

October 4, 2004

Larry E. Guess – Contracting Officer
Centers for Disease Control and Prevention
Acquisition and Assistance Field Branch
Post Office Box 18070
626 Cochran Mill Road – B – 140
Pittsburgh, PA 15236-0070

Re: Contract No. 200-2004-03805
Conflict of Interest Plan/Quality Assurance Project Plan

Dear Mr. Guess:

S. Cohen & Associates (SC&A) is pleased to submit the revised drafts of the *Conflict of Interest Plan* (revised draft dated October 1, 2004) and the *Quality Assurance Project Plan* (revised draft dated October 1, 2004). These documents, originally submitted on June 29, 2004, incorporate the review comments received by the Advisory Board, and have undergone additional internal reviews by SC&A.

The *Conflict of Interest (COI) Plan* will put into place a formal method to ensure that project personnel and companies on the SC&A team avoid potential conflicts of interest. The plan codifies practices that the team has employed since the beginning of the project to avoid such conflicts.

The *Quality Assurance Project Plan (QAPP)* describes the project-specific methods employed by SC&A to ensure achievement of quality goals, whereby all work is done in accordance with the highest professional standards and in compliance with all applicable regulatory, contractual, and other requirements. In addition, all aspects of the project are controlled and documented in a transparent and systematic fashion, so that the records can provide a clear picture of how a particular project deliverable arose. Adoption of the QAPP will put into place a formal method to meet quality goals and to codify practices that the team has employed since the beginning of the project to ensure quality.

Should you have any further questions regarding these documents, please do not hesitate to contact me at 732-530-1014.

Sincerely yours,



John Mauro
Project Manager

cc: S. Ostrow
Project File (ANIOS/003)

**ADVISORY BOARD ON RADIATION
AND WORKER HEALTH**

Quality Assurance Project Plan

Contract No. 200-2004-03805

Prepared by

S. Cohen & Associates
6858 Old Dominion Drive, Suite 301
McLean, Virginia 22101

October 2004

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 1 of 15
-------------------------------	-------------------	-------------------------------	---------------------

S. Cohen & Associates: <i>Technical Support for the Advisory Board on Radiation & Worker Health Review of NIOSH Dose Reconstruction Program</i>	Document No. SCA-PLAN-0001
	Effective Date: Final draft October 1, 2004
	Revision No. 0
QUALITY ASSURANCE PROJECT PLAN	Page 1 of 15
QA Manager: _____ Date: _____ <i>Stephen Ostrow</i>	Supersedes: N/A
Project Manager: _____ Date: _____ <i>John Mauro</i>	

TABLE OF CONTENTS

1.0	BACKGROUND	3
2.0	PURPOSE.....	4
3.0	SCOPE	4
4.0	ORGANIZATION	4
5.0	QUALITY PROGRAM RESPONSIBILITIES	5
6.0	PLANS AND PROCEDURES	7
6.1	Quality Assurance Project Plan	7
6.2	Conflict of Interest Plan	7
6.3	SC&A Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures.....	7
6.4	A Protocol for the Review of Procedures and Methods Employed by NIOSH for Dose Reconstruction	8
6.5	Site Profile Review Procedure	8
6.6	Deliverables	8
7.0	MANAGEMENT PROCESS	9
7.1	Review and Distribution of Task Orders in a Timely Manner	9
7.2	Tracking Progress of Cases and Task Orders	10
7.3	Cost Projection Accuracy	10
7.4	Subcontractor Management	11
7.5	Problem Resolution.....	12
8.0	DOCUMENTATION	12
9.0	QAPP TRAINING	12
10.0	CONFIDENTIALITY AND SECURITY OF INFORMATION	13
10.1	Privacy Act.....	13
10.2	Confidentiality of Information.....	13
10.3	Security Safeguards	13
11.0	References.....	14
	EXHIBIT A: QUALITY ASSURANCE PROJECT PLAN ACKNOWLEDGMENT FORM	15

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 3 of 15
-------------------------------	-------------------	-------------------------------	---------------------

1.0 BACKGROUND

S. Cohen & Associates (SC&A) holds Contract No. 200-2004-03805 in support of the National Institute of Occupational Safety and Health (NIOSH) Advisory Board on Radiation and Worker Health (the Advisory Board) to perform an independent review of the NIOSH dose reconstruction program under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000. All work on this project is performed under a highly structured quality assurance/quality control and documentation process, which includes procedures, plans, audit forms, and checklists that correspond to the requirements of Title 42, Parts 81 (Probability of Causation), 82 (Dose Reconstruction), and 83 (Special Exposure Cohorts) of the Code of Federal Regulations (42 CFR 81, 82, and 83) and of the NIOSH *External Dose Reconstruction Implementation Guidelines* (OCAS-IG-001) and *Internal Dose Reconstruction Implementation Guidelines* (OCAS-IG-002).

All projects performed at SC&A are conducted under the guidance of the corporate Quality Management Plan (QMP), which ensures adherence to the highest standards of quality and project control. SC&A considers the QMP to be an over-arching blueprint for conducting quality work on all projects in which SC&A participates. Some basic definitions appearing in U.S. Department of Energy Order O 414.1A, "Quality Assurance" (Chg.1, 7-12-01), can help clarify what is meant by "quality":

- **Quality** is "the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations."
- **Quality Assurance** is composed of "all those actions that provide confidence that quality is achieved."
- **Quality Assurance Program** is "the overall program (management system) established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work."

Individual projects require their own project-specific Quality Assurance Project Plans (QAPPs), which reflect project-specific conditions and requirements (e.g., regulatory and contractual). As discussed further in Section 6.0, SC&A has prepared a detailed set of Standard Operating Procedures (SOPs) and checklists for review of dose reconstruction procedures and methods and site profiles, as well as for other purposes. These SOPs (procedures and plans) are tied to the Office of Compensation Analysis and Support (OCAS) guidelines for dose reconstruction for external and internal exposures and the requirements set forth in 42 CFR 82 and 83, and constitute the principal part of the QAPP.

Specifically, the QAPP and associated SOPs ensure and document that the following has been done:

- Task technical and quality objectives are identified and agreed upon.
- Activities affecting the achievement of the quality objectives are identified and, via SOPs, conducted in a controlled manner.

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 4 of 15
-------------------------------	-------------------	-------------------------------	---------------------

- SOPs implementing quality requirements are identified and in place prior to the start of work.
- The intended measurements or data acquisition methods are appropriate for achieving task objectives; the assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained; and that any limitations on the use of the data can be identified and documented.

2.0 PURPOSE

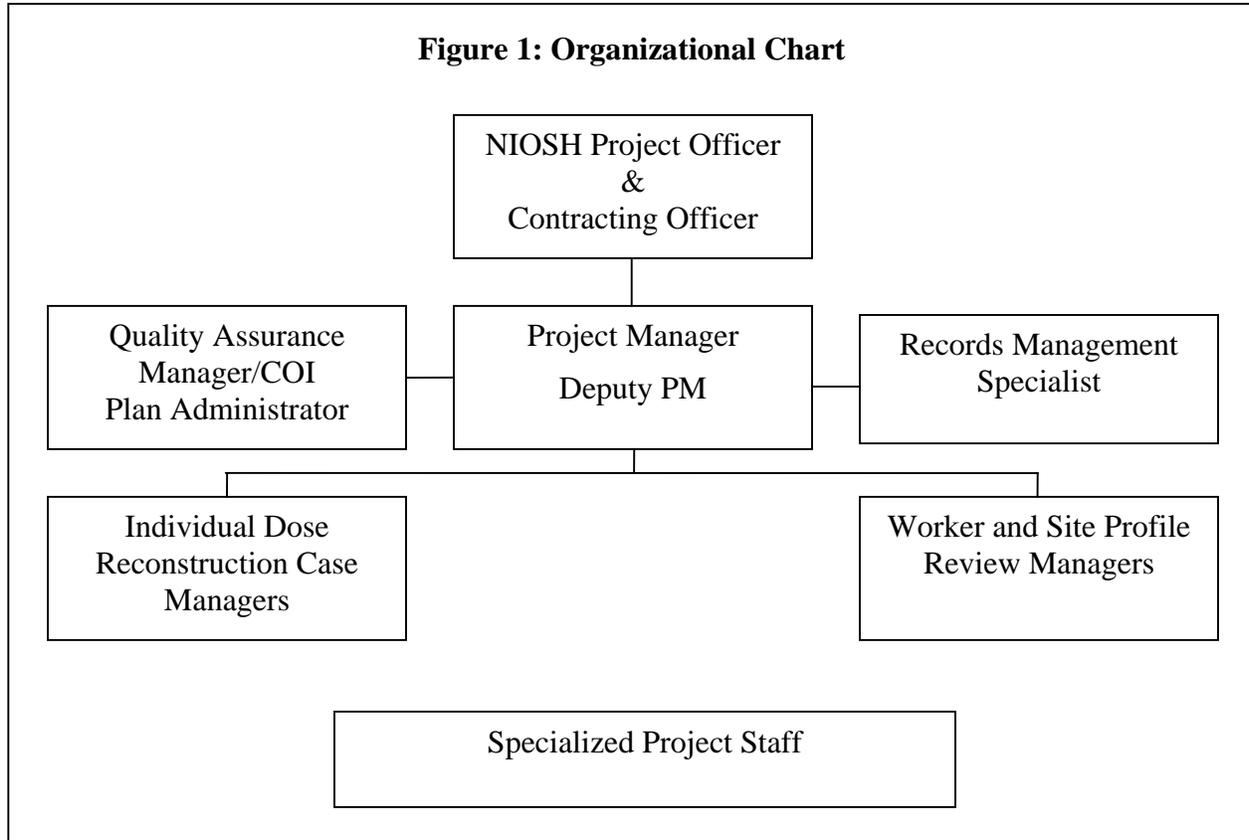
The QAPP describes the project-specific methods employed by the SC&A team to ensure achievement of quality goals whereby all work is done in accordance with the highest professional standards and in compliance with all applicable regulatory, contractual, and other requirements. In addition, all aspects of the project are controlled and documented in a transparent and systematic fashion so that the records can provide a clear picture of how a particular project deliverable was produced.

3.0 SCOPE

The provisions of the QAPP apply to all activities conducted under the SC&A contract (by SC&A and its subcontractors on the team) with the Advisory Board. These activities include, but are not limited to, site profile and dose reconstruction review, as well as review of procedures, plans, and documentation. The QAPP also governs documentation and filing of all work, and compliance with any confidentiality and security provisions on information that may be gathered, examined, or developed by project personnel. Furthermore, the QAPP outlines the process and organization by which the project is managed and controlled.

4.0 ORGANIZATION

Figure 1 illustrates the organizational structure of the project team, whose members are drawn from SC&A (the prime contractor) and its two primary subcontractors, Saliant, Inc., and the Radiation Safety Academy. The team is integrated so that the best qualified to perform a specific task is selected to do so. The Project Manager reports to the NIOSH Project Officer/Advisory Board Representative and has under him several task managers, the QA Manager, the Conflict of Interest Manager, and the Records Management Specialist. Other specialized workers from the project team staff the different tasks as required. Although not shown on the chart as part of the project organization, within SC&A, the Project Manager reports to the company's Chief Operating Officer and has available a number of staff services.



5.0 QUALITY PROGRAM RESPONSIBILITIES

President of SC&A: The President of SC&A, in consultation with the Project Manager, ensures that the project has adequate resources to fulfill its obligations under the contract in support of the Advisory Board. The President is also available as a liaison to the Advisory Board to discuss any concerns or issues that may arise during the project.

SC&A Contract Manager: The SC&A Contract Manager ensures that the SC&A team meets all of its contractual obligations with respect to project control and reporting, and also oversees the subcontracts with the other companies on the SC&A team.

Project Manager: The Project Manager directs work to accomplish the authorized tasks. The Project Manager obtains the necessary SC&A resources, assigns qualified task managers and other personnel from SC&A and its subcontractors to the various tasks, oversees their work to ensure fulfillment of all requirements and production of quality work products, sets and maintains schedules, prepares technical and cost proposals in response to task order request packages, and manages expenditures within budget. The Project Manager also coordinates with the other organizations in the team to ensure that they comply with all requirements, such as with the QAPP. In addition, the Project Manager serves as the principal liaison with the Advisory Board for non-contractual matters.

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 6 of 15
-------------------------------	-------------------	-------------------------------	---------------------

Deputy Project Manager: The Deputy Project Manager assists the Project Manager in all aspects of the project and will fulfill the project management responsibilities when the Project Manager is unavailable. On this project, the Deputy Project Manager also has task management responsibilities in the area of Site Profile Reviews.

Quality Assurance Manager: The Quality Assurance (QA) Manager establishes, oversees the implementation of, and revises the project-specific Quality Assurance Project Plan as necessary. With the participation of the Project Manager, the QA Manager (1) establishes and implements quality policy, (2) develops quality-related procedures, processes, and guidelines, (3) ensures that the QAPP is understood and implemented by all project personnel, (4) assesses and documents the adequacy of quality systems by reviewing new and revised procedures and auditing work products (audit frequency is determined as appropriate to the work product, and review and audit findings are documented by memo to the Project Manager and placed in the QA files), and (5) determines any corrective actions required to improve quality on the project.

The QA Manager ensures that all project personnel receive copies of, and are trained in, the QAPP and other applicable procedures and plans, and that records of such training are maintained in the project files. The QA Manager periodically conducts audits of the work products and processes of the SC&A team to verify that work is conducted and documented according to established procedures. The QA Manager reports to the Project Manager, but can bring any concerns related to the Quality Program directly to the President of SC&A, who is also the designated Corporate QA Manager. If any segment of the project is found to be severely deficient, the QA Manager documents the deficiency and notifies the Project Manager and associated Task Manager. Depending on the severity of the deficiency, the QA Manager may stop work until the cited deficiency is resolved.

COI Plan Administrator: The COI Plan Administrator leads the effort to avoid any real or perceived conflict of interest between other work that team members may be doing or have done and the scope of work under this contract for the NIOSH Advisory Board. As set forth in greater detail in the Conflict of Interest (COI) Plan (discussed in Section 6.2), the COI Plan Administrator distributes and revises the COI Plan as required.

Records Management Specialist: The Records Management Specialist is responsible for keeping important documents in the project files to provide a clear record of the process undertaken in each work task. As discussed in Section 8.0, records are controlled and kept in a secure location in accordance with SC&A practices. The Records Management Specialist receives and distributes documents at the direction of the project team.

Individual Dose Reconstruction Case Managers: Case Managers and others who may report to them review individual dose reconstructions at different levels of detail depending on the requirements of a particular task order to ensure that all dose reconstructions are done in a fair and consistent manner, as described in regulatory and guidance documents. Dose reconstructions follow a project procedure, which is discussed in Section 6.3. Assignment of Case Managers to closely oversee the review process helps to ensure accountability and transparency for each case.

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 7 of 15
-------------------------------	-------------------	-------------------------------	---------------------

Worker and Site Profile Review Managers: Highly qualified individuals from the project team perform and lead worker and site profile reviews in which they review selected worker and site profiles from NIOSH's database to ascertain the quality and completeness of the database and to support individual dose reconstructions. The review process is governed by a procedure outlined in Section 6.5.

Specialized Project Staff: SC&A and its subcontractors maintain a pool of specialized staff to perform different tasks on the project. All individuals on the project review the QAPP (and its revisions) and acknowledge their understanding of its provisions to ensure their compliance with them via a QAPP Acknowledgment Form. Individuals performing specific tasks review the corresponding procedures and acknowledge their understanding of their provisions with an appropriate form.

6.0 PLANS AND PROCEDURES

Team members perform all work on the project according to approved procedures. Appropriate procedures are distributed to each individual working on a particular task, and he or she acknowledges receipt and understanding of the procedures by signing an acknowledgement form and returning it to the McLean office for inclusion in the project files. The project operates under the following plans and procedures; revisions of existing plans and procedures or creation of additional ones may occur during the project as conditions warrant.

6.1 Quality Assurance Project Plan

This QAPP governs all processes and tasks, and applies to all individuals working on the project. It is a high-level document that contains commitments and guidance related to maintaining and improving quality in all activities in accordance with the highest professional standards and applicable contractual and regulatory requirements. It also establishes training and record-keeping procedures.

6.2 Conflict of Interest Plan

The COI Plan describes the methods employed by SC&A and its team members to detect, avoid, and mitigate any potential conflicts of interest on both a corporate and an individual level, whereby a company's or an individual's current or past work assignments may cause bias or the perception of possible bias when performing under this contract.

6.3 SC&A Procedure to Perform QA Reviews of NIOSH/ORAU Dose Reconstruction Procedures

This procedure specifies how the SC&A team evaluates the approach taken in the NIOSH and ORAU documents with respect to Quality Assurance/Quality Control (QA/QC) requirements appearing in regulatory and other documents and good practices for the nuclear industry in order to provide a high level of assurance that QA/QC requirements, issues, and concerns have been

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 8 of 15
-------------------------------	-------------------	-------------------------------	---------------------

adequately addressed. This procedure applies only to individuals performing QA/QC reviews of the NIOSH and ORAU documents.

6.4 A Protocol for the Review of Procedures and Methods Employed by NIOSH for Dose Reconstruction

This procedure provides a general outline and methodology for conducting independent and critical reviews of all relevant procedures identified by the Advisory Board and currently used by NIOSH/ORAU for dose reconstructions. The purpose of this procedural protocol is to provide a structured and systematic review process that, in broad terms, will (1) determine whether procedures are consistent with the philosophy, intent, and statutory directives cited in EEOICPA, and (2) determine the extent to which procedures are consistent and comply with the regulatory methods and guidelines provided in 42 CFR 82. This procedure applies only to individuals reviewing NIOSH dose reconstruction procedures and methods.

6.5 Site Profile Review Procedure

The NIOSH Site Profile database is designed to support the conduct of individual dose reconstructions by compiling data other than dosimetric information, such as that related to facility operations and processes over time; radiological source term characterization; chemical and physical forms of the radionuclides; historic workplace conditions and practices; and incidents and accidents involving potential exposures. The Site Profile Review Procedure provides the structure by which the SC&A team evaluates the approach taken in the NIOSH site profiles to gauge the adequacy, completeness, and validity of the information used to determine individual eligibility for compensation pursuant to the methods stipulated in 42 CFR 82, OCAS-IG-001, and OCAS-IG-002. This procedure applies only to individuals performing site profile reviews.

6.6 Deliverables

The following requirements apply to all deliverable under this contract:

- All contract deliverables must be signed and dated by the author and assigned a revision number.
- The task manager is required to check, sign, and date all contract deliverables.
- If the task manager is the author of the deliverable, the Project Manager, or his designee, must check, sign, and date the deliverable.
- The QA Manager must independently audit this process.

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 9 of 15
-------------------------------	-------------------	-------------------------------	---------------------

7.0 MANAGEMENT PROCESS

The project is conducted in an organized fashion, governed by Standard Operating Plans – plans and procedures – to accomplish the tasks to produce a superior work product in accordance with contract, regulatory, and other applicable requirements. Sections 7.1 through 7.5 present the process that SC&A is implementing to ensure effective management of the contract Statement of Work (SOW) areas.

7.1 Review and Distribution of Task Orders in a Timely Manner

The contract calls for organizing the overall work by separately tracked, budgeted, and scheduled task orders, which are issued by the Advisory Board to the SC&A Project Manager in the form of individual Task Order Request Packages (TORPs). The following is accomplished within fourteen calendar days after receipt of a TORP:

- When the Project Manager receives a TORP from the Project Officer, it is logged in, date stamped, assigned a Task Order Number, and placed into the dedicated project file, which is maintained in a secure location pursuant to SC&A's records management procedure.
- As a means of tracking performance of each case or task comprising the TORP, the TORP may be subdivided into individual cases and/or subtasks.
- The Project Manger reviews the TORP with the Conflict of Interest (COI) Plan Administrator to ascertain whether there may be an actual or perceptual conflict of interest. The details of this assessment appear in the Conflict of Interest Plan outlined in Section 6.2
- The Project Manager assesses the requirements of the TORP with other knowledgeable members of the team to determine how best to meet its requirements without adversely impacting the resources available for ongoing tasks. At this point in the process, the Project Manager, in consultation with the Deputy Project Manager, sorts the tasks into categories regarding scope and effort.
- After the Project Manager has allocated resources, he selects the task or Case Managers, who perform or oversee the work contained in the TORP.
- If necessary, the Project Manager, Deputy Project Manager, and task or Case Managers contact the Project Officer or his designee to clarify any issues that are unclear in the TORP and to gain a more complete understanding of the scope of work. After that interaction (which may be in person, by telephone, or by e-mail), the Project Manager, in consultation with the Deputy Project Manager and the designated task or Case Managers, commence preparation of the technical and cost proposal for the TORP.

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 10 of 15
-------------------------------	-------------------	-------------------------------	----------------------

7.2 Tracking Progress of Cases and Task Orders

Once the Project Officer approves the TORP, the Contracting Officer issues a Task Order to the SC&A Contracts Manager. The Project Manager oversees the Task Order in accordance with established management, QA, procedure, and information system requirements. Technical and administrative communications are maintained within the SC&A team and with the Project Officer by the SC&A Project Manager, Deputy Project Manager, and/or task or Case Managers, under the cognizance and direction of the Project Manager.

The level of effort for each participant on each task and case and on the overall Task Order is stated in the technical and cost proposal for the associated TORP, and each participant is informed of the scope of work and the estimated labor commitment made for his or her time. Each participant's actual level of effort is monitored carefully each month through job-cost reports by the task or Case Manager and the Project Manager, who hold conferences to discuss issues, problems, and potential solutions related to the project. Such conferences are held at least weekly.

SC&A uses its existing automated Project Management System (PMS) and Management Information System (MIS) programs to track and control the contract, which may involve multiple task orders and multiple cases and/or subtasks within each Task Order.

7.3 Cost Projection Accuracy

The SC&A project control system software produces monthly invoices, progress reports, projection reports, and deviation reports. This system allows tracking and controlling cost and schedule performance for individual task orders at the task, case, and subtask levels. The system is supported by input data from the SC&A accounting system. A separate database is used to track subcontractor hours and costs.

At the time a task order is issued, SC&A assigns a job identifier to the project. If necessary, an identifier is assigned to each case and/or subtask within the task order. SC&A employee time sheets, Associate invoices, and subcontractor invoices are received and posted on a monthly basis. Individuals working on the project charge their time to the appropriate job identifiers. For quick-response task orders, charges are obtained by the task or Case Managers weekly or even daily, if required, for budget control. Project charges on time sheets and Associate invoices are certified by the individual and reviewed by the task or Case Managers, the Project Manager, and the accounting department. Other direct costs (ODCs) are checked for correct authorization and are processed in the same manner. Subcontractors follow similar procedures.

This system of reporting and approving contract expenditures is used to produce a Cost Management Report for comparison to the Cost Plan. The Cost Management Report is used for project management and control to determine accrued costs for the current reporting period, to forecast costs for subsequent reporting periods, and to project total costs for project completion.

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 11 of 15
-------------------------------	-------------------	-------------------------------	----------------------

The Cost Plan provides a baseline for measuring cost variance on a contract and basic information for projecting costs and re-budgeting, if necessary. It also addresses each specific task order, case, subtask, project phase, or any other work elements required by the contract.

The Project Manager checks the actual and projected costs against the Cost Plan to ensure that the work is proceeding within budget. Weekly informal review meetings (by telephone, if necessary) are held among the Project Manager, Deputy Project Manager, the task or Case Managers, and technical staff to discuss technical progress, expenditure rates, and schedule progress in order to keep these three aspects of the project in balance. Potential problem areas are identified so that they can be dealt with at the earliest possible stage to minimize their impact on the project. At least one of the weekly meetings each month includes a formal review of progress and budget.

Under either the accounting system or the MIS, SC&A can provide the Project Officer or Contracting Officer with any kind of *ad hoc* report or cost projection that they might request. Although the complete range of such requests may vary, listed below are some of the *ad hoc* reports that may be produced:

- Estimates of costs and hours to complete
- Reconciliation of booked versus billed costs for the contract as a whole or for a specific task order
- Schedules of ODCs by cost element
- Labor costs and ODCs by cost element for specific subcontractors under specific task orders, cases, or subtasks
- List of task orders with ODCs greater than a specified percentage of the total estimated cost

Finally, SC&A has in place an approved Government Property Control System, which governs the management of any government-furnished property under this contract.

7.4 Subcontractor Management

As the prime contractor, SC&A is responsible for overall project management. In the case of task orders with substantial subcontractor participation, SC&A exercises rigorous oversight of subcontractor work, closely monitoring costs, schedules, and deliverables.

SC&A has in place a subcontract with each subcontractor. The subcontracts contain SC&A's standard terms and conditions and any particular clauses required by SC&A's contract with the Centers for Disease Control and Prevention. SC&A's Contract Manager, in consultation with the Project Manager, is responsible for ensuring that the subcontractors follow contract requirements. The Project Manager regularly interfaces with the subcontractor Project Managers, who assume dual roles — as subcontractor point-of-contact, responsible for subcontractor performance in completing work assignments under the contract, and as technical performers on work assignments.

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 12 of 15
-------------------------------	-------------------	-------------------------------	----------------------

For work requiring a specialty niche contractor not already on the team, SC&A searches for the capabilities required and solicits proposals from qualified firms. A sole-source award is made if the requirement is not excessively large and it is clear that, by virtue of location and capabilities, a particular offeror is eminently qualified to perform the work. In this case, a cost proposal is solicited from the offeror and a subcontract negotiated and submitted to the Contracting Officer for approval (if a fixed price, level-of-effort (LOE) subcontract under \$25,000 is negotiated, consent is not required from the Contracting Officer). If a sole-source award is not appropriate, a competition of a few (probably three) firms is held over a short time period. Proposals are evaluated and a subcontract awarded to the firm that offers the most advantageous proposal to the government, considering both technical and cost factors. If consent is required, the subcontract is submitted to the Contracting Officer prior to its execution by SC&A.

7.5 Problem Resolution

SC&A prepares a work plan for every Task Order received from NIOSH. This practice allows early identification during the proposal preparation process of potential problems or schedule slippages that may arise from each task order and formulation of remedial actions, if needed. Close communication among the Project Manager, Deputy Project Manager, and task or Case Managers should identify and resolve potential problems early in a task. In addition, the Project Manager keeps the Project Officer informed of potential problems and remedial actions taken to mitigate the severity of their impact on the project. When a schedule delay is unavoidable, the Project Manager works with the Project Officer and Contracting Officer to minimize the impact of the delay on the overall project goals. In addition, should a concern arise that a change may be needed in task or program direction, the Case Manager immediately informs the Project Manager and Deputy Project Manager, who then consult with the Project Officer and Contracting Officer. SC&A either continues work or stops work while the issue is being resolved.

8.0 DOCUMENTATION

Document control is an important aspect of maintaining quality on the project. Documents are created, reviewed, approved, distributed, acknowledged, used, revised, and filed in an organized fashion according to SC&A standard practices. Specifically, with reference to this plan, the QAPP and the QAPP Acknowledgment Forms, signed by the project members, are maintained in a secure file at the SC&A Headquarters in McLean, Virginia, under the direction of the Quality Assurance Manager, and are available at any time during normal business hours for review by the Advisory Board, the Contracting Officer, or their designee. The QAPP is reviewed annually for applicability and completeness, and changes are made as necessary and submitted to the Project Officer for approval.

9.0 QAPP TRAINING

The QA Manager supervises training of each individual working on the contract in the basic principles of a quality program upon inception of his or her involvement in the contract and retraining thereafter whenever the QAPP is revised. The QA Manager distributes a copy of this

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 13 of 15
-------------------------------	-------------------	-------------------------------	----------------------

QAPP, along with the QAPP Acknowledgement Form, which each team member fills out, signs, and returns to project files. The individual certifies on the QAPP Acknowledgement Form that he or she understands the provisions of the QAPP and his or her specific responsibilities. This process constitutes documentation of QAPP training.

10.0 CONFIDENTIALITY AND SECURITY OF INFORMATION

SC&A recognizes the importance of protecting personal, proprietary, and other sensitive information to which it may have access under this contract. SC&A has reviewed the provisions contained in HHSAR 352.224-70, *Confidentiality of Information*; FAR 52.224-1, *Privacy Act Notification*; FAR 52.224-2, *Privacy Act*; and FAR 52.239-1, *Privacy or Security Safeguards*, and is committed to fully complying with all the requirements contained in these documents. All obligations with respect to confidentiality and security of information flow down to subcontractors at any tier.

10.1 Privacy Act

SC&A, its team members, and individuals working on this contract with access to data protected by the Privacy Act are aware of and comply with restrictions on disclosure of records maintained on individuals and the conditions that must be met in order for disclosure to be permissible under the Privacy Act, Section 552a(b)(1)-(12).

10.2 Confidentiality of Information

In addition to the requirements of the Privacy Act, the SC&A project team is subject to compliance with the provisions of HHSAR 352.224-70. The team obtains written consent from any affected individual, institution, or organization prior to disclosing confidential/proprietary information or data about that individual, institution, or organization. The team provides the Contracting Officer with at least 45 days advance notice in the event that it intends to release findings of studies or research that may have adverse effects on the agency. Finally, if the team is unsure of the proper handling of material or information under this contract, or if the material in question is subject to the Privacy Act or is considered confidential under HHSAR 352.224-70, the team contacts the Contracting Officer in writing and obtains a written determination from him or her prior to releasing, disclosing, disseminating, or publishing such information or material.

10.3 Security Safeguards

The SC&A project team does not publish or disclose any safeguards it develops or implements under this contract without the prior written consent of the Contracting Officer. Furthermore, the team commits to cooperate fully with the government should it be necessary to carry out a program of inspection to safeguard against threats and hazards to the security, integrity, and confidentiality of government data; SC&A will provide the government reasonable access to its facilities, installations, technical capabilities, operations, documentation, records, and databases upon request.

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 14 of 15
-------------------------------	-------------------	-------------------------------	----------------------

11.0 REFERENCES

The following documents constitute the statutory and regulatory bases for the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000, or provide applicable QA/QC program information, and have been examined for guidance in designing the Quality Assurance Project Plan. The SC&A corporate Quality Management Plan (QMP) was also consulted in formulating the QAPP. Outside agency documents, such as the U.S. Department of Energy (DOE) "Quality Assurance" order (referenced below), are applied as applicable to the NIOSH project using (in the language of the DOE document) "a graded approach":

- "Energy Employees Occupational Illness Compensation Program Act of 2000, as Amended," 42 U.S.C. §7384 et seq., October 30, 2000 (Pub. L. 106-398, XXXVI, §3661, "The Act").
- Executive Order 13179, "Providing Compensation to America's Nuclear Weapons Workers," *Federal Register*, Vol. 65, No. 238, December 11, 2000.
- 42 CFR Part 81, "Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule," May 2, 2002.
- 42 CFR Part 82, "Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule," May 2, 2002.
- 42 CFR Part 83, "Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule," May 28, 2004.
- DOE Order 414.1A, "Quality Assurance," Chg. 1, July 12, 2001.
- ORAU contract with Centers for Disease Control (CDC), No. 200-2002-00593.
- "Quality Assurance Program Plan," ORAUT-PLAN-0001, Rev. 0, January 30, 2003.
- "Document Program," ORAUT-PROC-0001, Rev. 1, October 6, 2003.
- SC&A, Inc., "Quality Management Plan," January 2003.

Effective Date: 10/01/2004	Revision No. 0	Document No. SCA-PLAN-0001	Page No. 15 of 15
-------------------------------	-------------------	-------------------------------	----------------------

**EXHIBIT A: QUALITY ASSURANCE PROJECT PLAN
ACKNOWLEDGMENT FORM**

QUALITY ASSURANCE PROJECT PLAN
ACKNOWLEDGMENT FORM
UNDER
CDC CONTRACT NO. 200-2004-03805

Plan Name: Quality Assurance Project Plan

Document No.: SCA-PLAN-0001

Plan Version: (to be filled in when the Plan is distributed)

Plan Date: (to be filled in when the Plan is distributed)

I have read the Quality Assurance Project Plan referenced above and certify that I understand the general definition and goal of quality on the project, as well as specific provisions that may apply to aspects of the work that I may perform.

Individual Name

Signature

Date

Company Name