

4.0 TASK 4 - DOSE RECONSTRUCTION REVIEW TRACKING

This section presents SC&A's proposal for performing Task 4, Dose Reconstruction Review Tracking.

4.1 UNDERSTANDING OF THE TASK AND ITS OBJECTIVES

It is our understanding that this task requires the development of a dose reconstruction review tracking system that will, at a minimum:

Collate, track, and maintain all pertinent and necessary parameters provided with a data file (e.g., case number, date case was received, cancer type, primary radiation exposures type, DOLs Probability of Causation determination, etc.) to ensure the Board-approved sampling strategy for identifying individual cases for review meets its design of a random selection process

Track the status of the review process and progress associated with each individual case.

4.2 TECHNICAL APPROACH

To accomplish these objectives, SC&A will develop, manage, update, and maintain a functional review tracking system that:

- (1)** contains all pertinent data elements and is capable of sorting and reporting key parameters necessary for ensuring that the Board-approved case sampling strategy is achieved
- (2)** provides an effective method of documenting and tracking all aspects of the technical review process to ensure that progress can be evaluated at any point during the course of performance
- (3)** is compatible with the NIOSH relational database management system
- (4)** is designed as a flexible tool, which can be expanded to meet the needs of the Advisory Board

4.2.1 Tracking System Design

The dose reconstruction review tracking system will consist of one or more relational databases that are compatible with NIOSH's SQL Server 20000 database. It is envisioned that the tracking system will be designed as a dynamic tool that can expand and evolve based on project demands. This may be best accomplished with the use of multiple, linked relational databases.

4.2.2 Data Elements

Based on the TORP Nos. 1, 2, and 3, SC&A's tracking system will, at a minimum, be populated with the following key categories of information as appropriate for each individual case:

Case Demographics/Board-Provided Data Files (e.g., Task Order number, Case number, cancer type, primary radiation exposure type, etc.)

All Steps of the Basic/Advanced/Blind Dose Reconstruction Review Process (Internal/External Dose Reconstruction, Worker Profile, Interviews, Site Profile)

Site Profile Reviews

Dose Reconstruction Procedures and Methods Review

4.2.2.1 Case Demographics

The relational database will be populated with all relevant parameters necessary for identifying, tracking, and sorting cases by site (e.g., Hanford, Savannah River, etc.), category of site (e.g., uranium processing facilities, FUSRAP sites, etc.), category of exposure (e.g., external gamma, plutonium inhalation), results of audit (e.g., areas where audit identified inconsistencies), and any other parameters that may serve the Advisory Board's purposes.

4.2.2.2 Dose Reconstruction Review Process

Basic Review. As a means of conducting the basic reviews in a systematic, consistent, efficient, and transparent manner, SC&A has developed procedures, as described in Task 1, Section 1.3.1.1 of this proposal and a comprehensive checklist, as identified in Appendix A. The procedure and checklist were designed to follow guidance specified in *U.S. Code of Federal Regulations* (CFR) Title 42, Part 82 and External and Internal Dose Reconstruction Implementation Guidelines (OCAS-IG-001 and OCAS-IG-002, respectively). The basic individual dose reconstruction checklist includes a step-by-step evaluation of the following areas: (1) data collection process, (2) interview/claimant documentation, (3) external dose reconstruction process, (4) internal dose reconstruction process, and (5) applicable portions of NIOSH procedures and methodologies associated with the reconstruction of dose for each individual case. Each element of the checklist will be incorporated into the relational database and will serve as a means of tracking and formally documenting the individual steps completed throughout the audit process.

Advanced Review. As with the basic reviews, SC&A has developed a procedure and checklist for the advanced reviews, which are described in Task 1, Section 1.3.1.2 and Appendix A, respectively, of this proposal. The advanced dose reconstruction procedure and checklist include all the above-cited elements of the basic review as well as steps that allow for a more thorough comparison of available data and a more extensive review of the (1) data gathering, (2) work-history interview and documentation provided by claimant, and (2) external/internal dose reconstruction processes. The advanced review procedure and checklist is also designed to take

into account guidelines established in the 42 Part 82, OCAS-IG-001, and OCAS-IG-002, as well as any other technical documents considered relevant.

Blind Review. A procedure for providing guidance to the auditor who is conducting a blind review is included in Task 1, Section 1.3.2 of this proposal. Due to the nature of a blind review, specific checklists have not been developed. It is assumed that the auditor will have access to all available data (i.e., the entire administrative record, worker profile, and site profile) and will also follow guidelines established for the basic and advanced reviews (i.e., 42 CFR 82, OCAS-IG-001, and OCAS-IG-002). Upon completion of each blind review, the work products will receive the same independent advanced review audit procedure as performed for NIOSH dose reconstructions to serve as a form of quality assurance documentation. As with the advanced reviews, all elements of the review process will be entered into the tracking system.

Documents Not Included in the Case File. In addition, SC&A's relational database will include a listing of all relevant materials identified as part of the basic, advanced, or blind reviews that were not identified or incorporated into the original case file. These records/documents will also be maintained in a filing system and duplicated and provided to NIOSH with the audit report.

4.2.2.3 Site Profile Review

Review of specific site profiles will be conducted using SC&A-developed, Board-approved procedures. A draft framework for a site profile review procedure is presented in Task 2, Section 2.2.1 of this proposal. This draft procedure identifies four areas of review, which include (1) reviewing the site's operational history, (2) reviewing relevant data sources, (3) conducting individual or group interviews, and (4) evaluating worse case doses. When this procedure is finalized, it is envisioned that, for each of these areas of review, a checklist or audit review form will be developed. Upon completion and Board approval of the checklist/audit form, SC&A will incorporate all review parameters into its relational database.

4.2.2.4 Dose Reconstruction Procedures and Methods Review

Task 3 of the TORP requires a baseline review of procedures and methods in place for implementing the dose reconstruction program. In order to conduct this review, Task 3 also specifies that SC&A will develop a review methodology, which meets the approval of the Advisory Board. When approved, each item of the checklist will be incorporated into SC&A's tracking system.

With the approval of the Board, SC&A's plans to use similar review methodology and data tracking documents for assessing pertinent components of the following dose reconstruction process specified in Task 3:

Internal and External Radiation Dose Reconstruction Technical Basis Documents
Methods for Estimating "Missed Dose" and "Unmonitored Dose"
Statistical Approaches for Multiple Dose Reconstructions
Procedures Used for Determining Whether Sufficient Data Exists to Make a Reasonable Dose Estimates

Procedures Used for Substituting Exposure Information for unavailable/Incomplete Information
Methods for Estimating Uncertainty Associated with Internal/External Dose Reconstructions
Procedures/Questionnaires Used for Interviews
Quality Assurance Plans and Procedures
Procedures Used for Data Acquisition
Procedures Related to Site Profile and Worker Profiles
Methods, Procedures and Performance in Evaluating, Analyzing, and Validating all Contractor Work Products

4.3 TASK MANAGEMENT

██████████ Database Manager, will be responsible for designing and developing SC&A's dose reconstruction review tracking system, which will be compatible with NIOSH's SQL Server 2000 database.

██████████ has over 20 years experience in designing and developing databases, including recent experience with Access, SQL Server 2000. Among other projects, ██████████ aided in designing a database that tracked documents supporting a CDC dose reconstruction document collection effort, designed and developed a LIMS system that has been in operational use for over 5 years by a radiological lab, designed and developed an dose tracking system used by EPA Headquarters, and has supported the programming and database needs of numerous dose modeling programs.

██████████ will be assisted by ██████████ who will serve in the position of Records Management Specialist. She will be the central repository for all documents and records received from the Project Officer pertaining to this task order, all project procedures, all project deliverables, and all internal and external correspondence. She will establish a hard copy and electronic filing system that will maintain information confidential but accessible to authorized individuals, in accordance with project SOPs.

4.4 WORK HOUR ALLOCATION AND SCHEDULE OF DELIVERABLES

A preliminary case database will be developed within one month from authorization to proceed. Upon approval of SC&A's dose reconstruction tracking system, subsequently quarterly updates to this database will be provided to the Board. SC&A will also submit to the Board a written monthly update on cases reviewed.

The hours estimated for Task 4 are presented in Exhibit 4-1