Technical Support for the Advisory Board on Radiation and Worker Health Review of NIOSH Dose Reconstruction Program

Volume 2: Technical Approach to Sample Task 1
Request for Proposal (RFP) 2003-N-00768

Submitted to:

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TABLE OF CONTENTS

1. PREPARATION OF THE TECHNICAL PROPOSAL 2

2. TASK ORDER TEAM 3

3. TECHNICAL APPROACH 7

4. WORK HOUR ALLOCATION AND SCHEDULE OF DELIVERABLES 11

LIST OF TABLES

Table 1. Sample Task 1 1
Table 2. Matrix of Required Capabilities 4
Table 3. Assigned Case Managers 7
Table 4. Quality Assurance Checklist No. 1 for Data/Records Entry 8
Table 5. Work Hour Allocation for Sample Task 1 12

SAMPLE TASK 1
INDIVIDUAL DOSE RECONSTRUCTION REVIEW:
20 BASIC REVIEWS

This section presents SC&A's technical proposal for the sample task provided in Attachment E of the Solicitation. Extensive cross-reference is made to the procedures and checklists provided in Section 3 and Appendix C of Volume 1 - Technical Proposal, which provides detailed descriptions of the procedures and checklists we plan to use for basic and advanced reviews.

This section presents a detailed work plan, levels of effort (costs are provided under a separate cover), and schedule for completing Basic Dose Reconstruction Reviews for the 20 cases listed in Table 1, assuming that five cases are required to be delivered in each quarter. (Some of the material restates points made in Section 3 (Technical Approach of Volume 1 - Technical Proposal) to facilitate the review of this section without having to cross-reference too extensively.)

Table 1. Sample Task 1

1st Quarter Site	No. of cases	2nd Quarter Site	No. of cases	3rd Quarter Site	No. of cases	4th Quarter Site	No. of cases
Hanford	2	Y-12	2	Savannah River	1	Rocky Flats	1
INEEL	1	Metals and Controls, MA	1	Combustion Eng., CT	1	LANL	1
Mallinckrodt, MO	1	NUMEC, PA	1	Nevada Test Site	1	WR Grace, TN	1
Allied Chemical, Ill	1	Linde Ceramics, NY	1	Maywood, NJ	1	Pantex, TX	1
				Harshaw Chemical, OH	1	Lawrence Livermore, CA	1
Total	5		5		5		5

We recognize that the level of effort and time required for the performance of each basic review will decline as we develop more and more experience with the worker and site profiles. Hence, the level of effort and time required to perform each basic review, as described below, takes into consideration the fact that, in the first year of the project, we will perform 70 basic reviews, 70 advanced reviews, 10 blind dose reconstructions, 5 worker profile reviews, and 5 site profile reviews. The level of effort for each basic review reflects the average time required for each basic review among the 70 basic reviews performed during the first year and takes credit for "moving up the learning curve" as a result of performing all of this work, along with the two weeks invested in preparing the technical and cost proposal.

Finally, as indicated in Section 2.1 and Section 4 of Volume 1 - Technical Proposal, we have a large, highly qualified staff to draw upon. In theory, we could assign a single person to each case and have all case reviews proceed in parallel. In this way, the entire set of 20 basic reviews could be completed in less than one month. However, we recognize that, along with these 20 basic reviews, we may have a number of advanced reviews, blind dose reconstructions, and perhaps a review of one or more site and worker profiles, and perhaps even one or more SEC petition reviews. As such, we will not have the luxury to move all 20 cases in parallel. Hence, we allocated resources taking into consideration that other Task Orders may be ongoing in parallel with this one.

1. PREPARATION OF THE TECHNICAL PROPOSAL

All Task Order Request Packages (TORPs) will be logged in, technical and cost proposals will be prepared, and work will commence upon receipt of an approved Task Order. All Task Orders will be processed, documented, and the work products delivered under a highly transparent, structured project management, and quality assurance process. Upon arrival at SC&A, the TORP will be date stamped, assigned a TORP number, and placed in the dedicated project file under lock and key under the control of records management (see Volume 1 - Technical Proposal, Section 2.7 on Confidentiality and Security Provisions). As a means of tracking performance of each case or task comprising the TORP, the technical and cost proposal will be subdivided into individual cases, and, as required by each case, each case may be further subdivided into individual tasks, such as dose reconstruction review, worker profile review, interview record review, and site profile review. Filing and tracking the cost and performance of each TORP will be performed under the following work breakdown structure:

Tier 1: Task Order Number
- Tier 2: Case Number
  - Tier 3: Dose Reconstruction
  - Tier 3: Worker Profile
  - Tier 3: Interviews
  - Tier 3: Site Profile

Using a relational database, we can also sort according to site (e.g., Hanford, Savannah River, etc.), category of site (e.g., FUSRAP site, uranium processing facilities, etc.), category of exposure (e.g., external gamma, plutonium inhalation), or any other parameter that will serve to appropriately identify the work package.

While the task order filing system is being established, each key member of the project team (see Section 2-1 of Volume 1 - Technical Proposal) will receive copies of the TORP for initial inspection with respect to scope, schedule, and conflict-of-interest issues. A meeting will be held by the key members of the project team to discuss the TORP and any supporting records and documentation provided with the TORP. The meeting will be designed to accomplish the following objectives:

- Identify questions and concerns to be discussed with the Project Officer and/or Advisory Board representatives
- Identify the Case Managers for performing the work required by each case contained in the TORP
- Prepare a schedule for completion and delivery of the technical and cost proposal in response to the TORP

Under the direction of the Project Manager, a comprehensive technical and cost proposal will be prepared and delivered to the Project Officer within 14 calendar days of receiving the TORP. The following presents the technical proposal for this sample task order using the assumptions described in the above introduction.

2. TASK ORDER TEAM

Case Managers will be selected based on either their familiarity with the site or category of the site and/or special technical issues associated with the exposures (e.g., the case is limited to reviewing the dose reconstruction of a person who experienced internal exposures to inhaled plutonium and the associated bioassay data). For the 20 cases and 18 sites identified in the sample problem, we grouped the sites/cases into related categories. Table 2 presents a draft matrix that was prepared to help identify those individuals best suited to review each case. By mapping the information in Table 2 back onto Exhibit 4-1 in Volume 1 - Technical Proposal, we can begin to identify those individuals who are best qualified to serve as Case Managers for each basic review. For an actual TORP, the records provided with the cases should help to better define the qualifications of the Case Managers and technical specialists that will be assigned to each case. For the purpose of this sample task, we assigned case managers based on whether the exposures are anticipated to be primarily external versus internal.

We expect that, for most basic reviews, only a single person (the Case Manager) will be assigned to perform the review, and the review will require, on average, about one week to complete from the date of authorization to proceed. The criteria for designating a Case Manager is the person's expertise with regard to the primary "dosimetric drivers" for the case (e.g., external gamma or neutron exposures and associated dosimetry or inhalation exposures to plutonium and associated bioassays, etc.).[1] However, even for basic reviews, it is likely that each case may require some additional specialty support to confirm the key findings of the review.

The Case Manager for each case is presented in Table 3. Each Case Manager can draw upon any of the other specialists on the project team as needed to perform Tasks A, B, and C for the basic reviews, as delineated in Attachment E of the solicitation.

We believe that after approval of the technical and cost proposal, a basic review will require about to complete, including the review, auditing the review package in accordance with our QA procedures, and then filing and delivery in accordance with our file-management procedures. Hence, from the date of authorization, the review, documentation, and delivery of each basic review will require about . More complex cases may require as many as

[1] As will be discussed in Sample Task 2, dealing with Advanced Reviews, the criteria for the selection of a Case Manager may give greater emphasis to familiarity with the site.

Table 2. Matrix of Required Capabilities

Site	Category of Facilities	Exposure Settings/Scenarios							
		External gamma	External neutron	Plutonium, including other TRU	NORM (Ra/Th)	Uranium	Tritium	Thorium-232+ Progeny	Other Internal
Hanford	Reactors	✓	✓				✓		✓
	Chemical processing	✓		✓		✓	✓		✓
	High-level waste storage	✓		✓			✓		✓
	Fuel fabrication	✓		✓		✓			
	Plutonium finishing	✓	✓	✓					
	Nuclear fuel testing	✓	✓	✓		✓	✓		
	Environmental restoration	✓		✓		✓	✓		✓
INEEL	Reactors	✓	✓				✓		✓
	Chemical processing	✓		✓		✓	✓		✓
	Waste storage and disposal	✓		✓		✓	✓		✓
	Environmental restoration	✓		✓		✓	✓		✓
Mallinckrodt, MO	Historically uranium and more recently Radiopharmaceuticals and radiochemicals	✓			✓	✓	✓	✓	✓
Allied Chemical, IL	Uranium conversion	✓				✓			
Y-12	Uranium enrichment	✓				✓			
	Weapons component manufacturing, disassembly and storage	✓	✓	✓		✓	✓		
	Waste management	✓		✓		✓	✓		

Table 2. Matrix of Required Capabilities (continued)

Site	Category of Facilities	Exposure Settings/Scenarios							
		External gamma	External neutron	Plutonium, including other TRU	NORM (Ra/Th)	Uranium	Tritium	Thorium-232+ Progeny	Other Internal
Metals and Control, MA	Uranium oils and fuel manufacturing	✓				✓			
NUMEC, PA	Nuclear fuel fabrication					✓			
Linde Ceramics, NY	FUSRAP	✓			✓				
Savannah River	Reactors	✓	✓				✓		✓
	Fuel reprocessing and material recovery	✓		✓		✓	✓		✓
	Plutonium processing		✓	✓					
	Tritium processing						✓		
	High- and low-level waste management, storage and disposal	✓		✓		✓	✓		✓
Combustion Engineering, CT	Fuel fabrication	✓				✓			
Nevada Test Site	Weapons testing	✓	✓	✓		✓	✓		✓
	Neutron and gamma ray interaction studies	✓	✓						
	Reactors	✓	✓				✓		✓
	Low-level waste management and disposal	✓		✓		✓	✓		✓
Maywood, NJ	FUSRAP	✓			✓				
Harshaw Chemical, OH	Uranium conversion	✓				✓			

Table 2. Matrix of Required Capabilities (continued)

Site	Category of Facilities	Exposure Settings/Scenarios							
		External gamma	External neutron	Plutonium, including other TRU	NORM (Ra/Th)	Uranium	Tritium	Thorium-232+ Progeny	Other Internal
Rocky Flats	Weapons components production	✓	✓	✓		✓	✓		
	Plutonium recovery and purification			✓					
LANL	Weapons research	✓	✓	✓		✓	✓		✓
	Plutonium processing		✓	✓					
	Nuclear fuel reprocessing	✓		✓		✓	✓		✓
	Polonium and actinium processing								✓
WR Grace, TN	Rare earth metal facility	✓			✓				
Pantex, TX	Nuclear weapons assembly, maintenance, and disassembly	✓	✓	✓		✓	✓		
Lawrence Livermore, CA	Material test accelerator	✓	✓	✓		✓	✓		✓
	Nuclear weapons research	✓	✓	✓		✓	✓		✓

Table 3. Assigned Case Managers

1st Quarter Site	2nd Quarter Site	3rd Quarter Site	4th Quarter Site
Hanford	Y-12	Savannah River	Rocky Flats
INEEL	M & C	Combustion Eng., CT	LANL
Mallinckrodt, MO	NUMEC	Nevada Test Site	WR Grace, TN
Allied Chemical	Linde Ceramics	Maywood, NJ	Pantex, TX
		Harshaw Chemical, OH	Lawrence Livermore, CA

3. TECHNICAL APPROACH

The basic reviews for the 20 cases delineated in Sample Task 1 will be performed in accordance with the SOPs provided in Section 3 and Appendix C provided in Volume 1 - Technical Proposal, which presents the procedures and checklists that will be used to perform reviews of the data collection process, claimant-interview reviews, external and internal dose-reconstruction reviews, reviews of the relevant portions of NIOSH procedures/methods for conducting the dose reconstruction for each case, worker-profile reviews, and site-profile reviews, to the extent to which the NIOSH worker-profile and site-profile databases were used to support the dose reconstruction. **The forms in Appendix C of Volume 1 represent the technical underpinning of all basic reviews that will be performed on this project.**

Review Data Collection

SC&A will use the following procedure to determine:

(1) if NIOSH received all requested data for the DOE or AWE site from any relevant source or repository, and

(2) whether the data used by NIOSH for the case were adequate to make a determination with regard to probability of causation.

The first step in the audit will be to confirm that the checklist in Table 4 (or the equivalent) was in fact completed by NIOSH . This step is defined as a mini-review that establishes threshold criteria for use in determining whether the claim package can be docketed within our system. We have adopted this mini-review approach based on the methods used by the U.S. Nuclear Regulatory Commission for accepting regulatory products (such as safety analysis reports and other types of license applications) for docketing and formal review. It is assumed that this first step is required to be performed by NIOSH as part of the requirements set forth in 42 CFR 82. If these steps were not taken by NIOSH, it would be inappropriate to docket the TORP and continue the audit. In fact, it may be most efficient for this step to be performed during the preparation of the technical proposal.

Table 4. Quality Assurance Checklist No. 1 for Data/Records Entry

The following form will be used for docketing claims packages for auditing:

Claim No.: _____

Inspection No.: _____

Name of Inspector:_____

Name of Data Entry Personnel:_____

Date of Inspection:_____

Location of Inspection:_____

QA Manager Sign-off/date:_____

Data Entry Personnel Sign-off/Date:_____

Data Entry Manager Sign-off/Date:_____

Performance Objective Metric	Method	Pass/Fail
Was claim or inquiry date-stamped on day of arrival?	Check if post mark date corresponds with date stamp	
Was claim or inquiry entered into the case file database management system within 7 calendar days of arrival?	Compare date stamp with log in date in database	
Was the electronic or hard copy of the data or record entered correctly into the database?	Judgment as to the completeness and accuracy of the data/record as entered	
Were hard copies of claims or inquiries filed in accordance with approved SOPs, including Privacy Act and security requirements?	Determine if the hard copies are physically located in the designated file as required to meet filing, privacy, and security requirements.	
Were the hard copy and electronic data and records returned to the NIOSH in accordance with approved SOPs?	Follow-up with NIOSH to confirm receipt of returned files	
Do the data/records entry personnel meet the education, training, and experience requirements as required by the project?	Check training and qualifications records	
Do the data/records entry personnel meet the conflict of interest avoidance requirements as required by the project?	Check COI requirements and personnel background	
Is access to the electronic and hard copy files secured?	Check to ensure that approved access controls are in place, including controls over the transmittal and reproduction of the material.	

Table 4. Quality Assurance Checklist No. 1 for Data/Records Entry (continued)

Performance Objective Metric	Method	Pass/Fail
Did data entry employ double blind procedures to ensure data entry quality?	Check the double blind entry files.	
Have back-up files been established at a secure physically separated location?	Check to determine that back-up files exist at a physically separate and secure location.	
Have unambiguous linkages been established between scanned files and their corresponding hard copies?	Check for ability to find hard copies of scanned records.	
Comments:		

Assuming that the claimant package passes the mini-review, it will then be docketed and be formally reviewed according to our procedures.

With respect to the first step in the procedure to review data collection, we will review all correspondence between the Department of Labor and DOE regarding written requests for information in accordance with 20 CFR Part 30 and 42 CFR Part 82.10, and any additional records compiled by NIOSH relevant to internal and external exposures to ionizing radiation, including exposures from medical screening x-rays that were required as a condition of employment.

At this point in the review process, no judgment will be made regarding the adequacy of the records. We will simply check (1) NIOSH correspondence requesting records, (2) correspondence that transmits those records, and/or (3) correspondence that provides for reasonable closure regarding the request for records. Reasonable closure is defined as correspondence that documents that the requested records either exist or do not exist. We expect that there will be occasions where one party believes that the requested records were not provided, while the other party believes that the requested records were in fact provided. These types of disputes can arise due to a breakdown in communication, usually based on judgments regarding what constitutes or does not constitute the composition of a given category of record. We will make judgments regarding these matters and incorporate our findings into the audit record.

During the second step in the data collection review procedure, we will follow the guidance provided in 42 CFR Parts 82.15, 16, and 17. In this regard, we will review the record to determine whether NIOSH evaluated and documented the completeness and adequacy of the individual's monitoring data as required by Part 82.15 (a) and (b), add monitoring data as per part

82.16, and supplement or substitute data as per Part 82.17. At this point in the review process, we will simply check that the record indicates that the tests for adequacy as delineated in Part 82.15, 16, and 17 were, in fact, performed and documented. This will be a pass/fail evaluation.

The next step in the process will determine whether the collected data were adequate to make a determination regarding probability of causation. When the external and internal dosimetry records are complete and internally consistent based on inspection of the claimant's occupational exposure records and worker interview records, or if gaps/inconsistences can be resolved with co-worker records, worker profile databases, and/or site profile databases (including area and process monitoring records), one can assume the records are adequate for performing probability of causation calculations. However, there will be circumstances in which the records compiled under 42 CFR Parts 82.15, 16, and 17 will be incomplete and/or contradictory and, based on this initial document review, it appears that these data limitations would prevent the completion of a dose reconstruction. When these circumstances arise, we will withhold judgment regarding the adequacy of data until the entire dose reconstruction process has been reviewed.

After review of the entire individual dose reconstruction, a special meeting will be held to reassess the adequacy of the data used for determination of doses. The meeting will be recorded and a consensus judgment will be made, including minority opinions, and the judgments will be fully documented and transparent. The basic decision criteria that will be used to make these determinations will be identical to those used to evaluate SEC petitions. In both cases, the underlying decision criterion will be the inability to compile the input data required to run IREP. In many cases, though dosimetry data are lacking, overwhelming circumstantial evidence (e.g., worker profile and site profile databases) may indicate that exposures could not have been large enough to result in a probability of causation of 0.5. Under these conditions, we would conclude that the data are adequate to make a determination with regard to probability of causation. However, if dosimetry data are lacking, but circumstantial data, which were not considered in the dose reconstruction, indicate that the potential existed for substantial exposures, we would conclude that the data are not adequate to develop input distributions for IREP (using OCAS guidelines), and, therefore, not adequate to make a determination with regard to probability of causation.

Review Interview and Documentation Provided by Claimant

This part of the audit will involve a two-step process:

(1) Review of the adequacy of the standardized claimant interview form from the perspective of the claimant exposure records, worker profile, and site profile (as appropriate for the case, site basic reviews may not need to include reviews of worker and site profile databases if those databases were not used by NIOSH to perform the dose reconstructions).

The purpose of this review will be to determine if the form requests information that is adequate and sufficient as it relates to the issues attendant to the particular claim. Section 3 of Volume 1 of our proposal presents the methods that we will

use to review the adequacy of the claimant interview forms as they apply to a particular case. A report will accompany this review and assign a pass/fail to this review.

(2) The completed form will be reviewed for completeness, internal consistency, and compatibility with other claimant records (and, if necessary, with NIOSH worker profile and site profile databases).

Using the protocols provided in Section 3 and the checklist in Appendix C of Volume 1 of our proposal, we will determine whether NIOSH appropriately addressed all of the reported work history and events represented by the claimant including, but not limited to, incidents or occurrences, actual monitoring practices, and work practices. Areas of incompatibility will be identified and documented. A plan will then be put into place to achieve closure on incompatibilities. Unresolved incompatibilities will be documented and carried through the audit process in order to evaluate whether these incompatibilities could affect the outcome of the dose reconstruction in a substantive manner (e.g., have the potential to result in a possible reversal of an adjudicated decision).

Review of Internal/External Dose Estimates and NIOSH Dose Reconstruction Procedures/ Methods

Internal and external dose estimates as well as relevant portions of NIOSH procedures and methods for reconstructing dose for the case will be reviewed in accordance with the procedures and checklist provided in Appendix C of Volume 1 of our proposal for external and internal exposures.

4. WORK HOUR ALLOCATION AND SCHEDULE OF DELIVERABLES

Table 5 presents the work hour allocation by category of personnel for the 20 cases that comprise Sample Task 1. Since the sample task does not include supporting records, we have not attempted to assign any specific category of specialty investigators to the tasks (i.e., we have not assigned work hours to specific scientific specialties as delineated in the box at the bottom half of Exhibit 2-1 of Volume 1). However, in anticipation that each case will require some level of specialty investigation, we assigned about 10 percent of the level of effort to a non-designated specialty investigator. We estimate that, on average, approximately will be required to complete each basic review. This includes the review itself, and all management, quality assurance, and records management activities. This would appear to be a relatively low estimate for the average level of effort per basic review. However, since the basic reviews will be confined to records that already exist in the administrative record and will focus on those data used by the dose reconstructionist, we expect this level of effort to be adequate.

The output of these reviews will be reports that address items A, B, and C of Attachment E of the solicitation. Our work products will also include completed audit forms with accompanying text that provides the following:

- The degree to which the audit concurs with the reconstructed doses and the IREP input distributions provided in the administrative record and other material provided by NIOSH

- A discussion of areas where the dose reconstruction for each individual case could be improved

- A discussion of areas where the overall dose reconstruction process could be improved

Table 5. Work Hour Allocation for Sample Task 1

Personnel	20 Basic Reviews (Work Hours)
Project Manager	
QA	
Records Management	
Dose Reconstruction Dose Reconstruction Team	
Worker Profiles	
Interview Records Dose Reconstruction Team	
Site Profiles (if required)	
Uncertainty Analysis	
Specialty Investigator	
Total For Sample Task 1	*

*The level of effort could increase if worker and site profile reviews or specialty reviews are required.

All audits will be documented and electronically filed in an approved relational database-management system, and each inspection and audit finding will be accessible according to individual claim, inquiry identification numbers, or any other field in the database.

Assuming that each basic review requires about 1 week or less to complete from the date of authorization, the 5 cases in the first quarter will require about to complete, since 3 of the 5 cases are assigned to the same person ( ). The same is true for the cases in the second quarter. For the third quarter, the 5 cases should be completed in since only 2 of the 5 cases are assigned to the same person ( ). The fourth quarter will require about to complete since 4 of the 5 cases are assigned to the same person (i.e.,).