

Quality Assurance Project Plan
(QAPP)

**Technical and Regulatory Support to Develop a Rulemaking
to Modify the NESHAP Subpart W Standard
for Radon Emissions from Operating Uranium Mills
(40 CFR 61.25)**

Revision No. 1

Prepared by

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Under

Contract Number EP-D-05-002
Work Assignment No. 4-11

Prepared for

U.S. Environmental Protection Agency
Office of Radiation and Indoor Air
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Reid J. Rosnick
Work Assignment Manager

September 16, 2008

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PURPOSE AND BACKGROUND OF THE QAPP


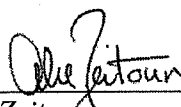
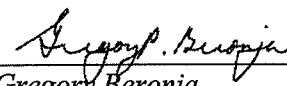
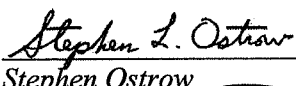
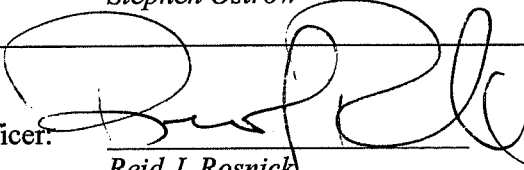
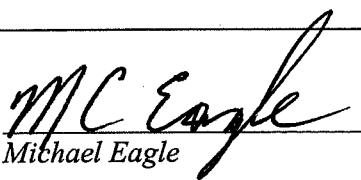
This is a task-specific Quality Assurance Project Plan (QAPP) for *Technical and Regulatory Support to Develop a Rulemaking to Modify the NESHAP Subpart W Standard for Radon Emissions from Operating Uranium Mills (40 CFR 61.25)* under Task 2 of Work Assignment (WA) 4-11. Details of the Work Assignment are found in the Environmental Protection Agency (EPA) WA 4-11 and the SC&A Work Plan for WA 4-11. To some extent, this work relies on information collected under WAs 1-10 (July 27, 2005), 2-03 (September 27, 2005), and 3-15, Technical Direction No. 1 (August 20, 2007). The purpose of the QAPP is to ensure the reliability/quality of SC&A's deliverable reports in Tasks 4, 5, 6, 7, 8.

The names of the key personnel related to the assurance of quality and their functions appear in Section A.4, a discussion and background of the overall project appear in Section A.5, and a summary of the specific tasks within the Work Assignment appears in Section A.6.

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A. PROJECT MANAGEMENT

A.1 Title and Approval Sheet

S. Cohen & Associates: <i>Radiological, Analytical, and Evaluation Support for Radiation Protection Programs</i>	Document No. QAPP 4-11
	Effective Date: September 16, 2008
	Revision No.: 1
Work Assignment 4-11: <i>Technical and Regulatory Support to Develop a Rulemaking to Modify the NESHAP Subpart W Standard for Radon Emissions from Operating Uranium Mills (40 CFR 61.25)</i> Quality Assurance Project Plan (QAPP)	Supersedes: N/A
Work Assignment Task Manager: <u></u> Harry Pettengill	Date: <u>09/16/2008</u>
Project Manager: <u></u> Abe Zeitoun	Date: <u>09/16/2008</u>
Corporate Quality Assurance Mgr: <u></u> Gregory Beronja	Date: <u>09/16/2008</u>
Work Assignment QA Manager: <u></u> Stephen Ostrow	Date: <u>09/16/2008</u>
EPA Task Order Project Officer: <u></u> Reid J. Rosnick	Date: <u>09/17/08</u>
EPA Quality Assurance Manager: <u></u> Michael Eagle	Date: <u>09/17/08</u>

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Revision Log

Revision No.	Date	Description	Affected Sections
0	4/11/08	Original	All
1	9/16/08	Reflect addition of Tasks 7 and 8 in WA 4-11, Change No. 2, June 8, 2008	<ul style="list-style-type: none"> • Purpose and Background of QAPP • A.5 • A.6 • References • Exhibit A

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A.3 Distribution List

This Quality Assurance Project Plan (QAPP) applies to all SC&A, subcontractor, and consultant personnel performing any work function on WA 4-11. A distribution list of personnel required to receive the QAPP will be maintained and placed in the project files by the Records Management Specialist.

A.4 Project/Task Organization

The following describes responsibilities of personnel related to implementation of the Work Assignment's Quality Program and fulfillment of the specific scope of work covered by the EPA Work Assignment.

Work Assignment QA Manager: *Dr. Stephen L. Ostrow (SC&A Senior Vice President for Advanced Technology).* The Work Assignment QA Manager is responsible for the Work Assignment-specific implementation of the overall Quality Program; he is responsible for performing QA reviews to verify the reliability/quality of technical reviews performed by the Work Assignment Task Manager. He verifies 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 (see Exhibit A of this plan) are maintained in the project files. He conducts and directs reviews of the quality aspects of the project, as discussed in Section C. He also reviews all deliverables to verify achievement of quality objectives and, when found satisfactory, signs those documents signifying his acceptance; his signature is the final one on all deliverable documents. He may employ QA Technical Specialists to assist him in his assessments.

The Work Assignment QA Manager reports to the Project QA Manager, and can also bring concerns related to the Quality Program directly to the Corporate QA Manager. If any segment of the Work Assignment is found to be severely deficient, the Work Assignment QA Manager documents the deficiency and notifies the Project Manager and associated Work Assignment Task Manager. Depending on the severity of the deficiency, the Work Assignment QA Manager has the authority to stop work until the cited deficiency is resolved to his satisfaction.

Project Manager: *Dr. Abe Zeitoun (SC&A Senior Vice President for Environmental, Waste Management, and Nuclear Programs).* The Project Manager is responsible for overseeing the day-to-day activities of the contract and is ultimately responsible for the transmission of contractual deliverables to the EPA Office of Radiation and Indoor Air (EPA/ORIA). The Project Manager provides the Work Assignment Task Manager with required resources, including qualified SC&A, subcontractor, and consultant personnel, to complete the task to the highest professional standards, within schedule and budget parameters. The Project Manager reviews and signs all Work Assignment deliverables before they are submitted to EPA/ORIA. In addition, he serves as the principal liaison with EPA/ORIA for non-contractual matters.

Work Assignment Task Manager: *Dr. Harry Pettengill.* The Work Assignment Task Manager (Task Manager) is responsible for the successful completion of this Work Assignment, which includes achievement of quality objectives. Working with the Project Manager, the Task Manager obtains the necessary project resources, oversees his staff's work to ensure fulfillment of all requirements and production of quality work products, sets and maintains schedules, and manages expenditures within budget. The Task Manager also distributes the QAPP to all project

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personnel. In addition, the Task Manager serves as the principal liaison with the EPA/ORIA Work Assignment Manager (WAM) for technical matters on this Work Assignment.

Contract Manager: *Ms. Laurie Loomis (SC&A Contract Manager)*. The Contract Manager ensures that SC&A meets all of its contractual obligations with respect to project control and reporting, and also oversees the subcontracts with the other companies and consultants on the SC&A team. In addition, the Contract Manager serves as the principal liaison with EPA/ORIA for contractual matters.

Corporate QA Manager: *Mr. Gregory Beronja (SC&A Chief Operating Officer)*. The Corporate QA Manager develops and implements the corporate Quality Management Plan (QMP), ensures that the applicable portions of the QMP flow down to the projects and are followed, ensures that projects have adequate QA support, and may conduct periodic project assessments and perform independent reviews of reports prepared by project staff. He has the authority to stop work and initiate or approve corrective actions when warranted. He also ensures that the SC&A Work Assignment QA Manager and QA Technical Specialists are provided with sufficient authority, access to work areas, and organizational freedom to identify problems with the reliability of SC&A technical reviews of DOE's proposed changes, verify implementation of corrective actions to problems with reliability, and ensure that further use of SC&A technical reports is controlled until corrective actions are implemented.

Project QA Manager: *Dr. Sanford Cohen (SC&A President)*. The Project QA Manager is responsible for establishing plans, schedules, and methods of coordination to ensure that appropriate quality-related procedures, such as the corporate QMP, are followed for the subject project. He is also responsible for assessing the QA work of the project team, including subcontractors, and may require reviews to resolve quality-related problems.

Records Management Specialist: *Ms. Judy Eley*. The Records Management Specialist, under the direction of the Work Assignment QA Manager, will distribute the task-specific QAPPs to the personnel on the Distribution List (Section A.3), collect their QAPP Acknowledgment Forms (Exhibit A), and maintain these and all other quality documents in the project files in a secure location at the SC&A headquarters. As stated in Section A.9, "quality records that will be maintained in project files include the QAPP, the QAPP distribution list, the QAPP Acknowledgment Forms (Exhibit A) signed by project personnel on the distribution list, reports, procedures, computer code documentation, QA review reports, and any other significant documents generated or used by SC&A."

A.5 Problem Definition and Background

The following background description is taken from Section 1 of the EPA WA 4-11:

The Office of Radiation and Indoor Air (ORIA) promulgated a National Emission Standard for a Hazardous Air Pollutant (NESHAP) for radon emissions from operating uranium mill tailings impoundments (Subpart W) on 12/15/1989. Subpart W includes two separate standards. First, existing sources must ensure emissions from tailings impoundments not exceed 20 pCi/m²-sec of radon-222. Second, new sources must comply with the requirements for constructing one of two types of impoundment structures. Subpart W requires that existing sources file an annual report of the facility's emissions. Section 112(q) of the Clean Air

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Act, as amended (CAAA) requires EPA to review, and if appropriate, revise, this standard on a timely basis (10 year interval). The Agency has not reviewed this standard in the period allotted and now desires to do so.

EPA amended the Work Assignment on June 8, 2008 (WA Change No. 2) by the addition of Tasks 7 and 8. As stated in the Purpose section of the Work Assignment: “The purpose of this amendment to work assignment 4-11 is to add tasks to contractor support for the development of a Background Information Document [Task 7] and an Economic Impact Analysis [Task 8].”

A.6 Project/Task Description

Under WA 4-11, SC&A provides technical and regulatory support to EPA/ORIA to help the agency develop a potential rulemaking to update the NESHAP Subpart W standard from uranium mill tailings impoundments. The six tasks in this Work Assignment are described in the SC&A Work Plan and are summarized below:

Task 1 – Work Plan/Cost Proposal:

SC&A prepared its WA 4-11 Work Plan (the task deliverable), which includes costs associated with the tasks.

Task 2 – Prepare a Quality Assurance Project Plan and a Quality Assurance Report:

SC&A will prepare a Quality Assurance Project Plan (QAPP – a task deliverable) and, at the conclusion of the project, a Quality Assurance Report (QAR – task deliverable) documenting compliance of verification activities performed by SC&A with quality requirements appearing in the QAPP.

Task 3 – Communication

SC&A will communicate with the EPA WAM on a timely and regular basis and document all communications. In addition, SC&A will prepare monthly reports (task deliverables) for the WAM that discuss work accomplished and any issues that may have arisen and remedial actions undertaken during the month, and an estimate of the level of effort that will be accomplished in the upcoming month.

Task 4 – Historical Research

SC&A will evaluate regulatory information provided by EPA and compare and contrast it to current risk assessment modeling methodologies. SC&A will document its findings and assessment of the impact on the original radon risk standard appearing in Subpart W in a report (the task deliverable).

Task 5 – Survey of Existing Technologies

Following receipt from EPA of an IAEA report, *The Long-Term Stabilization of Uranium Mill Tailings*, SC&A will compile a list of existing and proposed uranium mill tailings facilities and associated containment technologies, and evaluate the enumerated technologies against the

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engineering requirements of RCRA Subtitle C land disposal facilities. SC&A will summarize all of the information developed in this task in a report (the task deliverable), including an analysis of radon emitted versus technology employed.

Task 6 – Compliance with Method 155

According to 40 CFR 61.253, demonstration of compliance with the existing emission standard is achieved through the use of Method 155, as prescribed in 40 CFR 61 Appendix B. Under this task, SC&A will evaluate this method to determine if it is current and evaluate any other methods using current technology that could be employed to meet the requirements of Subpart W. SC&A will prepare a report (the task deliverable) documenting its review and assessment of these technologies.

Task 7 -- Prepare Comprehensive Outline/Index and an Introductory Chapter for a Background Information Document that Supports a Proposed Rulemaking for NESHAP Subpart W

SC&A will prepare a first and second draft of an outline/index and introductory chapter for the Background Information Document (BID). Topics addressed in the BID will include “characterization of the problem being addressed, data and scientific analyses needed to make the decision, historical background, and risk assessment” (WA 4-11, CN. 2, Scope of Work).

Task 8 – Prepare a Comprehensive Outline/Index for an Economic Impact Analysis That Supports a Proposed Rulemaking for NESHAP Subpart W

SC&A will prepare a first and second draft of an outline/index and introductory chapter for the Economic Impact Analysis (EIA). Topics addressed in the EIA will include: “characterization of the industry and the problem being addressed, costs and benefits of options, and cross-media issues” (WA 4-11, CN. 2, Scope of Work).

Schedule of Deliverables

Task	Deliverable	Schedule
1	Work Plan and Cost Estimate	March 4, 2008
2	QAPP QAR	March 21, 2008 September 15, 2008
3	Documented Communications Monthly Reports	Monthly on the 15 th of the following month
4	Report	120 days after Work Plan approval
5	Report	150 days after Work Plan approval
6	Report	170 days after Work Plan approval
7	BID Outline/Index: 1 st draft 2 nd draft	August 15, 2008 September 26, 2008
8	EIA Outline/Index: 1 st draft 2 nd draft	August 15, 2008 September 26, 2008

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A.7 Quality Objectives and Criteria

The purpose of this QAPP is to ensure and verify the quality of the SC&A work product developed under this WA; i.e., that the reported conclusions are reliable. It is assumed that decisions based on SC&A's work should *not* be classified as having a *major impact*, as defined in Section 2.2.3 of the EPA's *Peer Review Handbook* (EPA 100-B-00-001, pp. 26–27) and, therefore, this QAPP does not require invoking this handbook. As stated in Section 3 of the EPA Work Assignment:

In meeting the requirements of this work assignment, the contractor [SC&A] shall be in a support role, and will not be involved in the development of EPA policy, nor in any other activity this an "inherently governmental function."

All work conducted on this project by SC&A and any subcontractors is performed under a quality assurance/quality control (QA/QC) and documentation process that corresponds to the requirements and guidance of EPA documents EPA QA/G-4, EPA QA/R-5, EPA QA/G-5, and EPA/260R-02-008. The EPA quality policy is established in EPA Order 5360.1 A2, which requires that the collection of environmental data be supported by a Quality System. This requirement is extended to contractors in 48 CFR 46, *Quality Assurance*. SC&A's Quality Management Plan (QMP), which applies to all tasks, is based upon the criteria and guidance provided in the National Consensus Standard ANSI/ASQC E4 (adopted by EPA Order 5360.1 A2 as the basis for QA/QC in the Agency), and is designed to produce quality results in projects where collecting, evaluating, and using environmental data, or designing, constructing, and operating environmental technology is important. Full bibliographic citations of the above-mentioned documents appear in the Reference section of this plan.

While all projects performed at SC&A are conducted under the guidance of the corporate QMP, which ensures overall adherence to the highest standards of quality and project control, individual projects may require their own project-specific Quality Assurance Project Plans (QAPPs), which reflect project-specific conditions and requirements (e.g., regulatory and contractual). This particular task assignment requires a task-specific QAPP by direction of EPA in its Work Assignment. The QAPP describes the methods employed by SC&A to achieve and verify the achievement of quality goals, whereby all work is done in accordance with the highest professional standards in compliance with all applicable regulatory, contractual, and other requirements that may apply, and that the user of the results and conclusions may be confident in their reliability. 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.

The organization (format and content) of this QAPP follows the guidance of EPA QA/G-5 for convenience. In addition, implementation of QA provisions, including reviews, follows a "graded-approach," which is defined in EPA QA/G-5:

The term "graded approach" appears in the Quality Manual [EPA Order 5360.1 A1, EPA Quality Manual for Environmental Programs, 2000], where it states that the level of detail in the quality management plan should be "based on a common sense, graded approach that establishes QA and QC activities commensurate with the importance of the work, the available resources, and the unique needs of the organization (EPA QA/G-5, Section 1.2).

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The Task Assignment QA Manager verifies training of each individual working on the assignment in the principles of a quality program upon inception of his or her involvement in the contract, and retraining whenever the QAPP is materially revised thereafter. The Work Assignment Task Manager distributes a copy of this QAPP to each person on the distribution list (Section A.3), along with the QAPP Acknowledgment Form (Exhibit A). Each recipient then fills out the Acknowledgment Form, signs it, and returns it to the project files. The individual certifies on the Acknowledgment Form that he or she understands the provisions of the QAPP and his or her specific responsibilities; this process constitutes documentation of QAPP training.

A.8 Special Training/Certifications

Not applicable.

A.9 Documentation and Records

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. Quality records that will be maintained in project files include the QAPP, the QAPP distribution list, the QAPP Acknowledgment Forms (Exhibit A) signed by project personnel on the distribution list, reports, procedures, computer code documentation, QA Reports (QARs prepared by the Task Assignment QA Manager), and any other significant documents generated or used by SC&A. At the conclusion of the project, the Records Management Specialist will file all applicable documents and records (including CDs containing, for example, data and spreadsheets) in a secure location at the SC&A Headquarters in Vienna, Virginia, and make them available for review by EPA during normal business hours. The QAPP is reviewed at least annually for applicability and completeness, and changes are made as necessary. Revised plans go through the same approval, distribution, acknowledgment, and records management process as the original plan.

B. DATA GENERATION AND ACQUISITION

Sections B.1 through B.8 refer to sample collection and measurement and are not applicable to this Work Assignment. Sections B.9 and B.10, however, pertain to obtaining technical data from existing data sources and data management, respectively, and are applicable.

B.1 Sampling Process Design (Experimental Design)

Not applicable.

B.2 Sampling Methods

Not applicable.

B.3 Sample Handling and Custody

Not applicable.

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B.4 Analytical Methods

Not applicable.

B.5 Quality Control

Not applicable.

B.6 Instrument/Equipment Testing, Inspection, and Maintenance

Not applicable.

B.7 Instrument/Equipment Calibration and Frequency

Not applicable.

B.8 Inspection/Acceptance of Supplies and Consumables

Not applicable.

B.9 Non-Direct Measurements

Any task that may require obtaining data and computer codes shall include in all reports and other documents forming part of the deliverables citations of data and computer code sources and their associated quality records.

B.10 Data Management

It is expected that data (of various kinds and forms) will be gathered and generated in a variety of media and formats. SC&A will take care to control data inputs and associated documents to ensure proper identification of all data sources in generated reports and model results. In accordance with SC&A practices, copies of all significant documents received and generated (including CDs and e-mails) will be placed in the project files by the Records Management Specialist, as described in Section A.9 of this plan. While code and model development, data, code runs, inputs, and outputs may reside or be conducted on the individual performers' computers, final products (such as records of modifications to programs, users' manuals, and computer run outputs) will be transmitted to the SC&A Records Management Specialist by the end of the project in an appropriate form for long-term documentation and record-keeping purposes.

The Work Assignment QA Manager will verify the traceability of individual data and outputs to documented sources or computer model runs by spot checking records. In addition, all reports will be examined for technical accuracy and completeness (including data source references) by the Project Manager and Work Assignment Task Manager, who will require revision of any suspect items. The Work Assignment QA Manager will examine all deliverables to assess their compliance with quality objectives (see QAPP, Section C.1).

C. ASSESSMENT AND OVERSIGHT

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C.1 Assessment and Response Actions

In addition to having a Work Assignment-specific QAPP in place, it is essential to ensure that the plan is actually being implemented on the project in order to provide confidence that the end result of the work is a quality product. Consequently, the Work Assignment QA Manager will perform two reviews: (1) review each deliverable work product of WA 4-11 with respect to achievement of quality goals and sign them (after any required revision and as the "last signature") to signify their compliance with quality requirements, and (2) conduct an overall review of the Work Assignment to assess compliance with the provisions of the QAPP; this review will be documented in a Quality Assurance Report (QAR). The reviews will include examining the work products to ensure that proper procedures are followed; that the methodology, assumptions, data, and conclusions are technically supported; that codes used are adequately documented; and that performing personnel are trained in the procedures and are technically qualified to do the work by experience, education, and training.

The Work Assignment QA Manager may enlist the assistance of an independent (i.e., not connected with the performance of the assignment or having a personal stake in its outcome, but who may be an SC&A employee or Associate) QA Technical Specialist (or Specialists) to help conduct the reviews. QAPP Exhibit B, "QA Review Procedure," and Exhibit C, "QA Review Report Checklist and Outline," provide guidance for conducting and documenting QA reviews.

The Work Assignment QA Manager or his designee will also inspect the project files to assess their physical security (i.e., limited access in a secure location), and whether QA-related and other project records are present, identifiable, and readily available. Suggested corrective actions of any observed deficiencies related to quality will be presented to the Work Assignment Task Manager.

SC&A's QMP requires the independent review and sign-off of all deliverable work products to insure that the assumptions, methodologies, and technical results are correct and in accordance with the project goals and directions. Particular attention will be paid to assessing whether existing data sources represent the best available information, that they are cited correctly in reports, and that quality-related information accompanying the data is properly recorded. Another major focus of reviews will be whether any computer codes that are used for modeling are documented and used properly, and individual runs are adequately documented to indicate code version, methods, assumptions, inputs, and outputs.

The Work Assignment QA Manager will review and sign (signifying approval) all WA 4-11 deliverables before they are finalized and forwarded to EPA. His approval will signify that the deliverables are of sufficient quality to achieve the goals of the Work Assignment. Any deficiency findings from his review will be noted, and the work product will be returned for remediation by the originator, who will then resubmit the work product for further review.

C.2 Reports to Management

The Work Assignment QA Manager will write a QA Report to management (i.e., Project Manager, Task Manger, and Project QA Manager) presenting the details of the reviews, including the purpose, personnel contacted, records examined, findings, and recommended corrective actions, if any. The Work Assignment QA Manager will also monitor the

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implementation of corrective actions. QAPP Exhibit C elaborates on what is contained in the QA Report. The final QA Report will be forwarded to the EPA Work Assignment Manager.

D. DATA VALIDATION AND USABILITY

D.1 Data Review, Verification, and Validation

Data and other information included in the deliverables will be checked by the Task Manager and verified by the Work Assignment QA Manager to ensure that all quality requirements, as appear in the EPA Work Assignment and the SC&A Work Plan, have been fulfilled. Data verification will evaluate data completeness and correctness of individual data used (as opposed to overall data sources; e.g., as discussed in Section C.1) and data validation will determine whether the measured and generated data satisfy all requirements.

D.2 Verification and Validation Methods

Verification of data will be accomplished by tracing them back to the original source and assessing whether they are applicable to the particular task, were properly recorded, and were correctly transformed into their final, presented forms. Particular attention will be given to determining the original source of reported data; a field measurement, a laboratory analysis result, an output from a computer code, or expert judgment. Validation of data will be accomplished by comparing the type of data to those specified in the Work Assignment and the Work Plan.

D.3 Reconciliation with User Requirements

This element is concerned with whether the validated data meet the requirements of the Work Assignment. As stated in Section D.2, the data and information generated and obtained will be assessed for correctness and for compliance with EPA/ORIA's requirements. Any limitations or caveats on the applicability of the final results will be noted in the deliverable reports.

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REFERENCES

- ANSI/ASQC E4-1994, *Specifications and Guidelines for Environmental Data Collection and Environmental Technology Programs*, January 1995.
- EPA Order 5360.1 A2, *Policy and Program Requirements for the Mandatory Agency-Wide Quality System*, May 2000.
- EPA WA 4-11, *Technical/Regulatory Support for Subpart W of NESHAPS*, Contract EP-D-05-002, February 19, 2008.
- EPA WA 4-11, *Technical/Regulatory Support for Subpart W of NESHAPS*, Change No. 2, Contract EP-D-05-002, June 8, 2008.
- EPA QA/G-4, *EPA Guidance for the Data Quality Objectives Process*, EPA/600/R-96/055, August 2000.
- EPA QA/R-5, *EPA Requirements for Quality Assurance Project Plans*, EPA/240/B-01/003, March 2001.
- EPA QA/G-5, *EPA Guidance for Quality Assurance Plans*, EPA/240/R-02/009, December 2002.
- EPA 100-B-00-001, *Science Policy Council Handbook: Peer Review*, 2nd Edition, December 2000.
- EPA/260R-02-008, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, October 2002.
- SC&A *Quality Management Plan*, May 28, 2004.
- SC&A Work Plan, WA 4-11, *Technical and Regulatory Support to Develop a Rulemaking to Modify the NESHAP Subpart W Standard for Radon Emissions from Operating Uranium Mills (40 CFR 61.25)*, February 27, 2008.

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EXHIBIT A: QAPP ACKNOWLEDGMENT FORM

QUALITY ASSURANCE PROJECT PLAN
ACKNOWLEDGMENT FORM
UNDER
EPA CONTRACT NO. EP-D-05-002

Plan Name: Work Assignment 4-11 QAPP: *Technical and Regulatory Support to Develop a Rulemaking to Modify the NESHAP Subpart W Standard for Radon Emissions from Operating Uranium Mills (40 CFR 61.25)*

Plan Version: Rev. 1

Plan Date: September 16, 2008

I have read the Quality Assurance Program 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

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EXHIBIT B: QA REVIEW PROCEDURE

1. Introduction

As required by Section C.1 of this Work Assignment's Quality Assurance Project Plan (QAPP), the Work Assignment QA Manager will conduct a review to assess compliance with the QAPP and verify that quality has been achieved in the Work Assignment. The review will include examining the work products, such as report(s), to ensure that proper procedures are followed; that the methodology, assumptions, data, and conclusions are technically supported; and that performing personnel are trained in the procedures and are technically qualified to do the work by experience, education, and training. Exhibit B is intended to supplement the requirements of the QAPP by providing guidance on how to conduct reviews of the work products.

Specifically, as stated in the EPA Work Assignment and the SC&A Work Plan, SC&A will conduct independent internal QA reviews of the deliverables listed in Tasks 4, 5, and 6. At the discretion of and under the supervision of the Work Assignment QA Manager, the reviewers will use QA Technical Specialists to help conduct the reviews and to provide an overview assessment of the reliability of the WA 4-11 results. People conducting the QA reviews may be SC&A employees or Associates, not associated with performing the work subject to the QA review.

This review procedure has been developed by adopting for convenience applicable sections and guidance of the EPA's *QA/R-5 Requirements for Quality Assurance Project Plans* (EPA/240/B-01/003, March 2001) to the particular characteristics and requirements of the Work Assignment.

2. QA Review Process

The key steps in the QA review process follow.

2.1 Develop the Charge

The first step in the review process is to develop the Charge for the QA Technical Specialist(s), which is a statement of the issues and particulars that the review is to address. This document will be produced by the Work Assignment QA Manager, in consultation with the Work Assignment Task Manager and EPA. The essential elements of a Charge are as follows:

- a. Brief overview or introduction (describe what the work product is, how it was developed, how it will be used)
- b. As needed, a brief description or listing of any background materials provided to the QA Technical Specialist(s)
- c. The issues or questions to be addressed by the QA Technical Specialist(s)
- d. The due date of reviewers' comments, the format of reviewer responses, and the point of contact, in case the reviewer(s) have questions

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2.2 Set the Timelines, Including Deadlines

To the extent possible, the review schedule should take into account the overall task schedule, so that the review takes place at such a time and with such duration that any resulting required or suggested modifications to the work process or work product can be affected in a timely fashion without having a deleterious impact on the overall schedule.

2.3 Select Independent QA Technical Specialist(s)

Proper selection of QA Technical Specialists is an essential component to assuring that the greatest benefit is derived from the QA review process. All QA Technical Specialists must be independent and technically qualified by education and experience to adequately review the work. The issue of "independence" is addressed in the EPA's *Peer Review Handbook* (2nd Ed., EPA 100-B-00-001, December 2000) and is adopted for guidance purposes for this QAPP as follows:

An independent technical reviewer is an expert who wasn't associated with the generation of the specific work product either directly by substantial contribution to its development or indirectly by significant consultation during the development of the specific product. The independent technical reviewer, thus, is expected to be objective. ... Ideally, technical reviewers should be free of real or perceived conflicts-of-interest or there should be a balancing of interests among technical reviewers.

2.4 Send the Materials to QA Technical Specialist(s) and Conduct Review

The Work Assignment QA Manager ensures that the QA Technical Specialists receive the Charge, the work product, the QA Review Procedure (this document), and any other documents or computer files required for an effective assessment. If the Work Assignment involves the use of specialized computer codes that even a subject matter expert may not be familiar with, the Work Assignment performers may brief the QA Technical Specialists as required, taking care to not unduly influence their judgment and, thus, compromise the independence of the review. Details of the review process specific to this Work Assignment Task appear in Section 3.0. The QA Technical Specialists are to produce a technical review record (QA Review Report), which should include a full record of the review process. The following lists what should be included in the review record/report (in addition to any other information required by the Charge as listed in Section 2.1):

- a. The draft work product submitted for review; this may be incorporated by reference.
- b. Material and information (including the Charge) given to the reviewer(s); this may be incorporated by reference.
- c. Written comments, information, and materials received from the reviewer(s).
- d. Information about the reviewer(s) (such as the reviewers' names, affiliations, and a statement concerning potential conflicts and their resolution). A summary of the reviewers' education and experience related to the subject matter should also be included.
- e. Logistical information about conduct of the review (such as times and locations of meetings).

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- f. A memorandum or other written record approved by the Work Assignment Task Manager responding to the review comments specifying acceptance or, where thought appropriate, rebuttal and non-acceptance.
- g. The final work product; this may be incorporated by reference.

The record/report should be placed and maintained in the project files in a section dedicated to QA reviews.

2.5 Finalize the Work Product

Following completion of the QA technical review, reviewer comments are evaluated by the work product performer, the Work Assignment Task Manager, and the Work Assignment QA Manager, and those found significant are incorporated into the work product. Depending on the nature of the comments, it may be useful for the reviewer(s) to present and discuss his or her findings in a briefing. If any comments are not incorporated, the reasons for making that decision are included in the work product documentation. The Work Assignment QA Manager and the Work Assignment Task Manager will make the final determination in case there are any disputes about how to revise the work product (with the Work Assignment QA Manager having the "last" signature on the work product). The final work product (with the appropriate sign-offs) will include a brief summary of the review process and findings, and will then be placed in the project files.

3.0 Review Elements Specific to this Work Assignment

The preceding sections covered the general procedure for conducting a QA review of the work product. This section presents some Work Assignment Task-specific considerations for reviewing WA 4-11 activities, which are discussed in Section A.6 of the QAPP. The following activities will be performed by the Work Assignment QA Manager or a designated QA Technical Specialist working under the direction of the former.

- a. Verify that the people performing the technical work are qualified to do so by consideration of education, training, and experience.
- b. Verify that the work product contains a sound and thorough discussion of the problem under investigation, the methodology employed, assumptions made, sources of data, and a discussion of the significance of the results.
- c. Review that assumptions, parameter values, and data sources going into the work product are appropriate.
- d. Verify that the package comprising the work product and all other associated documents is properly maintained in the project files at the conclusion of the assignment.

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EXHIBIT C: QA REVIEW REPORT CHECKLIST AND OUTLINE

Review Number:

Review Signoff:

Name/Signature	Title	Date
_____	Lead Reviewer	
_____	Work Assignment QA Manager	
_____	Corporate QA Manager	
_____	Project QA Manager	

Dates Conducted:

Start Date:

End Date:

Review Type:

QA Technical Review

Review Team:

Name	Title	E-mail	Phone No.
	(Lead Reviewer)		

Project Personnel Contacted:

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Name	Title	E-mail	Phone No.

Purpose:

Scope:

Review Performance:

- a. Verify that the people performing the technical work are qualified to do so by consideration of education, training, and experience.
- b. Verify that the work product contains a sound and thorough discussion of the problem under investigation, the methodology employed, assumptions made, sources of data, and a discussion of the significance of the results.
- c. Review that assumptions, parameter values, and data sources going into the work product are appropriate.
- d. Verify that the package comprising the work product and all other associated documents is properly maintained in the project files.
- e. Does the work product contain a sound and thorough discussion of the problem under investigation, the methodology employed, and a discussion of the significance of the results?
- f. Have uncertainties been appropriately considered in the review?
- g. Does the review/analysis support the final recommendations/conclusions?

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Review Summary:

[Summary of the review results, including educational and experiential qualifications of performing personnel, strengths, weaknesses, and corrective actions done in the course of the review and planned after the conclusion of the review]

Strengths:

Weaknesses:

Findings:

Corrective Actions:

Conclusions:

Attachments:

[Copies of the Charge and of any other applicable documents]