, (D) Typical Site Profile Content, and (E) Site Profile Team Leader TBD Review Declaration.

4.4.4 Review Comments

The DOE *Technical Basis Document Development, Review, and Approval Process* procedure provides adequate guidance to ORAU to develop, review, and revise site profile TBDs. It is detailed and clear, and specifies the information to be provided in each TBD section; useful examples of tables are included. Attachment 3 contains flowcharts for the internal and external review and approval process, which should aid the procedure user. The following comments, observations, and suggestions are made to improve the procedure in future revisions:

(1) Section 4.2.1 appears to incorrectly reference other sections in the procedure. The correct reference should be: "Sections 6.3.10 through 6.2.15."

(2) Section 4.2.7 refers to "sensitive information," but does not define what is meant by that term. The definition section (Section 9.0) likewise does not define that term.

(3) The procedure covers TBD revision reflecting comments from NIOSH and worker outreach activities, but does not mention those received from reviews by the Advisory Board or its contractors. Is it assumed that such comments come through NIOSH and are considered that organization's comments?

4.5 ORAUT-PROC-0065: INTERNAL FINDING AND CORRECTIVE ACTION TO PREVENT RECURRENCE

This review of ORAUT-PROC-0065, *Internal Finding and Corrective Action to Prevent Recurrence*, Rev. 00 PC-1, dated November 3, 2005, was prepared by Stephen L. Ostrow, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006

4.5.1 Purpose of Procedure

The stated purpose of this procedure is "… to establish a methodology to respond to and rectify deficiencies identified by employees and/or internal Auditors. The process provides a means for developing corrective actions or improvement plans, completing these actions or plans on schedule, and addressing preventive measures to ensure continual process improvements" (Section 1.0).

4.5.2 Review Protocol

Since the ORAU procedure is part of that organization's quality assurance program (and is referenced in Section 3.1 of ORAUT-PLAN-0001, *Quality Assurance Program*, Rev. 1, January 31, 2005), it is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Table 4.5-1, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review.

Table 4.5-1: QA-related Document Compliance Checklist

Document No.: ORAUT-PROC-0065, Rev. 00 PC-1	**Effective Date:** 11/03/05
Document Title: Internal Finding and Corrective Action to Prevent Recurrence	
Reviewer: Stephen L. 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	
1.8	Are there procedures covering all work activities of the project?	N/A	

No.	Question	Y/N	Comments
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 the first page; however, the other items appear on each page and 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 the Task 9 Manager, Project Director, and Associate Director for Science.
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	Y	Log shows internal revisions before final issue of Rev. 00 PC-1.
2.5	Are revisions clearly indicated on affected pages?	Y	Sidebars added on revised pages referred to in revision log.
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	Abbreviations and acronyms are explained as they occur in the text. In addition, Section 9 provides definitions of some key terms and acronyms.
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	The procedure is "administrative," not "technical."

4.5.3 General Comments

Section 6.12.2.2, Internal Audits, Assessments, and Surveillances, of the ORAU *Quality Assurance Program* requires a mechanism for "developing, implementing, and tracking corrective actions and improvement plans to resolve findings and observations;" ORAUT-PROC-0065 is listed and provides that mechanism. As emphasized in Section 2.0 of the subject procedure, it addresses only *internal* findings and observations, not *external* ones (e.g., those developed by NIOSH), which are treated in ORAUT-PROC-0069.

The subject procedure contains sections on purpose, scope, references, responsibilities, general matters, procedure, records, applicable documents, and definitions and acronyms. It describes the responsibilities and interactions of various project personnel as they implement the different

steps of the procedure. It also includes an Internal Finding form, a Root Causes form, and an Observation Response form as attachments.

4.5.4 Review Comments

The *Internal Finding and Corrective Action to Prevent Recurrence* procedure is clear and provides adequate guidance to ORAU to comply with the requirements of the *ORAU Quality Assurance Program* (as expressed in ORAUT-PLAN-0001). Section 6, Procedure, is especially clear in outlining all the steps to be taken from the identification of a deficiency (finding, observation, or neither) to its disposition. The following comments, observations, and suggestions are made to improve the procedure in future revisions:

(1) The procedure ought to provide a general discussion of how this implementing procedure fits into the overall ORAU Quality Assurance Program.

(2) A flowchart keyed to the sections of the procedure would be helpful to the reader, given the length and level of detail of the procedure.

4.6 ORAUT-PROC-0066: QUALITY ASSURANCE RECORDS MANAGEMENT

This review of ORAUT-PROC-0066, *Quality Assurance Records Management*, Rev. 0, dated September 3, 2004, was prepared by Stephen L. Ostrow, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006.

4.6.1 Purpose of Procedure

The stated purpose of this procedure is as follows:

> *. . . to describe the activities and responsibilities necessary for the identification, control, storage, retrieval, and disposition of Task 9 Quality Assurance (QA)-related records and documents for the Oak Ridge Associated Universities (ORAU) Team Dose Reconstruction Project for the National Institute for Occupational Safety and Health (NIOSH).* (Section 1.0).

4.6.2 Review Protocol

Since the ORAU procedure is part of that organization's quality assurance program, it is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Table 4.6-1, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review.

Table 4.6-1: QA-related Document Compliance Checklist

Document No.: ORAUT-PROC-0066, Rev. 0	**Effective Date:** 9/03/04
Document Title: Quality Assurance Records Management	
Reviewer: Stephen L. Ostrow, PhD	

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	
1.8	Are there procedures covering all work activities of the project?	N/A	

No.	Question	Y/N	Comments
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 the first page; however, the other items appear on each page and 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 the Task 9 Manager and Project Director.
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	Y	Log shows internal revisions before final issue of Rev. 0.
2.5	Are revisions clearly indicated on affected pages?	N/A	The 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	Abbreviations and acronyms are explained as they occur in the text. In addition, Section 9 provides definitions of some key terms and acronyms.
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	The procedure is "administrative," not "technical."

4.6.3 General Comments

Section 6.12.2.2 of the *ORAU Quality Assurance Program* (ORAUT-PLAN-0001) mandates quality assurance-related record keeping on the project to support audits, assessments, and surveillances:

> *Requirements, responsibilities, and procedures for conducting internal QA audits, assessments, and surveillances; for developing, implementing, and tracking corrective actions and improvement plans to resolve findings and observations; and for reporting and maintaining QA records related to these activities are included in the following Project documents [ORAUT-PROC-0066 is listed]:* (ORAUT-PLAN-0001, Rev. 1, 1/31/05, Section 6.12.2.2).

The subject procedure contains sections on purpose, scope, references, responsibilities, general matters, procedure, records, applicable documents, and definitions and acronyms. It describes the responsibilities and interactions of various project personnel as they implement the different

steps of the procedure. It also includes attachments; (1) "Guidance for Identification of QA Records and Nonrecords," (2) "Guidance for QA Numbering of Audits, Assessments, and Surveillances," and (3) "Audit/Assessment/Surveillance Record File Checklist."

Section 5.6 presents the requirement for personnel training in the provisions of the Privacy Act to protect records containing personal information of claimants; training is provided in ORAUT-PROC-0079.

4.6.4 Review Comments

The *Quality Assurance Records Management* procedure is clear and provides adequate guidance to ORAU for the management of quality assurance records and "nonrecords" (it defines this term) in accordance with the requirements of the *ORAU Quality Assurance Program* (as expressed in ORAUT-PLAN-0001). The following comment, observation, and/or suggestion is made to improve the procedure in future revisions:

(1) A general discussion of how this implementing procedure fits into the overall ORAU Quality Assurance Program would help orient the reader.

4.7 ORAUT-PROC-0067: CONDUCT OF QUALITY ASSURANCE SURVEILLANCES

This review of ORAUT-PROC-0067, *Conduct of Quality Assurance Surveillances*, Rev. 0, dated September 14, 2004, was prepared by Stephen L. Ostrow, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006.

4.7.1 Purpose of Procedure

The stated purpose of this procedure is as follows:

> *. . . to establish the process and responsibilities for administering and conducting independent Quality Assurance (QA) surveillances of the Oak Ridge Associated Universities (ORAU) Team Dose Reconstruction Project for the National Institute for Occupational Safety and Health (NIOSH).* (Section 1.0)

4.7.2 Review Protocol

Since the ORAU procedure is part of that organization's quality assurance program, it is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Table 4.7-1, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review.

Table 4.7-1: QA-related Document Compliance Checklist

Document No.: ORAUT-PROC-0067, Rev. 0	**Effective Date:** 9/14/04
Document Title: Conduct of Quality Assurance Surveillances	
Reviewer: Stephen L. Ostrow, PhD	

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	
1.8	Are there procedures covering all work activities of the project?	N/A	

No.	Question	Y/N	Comments
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 the first page; however, the other items appear on each page and 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 the Task 9 Manager, Project Director, and Associate Director for Science.
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	Y	Log shows internal revisions before final issue of Rev. 0.
2.5	Are revisions clearly indicated on affected pages?	N/A	The 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	Abbreviations and acronyms are explained as they occur in the text. In addition, Section 9 provides definitions of some key terms.
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	The procedure is "administrative," not "technical."

4.7.3 General Comments

Section 6.12.2.2 of the *ORAU Quality Assurance Program* (ORAUT-PLAN-0001) mandates the performance of surveillances on the project:

> *The Project shall conduct internal audits, assessments, and surveillances at planned intervals to determine whether the QMS [Quality Management System] conforms to its plan and to the QMS requirements established by the Project and whether QMS implementation and maintenance has been effective.* (ORAUT-PLAN-0001, Rev. 1, 1/31/05, Section 6.12.2.2)

The Quality Assurance Program document, which is a high-level project plan, goes on to delineate the requirements of surveillances, and references the subject procedure (an

implementing procedure), *Conduct of Quality Assurance Surveillances,* as part of the quality management system. The subject procedure applies to the following:

> *…all qualified ORAU team personnel that conduct a QA surveillance on a Project process, activity, or item including participating subcontractors, vendors and suppliers at their various locations and facilities to verify conformance to specified requirements and to evaluate the adequacy and effectiveness of the process, activity or item (Section 2.0).*

The procedure contains sections on purpose, project, scope, references, responsibilities, procedure, records, applicable documents, and definitions.

A surveillance, which "is generally more limited in scope than an audit or assessment," may be either scheduled or unscheduled; the latter may arise from a request by project personnel or by the Customer (i.e., NIOSH) (Section 5.1). The procedure describes the overall process by which ORAU personnel conduct assessments, outlines the responsibilities and interactions of key personnel, describes the record generation and documentation process, and references other relevant ORAU procedures relating to surveillances. An example of the latter is reference to ORAUT-PROC-0070, *Qualification of Quality Assurance Auditors*, which establishes training requirements of all personnel conducting surveillances (Surveillants). The procedure also includes as illustrative attachments a surveillance report form (ORAUT-FORM-0021) and a Quality Assurance Checklist.

4.7.4 Review Comments

The *Conduct of Quality Assurance Surveillances* procedure is generally clear and provides adequate guidance to ORAU for the conduct of such surveillances in accordance with the requirements of the ORAU Quality Assurance Program (as expressed in ORAUT-PLAN-0001). Section 6.0, Procedure, provides numerous helpful notes commenting on some of the requirements. The following comments, observations, and suggestions are made to improve the procedure in future revisions:

(1) The procedure leads the reader through the surveillance process, delineating requirements, responsibilities, and actions at each step. Nonetheless, it would be beneficial for greater clarity to provide a flowchart at the beginning of Section 6.0, Procedure, with the section text keyed to particular locations in the chart.

(2) A general discussion of how this implementing procedure fits into the overall ORAU Quality Assurance Program would help orient the reader.

4.8 ORAUT-PROC-0069: EXTERNAL NONCONFORMANCE AND CORRECTIVE ACTION TO PREVENT RECURRENCE

This review of ORAUT-PROC-0069, *External Nonconformance and Corrective Action to Prevent Recurrence*, Rev. 0, dated September 9, 2004, was prepared by Stephen L. Ostrow, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006.

4.8.1 Purpose of Procedure

The purpose of this procedure is stated in Section 1.0:

> *This procedure establishes the process for responding to nonconformances issued by External Auditors and provides instruction for identifying the root cause, developing corrective actions to rectify existing conditions and to prevent these nonconformances from recurring."*

4.8.2 Review Protocol

Since the ORAU procedure is part of that organization's quality assurance program, it is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Table 4.8-1, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review.

Table 4.8-1: QA-related Document Compliance Checklist

Document No.: ORAUT-PROC-0069, Rev. 0	**Effective Date:** 9/09/04
Document Title: External Nonconformance and Corrective Action to Prevent Recurrence	
Reviewer: Stephen L. Ostrow, PhD	

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	

No.	Question	Y/N	Comments
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	
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 the first page; however, the other items appear on each page and 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 the Task 9 Manager and Project Director.
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	Y	Log shows internal revisions before final issue of Rev. 0.
2.5	Are revisions clearly indicated on affected pages?	N/A	The 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	Abbreviations and acronyms are explained as they occur in the text. In addition, Section 9 provides definitions of some key terms and acronyms.
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	The procedure is “administrative,” not “technical.”

4.8.3 General Comments

Section 6.12.2.2 of the *ORAU Quality Assurance Program* (ORAUT-PLAN-0001) mandates quality assurance-related record keeping on the project to support audits, assessments, and surveillances:

> *Requirements, responsibilities, and procedures for conducting internal QA audits, assessments, and surveillances; for developing, implementing, and tracking corrective actions and improvement plans to resolve findings and observations; and for reporting and maintaining QA records related to these activities are included in the following Project documents [ORAUT-PROC-0066 is listed]:* (ORAUT-PLAN-0001, Rev. 1, 1/31/05, Section 6.12.2.2).

The subject procedure contains sections on purpose, scope, references, responsibilities, general matters, procedure, records, applicable documents, and definitions and acronyms. It describes the responsibilities and interactions of various project personnel as they implement the different steps of the procedure. It also includes as attachments; (1) "Guidance for Identification of QA Records and Nonrecords," (2) "Guidance for QA Numbering of Audits, Assessments, and Surveillances," and (3) "Audit/Assessment/Surveillance Record File Checklist." The subject procedure, which treats *external* findings of nonconformance, is companion to ORAUT-PROC-0065, which treats *internal* findings.

Section 5.6 presents the requirement for personnel training in the provisions of the Privacy Act to protect records containing personal information of claimants; training is provided in ORAUT-PROC-0079.

4.8.4 Review Comments

The *Quality Assurance Records Management* procedure is clear and provides adequate guidance to ORAU for the management of quality assurance records and "nonrecords" (it defines this term) in accordance with the requirements of the *ORAU Quality Assurance Program* (as expressed in ORAUT-PLAN-0001). The following comment, observation, and/or suggestion is made to improve the procedure in future revisions:

(1) A general discussion of how this implementing procedure fits into the overall ORAU Quality Assurance Program would help orient the reader.

4.9 ORAUT-PROC-0077: DOSE RECONSTRUCTION ERROR TRACKING AND REPORTING

This review of ORAUT-PROC-0077, *Dose Reconstruction Error Tracking and Reporting*, Rev. 00, dated March 28, 2005, was prepared by Stephen L. Ostrow, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006.

4.9.1 Purpose of Procedure

The stated purpose of this procedure is to provide "… the process for review disposition, correction, tracking, and trending of Dose Reconstruction Report errors and comments received by the Oak Ridge Associated Universities (ORAU) Team Dose Reconstruction Project for the National Institute for Occupational Safety and Health (NIOSH)" (Section 1.0). The "errors and comments" referred to are those generated directly by NIOSH reviewers, who review all dose reconstruction reports, or by Department of Labor or Final Adjudication Board personnel.

Section 1.0 also notes that, "This procedure is incorporated by reference into ORAUT-PLAN-0009, Project Management Plan."

4.9.2 Review Protocol

Since the ORAU procedure is part of that organization's quality assurance program (ORAUT-PLAN-0001, *Quality Assurance Program*, Rev. 1, 1/31/05), it is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Table 4.9-1, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review. Section 2.0 of the *Quality Assurance Program* states that "Implementation of this procedure, in conjunction with ORAUT-PROC-0059, Peer Review of Dose Reconstructions, shall constitute a quality review process as defined by ORAUT-PLAN-0001, Quality Assurance Program."

4.9.3 General Comments

Section 6.12.2.1 of the ORAU *Quality Assurance Program* discusses NIOSH requirements and processes to evaluate and process nonconformances:

> *The following Project management documents have been established to define the requirements and processes to be used to evaluate any nonconformances identified by NIOSH and to develop, implement, verify, track, and report completion of corrective actions* (ORAUT-PLAN-0001, p. 25).

The subject procedure is referenced and described in the list following the above quotation. As previously mentioned, in addition to NIOSH comments, there may also be comments from the Department of Labor or the Final Adjudication Board.

The subject procedure contains sections on purpose, scope, references, responsibilities, general matters, procedure, records, applicable documents, and definitions and acronyms. It describes the responsibilities and interactions of various project personnel as they implement the different steps of the procedure. It also includes a Dose Reconstruction Review form (ORAUT-FORM-0035) as an attachment.

Table 4.9-1: QA-related Document Compliance Checklist

Document No.: ORAUT-PROC-0077, Rev. 0	**Effective Date:** 3/28/05
Document Title: Dose Reconstruction Error Tracking and Reporting	
Reviewer: Stephen L. Ostrow, PhD	

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	
1.8	Are there procedures covering all work activities of the project?	N/A	

No.	Question	Y/N	Comments
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 the first page; however, the other items appear on each page and 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 the Task 5 Manager, Project Director, and Associate Director for Science.
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	Y	Log shows internal revisions before final issue of Rev. 00.
2.5	Are revisions clearly indicated on affected pages?	N/A	This is Rev. 00.
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	Abbreviations and acronyms are explained as they occur in the text. In addition, Section 9 provides definitions of some key terms and acronyms.
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	The procedure is "administrative," not "technical."

4.9.4 Review Comments

The *Dose Reconstruction Error Tracking and Reporting* procedure is clear and provides adequate guidance to ORAU to comply with the requirements of the ORAU *Quality Assurance Program* (as expressed in ORAUT-PLAN-0001). The Procedure section (No. 6.0) is especially thorough and clear in describing the five major reasons why NIOSH would return dose reconstruction reports, and outlining the subsequent steps to be taken by the ORAU Team. The following comments, observations, and suggestions are made to improve the procedure in future revisions:

(1) A general discussion of how this implementing procedure fits into the overall ORAU Quality Assurance Program and Project Management Plan would help orient the reader.

(2) Although the procedure (Section 6.0) is fairly straightforward, it is lengthy and somewhat detailed; the user would benefit from a flowchart keyed to text sections.

(3) Section 4.5, describing the responsibilities of the Claims Processing Support Manager, refers to ensuring processing in a "timely manner in accordance with the applicable Cost Plus Award Fee (CPAF) goals." Reference to financial incentives does not belong in a QA procedure.

4.10 ORAUT-PROC-0080: CONDUCT OF QUALITY ASSURANCE AUDITS

This review of ORAUT-PROC-0080, *Conduct of Quality Assurance Audits*, Rev. 00, dated September 9, 2004, was prepared by Stephen L. Ostrow, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006.

4.10.1 Purpose of Procedure

The stated purpose of this procedure is presented in Section 1.0:

> *… establish the process and responsibilities for the administration and performance of formal independent quality audits and assessments of activities performed for the Oak Ridge Associated Universities (ORAU) Team Dose Reconstruction Project for the National Institute for Occupational Safety and Health (NIOSH).*"

4.10.2 Review Protocol

Since the ORAU procedure is part of that organization's quality assurance program (ORAUT-PLAN-0001, *Quality Assurance Program*, Rev. 1, 1/31/05), it is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Table 4.10-1, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review. Section 3.1 of the *Quality Assurance Program* lists the subject procedure as a Quality Management System document incorporated by reference.

Table 4.10-1: QA-related Document Compliance Checklist

Document No.: ORAUT-PROC-0080, Rev. 0	**Effective Date:** 9/9/04
Document Title: Conduct of Quality Assurance Audits	
Reviewer: Stephen L. Ostrow, PhD	

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	
1.8	Are there procedures covering all work activities of the project?	N/A	

No.	Question	Y/N	Comments
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 the first page; however, the other items appear on each page and 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 the Task 9 Manager, Project Director, and Associate Director for Science.
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	Y	Log shows internal revisions before final issue of Rev. 00.
2.5	Are revisions clearly indicated on affected pages?	N/A	This is Rev. 00.
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	Abbreviations and acronyms are explained as they occur in the text. In addition, Section 9 provides definitions of some key terms and acronyms.
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	The procedure is "administrative," not "technical."

4.10.3 General Comments

Section 6.12.2.2 of the ORAU *Quality Assurance Program* states that "Requirements, responsibilities, and procedures for conducting internal QA audits, assessments, and surveillances; for developing, implementing, and tracking corrective actions and improvement plans to resolve findings and observations; and for reporting and maintaining QA records related to these activities are included in the following Project documents," and references the subject procedure.

The subject procedure contains sections on purpose, scope, references, responsibilities, general matters, procedure, records, applicable documents, and definitions and acronyms. It describes the responsibilities and interactions of various project personnel as they implement the different steps of the procedure. It also includes Quality Assurance Audit Plan (coversheet), Quality Assurance Checklist, and Model Format for Quality Assurance Audit Reports as attachments.

4.10.4 Review Comments

The *Conduct of Quality Assurance Audits* procedure is clear and provides adequate guidance to comply with the requirements of the ORAU *Quality Assurance Program*. The Procedure section (No. 6.0) is especially detailed in presenting the sequence of events from planning an audit, to conducting it, to documenting it, and to following it up. The following comments, observations, and suggestions are made to improve the procedure in future revisions:

(1) A general discussion of how this implementing procedure fits into the overall ORAU Quality Assurance Program would help orient the reader. There are many interrelated procedures mentioned in the course of the discussion of the subject procedure, and an overview would be welcome.

(2) The procedure (Section 6.0) is quite lengthy and detailed. With many activities conducted by different people at different times, the user would benefit from a flowchart keyed to text sections.

4.11 ORAUT-PROC-0091: DOSE RECONSTRUCTION SUBMITTAL

This review of ORAUT-PROC-0091, *Dose Reconstruction Submittal,* Rev. 00, dated June 29, 2005, was prepared by Stephen L. Ostrow, PhD, and approved by John Mauro, PhD, CHP, on March 31, 2006.

4.11.1 Purpose of Procedure

The stated purpose of this procedure is to establish "… the process for the receipt, modification, and submittal of draft dose reconstruction reports (DRRs) once the dose reconstruction has been completed by Task 5. These DRRs are generated by the Oak Ridge Associated Universities (ORAU) Team Dose Reconstruction Project for the National Institute for Occupational Safety and Health (NIOSH)" (Section 1.0). As noted in Section 5.1, the procedure applies to all dose reconstruction reports submitted by ORAU to NIOSH.

4.11.2 Review Protocol

The subject procedure lists the ORAU Quality Assurance Program (ORAUT-PLAN-0001, *Quality Assurance Program,* Rev. 1, January 31, 2005) as a driver; hence, the procedure (which is administrative rather than technical) is reviewed according to *SC&A's Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures* (Rev. 0, Draft, April 12, 2004). Table 4.11-1, which is a checklist taken from Attachment A of the SC&A procedure, summarizes the review.

Table 4.11-1: QA-related Document Compliance Checklist

Document No.: ORAUT-PROC-0091, Rev. 0	**Effective Date:** June 29, 2005
Document Title: Dose Reconstruction Submittal	
Reviewer: Stephen L. Ostrow, PhD	

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	
1.8	Are there procedures covering all work activities of the project?	N/A	

No.	Question	Y/N	Comments
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 the first page; however, the other items appear on each page and 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 the Task 4 Manager, Project Director, and Associate Director for Science.
2.4	Does the procedure or document include a revision log showing revision number, date, and brief description?	Y	Log shows internal revisions before final issue of Rev. 00.
2.5	Are revisions clearly indicated on affected pages?	N/A	This is Rev. 00.
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	Abbreviations and acronyms are explained as they occur in the text. In addition, Section 9 provides definitions of some key terms and acronyms.
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	The procedure is "administrative," not "technical."

4.11.3 General Comments

The subject procedure contains sections on purpose, scope, references, responsibilities, general matters, procedure, records, applicable documents, and definitions and acronyms. It describes the responsibilities and interactions of various project personnel as they implement the different steps of the procedure. As Section 5.9 of the procedure states, "There are no paper records generated during the submittal process;" all records are electronic, so much of the procedure deals with details of creating, modifying, or transferring records on various databases.

4.11.4 Review Comments

The *Dose Reconstruction Submittal* procedure provides adequate guidance to ORAU to process the dose reconstruction records submitted to Task 4 by Task 5 (within ORAU), and to transmit

them to NIOSH for review. The following comments, observations, and suggestions are made to improve the procedure in future revisions:

(1) A general discussion of how the subject procedure fits into the overall ORAU dose reconstruction process would help orient the reader. There are many interrelated procedures in the process and an overview would be welcome.

(2) The dose reconstruction records treated in the subject procedure contain Privacy Act Records, yet the procedure does not reference the appropriate ORAU procedure for compliance with the Privacy Act; it should do so.