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.

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.