APTUIT RESPONSE TO
NRC REVIEW OF LICENSE AMENDMENT REQUEST REGARDING
DECOMMISSIONING PLAN AND REQUEST FOR ADDITIONAL
INFORMATION – APTIUIT, LLC (MAIL CONTROL NO. 579062)
February 20, 2013

RAI-001: The licensee is requested to provide additional information that describes the location of the waste storage building referred to as "The Hill" in relation to the other Aptuit buildings shown in Figure 1-1. The licensee is also requested to add the location of the waste storage building to Figure 1-1 of the DP.

The north hill waste storage building (aka the Hill), located on the north side of the campus, is owned by Sanofi-Aventis and leased by Aptuit. Text describing the location has been added to the Executive Summary and the waste storage building has been added to Figure 1-1 of the DP.

RAI-002: The licensee is requested to provide additional information providing a justification for why it is believed that Na-22 should be not be considered a contaminant of concern at the Aptuit facility. The licensee is also requested, should the Na-22 contaminant be a concern at the Aptuit facility, to provide an appropriate level of detail concerning the decontamination procedures, safety precautions, and waste disposal to ensure the safe handling and disposal of the contaminant.

Sodium-22 (Na-22) was added to the license with Amendment No. 15 issued in January of 1992. The license limit was 20 mCi. This radionuclide was no longer authorized in Amendment No. 17 issued in September 1993. There is no record of use of Na-22 at the facility nor was it identified as a contaminant of concern in any previous site investigations. The short half-life (2.6 years), the time since Na-22 was authorized on the license (19.5 years), combined with a lack of evidence of any use effectively eliminates Na-22 as a contaminant of concern. Sections I (Executive Summary) and II.B (License History) have been revised to address Na-22 and the other short-lived radionuclides that at one time have been authorized on the license but have been eliminated as contaminants of concern.

RAI-003: The licensee is requested to provide additional information associated with the physical location of the "3 room suite" as described in the comments section for the line item of Amendment No. 8 of Table 1-1.

The "3 room suite" consisting of Rooms 119, 120, and 122 was mentioned in the application for Amendment No. 8. Aptuit has determined that these rooms were in the B Building. This area has been renovated as shown in the attached figure (Attachment 1, Figure 1) with an overlay of the existing area. Room 119 mentioned in the Amendment No. 8 application is included as part of the current B2-119 decommissioning. Rooms 120 and 122 have been renovated into the current rooms

B2-121 and B2-122 and hallway B2-134. Scoping surveys have been performed in B2-121, B2-122, and B2-134 to confirm that these areas are not impacted. Scoping surveys consisted of scanning and biased direct measurements and wipes. Results of scoping surveys verify that these areas are not impacted. All results were below Aptuit's acceptable surface contamination levels of 5,000 dpm/100 cm^2 total activity and 1,000 dpm/100 cm^2 removable activity. Figure 2-7 and Appendix D of the DP, Historical Use Areas, has been revised to address these rooms.

RAI-004: The licensee is requested to provide additional information that clarifies whether the water that was disposed of through the sanitary sewer during the spill event referenced above was contaminated with H-3 and C-14. The licensee is also requested to provide additional information on whether this spill event had an impact on the on-site pH treatment building and/or the city sewage system. If these systems were impacted, the information should describe what the licensee's plans are to demonstrate these systems will be suitable for unrestricted use before license termination.

The spill that occurred in B2-166 on November 2, 2008 resulted in approximately 110 gallons of water being discharged to the sanitary sewer. Analytical results indicated that the water contained approximately 77 microcuries of C-14 with H-3 at background levels. The average water discharge from the site at the time was 12,100 gallons per day. This results in an average concentration on the day of the incident of 1.7E-6 μCi/ml (3.6 dpm/ml) or a monthly average discharge of 5.6E-8 μCi/ml (0.1 dpm/ml). At these concentrations there is no reason to suspect any impacts to the on-site pH treatment building or to any systems downstream of that facility from the spill. However, as stated in the DP, an investigation of the drains will be conducted in accordance with Aptuit WI-007. For reference the monthly average sewer discharge limit for C-14 is 3E-4 μCi/ml with an annual limit of less than 1 curie (10 CFR 20.2003 and Appendix B to Part 20).

RAI-005: The licensee is requested to define under what conditions the ALARA principle, as required by Title 10 Code of Federal Regulations 20.1101(b), has been met prior to leaving radioactive material in place.

As stated in the DP, for ALARA considerations the selected DCGL is 10% of the NRC screening value for C-14. In addition, areas that exceed the Investigation Levels (Section XIV.D of the DP) will be investigated and remediated if possible. Also, as described in Section XIV.A of the DP, areas that exceed the DCGL will be remediated to below the DCGL. Section VIII.A of the DP has been revised to read "Survey results will be used to determine if remedial actions are needed to meet release criteria (i.e. activity below DCGL and reduced to ALARA). Surfaces that are found to meet the radiological release criteria (i.e. activity below DCGL and reduced to ALARA) will be left in place."

RAI-006 The licensee is requested to place into Figure 9-1 the position of Site Supervisor as it relates to the management structure.

The Site Supervisor has been added to Figure 9-1 as requested.

RAI-007: The licensee is requested to further define and/or provide examples of a "non-radiological program."

Examples of non-radiological programs provided for D&D tasks include lockout/tagout, hazard communication, fall protection, etc. The text in Section IX.A has been revised to include these examples.

RAI-008: The licensee is requested to modify Figure 9-1 to reflect that the Project QA manager reports directly to a Corporate QA manager (Aptuit) and indirectly to the project manager.

Figure 9-1 has been revised as requested.

RAI-009: The licensee is requested to provide additional detail (e.g. in checklist form) on the issues or items that will be considered when developing an RWP.

The attached RWP Evaluation Form (Attachment 2) provides a list of the items or issues that are considered when developing an RWP.

RAI-010: The licensee is requested to provide additional information on the experience of the RSO or his designee to be the sole reviewer and approver of an RWP. In addition, the licensee should consider whether other individuals or groups within the management organization, such as the Radiation Oversight Committee, could be utilized regarding the review and approval of an RWP.

RWPs are prepared by Project CHP and are reviewed by both the Site Supervisor (also an HP) and the RSO. The RSO has experience and knowledge of the types of activities being performed and the levels and radionuclides involved. The RSO has experience in decontamination and decommissioning at a facility performing similar operations (former EaglePicher Pharmaceutical Services, LLC). In addition the RSO has responsibility for all activities performed under the license. Preparation of the RWPs by the Project CHP with subsequent review by two HPs, including the RSO, is sufficient review.

RAI-011: The licensee is requested to provide NRC documentation that the RSO has the appropriate education and experience commensurate with decommissioning activities.

The Aptuit RSO has 14 years experience as an RSO in radiosynthesis labs. This experience includes establishing and maintaining radiological controls for facilities authorized to handle up to 5,000 Ci of H-3 and 500 Ci of C-14. The RSO's experience includes licensing, maintaining compliance with license and regulatory requirements, conducting radiation safety training, shipping radioactive materials, managing radioactive waste disposal, and interacting with regulatory agencies. His duties include performing radiological surveys, exposure tracking, and maintaining exposures to levels that are ALARA (as low as reasonably achievable). The RSO's experience has included emergency response and overseeing decontamination efforts.

The RSO received the following applicable training in radiological controls and health physics in the Navy:

Nuclear Power School and Nuclear Prototype Training Unit

Machinist's Mate Nuclear Field "A" School

Engineering Laboratory Technician School

Operational Water Chemistry and Radiological Controls School

The RSO's training and experience are appropriate for providing oversight for the radionuclides, activity levels, and tasks that will be encountered during decommissioning activities.

RAI-012: The licensee is requested to further describe the statement regarding the use of financial assurance for disposal. E.g.: Does the license plan on using resources from its financial assurance plan submitted to the NRC or is this an internal resource not subject to NRC regulations?

That statement referenced above was simply meant to illustrate that Aptuit is aware of the potential, though not expected, to generate mixed waste. It was not meant to imply that resources from the financial assurance plan would be used. Any disposal costs associated with mixed wastes will come from internal Aptuit resources not subject to NRC regulations.

RAI-013: The licensee is requested to provide additional information on the definition of "sizable quantity." Specifically, the licensee should provide a number or range of values with the appropriate units which would further define "sizable quantity."

If mixed waste is generated it is anticipated to be less than 500 lbs. Section XII.C of the DP has been revised to say that any mixed waste generated is anticipated to be less than 500 lbs.

RAI-014: The licensee is requested to provide the name(s) of the waste disposal contractor(s) that will be used to disposal of any solid, liquid or mixed waste from any decommissioning activities.

Aptuit plans on using Bionomics, Inc. for disposal of any mixed wasted generated from decommissioning activities. However, Aptuit reserves the right to contract with another appropriately licensed waste disposal contractor depending on a number of factors including cost, schedule, services provided, etc. Section XII.C of the DP has been revised as stated above. The contact information for Bionomics, Inc. is:

Bionomics, Inc.
P.O. Box 817
Kingston, TN 37763
Phone (865) 220-8501
Fax (865) 220-8532

BionomicsJohn@comcast.net

RAI-015: The licensee is requested to provide further clarification, either in the statements above or Figure 9-1, regarding the authority of the QA organization to bring matters directly to the attention of the Aptuit RSO or Aptuit Decommissioning Project Manager.

Figure 9-1 has been revised to show that the QA organization reports directly to a Corporate QA manager (Aptuit) and indirectly to the project manager. Section XIII.A of the DP has been revised to say "Due to the size and scope of the project the QA manager may also serve as the project and site QC manager."

RAI-016: The licensee is requested to provide a specific frequency (e.g.: daily, every 8 hours of work, etc…) regarding follow-up inspections and surveillance while work is in progress.

Follow-up inspections and surveillances of work in progress will be conducted weekly during field activities.

RAI-017: The licensee is requested to specifically state that the licensee will develop, implement and maintain procedures associated with any decommissioning activities and which are approved by licensee management.

Should additional procedures associated with decommissioning activities be needed, Aptuit will develop, implement and maintain procedures associated with those decommissioning activities.

These procedures will be approved by licensee management. Section XIII. B of the DP has been revised to read: Should additional procedures associated with decommissioning activities be needed, Aptuit will develop, implement and maintain procedures associated with those decommissioning activities. These procedures will be approved by Aptuit management.

RAI-018: The licensee is requested to specifically define "periodic" as a timeframe.

Management assessment of project activities will occur monthly during active field work.

RAI-019: The licensee is requested to make a definitive statement on how often reviews are performed of the project. The licensee shall consider the amount of time to complete the project in its determination.

Project status reviews will be conducted monthly.

RAI-020: The licensee is requested to specifically commit to who shall be attending the status review meeting. The licensee shall consider the minimum type, number and authority of staff and management necessary to successfully conclude the status review meeting.

The project status review meeting shall be attended by the Project Manager, the QA Manager, the RSO, and the Site Supervisor.

RAI-021: The licensee is requested to provide NRC information on why a formal training program is not required.

In this context, a formal training program refers to a training program with a formal curriculum, established duration, and competency testing based on established objectives. The training required for this project includes:

- **Site Specific Awareness Indoctrination (radiation safety requirements of the project, license, and the Radiation Safety Program Manual)**
- **Radiation Worker Training**
- **40 Hour OSHA and subsequent 8 Hour HAZWOPER Training**

Since D&D workers will receive site specific training and have current radiation worker and OSHA HAZWOPER training, it was determined that it would not be necessary to develop another formal training program for decommissioning activities.

RAI-022: The licensee is requested to further define the frequency of each self assessment.

Self-assessments will be conducted weekly.

RAI-023: The licensee is requested to define the roles, responsibilities, capabilities and training and/or experience requirements for a subject matter expert.

A SME is a professional who has acquired knowledge and skills through study and practice in a particular discipline. A SME will have at least 10 years experience in the subject area or possess professional certification in the applicable field (e.g. CHP for health physics related reviews, PE for engineering drawings, etc). SME's will prepare or review and approve procedures and review engineering drawings prepared for the project.

RAI-024: The licensee is requested to further define periodic in the form of a timeframe. (e.g.: days, weeks, etc…)

QA assessments of records and document control will be performed monthly.

RAI-025: The licensee is requested to provide the D&D Subcontractor's procedures for NRC review.

The following D&D Subcontractors are submitted as requested:

- **Procedure No: EIP-Q-005 Revision No.: 2, Inspection**
- **Procedure No: EIP-Q-006 Revision No.: 2, Surveillance**
- **Procedure No: EIG-Q-009 Revision No.: 2, Quality Audits**

RAI-026: The licensee is requested to provide specific timeframes associated with the frequency of assessments.

Independent assessments (inspections and surveillances) of project activities will be conducted monthly.

RAI027: The licensee is requested to provide the definition of "Periodically." Example: Daily, weekly, within 8 hours of when work is being performed, etc…

The Site Supervisor will observe D&D tasks weekly when D&D tasks are active.

RAI-028: The licensee is requested to provide any additional information or clarification which would address the apparently lack of information to be included in the above statement.

There was a formatting error in the procedure. The bullets following the statement "Management of the sanitary sink trap RDW will include the following:" are the steps to be followed in managing RDW wastes from the sink traps. Those steps should have been indented. Section 6.1.2 of Work Instruction WI-006 has been revised to show the proper indenting.

RAI-029: The licensee is requested to provide the NRC the Aptuit RSPM for review.

The Aptuit RSPM was submitted to the NRC with the license amendment request dated April 1, 2008. It is attached for your review.

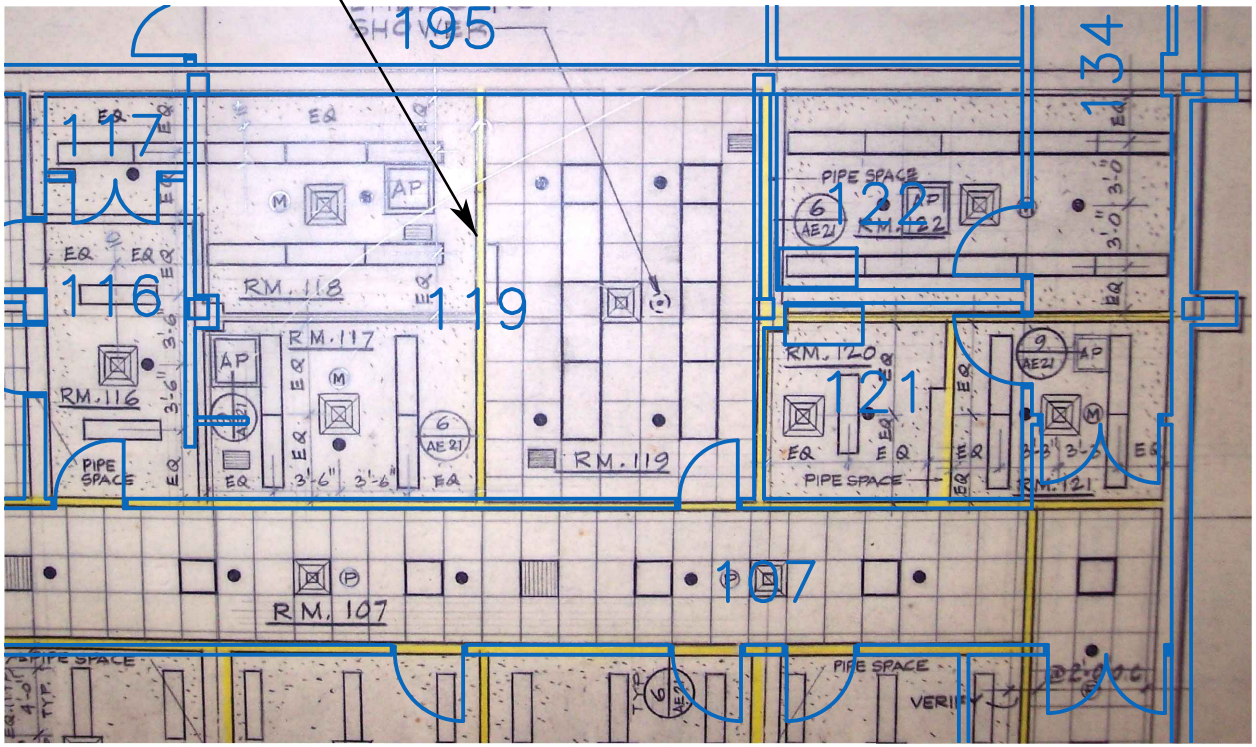
Attachment 1
Figure 1

aptuit_api_fssc_temp001.dgn sammccawley 2/13/2013 8:13:59 AM PDF_with_Levels.plt sei_textsub_only.tbl

LEGEND:

CURRENT ROOM LAYOUT

HISTORIC 1984 LAYOUT



NOTES:

1. A THREE ROOM SUITE (119, 120, 122) WAS MENTIONED IN THE LICENSE AMENDMENT REQUEST FOR AMENDMENT 8.
2. HALLWAY (134) WAS ADDED OUTSIDE OF ROOMS 121 AND 122. ROOM 119 WAS EXPANDED TO INCLUDE THE OLD ROOMS 117 AND 118. THE OLD ROOM 116 BECAME ROOMS 116 AND 117. THE OLD ROOM 118 IS NOW PART OF ROOM 119.

FIGURE 1
HISTORIC USE AREAS
B2-119, B2-120, AND B2-122

SCALE IN METERS

0 3 6

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Attachment 2

RWP Evaluation Form

RWP Task Evaluation Form

1. Areas covered by RWP:
2. Tasks to be performed:
3. Radionuclides of concern:
4. Tools or equipment needed:
5. Approximate start date:
6. Expected task duration:
7. Intrusive work activities:
8. Contamination levels (removable):
9. Contamination levels (total):
10. Radiation levels:
11. Unique or unusual radiation hazards:
12. Potential for airborne radioactive materials:
13. Chemical/physical hazards:
14. Special conditions or permits:

Attachment 3

Audit, Inspection, and Surveillance Procedures

1. PURPOSE

This procedure describes the methods and responsibilities for performing and documenting inspections on project work activities and materials to ensure compliance with established requirements.

2. SCOPE

This procedure applies to inspections performed during the course of performing project work activities.

3. REFERENCES

- EI-MAN-Q001, *Quality Management System Manual*
- EIP-Q-004, “Receipt Inspection”
- EIG-Q-007, “Nonconformance Reporting”
- E&I Construction Inspection Procedures & Checklists

4. DEFINITIONS

- **Inspection**—Examination or measurement to verify whether an item or activity conforms to a specified requirement(s).
- **Inspector**—Personnel performing inspection activities with the necessary expertise in the area to be inspected.
- **Record**—A document stating results achieved or providing evidence of activities performed.
- **Definable Feature of Work**—A task that is separate and distinct from other tasks and has separate control requirements.

5. RESPONSIBILITIES

5.1 Responsible Manager

The Responsible Manager or assigned personnel must ensure that an adequate inspection program is established for the work and is in full support of inspection activities. The Responsible Manager is also responsible for scheduling and providing prior notification to inspection personnel when items, systems, or activities requiring inspection are approaching readiness. The Responsible Manager may be the Project Manager, Construction Manager, Project Engineer, or other qualified designated personnel, depending on the project.

5.2 Project Quality Representative

The Project Quality Representative or assigned personnel is responsible for performing or verifying the status of inspections and tests performed during project activities, and for controlling and recording the unique identification of items where traceability is required.

5.3 Inspectors

Inspectors shall be responsible for conducting inspections in accordance with established criteria. Inspectors shall be responsible for maintaining any external credentials/qualifications for performing inspections deemed necessary by responsible management. Inspectors are

responsible for notifying the Responsible Manager if their qualifications have lapsed or if they are no longer qualified to perform a valid inspection.

6. PROCEDURE

6.1 Qualification of Inspectors

The inspector shall have the necessary expertise and qualifications in the area to be inspected and shall be sufficiently independent of the activity performed.

Prior to the performance of inspection activities, personnel designated for that responsibility shall review and be thoroughly familiar with the procedures, regulations, etc. governing the activities to be inspected.

6.2 Inspections

Inspection activities will be used to monitor project activities and materials. The objective of inspections is to determine whether the properties or composition of materials, or performance of activities, are within established requirements. Inspections shall be performed and documented as required by quality control activities and project requirements. Inspections shall be scheduled and performed to prevent unintended use or installation, to provide monitoring, to minimize delays in work, and to identify nonconformances while they are still correctible without significantly impacting work.

6.2.1 Inspection Requirements and Criteria

Inspections shall be performed upon materials or services to determine compliance with contractual, planning, or other requirements. Materials inspections may include evaluating the quality of components, material assemblies, supporting documentation, and/or techniques employed and verifying installation or performance under specified test conditions. Inspections related to services will include continuous monitoring and review of the service provided. Evaluations will be based upon requirements in the contract or other procurement documentation.

Inspection criteria shall be established prior to the inspection and shall be based upon project specifications, requirements, code specifications, and product acceptability. Acceptance criteria shall be adequate for the material or activity and shall be verified during inspection activities.

Inspections may be performed and verified through visual observation, measurement of materials or equipment, examination of documentation/certifications, evaluation of performance, or testing. Testing may be destructive or nondestructive, and it may be performed on samples taken of materials or may be performed in situ.

6.2.2 Inspection Performance and Documentation

The number and extent of Inspections shall be based upon the complexity of the item or task. Inspections shall be documented, preferably through the use of checklists. An example of an inspection checklist is provided in Section 8. A comprehensive series of generic construction inspection procedures can be found on Governance > Policies and Procedures > Quality Assurance Policies and Procedures > Construction Quality Proceduresand checklists may be found on Governance > Policies and Procedures > Environmental & Infrastructure > QA/QC Forms > Construction Quality Forms on the Shaw intranet. Inspections shall consider and document the following, as applicable:

- Name of project and contract or project number
- Type of inspection to be performed
- Evaluation criteria

- Date of the inspection
- Specification, requirement, or process to be examined
- Pass or fail criterion
- Results of inspection
- Identification of inspectors

6.2.3 Receiving Inspection

Receiving inspections include the examination or measurement of materials from suppliers and vendors. A receiving inspection is performed to verify that materials, parts, components, and assemblies meet specifications and contract requirements. This inspection will be performed for materials where specifications and/or quality requirements have been provided in procurement documentation. Additional information regarding procurement and receiving inspections is provided in Procedure No. EIP-Q-004, "Receipt Inspection."

Items and materials that are purchased and brought on site by a subcontractor shall be inspected. The inspection will ensure the items meet the specifications and requirements in planning, contractual, and/or procurement documents.

6.3 Three-Phase Inspection Process

If warranted by contract requirements or the complexity of the project, the Project Quality Representative, in collaboration with the Project Manager, may require implementation of the Three-Phase Inspection process. This process includes preparatory, initial, and follow-up inspections conducted for inspection elements referred to as "Features of Work." Inspections shall be performed as required and shall be documented on the inspection checklist. This approach is further explained in the following sections. A three-phase inspection shall include the requirements as specified in this section as well as the requirements specified in the above preceding sections.above.

6.3.1 Preparatory Inspections

Preparatory inspections will include all the prerequisites prior to starting any feature of work. A preparatory meeting is usually held prior to beginning work on each definable feature of work to ensure that there is a mutual understanding of the level of quality expected. The inspections shall be performed by the Shaw E & I staff and all associated lower-tier subcontractors. These inspections include the following:

- A review of the scope of work, specifications, and contract requirements with project personnel
- Verification that provisions have been made to provide required field control testing and inspection
- Documented tolerances and workmanship standards
- Examination of the work area to ascertain that all preliminary work has been completed
- Verification of field dimensions, lines, and grades
- Physical examination of materials and equipment
- Confirmation of measuring and test equipment calibrations
- Assurance that required hazards analyses and safety inspections have taken place and been passed

6.3.2 Initial Inspections

Initial inspections are performed when work begins on a particular feature of work. An initial phase meeting should be held at the beginning of each definable feature of work. The initial inspections include an examination of the quality of workmanship and a review of control testing for compliance with contract and work plan requirements. The initial inspection will include the following:

- Establishing the quality and level of workmanship required
- Verifying that acceptable workmanship standards and contractual requirements are met
- Verifying required control inspection and testing requirements
- Verifying compliance with the activity hazard analysis and safety plans

Daily reports will be completed to ensure that control activities are working to provide continued compliance until completion of the task. Deficiencies shall be documented in the report. The Responsible Manager will propose corrective actions and ensure their completion. Inspections and test statuses will be clearly indicated on daily reports and inspection records. Nonconforming items shall be clearly marked or identified appropriately.

6.3.3 Follow-up Inspections

Follow-up inspections are performed at appropriate intervals as the work progresses on any particular definable feature of work to verify compliance with contract requirements. As-built drawings will be checked for accuracy as required during this phase. The inspections will continue until completion of that feature of the work. Final follow-up inspections will be conducted and all deficiencies corrected before the start of additional features of work that may be affected by the deficient work.

6.3.4 Reporting

Documentation of completed inspections shall be included in the daily report when required. When appropriate, additional drawings or inspection information may be attached to the inspection documentation.

Items or activities not conforming to inspection acceptance criteria will be resolved and, when determined necessary, documented as a nonconformance in accordance with Procedure No. EIG-Q-007, “Nonconformance Reporting.” The Nonconformance Report should be referenced on the Daily Quality Control Report.

6.4 Disposition and Corrective Actions

Items, activities, or services that do not meet inspection objectives or requirements will be documented, and corrective actions will be performed. Discrepancies discovered during inspection activities will be resolved by corrective actions which must be completed prior to the start of additional work if future work is affected. The extent of corrective actions must be appropriate for the magnitude of the condition and associated risk factors. Discrepancies that meet the criteria for a nonconformance will be handled in accordance with Procedure No. EIG-Q-007.

7. ATTACHMENTS

None

8. FORMS

- EIP-Q-005.01, Inspection Checklist

9. RECORDS

- EIP-Q-005.01, Inspection Checklists/Report
- Nonconformance Report

10. REVISION HISTORY AND APPROVAL

Revision Level Revision Date	Revision Description	Responsible Manager
00 4/14/2003	Initial issue	Cheryl Prince
01 02/15/2007	Reference to: Shaw Procedure No. PR310, Receipt of Supplies, Materials, and Services was added. Definition for Definable Feature of Work was added, responsibility title changes, extensive revision to procedure.	Bryan Koehler
02 01/04/2012	Modified format to align with Governance Management framework. 3.0 Added x-reference for EIP-Q004, Receipt Inspection & generic construction inspection procedures and checklists 6.2.2 Added x-reference for construction inspecton procedures and checklists	Bryan Koehler

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Uncontrolled when printed: Verify latest version on ShawNet/Governance

PROJECT NAME: [Project Name]	PROJECT NUMBER: [Project Number]	CONTRACT NO: [Contract Number]
LOCATION: [Location]		
FEATURE OF WORK: [Feature of Work]		SPECIFICATIONS: [Specifications]

Requirements/Reference	Hold Pt.*	Org.	Initials	Remarks
Preparatory/Initial/Follow-up (circle one) Inspection				
1.		Shaw E & I		
2.				
3.				
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11.				
12.				
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25.				

*Hold Point—Requires the checklist item to be answered YES for conforms or NO for does not conform

Identification of Participating Organizations

Shaw E&I Personnel _____

Shaw E&I Project Contractor Personnel _____

Client Representative _____

_____ _____

Project Quality Representative Date

1. PURPOSE

The purpose of this procedure is to provide instructions for performing and documenting the surveillance of project activities and functional areas.

While less formal than a quality assurance audit, a typical surveillance should provide an independent evaluation of items, activities, or processes (to include contractors) for conformance to specified requirements. Surveillances may be scheduled to supplement Shaw's Environmental & Infrastructure (Shaw E&I) Group Audit Program. Surveillances are initiated at the direction of a responsible level of management (Management Sponsor).

2. SCOPE

This procedure is applicable when conducting surveillances on Shaw E&I projects and functional areas. Surveillances may be completed by project personnel or Corporate Quality Services personnel. Quality Audits are managed in accordance with EIG-Q-009. Management Assessments are managed in accordance with EID-Q-014.

3. REFERENCES

- EIG-Q-007, "Nonconformance Reporting"
- EIG-Q-008, "Corrective Action Requests"
- EIG-Q-009, "Quality Audits"
- EID-Q-014, "Management Assessment"

4. DEFINITIONS

- **Assessor—**Individual assigned by Quality Services management or the management sponsor to plan and conduct surveillance activities, and report results. Individuals are selected based on experience or familiarity with areas included in the scope. Assessors may be resources from Corporate, projects, or qualified third parties.
- **Opportunity for Improvement (OFI)—**A recommendation for improvement not based upon requirements but focused upon process improvement opportunities. An OFI may also be a statement of fact regarding the potential for a noncompliance which could lead to a more serious problem if not identified and/or corrected, but which does not constitute a lack of compliance with established requirements.
- **Surveillance**—Monitoring and/or verifying methods, procedures, and or processes for further assurance of effective implementation and suitability.

5. RESPONSIBILITIES

5.1 Audit Program Manager

The Corporate Audit Program Manager is responsible for managing the E&I Surveillance Program for corporate sponsored surveillances. The Audit Program Manager is in the Quality Services functional department and reports to the Director of Quality Services. Responsibilities include scheduling, resource planning, and tracking of resolution of issues identified during surveillance activities.

5.2 QA Managers

QA Managers are responsible for providing the Audit Program Manager with input for corporate sponsored surveillance scheduling and scope. QA Managers should include the Audit Program Manager on distribution for surveillance reports completed for their areas of responsibility. QA Managers are responsible for assisting assessors with performance of surveillance activities at their respective office locations and on their respective projects. QA Managers will assume the responsibilities of the Audit Program Manager for the management of surveillances at their assigned projects and/or offices.

5.3 Responsible Manager

The Responsible Manager shall provide access to all personnel and material required for the performance of surveillance activities. This is to include any necessary training, clearances, and restrictions to include any photography limitations. He or she shall also ensure necessary and timely corrective action for any condition documented as adverse to quality. He or she shall disseminate any relevant corrective actions or lessons learned to their affected organizations to preclude recurrence.

5.4 Assessment Team Lead

The Assessment Team Lead should plan and schedule the surveillance and provide leadership for the team, when there is more than one assessor. Whenever possible, surveillance activities should be performed in a manner that is not disruptive to ongoing work or operations.

5.5 Assessor

Assessors should prepare for the surveillance by reviewing documents relevant to their assigned scope. Assessors shall follow directions of the Assessment Team Lead and conduct themselves in a professional manner consistent with the conduct of audits.

5.6 Management Sponsor

Surveillances shall be initiated at the request of a responsible level of management. This typically includes project managers, quality managers, functional directors, and business line senior management. Objectives of the activity should be defined.

6. PROCEDURE

Surveillances shall be based upon requirements and shall be performed to assess the conformance of an activity or function to the specified requirements as outlined in the attached flow chart. Surveillances are typically initiated by the request of a management sponsor or by a management approved schedule (i.e., work plan, quality plan). Surveillances may be corporate sponsored activities or activities initiated and completed within a specific project based on project management/project quality management input. Surveillances generally include the observation of real-time activities and/or the review of supporting documentation. Surveillances should be performed by an individual(s) who does not have direct responsibility for the activity subject to the surveillance.

Surveillances should be planned for in advance; however, emergent conditions may warrant an unplanned surveillance.

6.1 Planning

The Management Sponsor should be consulted to ensure the objectives of the surveillance are understood. Surveillance planning should include review of all documents and requirements relative to the subject and scope of the surveillance. Documents to be reviewed should include, but not be limited to, the following, as applicable:

- Shaw E&I Quality Management System Manual
- Shaw procedures that apply to the activity, product, or service
- Legal and contractual documents
- Specifications
- Codes, standards, or regulatory requirements
- Project work plans, instructions, drawings, and project specific procedures
- Project quality plans

A Quality Assurance Surveillance Plan (Form EIP-Q-006.02, or equivalent) should be completed to organize surveillance planning information.

6.2 Preparation

Based upon the scope and the documented requirements, the Assessment Team Lead shall determine the method for conducting the surveillance. Methods may include conducting personnel interviews, observing activities, and/or reviewing documentation.

Checklists or other aids should be developed to assist in determining conformance to requirements (Form EIP-Q-006.01, or equivalent). Checklists may be developed new or may consist of a requirement document used as a guide during the review. Checklists should include or reference the document and section from which the requirement originates.

Responsible management of the organization/area to be evaluated should be notified of surveillance logistics and scope by memorandum or e-mail. Attachment 2 provides a representative example. Communication of surveillances to vendor/suppliers shall be managed through the Shaw Contracts representative.

6.2.1 Surveillance Numbering

6.2.1.1 Corporate Sponsored Surveillances

For corporate sponsored surveillances, a surveillance number shall be obtained from the E&I Audit Program Manager during surveillance planning and recorded in the applicable log for tracking purposes. Format of surveillance numbering is as follows:

EI–S-AAA-XXX-FY-NN

Where:

EI denotes Environmental & Infrastructure Group
S denotes Surveillance
AAA denotes Surveillance Type (QMS; Process [e.g., list Design, Procurement, Records, etc.]; PROJ[Project])
XXX denotes Office or Project Abbreviation
FY denotes last two digits of fiscal year (i.e., 11 for 2011)
NN denotes sequential number provided by the Audit Program Manager

6.2.1.2 Vendor/Supplier Surveillances

For vendor/suppliers/subcontractor surveillances, the following numbering scheme shall be used:

EI-YR-VENDOR TITLE-QS (periodic monitoring of supplier performance as an approved supplier for the Company); or insert Project Designator (if auditing subcontractor at a specific project);

insert the sequential number provided by the Audit Program Manager.
(Example: EI-11-COMPANY-PROJ-S-01).

6.2.1.3 Project Surveillances

In instances where a project specifies requirements for surveillance numbering within their own quality program, the internally generated documentation shall be numbered in accordance with those unique requirements. The Project shall be responsible for logging and tracking surveillances.

6.3 Performance

Assessors shall use the following methods, as applicable to meet the surveillance objectives:

- Observe real time work performance or operational activity when possible.
- Review the supporting documentation and records as available.
- Conduct interviews with knowledgeable individuals.
- Based upon observations and reviews, determine the degree of conformance to the applicable requirements. Consider the potential consequences of not meeting requirements (impact to client requirements or mitigating Shaw's performance risk).
- Document this determination on the checklist and surveillance report.
- Photographs may be used to augment surveillance observations. Photographs should be documented by photographer, date, brief description of relevance of the photo.
- Include a reference to the documentation or activity reviewed and the personnel contacted on the checklist.

The surveillance should be performed in the time-frame initially established, when possible. Deviations from the schedule should be coordinated with responsible management of the area being evaluated.

6.4 Reporting

Efforts should be made during the surveillance process to clearly communicate observations to responsible supervision. A post-surveillance briefing shall be offered to the Responsible Manager and Management Sponsor to review results and any issues or deficiencies. This briefing should be verbal and may include a written draft summary.

Documentation of surveillance activities shall be sufficient to document "as-is" conditions so that someone other than the individual completing the surveillance would be able to reach a similar conclusion. Documentation of surveillance results may include general observations, nonconformances, corrective action requests, and opportunities for improvement.

Surveillance activities shall be documented on a final surveillance report. The Surveillance Report and documentation of any resultant deficiencies shall be completed within 30 days and presented to the Responsible Manager. Additional distribution, to include the client, shall be at the discretion of the responsible manager and the management sponsor. Checklists, if used, shall be retained in project files. A typical surveillance report format is provided as Attachment 2 to this procedure. The format may be modified as needed.

6.5 Corrective Action

An item, condition (e.g. in-process corrective actions), or material that deviates from drawings, specifications, or other requirements and which can be readily corrected within the scope of such

documents shall be corrected and documented in the surveillance report as an "in process corrective action."

Items, conditions, or materials that cannot be readily corrected shall be documented as a deficiency. Items that meet the criteria of reporting in accordance with Procedure No. EIP-Q-008, "Corrective Action Requests," or Procedure No. EIG-Q-007, "Nonconformance Reporting," shall be handled in accordance with the applicable process procedure.

The Responsible Manager is responsible for responding to the deficiency and for determining and implementing corrective actions. Corrective actions shall be sufficient to correct the issue or nonconformance and shall be completed and documented in a timely manner.

The Assessment Team Lead shall review and verify corrective actions performed prior to closure. Deficiency, corrective action performance, verification, and closure shall be documented and the deficiency status tracked until closed.

6.6 Records

Records generated as a result of this procedure shall be retained in a Central Filing System, unless otherwise specified (e.g., contractually-specified records management requirements, attorney-client work product). Records to be maintained include the following:

- Surveillance Notification
- Surveillance Plan
- Surveillance Report
- Checklists or annotated guidance documentation are required to be maintained only if needed as additional support for report conclusions.

7. ATTACHMENTS

- Attachment 1, Surveillance Process
- Attachment 2, Surveillance Notification (typical format and content)
- Attachment 3, Surveillance Report (typical format and content)

8. FORMS

- EIP-Q-006.01, Surveillance Checklist
- EIP-Q-006.02, Surveillance Plan

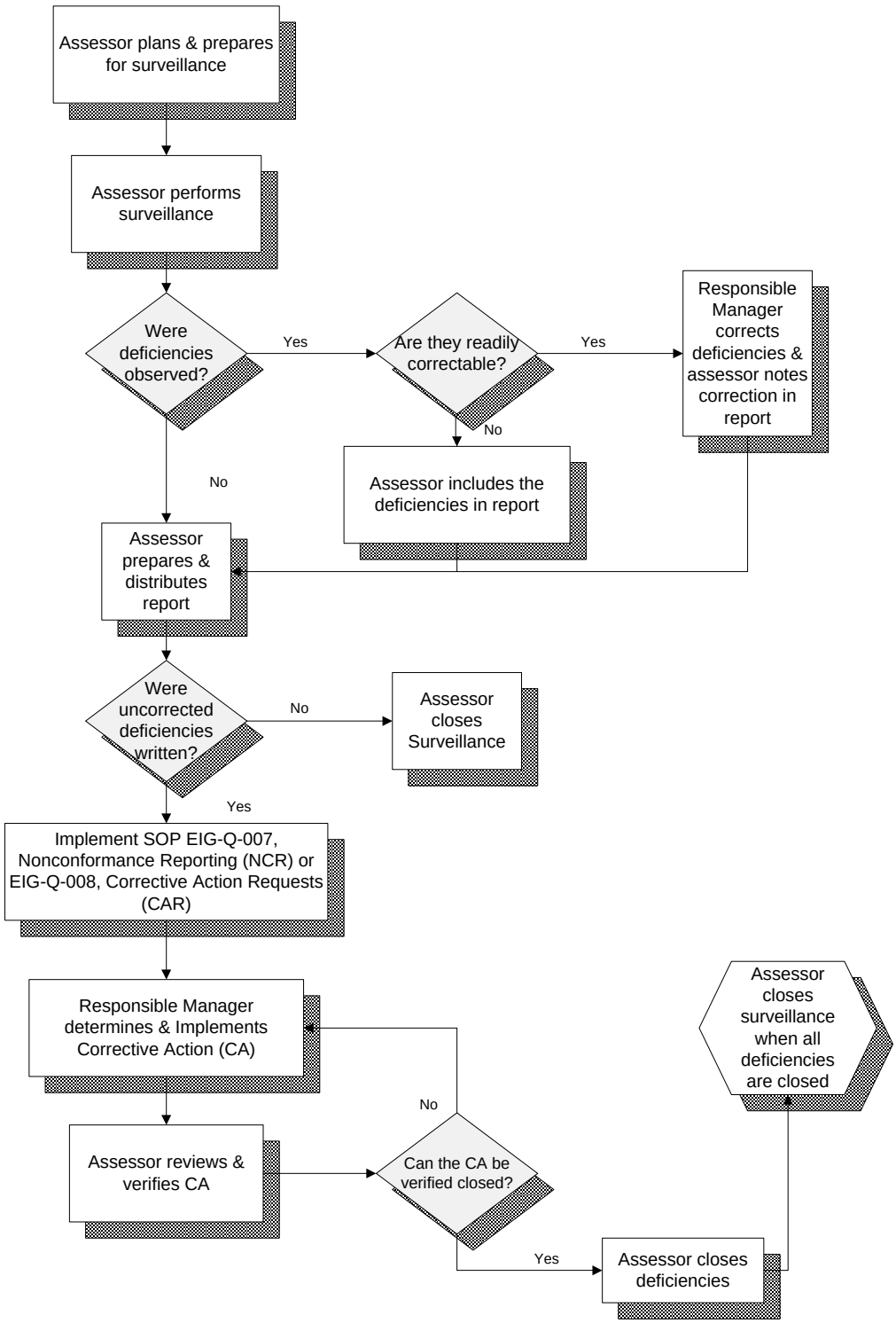
9. RECORDS

- Surveillance Notification
- Surveillance Report
- EIP-Q-006.01, Surveillance Checklist
- EIP-Q-006.02, Surveillance Plan

10. REVISION HISTORY AND APPROVAL

Revision Level Revision Date	Revision Description	Responsible Manager
00 8/22/2003	Initial issue	Cheryl Prince
01 02/15/2007	Numbering nomenclature updated. Sections 2 and 3 were revised. Major re-write of procedure.	Bryan Koehler
02 12/27/2011	Extensive revision. Also modified format to align with Governance Management framework.	Bryan Koehler

Attachment 1
Surveillance Process Flow



Attachment 2
Surveillance Notification Memo (typical format and content; e-mail may also be used)

Date: Month Day, Year

To: Management of Organization to be Evaluated
E&I Title or External Company Name

From: Assessment Team Lead

Re: E&I Quality Assurance Surveillance EI–S-AAA-XXX-FY-NN
Title or Subject

Shaw E&I Quality Services has scheduled a Quality Assurance Surveillance at [insert location] on [insert dates]. There will be a pre-surveillance entrance briefing [insert day, time, and location]. A post-surveillance briefing is tentatively scheduled for [insert day, time, and location]. Please provide this notification information to individuals in your organization that have not been included on distribution that should be made aware of the information.

The purpose of the surveillance is to [insert brief summary of surveillance purpose and scope including a list of specific activities or areas to be reviewed].

The team consists of [insert name] , Assessment Team Lead, and [insert names of other team members and roles such as Technical Specialist].

[Describe any actions needed by the organization to be evaluated such as logistics arrangements for the team, communications/computer equipment support needed, records retrieval support needed, tours, etc. These requests should generally be discussed prior to issuance of the notification with responsible personnel; agreed upon prior arrangements may not be discussed in the notification letter].

Should you have any questions, please contact me at [insert Assessment Team Lead phone number] or e-mail [insert Assessment Team Lead e-mail address].

cc: [Management of Evaluated Area (1 level above addressee of organization to be audited)]
[Management Sponsor (management requesting surveillance activity)]
[E&I Quality Services Director]
[E&I Audit Program Manager]
[Applicable Quality Assurance Managers]
[Applicable Project Manager]
[Applicable Sub-contract Administrator (for surveillances of sub-contractor activities)]
[Surveillance Team Members]
[Surveillance File]

****Distribution should be in alphabetical order when populated.**

Attachment 3
Surveillance Report (typical format and content)

Date: [Month Day, Year]

To: [Responsible Management of Surveillance Area]

From: [Assessment Team Lead]

Subject: Quality Assurance Surveillance of [Insert Function, Organization, or Project Title] [EI–S-AAA-XXX-FY-NN]

A Quality Assurance (QA) Surveillance was performed at the [Insert Location] on [Insert Dates] . The surveillance was performed by (Insert surveillance team member names/titles). The purpose of this QA surveillance was to evaluate (Insert purpose and scope of surveillance activities and associated project or activity). Applicable criteria/requirements included the following: (Provide a bulleted list of contracts, specifications, E&I procedures and titles, etc.).

-
-

Summary of Results

Overall, surveillance results indicate that (Organization or company) is managing the majority of the (insert as applicable: quality and operations programs) in a manner that meets (or does not meet) the minimum requirements stated in the referenced procedures and specifications. Surveillance activities identified (insert conclusions, e.g., weaknesses in Shaw's application of required training, inspections, etc.). (Ensure discussion of conclusions with basis for conclusions. Significance or impact of items identified should be discussed in the summary).

Attachment (A) provides the listing of surveillance participants. Attachment (B) provides a list of documents reviewed during surveillance activities. Attachment (C) includes copies of corrective action/nonconformance documentation for issues identified during surveillance activities.

The following table provides a brief summary of deficiencies identified during the surveillance that warrant a formal response:

Deficiency Document No.	Subject matter	Abstract	Action assigned to
(Insert Corrective Action Document Number, e.g., NCR, or CAR).	(Insert title of scope area where deficiency was identified, e.g., Training, Design Control, Inspection, etc.)	(Insert a concise description of deficiency identified).	(Insert name/title of individual responsible for correction of the identified issue).

Response is required for the above CARs by close of business (Insert agreed upon date for response to Quality Services). The response must address:

1. Cause of Problem

2. Extent of condition
3. Corrective and preventive actions that have been or will be taken
4. Title of person(s) assigned responsibility for taking the above actions
5. Actual or scheduled implementation dates for those actions

(If applicable, include a summary listing Surveillance Opportunities for Improvement that don't require a response to Quality Services). Example:

The following Opportunities for Improvement were identified during surveillance activities. These items do not warrant formal response to Quality Services; however, should be further evaluated by your organization:

OFI #	Subject matter	Abstract
(Insert sequential OFI #)	(Insert title of scope area where OFI was identified, e.g., Training, Design Control, Inspection, etc.)	(Insert a concise description of Opportunity for Improvement).

Please direct questions to [Name of Assessment Team Lead] (telephone number, e-mail address).

Respectfully Submitted:

_____

[Name of Assessment Team Lead]
[E&I Title]

Distribution: [Management of Evaluated Area (1 level above addressee of organization to be audited)]
[Management Sponsor (management requesting surveillance activity)]
[E&I Quality Services Director]
[E&I Audit Program Manager]
[Quality Managers (Office or Project Location)]
[Assessment Team Members]
[Surveillance File (Project and Central Location)]

Report Attachments:

Attachment A, Surveillance Participants

Attachment B, Documents Reviewed

Attachment C, Deficiency Reports (CARs, NCRs, etc.)

Surveillance Report, Attachment A
Surveillance Participants

Name/Title or Company	Entrance	Surveillance	Exit

Surveillance Report, Attachment B
Documents Reviewed
(List titles, revisions, and/or applicable dates)

Document Title/Applicable Number	Revision/and Date if noted

Surveillance Report, Attachment C

(Attach individual deficiency documents generated)

Shaw a world of Solutions	Title: Quality Assurance Surveillance Checklist	Form No: EIP-Q-006.01_2

Uncontrolled when printed: Verify latest version on ShawNet/Governance

Surveillance Title (Project Name/Organization/Function//Location as applicable): **Surveillance Date(s):**	**Surveillance Personnel:**

Surveillance No: EI–S-AAA-XXX-FY-NN **Project Number (if applicable):** ######

Item #.	Line of Inquiry (Include activity observed, reference requirement, etc.)	Status	Summary of Observations/Objective Evidence Reviewed/Notes (Include individuals contacted)

QUALITY ASSURANCE SURVEILLANCE PLAN	
Surveillance Number:	Organization:
Project/Contract Number (as applicable):	Location:
Surveillance Title/Scope:	

SURVEILLANCE PERSONNEL	SURVEILLANCE SCHEDULE
Assessment Team Lead: Technical Specialist:	Dates: Pre-Surveillance Briefing: Time: Post-Surveillance Briefing: Time:
Criteria/Reference Documents:	
Follow-up Items:	Special Concerns/Items:

SURVEILLANCE TEAM ASSIGNMENTS
Assessment Team Lead : Assessor: Technical Specialist:

SURVEILLANCE PLAN APPROVAL	
Assessment Team Lead :	Date:

1. PURPOSE

This procedure establishes the requirements for a comprehensive system of planned and documented quality audits to verify the effectiveness of the Quality Management System, mitigate performance risk, and promote continual improvement. The procedure also establishes requirements for audits of projects and subcontractors including verification of compliance to E&I procedures and applicable client contract requirements.

2. SCOPE

This procedure is applicable when conducting quality audits on the Shaw E & I Quality Management System, Shaw E & I functional areas (i.e., procurement; design; records), projects, and of Shaw E & I vendors/suppliers. Surveillances shall be conducted in accordance with procedure number EIP-Q-006, "Surveillance". Management assessments shall be conducted in accordance with procedure number EID-Q-014, "Management Assessment."

3. REFERENCES

- Shaw E&I Quality Management System Manual, EI-MAN-Q-001
- Shaw Procedure No. EIP-Q-006, "*Surveillance*"
- Shaw Procedure No. EIP-Q-007, "*Nonconformance Reporting"*
- Shaw Procedure No. EIG-Q-008, "*Corrective Action Requests*"
- Shaw Procedure No. EID-Q-010, "*Auditor and Lead Auditor Qualification Program*"
- Shaw Procedure No. EID-Q-014, "*Management Assessment*"

4. DEFINITIONS

- **Audit**—Systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
- **Audit Criteria**—Set of policies, procedures, or requirements used as a reference.
- **Audit Evidence**—[qualitative or quantitative] Records, statements of fact, or other information that are relevant to the audit criteria and verifiable.
- **Audit Team**—A group comprised of an Audit Team Lead, Auditors, and/or Technical Support/Specialists.
- **Audit Team Lead**—An individual assigned to organize and direct audits, report audit findings, and evaluate corrective action.
- **Auditor**—Person with the competence to conduct audit activities.
- **Conformance (or conformity)**—Fulfillment of a requirement.
- **Corrective Action**—Action to eliminate a detected nonconformity; often action to eliminate the cause of a detected nonconformity, or other undesirable situation.
- **Effectiveness**—Extent to which planned activities are realized and planned results achieved.

- **Finding**—A documented statement of fact concerning a noncompliance or deviation from established requirements.
- **Lead Auditor**—An individual who is formally qualified to organize and direct audits, report audit findings, and evaluate corrective action.
- **Nonconformity**—Non-fulfillment of a requirement. Nonconformities may be classified based on significance in accordance with E&I procedures. Nonconformities may include nonconforming items as well as processes.
- **Objective Evidence**—Data supporting the existence or verity [actuality or truth] of something.
- **Opportunity for Improvement (OFI)**—A recommendation for improvement not based upon requirements but focused upon process improvement opportunities. An OFI may also be a statement of fact regarding the potential for a noncompliance which could lead to a more serious problem if not identified and/or corrected, but which does not constitute a lack of compliance with established requirements.
- **Record**—Document stating results achieved or providing evidence of activities performed.
- **Surveillance**—Monitoring and/or verifying methods, procedures, and/or processes for further assurance of effective implementation and suitability.
- **Technical Specialist**—Person assigned to the audit team due to the specialized or technical aspects of the areas to be audited. Technical Specialists are selected based on knowledge, special abilities, specialized technical training, and/or prior experience in the technical aspect of the area to be audited.

5. RESPONSIBILITIES

5.1 Director of Quality Services

The Director of Quality Services is responsible for ensuring that an audit program is established and implemented. The Director of Quality Services is responsible for the development and maintenance of this procedure. Sufficient personnel will be qualified and available to implement the program. The Director of Quality Services is responsible for assuring that audit reports and associated findings are analyzed and identified trends reported to corporate management. The Director of Quality Services is responsible for Auditor/Lead Auditor certification of the Audit Program Manager.

5.2 Audit Program Manager

The Audit Program Manager is responsible for managing the E&I Audit Program, including schedule development and maintenance, coordination of audit team lead and team member assignments, participation in audits, qualification and certification of Auditors and Lead Auditors, tracking of audit findings through closure, and trending audit results. The Audit Program Manager will counsel auditors, develop audit guidance, and promote the professional development of audit personnel.

5.3 QA Managers

QA Managers are responsible for providing the Audit Program Manager with input to the annual audit schedule. QA Managers should include the Audit Program Manager on distribution of audit reports completed for their areas of responsibility. QA Managers are responsible for assisting audit teams with performance of audits at their respective office locations and on their respective projects. QA Managers may coordinate and/or participate on audits in regions and projects for which they are responsible.

5.4 Responsible Manager

The Responsible Manager shall provide access to all personnel and material required for the performance of audit activities. This is to include any necessary training, clearances, and restrictions to include any photography limitations. He or she shall also ensure necessary and timely corrective action for issues identified during audit activities. He or she shall disseminate any relevant corrective actions or lessons learned to their affected organizations to preclude recurrence.

When requested by the audit organization in the audit report, responsible management shall respond in writing indicating planned, completed, and/or preventive actions to address identified issues, cause(s) of identified issues, and a schedule for completion of associated corrective actions.

5.5 Audit Team Lead

The Audit Team Lead, or Lead Auditor, is assigned responsibility for managing a specific audit and making final decisions regarding the conduct of the audit and any findings. Specific responsibilities include assisting with selection of other audit team members, preparing the audit plan, representing the audit team with audited area management, submitting the audit report, and ensuring evaluation of audit responses and verification of resolution of findings. The Audit Team Lead, in coordination with the Audit Program Manager shall, within their discretion, escalate any issues to an appropriate level of management to help facilitate timely cooperation.

The Audit Team Lead for all corporate sponsored audits shall be a qualified Shaw E&I Lead Auditor. Lead Auditors shall be qualified and certified in accordance with Procedure No. EI-Q-010, “Auditor and Lead Auditor Qualification Program.”

5.6 Auditor/Technical Specialist

The Auditor/Technical Specialist(s) shall prepare for the audit by reviewing documents relevant to their assigned scope. The Auditor/Technical Specialist(s) shall follow directions of the Audit Team Lead and conduct themselves in a professional manner.

5.7 Management Sponsor

Audits shall be initiated at the request of a responsible level of management, identified as the Management Sponsor. This typically includes executive management, Operations Management, and Business Management leadership. Audit scope should be defined by the Management Sponsor in conjunction with the Responsible Manager and the Audit Team Lead.

6. PROCEDURE

6.1 Audit Types, Scheduling, and Numbering

This section provides discussion of different audit types, scheduling details, and numbering conventions.

6.1.1 Audit Types

Audits shall be completed to fulfill the intended objective for a documented, independent, objective evaluation of the extent to which established criteria have been met. This may include audits of the Quality Management System, specific processes, office locations, major projects, vendors/suppliers, and internal project audits. Audits may be completed by corporate resources and project resources.

6.1.1.1 QMS Audits/Process Audits

Corporate audits shall be scheduled and conducted to determine the effectiveness of the implementation and maintenance of the Quality Management System (QMS). The schedule will consider the status and importance of the processes and areas to be audited, as well as the results of previous audits. The scope of audits should consider significant changes in management, organization, policy, or requirements that could affect effectiveness of the Quality Management System.

6.1.1.2 Office Location Audits

A specific office audit may be performed to assess the execution of processes and projects managed from that location.

6.1.1.3 Corporate Sponsored Project Audits

Corporate sponsored audits of selected field site projects may be completed. They are typically scheduled when activity reaches a level where the results and potential corrective actions from the audits would provide benefit to the project. Such audits may be performed to verify compliance to E&I requirements, client requirements, or to evaluate subcontractor performance to project and contract requirements.

6.1.1.4 Vendor/Supplier Audits

Vendor/Supplier audits may be scheduled to assist in the selection of suppliers critical for company activities. Audit scope will vary based on service or product capability. For example, for prospective suppliers, audits may evaluate the supplier's ability to meet contract or purchase order requirements or may assist in determining types and extent of controls needed on the part of the Company beyond programs and processes implemented by the supplier. Vendor/Supplier audits may also be completed to assess ongoing conformance to contract requirements.

6.1.1.5 Project Directed Audits

Project directed audits are usually initiated at the request of the Project Manager or senior management. Audits conducted within projects may be managed by the project team to individual schedules, with project specific records requirements, etc. The Audit Program Manager should be contacted if audit resources are needed outside of the project team.

6.1.2 Scheduling

A corporate audit schedule shall be published by the Audit Program Manager based on the Shaw fiscal year. The corporate audit schedule shall be made available to executive leadership for their review. The schedule will be revised as needed to reflect changes to planned activities, status of completion, importance of activities, results of previous audits, etc.

Audits are scheduled to evaluate effectiveness of implementation of the Quality Management System. All processes defined by the QMS should be assessed during a three year period. Additional audits may be scheduled at the request of Operations or Business Management.

6.1.3 Numbering

6.1.3.1 Corporate Sponsored Audit

For corporate sponsored audits, an audit number shall be obtained from the E&I Audit Program Manager during audit planning and recorded in the applicable log for tracking purposes. Each audit will be uniquely identified. Format of audit numbering is as follows:

EI–AAA-XXX-FY-NN

EI - (Environmental and Infrastructure Group)
AAA - Audit Type (QMS; Process [e.g., list Design, Procurement, Records, etc.]; PROJ [Project])
XXX - (Office or Project Abbreviation)
FY - (last two digits of fiscal year, i.e., 11 for 2011)
NN - (sequential number provided by the Audit Program Manager)

For functional audits of specific QMS functions not specific to one project or office location, use QMS for the designator (e.g., EI-QMS-11-01).

For vendor/suppliers/subcontractor audits, use the following numbering scheme:

EI-YR-VENDOR TITLE-Q (qualification or periodic monitoring of supplier performance as an approved supplier for the Company); or insert Project Designator (if auditing subcontractor at a specific project); insert the sequential number provided by the Audit Program Manager.
(Example: EI-11-VENDOR-PROJ-01).

In instances where a project or office location specifies requirements for audit numbering within their own quality program, the internally generated audit documentation shall be numbered in accordance with those unique requirements.

6.1.3.2 Project Audits

Audits completed by individual projects shall be uniquely identified. Audit numbering may be based on the logic provided for corporate sponsored audits or a systematic approach that meets the needs of the project.

6.2 Audit Planning

Input from the Management Sponsor and the Responsible Manager should be solicited by the Audit Team Leader in developing audit scope. If necessary, the Legal Department should be consulted if the audit should be managed as a business sensitive work product. Audit planning should include review of all documents and requirements relative to the subject and scope of the audit. Documents to be reviewed may include the following, as applicable:

- Shaw E&I Quality Management System Manual
- Shaw E&I procedures that apply to the activity, product, or service
- Legal and contractual documents
- Specifications
- Codes, standards, or regulatory requirements
- Project work plans, instructions, drawings, and project-specific procedures
- Project quality plans
- Project status reports
- Input from senior and/or project management

The Audit Team Lead shall complete and sign an audit plan. A typical audit plan format is provided as Form EI-Q009.1. The audit plan should identify the following:

- Audit Number
- Contract Number (if applicable)

- Audited Organization and Location
- Audit Purpose and Scope
- Audit Personnel (including role on team, e.g., Audit Team Lead, Auditor, Technical Specialist)
- Audit Schedule
- Audit Criteria/Reference Documents (e.g., Quality Management System, regulations, codes, standards, applicable implementing procedures)
- Follow-up items, special concerns/items provided as input by the Management Sponsor, etc.
- Audit Team Assignments

6.3 Audit Preparation

Based upon the scope and the documented requirements, the Audit Team Lead should determine the method for conducting the audit. Methods may include personnel interviews, observing activities, and/or reviewing documentation.

The Audit Team Lead shall ensure that preparations for the audit are complete. The audit team may include auditors, auditors-in-training, and technical specialists. The Audit Team Lead will assure that if other audit team members are selected, they will be prepared prior to performance of the audit. Relevant information for audit preparation may include the audit plan; applicable policies, procedures and instructions; codes, standards, and regulations; contracts and specifications; prior audit reports; or management input. The Audit Team Lead shall ensure that the audit team is familiar with the audited organization and key individuals applicable to the audit scope. The Audit Team Lead shall ensure objectivity and impartiality of audit activities; auditors shall not audit their own work.

The Audit Team Lead is responsible for ensuring that audit checklists sufficiently cover the scope of the audit. New or existing checklists may be used. Existing checklists may be modified to meet the needs of the audit scope. Auditors and technical specialists may support the development of audit checklists. Other acceptable audit methods may be used in lieu of checklists to guide audit activities (e.g., audit objectives/criteria, procedures, work documents). A typical audit checklist format is included as Form EIG.Q-009.02.

6.4 Audit Notification

Appropriate management personnel of the audited organization shall be notified in advance of each audit. Notification shall be documented by the Audit Team Lead. Notification shall include the audit number, objectives, scope, schedule, and team lead and members. A typical audit notification format is included as Attachment 2. Notifications may be transmitted via email; records should be maintained of correspondence. If audit activities include subcontractor or vendor organizations, distribution should include the E&I subcontract administrator. Routing of notification documentation to the subcontract management contact should be handled by the applicable E&I subcontract administrator.

6.5 Audit Process

6.5.1 Pre-Audit Meeting

The Audit Team Lead shall offer to conduct a brief pre-audit meeting with management or supervisory personnel of the organization to be audited to accomplish the following:

- Confirm the audit scope and purpose
- Introduce the audit team

- Meet escorts and contacts
- Discuss any site Health and Safety requirements or concerns
- Discuss the audit sequence
- Establish a tentative time for the post-audit meeting
- Establish channels of communication

6.5.2 Audit Performance

Audits shall be performed by document reviews, personnel interviews, evaluation of products, and direct observations of activities, as applicable. Objective evidence shall be evaluated in sufficient depth to determine if selected elements are being effectively implemented. Details of audit activities should be documented on audit checklists, procedures, photographs, other guidance documents used, or in auditor notes. The checklist is intended as a tool for the audit team to ensure adequate coverage of the audit elements. It is not intended to restrict the team from looking at other areas or deviating from the checklist if questions or issues are identified that warrant evaluation. Completed checklists are intended to provide documented information to support development of the final audit report.

The Audit Team Lead and involved team members shall discuss potential findings as identified with individuals being audited so that any finding(s) reported are accurate and clearly understood. Supporting details must be available for development of audit findings. The Audit Team Lead shall ensure responsible management or appointed audit contacts are kept informed of emerging audit issues.

6.5.3 Post-Audit Meeting

The Audit Team Lead shall offer to conduct a post-audit meeting with management or supervisory personnel of the organization or activity audited. This post-audit meeting should accomplish the following:

- Discuss results of the audit including scope and activities observed
- Present the audit findings
- Discuss significance of findings
- Discuss expectations of reporting and any required corrective action response

6.6 Audit Reporting

The Audit Team Lead shall prepare and distribute a final audit report within 30 working days of completion of the audit (post-audit conference). The Audit Team Lead shall submit the report under cover of a letter or memorandum to the Responsible Manager of the audited organization or activity.

For corporate audits, distribution should include the audited area management; E&I Director of Quality Services; E&I Audit Program Manager, applicable Quality Assurance Managers; project management (if a project); subcontract administrator (if audit of subcontractor); and audit team members. Deviations from the aforementioned distribution should be coordinated with the Audit Program Manager. Correspondence to management of subcontract organizations shall be routed through the subcontract administrator for distribution.

For project audits, distribution should include the Responsible Manager, Project Manager, Quality Assurance Manager, and the Corporate QA Audit Program Manager, as a minimum.

Correspondence to management of subcontract organizations shall be routed through the subcontract administrator for distribution.

A typical format for an audit report cover memo is provided as Attachment 3. The letter or memorandum shall include the following:

- Date of the memo
- Recipient and sender information
- Subject of memo or letter (e.g., audit title and number)
- Brief summary of audit activities and results including Area/Project/Location audited and dates of audit
- Due date for response (if any)
- Distribution information

6.6.1 Report Content

Typical format and content for an audit report is provided as Attachment 4 to this procedure. The Audit Report shall provide the following information, at a minimum:

- Cover Page
  - Audit Number
  - Organization/Activity Audited
  - Location
  - Audit Dates(s)
  - Audit Report Approval
- Audit Report
  - Executive Summary
  - Audit Purpose/Scope
  - Audit Team (including role of each team member)
  - Audit Results (includes activities observed, areas audited, reference documents, conclusions and supporting information)
  - Audit Findings (CARs/NCRs)
  - Opportunities for Improvement (OFIs)
  - Attachments listing Audit Participants (personnel contacted), Documents Reviewed, and copies of corrective action documents issued

6.6.2 Opportunities for Improvement

Opportunities for Improvement shall be included in the text of the Audit Report under the applicable audited element and in abstract form in the associated table.

6.6.3 Audit Finding Reports

The audit report shall document any findings identified as a result of the audit. A Corrective Action Report (CAR) should be used for programmatic or process deficiencies. If a nonconformance is observed (specific hardware related nonconformity), an NCR should be documented to address

the specific nonconforming item. A CAR should also be considered for hardware related issues where a process breakdown caused the deficiency to ensure adequate investigation and resolution of the process deficiency. Reference EIP-Q-007, "Nonconformance Reporting" or EIG-Q-008, "Corrective Action Requests", as applicable, for documentation and processing requirements.

6.6.3.1 Subcontractor Findings

For findings written during an audit of subcontractor activities, further investigation may be needed to determine responsibility and accountability for response to the audit findings. If contract verbiage has not addressed response to noncompliant conditions, then E&I Project Management should be assigned as owner for the deficiency. Consideration should also be given to characterizing lack of effectiveness of E&I project oversight of subcontractor activities in development of such findings.

6.6.3.2 Prospective Supplier Findings

For audits done of prospective suppliers, audited supplier management may not be notified of findings or required to respond if the decision is made by the responsible Company representative that further interaction with the supplier is not desired. The results of supplier audits should be communicated to the E&I Director of Procurement to be considered for future sourcing decisions.

6.6.4 Issues Resolved During the Audit

Audit identified issues that are resolved during the course of the audit should be noted in the audit report. In-process corrective actions taken during the audit to address the identified issue should be included in the discussion. These items should be documented on a corrective action form (CAR or NCR) and documented as verified and closed during the audit; these issues require no further response from the audited organization.

6.7 Audit Finding Response, Follow-up, and Closure

6.7.1 Audit Finding Response

Responsible Managers must develop and approve a written corrective action response to each programmatic or process-related finding issued (CAR/NCR). Approval may be indicated by signature or e-mail cover page for electronic submittals. A written response is required within 30 days of receipt of the audit finding/report. The response must include the following:

- The basic cause(s) that lead to the condition reported in the finding
- The steps that have been or will be taken to correct the condition reported in the finding
- The steps that have been or will be taken to preclude recurrence (if appropriate)
- The dates when indicated action was or will be complete
- Responsible manager approval of response

NOTE: If required information is included on the associated CAR or NCR form, that form may be submitted for review by the Audit Team Lead in lieu of supplemental correspondence.

6.7.1.1 Response Extensions

The audited organization shall monitor the status of the audit response. If more than 30 days is required for completion than originally indicated on a finding response, a documented request for extension and revised due date shall be submitted to the Audit Team Lead (e-mail is acceptable). The response to corporate audits should include the Audit Program Manager on distribution. The

Audit Team Lead shall evaluate the request and make a formal response to the requesting organization.

6.7.1.2 Overdue Responses

When responses are overdue, the Audit Team Lead will notify the responsible organization (and the Audit Program Manager for corporate audits) by e-mail that responses are overdue. The audited organization should request a new response due date.

6.7.1.3 Evaluation of Responses

The Audit Team Lead, upon receipt of responses to audit findings, will coordinate with the Audit Team Members for the evaluation of responses. Audit responses must meet the satisfaction of the Audit Team Lead. Unacceptable audit responses will be documented and distributed to the responsible organization with the reason for rejection within two weeks of receipt of the response. A revised response will be solicited to include a new response due date. The final audit response shall be acceptable to the Audit Team Lead.

6.7.2 Audit Finding Corrective Action Completion, Tracking, Verification, and Closure

Corrective and preventive actions shall be completed as defined in the audit response. Upon completion, the audited organization (Responsible Manager or designee) shall notify the Audit Team Lead. Objective evidence of completed action should be submitted with the notification if possible.

The Audit Team Lead will coordinate with the applicable audit team members for the verification of corrective actions. The Audit Team Lead shall ensure that corrective action implementation is verified and shall document the results of verification. Verification may be performed by evaluation of objective evidence, field inspection, or other methods. Corrective actions that are determined unacceptable will be documented and the reason provided to the responsible organization.

Findings will be closed when the Audit Team Lead determines that corrective actions have been verified as complete.

6.7.2.1 Corrective Action Extensions

The audited organization shall monitor the status of audit corrective actions. If more time is required for completion than originally indicated on the audit response, a request for extension and revised due date shall be submitted to the Audit Team Lead. The Audit Team Lead shall evaluate the request and make a formal response to the requesting organization.

6.7.2.2 Overdue Corrective Action

When corrective actions are overdue, the Audit Team Lead will notify the responsible organization by e-mail that responses are overdue.

6.7.3 Audit Follow-Up

The Audit Program Manager shall track corporate audit related findings until the corrective actions are complete. The Audit Team Lead shall evaluate completed response, corrective actions, and conduct verification activities. Auditors may be assigned follow up and closure activities but the responsibility for closure is maintained by the assigned Audit Team Lead. If verification activities find ineffective or incomplete corrective actions, correspondence on the findings shall be forwarded to responsible audit area management for additional action.

6.7.4 Audit Close-Out

Upon close-out of all Audit Findings, the Audit Team Lead will notify the Responsible Manager from the audited organization by memorandum, e-mail, or letter that all actions are complete, corrective actions have been approved, and that the audit is closed.

6.8 Records

Original records shall be retained in a suitable records management system. The Audit Team Lead shall be responsible for compiling a completed record of the audit. If project requirements mandate that files be maintained at the project location, a copy of audit related information should be forwarded by the Audit Team Lead to the Audit Program Manager. Records required shall include:

- Completed Audit Schedule (end of year status)
- Audit Plan/Checklists (or other supporting documents if needed)
- Audit Report
- Completed Nonconformity/Finding Reports (CARs, NCRs)
- Audit Correspondence (initial response, and correspondence associated with delinquent, incomplete, or completed corrective action)
- Audit Follow up Report (if applicable)

NOTE: Completed checklists, auditor notes, or marked up guidance documents or procedures are not required as permanent records if the audit report includes adequate objective evidence to support report conclusions (e.g., list of documents reviewed, specific activities observed, audit objectives/criteria evaluated and results of each, etc.).

7. ATTACHMENTS

- Attachment 1, Quality Audit Flow Chart
- Attachment 2, Audit Notification (Typical Format)
- Attachment 3, Audit Report Cover Memo (Typical Format and Content)
- Attachment 4, Audit Report (Typical Format and Content)

8. FORMS

- EIG-Q-009.01, Audit Plan
- EIG-Q-009.02, Audit Checklist

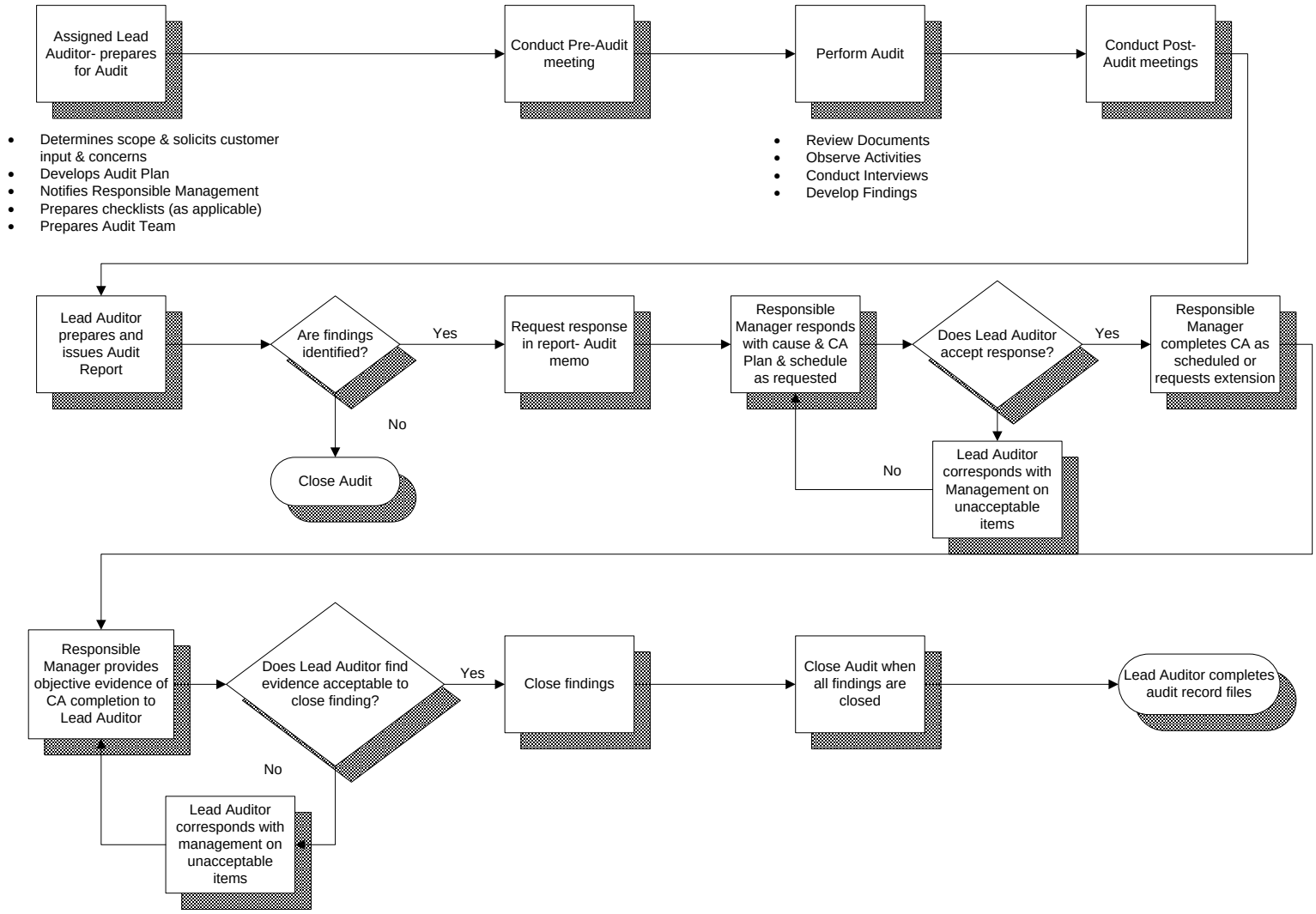
9. RECORDS

- EIG-Q-009.01, Audit Plan
- EIG-Q-009.02, Audit Checklist
- Audit Notification
- Audit Report Cover
- Audit Report

10. REVISION HISTORY AND APPROVAL

Revision Level Revision Date	Revision Description	Responsible Manager
00 04/14/2003	Initial issue	Cheryl Prince
01 02/15/2007	Section 1 Purpose updated, Section 3 References updated, Definitions for Opportunity for Improvement (OFI) and Proficiency were added. Procedure was revised. Attachment 1, Quality Audit Flow Chart was added.	Bryan Koehler
02 01/06/2012	Extensive Revisions. Modified format to align with Governance Management framework.	Bryan Koehler

Attachment 1
Quality Audit Flow Chart



Attachment 2
Audit Notification

To: Management of Audited Organization
E&I Title or External Company Name

From: (Insert Name), Audit Team Lead

Date: (Insert Month, Day, Year)

RE: E&I Quality Assurance Audit (Insert Audit Number and Title/Subject)

Shaw E&I Quality Services has scheduled a Quality Assurance Audit at (*insert location*) on (*insert dates*). There will be a pre-audit entrance meeting *(insert day, time, and location).* A post-audit conference is tentatively scheduled for *(insert day, time, and location).* Please provide this notification information to individuals in your organization that have not been included on distribution that should be made aware of the information.

The purpose of the audit is to (*insert brief summary of audit purpose and scope including a list of specific activities or areas to be reviewed.)*

The audit team consists of *insert name* (Audit Team Leader) and (*insert names of other audit team members and roles such as Technical Specialist, Auditor, etc.).*

(*Describe any actions needed by the audited organization such as logistics arrangements for the team, communications/computer equipment support needed, records retrieval support needed, tours, etc. These requests should generally be discussed prior to issuance of the notification with responsible personnel; agreed upon prior arrangements may not be discussed in the notification letter).*

Should you have any questions, please contact me at (*insert Audit Team Lead phone contact information*) or e-mail (*insert email address for Audit Team Lead*).

Cc: *Audit Area Management (1 organizational level above addressee of organization to be audited)*
E&I Director of Quality Services
E&I Audit Program Manager
Applicable Quality Assurance Managers

Applicable Project Manager
Applicable Sub-contract Administrator (for audits of sub-contractor activities)
Audit Team Members
Audit File
****Distribution should be in alphabetical order when populated.**

Attachment 3
Audit Report Cover Memo (Typical Format and Content)

Date: *Month, Day, Year*

To: *Responsible Management of Audited Area*

From: *Insert Audit Team Lead, Title*

Subject: Quality Assurance Audit, *Insert title and Audit Number*

Attached please find Shaw Environmental & Infrastructure (E&I) Quality Assurance Audit Report No. *insert audit number*, that provides the results of the audit of *insert Project Name or Office Location*, conducted *insert dates of audit*. The Audit Team consisted of *insert Audit Team Lead* (Audit Team Lead), and *insert Team Members (include role on team, e.g., Auditor or Technical Specialist)*.

The purpose of the audit was to evaluate conformance to requirements established by *insert requirements document used for audit criteria (e.g., E&I Quality Management System, contract requirements).* The scope of the audit included *insert areas included in the scope*. *Describe audit methods used for conduct of activities (e.g., interviews with Project personnel, reviews of documents and records, and observations of field activities).*

The results of the audit included *insert number of findings (e.g., CARs, NCRs)* requiring corrective action. Response to the Audit Team Lead is required for the CARs no later than *insert agreed upon date*. Response should address the following:

1. Cause of the Problem
2. Extent of condition
3. Corrective and preventive actions that have been or will be taken
4. Title of person(s) assigned responsibility for taking the above actions
5. Actual or scheduled implementation dates for those actions

The Audit Team also identified *insert number of* Opportunities for Improvement. These items do not warrant formal response to Quality Services; however, should be further evaluated by your organization.

Please direct questions to *insert Audit Team Lead, phone number, and email address.*

Respectfully submitted:

Audit Team Lead

Distribution: *Audited Area Management (one organization level about addressee)*
E&I Director of Quality Services
E&I Audit Program Manager

Applicable Quality Assurance Managers

Project Management (if a project)

Subcontract Administrator (if audit of subcontractor)

Audit Team Members

Attachment: Audit Report

Attachment 4

Audit Report (typical format and content)

E&I Quality Assurance Audit Report No. (Insert Audit Number)

ORGANIZATION/ACTIVITY AUDITED: (Insert Organization/Activity Audited)

LOCATION: (Insert Location Audited)

AUDIT CONDUCTED: (Insert Audit Dates)

AUDIT REPORT APPROVAL:

AUDIT TEAM LEAD _____DATE:_____

NOTE: A Table of Contents may follow the report cover page if desired. A Table of Contents is recommended for complex, lengthy audit reports.

EXECUTIVE SUMMARY:

(In the executive summary, the audit conducted should briefly be discussed, including location, dates of audit, and scope of the audit. An overall conclusion of the team should be included regarding effectiveness of implementation of requirements audited (i.e., overall implementation of the E & I Quality Management System and implementing procedures for Procurement and Document Control). A summary of significant audit findings should be included with discussion of actual or potential impact. This summary is designed to provide a management level overview of what was done, results, with emphasis on level of management focus needed to address issues identified.)

AUDIT PURPOSE/SCOPE

(Briefly describe why the audit was conducted and what scope elements were included).

AUDIT TEAM

(State team composition and roles. If a technical specialist participated indicate unique qualifications or scope targeted by the technical specialist to demonstrate added credibility of results).

AUDIT RESULTS

(This section should provide a more detailed discussion of elements audited and a summary of results for each. A brief discussion of audit approach such as items or activities observed, types of documents reviewed, and positions interviewed should be included. An attachment will be included that lists all documents reviewed, revision levels, etc. Discussion should provide sufficient facts to support overall conclusions, associated audit findings, observations, or opportunities for improvement. Each element audited should have an underlined number and title (e.g., I. Design Control; II. Organization). This section should include a summary of the audit finding with the reference number. All details aren't essential in this section; individual audit findings with supporting examples will be provided as a separate attachment. In the audit element sections, discussion should provide enough information for a reader to understand significance of results and findings.

Tables should be inserted at the end of the results section (following all individual element discussions) to provide an overview of specific findings and opportunities for improvement.)

TABLE 1 – Audit Findings (CARs/NCRs issued as a result of audit)

Finding # (CAR, or associated NCR)	Associated Audit Element	Condition/Finding Abstract
Example: EI-QMS-10-01-01	*Design Control*	*No independent engineering verification was performed for the change to the design of wall 256 of the oil reprocessing building.*

TABLE 2 – Opportunities for Improvement (OFI)

OFI # (Audit identifier prefixed with OFI and a sequential OFI #)	Associated Audit Element	OFI Abstract
Example: OFI EI-QMS-10-01-01	*Design Control*	*Guidance is needed in the design procedure for application of criteria.*

Audit Report - Attachment A

Audit Participants (Typical)

NAME	TITLE/ORGANIZATION/COMPANY	PRE-AUDIT CONFERENCE	CONTACTED DURING THE AUDIT	POST-AUDIT CONFERENCE
Example: John Autumn	Structural Engineer/Westinghouse		X	
Example: Jane Summer	Engineering Manager/Stoughton Design Center/Shaw	X	X	X

Audit Report - Attachment B

List of Documents Reviewed

(List documents reviewed during the audit, revision and date as needed. This attachment provides additional objective evidence to support reported audit results.)

Audit Report - Attachment C

Corrective Action or Nonconformance Documents Issued

(*Attach a copy of documentation for use by audited management in response, corrective action planning, disposition, etc.)*

Audit Plan

Audit Number:	Audited Organization:
Contract Number:	Location:
Audit Purpose/Scope:	

AUDIT PERSONNEL	AUDIT SCHEDULE
Lead Auditor: Auditor: Auditor: Technical Specialist:	Audit Dates: Pre-Audit Conference: Time: Post-Audit Conference: Time:
Audit Criteria/Reference Documents:	
Follow-up Items:	Special Concerns/Items:

AUDIT TEAM ASSIGNMENTS
Lead Auditor: Auditor: Auditor: Technical Specialist:

AUDIT PLAN APPROVAL	
Lead Auditor:	Date:

Audit Checklist

Organization/Project/Department Evaluated : **Audit Date(s):**	**Audit Personnel:**
Audit Number:	**Project Name/Number (if applicable):**

Item #	Line of Inquiry	Status[1]	Summary of Observations/Objective Evidence Reviewed/Interview Notes, etc.

[1]Status Key: A = Acceptable, U = Unacceptable, I = Issue/Finding; NA = Not Applicable; OFI = Opportunity for Improvement

Attachment 4

Aptuit Radiation Safety Program Manual

APTUIT RADIATION PROTECTION PROGRAM MANUAL

I. PURPOSE

This Radiation Protection Program (RPP) establishes safe work practices for protection against ionizing radiation hazards. Adherence to this program will ensure compliance with Federal and State regulations and provide for the radiological safety of employees, the general public, and the environment.

II. POLICY

It is the policy of Aptuit to perform all work involving radioactive materials in accordance with applicable Nuclear Regulatory Commission (NRC), Environmental Protection Agency (EPA), Missouri Department of Natural Resources (MDNR), and Department of Transportation (DOT) regulations, as well as any site license requirements. All work involving radiation-producing machines is to be performed in accordance with MDNR regulations.

It is the policy of Aptuit to ensure that exposures to personnel and the environment are maintained below the applicable standards and to a point that is as low as reasonably achievable (ALARA).

III. SCOPE

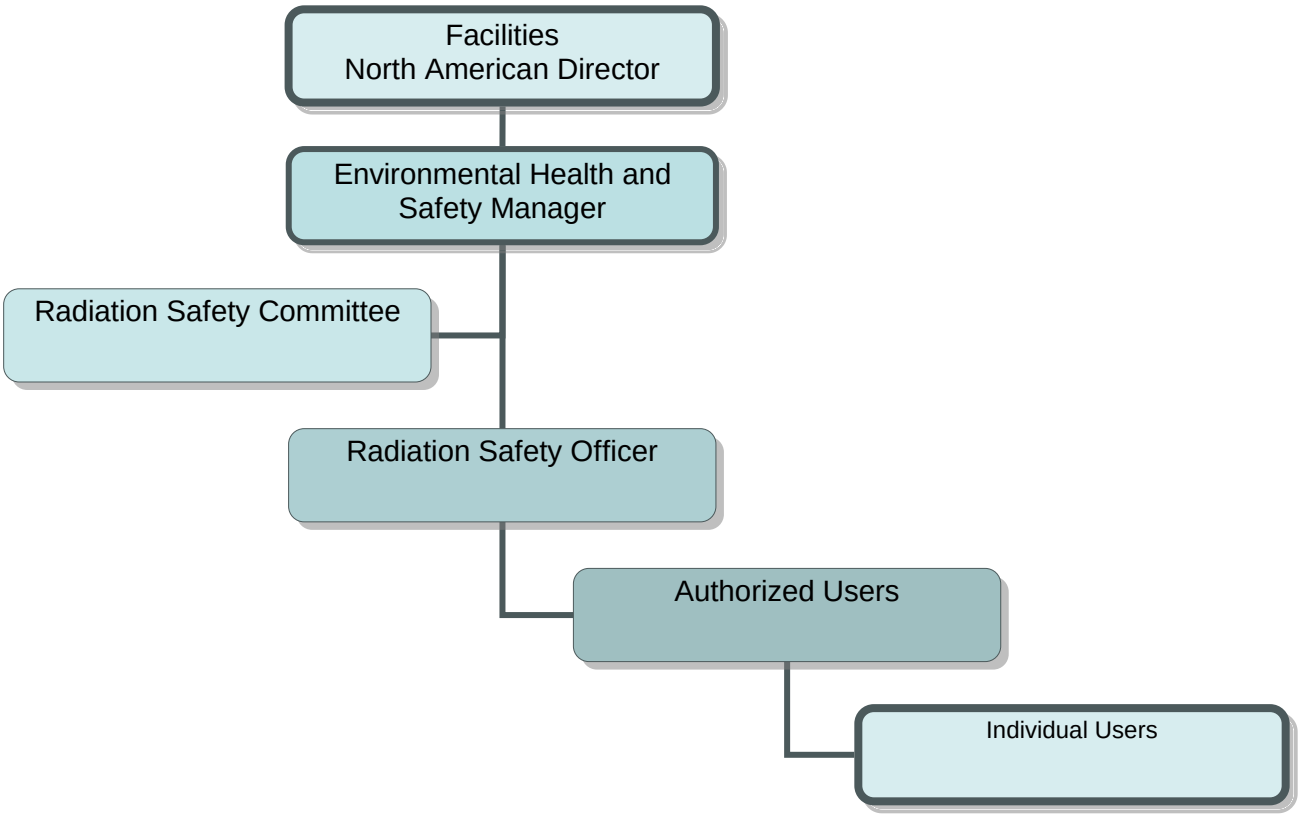
This RPP applies to all individuals who use radioactive materials at the Kansas City, Missouri (KCM) site.

IV. TABLE OF CONTENTS

V. RESPONSIBILITIES

Radiation Safety Organization

Aptuit operates the KCM radiation safety program under the guidance of the Facilities North America Director and the Environmental Health and Safety (EH&S) Manager. The Radiation Safety Officer (RSO) reports to the EH&S Manager. A Radiation Safety Committee (RSC) oversees the uses of radioactive materials at the KCM facilities. The radiation safety organization is represented in the following diagram:



Radiation Safety Officer (RSO)

The RSO is approved by the NRC and is responsible for the overall management of the radiation protection program, including implementation of ALARA principles. The RSO is responsible for:

a) Recommending policies for the control of radiation sources and determining compliance with procedures, rules, regulations, and license conditions through periodic audits.

b) Maintaining an accurate and up-to-date radioactive materials license and all required records including records that demonstrate compliance with limits on dose to the public.

c) Providing consultation to personnel on all aspects of radiation protection, including overseeing the radiation safety training program.

d) Maintaining personnel monitoring program, including the maintenance of exposure records and notification of employees, their supervisors, and Health Services.

e) Coordinating periodic surveys, monitoring of all sources and working areas where radionuclides are used or stored and maintaining records of all such surveys. Ensuring all radiation detection instruments are calibrated.

f) Coordinating order, receipt, storage, processing, shipping, disposal, and recordkeeping for all radionuclides, including sealed sources to ensure that licensed material is limited to the types and quantities of byproduct material authorized by the license.

g) Maintaining an inventory of all radioisotopes possessed under the license and maintaining the security of such.

h) Registering and tracking sealed sources. This includes coordinating leak tests on all sealed sources and recordkeeping for all such tests.

i) Coordinating the waste disposal program, with the assistance of the Environmental Specialist, including the maintenance of waste storage and disposal records.

j) Reviewing radiation incidents and providing advice on decontamination procedures. Instituting corrective actions to prevent similar incidents.

k) Serving as the point of contact and providing assistance in case of emergency (e.g., fire, etc.) to ensure that proper authorities are notified promptly in case of accident or other incidents that may involve the release or loss of licensed material.

l) Terminating any unsafe condition or activity that is found to be a threat to public health and safety or property.

Radiation Safety Committee

The RSC consists of the Facilities Director, the EH&S Manager, the RSO, and senior managers from each group using radioactive materials. Additional members may be assigned to serve by the RSC. The EH&S Manager serves as the committee chairman. Four members, including the RSO, must be present to constitute a quorum.

The responsibilities of the RSC include:

a) Perform, or cause to be performed, the annual review of the content and implementation of the radiation protection program.

b) Review proposed uses of radioactive materials and radiation producing equipment, radioactive material use and disposal procedures, and license amendment requests.

c) Review significant modifications in facilities or equipment that may impact the radiation safety of employees, the public, or the environment prior to submittal to the NRC for approval.

d) Review and recommend proposed users of radioactive material based on the training and experience requirements described below.

e) Provide technical advice to the Radiation Safety Officer (RSO).

f) Provide input for radiation safety training.

g) Review employee exposures and the ALARA program.

h) Review incident reports and reports of violations of radiation safety procedures and regulatory requirements.

Users

All employees using radioactive materials, working in areas where radioactive materials are used, or handling such materials are to be knowledgeable of appropriate safety and handling procedures.

Attendance at Aptuit Radiation Safety Training will be mandatory regardless of prior experience, as a prerequisite for approval to handle radiation sources.

There are two classes of users: Authorized and Individual.

Authorized Users: Those employees who have been officially authorized to use radioisotopes by the NRC. Authorized users must meet minimum requirements including an undergraduate degree with major coursework in the sciences, or equivalent work experience, and a combination of 40 hours training and hands-on experience working with radioactive materials. Employees qualified to be authorized users will submit the appropriate supporting information and documentation to the RSC prior to approval.

Individuals Users: Individuals who do not have the education, experience, and training required to be an authorized user may perform studies utilizing radioisotopes only when the studies are conducted under the supervision of an authorized user and with the prior approval of the RSO.

Authorized users are responsible for:

a) Ensuring that the RPPM and guidelines for the safe use of radioisotopes and radiation-producing machines are adhered to within their areas of responsibility.

b) Planning for radiation safety prior to beginning an experiment or procedure. This may include: outlining the procedure, identifying appropriate safety precautions to be taken to keep exposures and releases ALARA, and, when appropriate, perform a “dry run” of the procedure using non-radioactive materials.

c) Instructing those employees, for whom they are responsible, in the use of safe techniques and in the application of approved radiation safety practices and ensuring attendance at required radiation safety courses.

d) Notifying the RSO whenever major changes in operational procedures, new techniques, or new operations might lead to personnel exposure.

e) Complying with regulations governing the use of radioactive materials or radiation-producing machines.

f) Notifying the RSO prior to the purchase of any radioactive material, device containing radioactive material, or radiation-producing machine.

g) Report any incidents involving radionuclides or radiation-producing machines to the RSO in a prompt manner.

h) Preparing and updating, on a biennial basis, a *Background and Experience Handling Radioactive Materials* form (example as Attachment A).

All users (Authorized and Individual Users) are responsible for:

a) Understanding and abiding by all posted notices and safety regulations, for utilizing all appropriate protective measures, and for keeping exposure to radiation as low as possible.

b) Wearing prescribed monitoring devices and participating in bioassay procedures as directed by the RSO.

c) Completing Initial Radiation Safety Training prior to working with radioisotopes or a radiation-producing machine.

d) Maintaining good personal hygiene and keeping the laboratory neat and clean.

e) Labeling and isolating radioactive waste and equipment. Once used for radioactive substances, equipment should not be used for non-radioactive work until demonstrated free of contamination (see **Contamination Limits**).

f) Ensure area/equipment is free of contamination[1] (see Table 3) when requesting maintenance work.

g) Reporting any incident involving a radioactive material or radiation producing machine to his/her supervisor and the RSO.

h) Carrying out decontamination procedures when necessary, and taking the necessary steps to prevent the spread of contamination to other areas.

Health Services

Health Services is responsible for:

a) Implementing the long-range health program.

b) Scheduling the annual physical examinations for personnel working with radioactive materials.

c) Scheduling exit physicals for employees who have been in the personnel monitoring program upon termination of employment or transfer to other duties, when practicable.

d) Reviewing personal monitoring reports, keeping copies of exposure records as part of the employee's medical file and investigating any abnormal exposure.

VI. TRAINING

Occupationally Exposed Workers

Prior to beginning work with radioactive materials, employees must complete a formal radiation safety training program commensurate with their assigned duties. The training program will consist of the following topics:

- Radiological Fundamentals
- Biological Effects
- Radiation Detection and Measurement
- Principles of Radiation Protection
- Regulatory Requirements
- Aptuit Radiation Safety Program

Radiation safety training will be followed by a quiz. A score of 80% is required for successful completion of the training program.

[1] For C-14 and normal laboratory conditions using a pancake Geiger-Mueller (PGM) detector, an instrument reading of 2X the background count rate would indicate that contamination is present. See footnote "a" to Table 3.

In addition, employees will be given on-the-job training in safe handling procedures specific to their work areas. This training will be documented.

New employees with limited experience must work under the supervision of an authorized user. An initial evaluation of the employee's ability to work safely with radioactive materials will be conducted after three months of supervised work. Evaluations will continue monthly thereafter or until the authorized user is confident of the new employee's ability and understanding of NRC regulations, license provisions and Aptuit-specific safety procedures. The following criteria will be used to evaluate new employees with limited experience with radioactive materials:

- Completed Aptuit radiation safety training
- Read and understood Aptuit's Radiation Protection Program Manual
- Follows good contamination control procedures
- Observes postings
- Dons and doffs PPE correctly
- Frisks and performs surveys correctly and as required
- Follows waste minimization methods

Refresher training is conducted whenever major changes are made in the RPP or in regulations which affect the radiation protection aspects of the work. Refresher training is conducted at least annually.

The *Aptuit Radiation Protection Program Manual* will be available to all employees working with radioactive materials or radiation-producing machines.

Ancillary Personnel

Ancillary personnel such as maintenance, housekeeping and security whose duties require them to enter posted radioactive materials areas must receive radiation awareness training prior to entering the labs. This training will cover locations of use, health risks, and elements of radiation protection. This training will be provided under the direction of the RSO.

Refresher training for ancillary personnel will be required at least every two years.

VII. RADIOACTIVE MATERIAL ACCOUNTABILITY AND CONTROL

Aptuit will maintain accountability and control of licensed material sufficient to ensure that:

a) License possession limits are not exceeded;

b) Material balance can be used for emission calculations;

c) Licensed material in storage is secured from unauthorized access or removal;

d) Licensed material not in storage is maintained under constant surveillance and control;

e) Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.

f) Records of receipt, transfer, and disposal of licensed material are maintained by the RSO.

Procurement of Radionuclides

a) All purchase order requests for radioactive materials will be submitted to the RSO. Such requests should contain the name of the radioisotope, chemical form, activity in appropriate units (e.g. millicuries (mCi) or curies (Ci)), supplier, and person responsible for its use. The RSO must approve the order before it can be placed.

b) The RSO ensures the amount of radioactive material does not exceed amounts specified by the NRC License. For a copy of the NRC license, contact the RSO.

c) All shipments of radionuclides will be directed to the RSO or designee.

Security of Licensed Material

Unauthorized access to licensed material is accomplished by the use of multiple security features.

a) A chain link fence with barbed wire and gated entrances surrounds the perimeter of the Marion Park Campus, which includes the entire Aptuit KCM facility. The perimeter is patrolled by Security. There are two gate entrances. The entrances are manned by security personnel during normal working hours (6 AM-6 PM). During non-working hours the gates are closed and the campus can only be accessed with an electronic badge system. The gates and entrances are monitored by remotely operated closed-circuit television (CCTV) with viewing monitors located in the security console. The CCTV is recorded.

b) Building Entry: All entrances to the buildings are controlled by electronic badge readers. After hour entry requires a PIN in addition to the electronic badge. Building entrances are monitored by CCTV.

c) Areas where radioactive materials are used or stored have restricted access by badge readers.

Receipt of Packages Containing Radioactive Materials

a) All packages containing radioactive materials are picked up by the RSO (or designee) at the designated dock.

b) The RSO (or designee) will examine, survey, and open each package containing radioactive materials in accordance with established procedures.

c) Packages will be opened as soon as possible after receipt in accordance with established procedures.

Storage and Transportation of Radioactive Materials

a) All radioactive materials shall be stored in suitably shielded containers. The exposure to radiation, 3 inches from the walls of any container shall not exceed 1 mrem per hour.

b) All stock sources, when not in use, shall be stored in designated control storage areas of the Radioisotope Laboratories and shall be secured from unauthorized access or removal.

c) The transportation of all radioactive materials between laboratories or buildings must be done in a primary and secondary container. When transporting solutions, the cases must be leak proof and should contain sufficient absorbent material to absorb the entire solution.

d) All containers of radioactive material must be appropriately labeled with the isotope, compound name, activity, user's name, and any other relevant information available. Containers should be identified as containing radioactive material by the words "Radioactive Material", "Radioactive", or the radiation symbol.

Off-Site Shipping

a) All off-site shipping of radioactive materials will be done under the guidance and approval of the RSO (or designee).

b) The shipment will be packaged to meet U. S. Department of Transportation (DOT) or International Air Transportation Association (IATA) regulations. Packages must be surveyed and swiped to ensure that radiation and contamination levels are within acceptable limits prior to shipment. The RSO will provide guidance on the shipping requirements on a case-by-case basis.

c) The RSO (or designee) will contact the receiving site to notify them of the shipment. The RSO (or designee) will ensure that the shipment is in compliance with all applicable DOT and/or IATA regulations.

d) A Material Safety Data Sheet (MSDS) for the cold drug substance must be shipped with all samples of radio-labeled drug substance.

e) The RSO must possess a copy of the license, or otherwise verify that the receiving facility is authorized for receipt of the type, form and quantity of material being transferred, prior to shipment.

VIII. OCCUPATIONAL DOSE

Occupational Dose Limits

Radiation exposure limits have been established by the NRC as an upper limit on doses to which workers may be exposed. Assuming that all radiation exposure carries some risk, Aptuit has adopted the policy of maintaining all exposures as far below these upper dose limits as is reasonably achievable. This policy is known as ALARA.

Occupational exposure limits are found in Title 10 Part 20.1201 of the Code of Federal Regulations (10 CFR 20.1201). Exposure limits for adults and for the embryo/fetus of a declared pregnant woman are given below:

OCCUPATIONAL ANNUAL DOSE LIMITS

THE LESSER OF THE TOTAL EFFECTIVE DOSE EQUIVALENT	5 REM (0.05 SV) OR
THE SUM OF THE DEEP-DOSE EQUIVALENT AND THE COMMITTED DOSE EQUIVALENT TO ANY INDIVIDUAL ORGAN OR TISSUE	50 REM (0.5 SV)
EYE DOSE EQUIVALENT	15 REM (0.15 SV)
SHALLOW DOSE EQUIVALENT TO THE SKIN OR ANY EXTREMITY	50 REM (0.5 SV)
DOSE TO THE EMBRYO/FETUS OF A DECLARED PREGNANT WOMAN	0.5 REM (0.005 SV) DURING ENTIRE PREGNANCY

Declared Pregnant Worker

The NRC limits fetal radiation dose received as a result of a pregnant worker's occupational exposure to 500 mrem in the gestation period. For this limit to apply, the regulation requires the woman to declare pregnancy in writing and give the estimated date of conception. If a woman chooses not to declare her pregnancy, the normal occupational dose limit of 5,000 mrem per year would be in effect with the provision to maintain occupational radiation exposure ALARA.

A radiation worker who decides to declare a pregnancy would do so by submitting a Declaration of Pregnancy form or equivalent (Attachment B) to the RSO, Health Services, and her immediate supervisor. The Declaration of Pregnancy form and any dose records to the embryo/fetus are maintained with those of the declared pregnant worker (DPW). When pregnancy is declared in writing, an evaluation will be

performed by the RSO to determine the potential for the employee to exceed the regulatory exposure limit during the nine-month gestation period. The individual's potential exposure and their job functions will be reviewed by Health Services, Environmental Health and Safety (EH&S), and management. Recommendations on minimizing radiation exposure may be made on an individual basis after this evaluation. A DPW may revoke her declaration of pregnancy by submitting a letter to the RSO; however the lower dose limit for the embryo/fetus will no longer apply.

External Dose Monitoring

The RSO will determine the need for and type of personnel dosimetry in accordance with applicable NRC regulations and guidance documents (e.g. NUREG-1556, Vol. 7, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope). The personnel dosimetry program shall be conducted through a dosimetry provider that is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP).

It is the responsibility of employees who are assigned personnel dosimetry devices to wear and store them in accordance with the instructions of the RSO. Dosimetry reports will be reviewed by the RSO. Monitoring records will be maintained as part of the employee's health file. Employees will be notified of any exposures recorded above the dosimeter's minimum measurable quantity. A summary of the annual results will be provided to each employee participating in the personnel monitoring program.

Internal Dose Monitoring

Employees who routinely work in radiosynthesis will submit weekly urine samples. Other employees using ^{3}H, ^{14}C, ^{35}S, ^{125}I, or ^{131}I, at the levels indicated in Table 1 will be required to participate in the bioassay program as determined by the RSO. The RSO will determine participation in the bioassay program based on the amount and form of the isotope, type of use, control methods and in accordance with applicable NRC Regulatory Guides. Users are required to notify the RSO before using radionuclide form/activity combinations exceeding those in Table 1. Scheduling of bioassay tests will be coordinated through the RSO. In addition, appropriate bioassay may be performed whenever an internal exposure to radioactive materials is suspected.

Records of all monitored employee exposures are maintained by the RSO and also as part of the employee's permanent health record.

Table 1 - General guidelines for internal dose monitoring

Nuclide	Form	Use Level[2]	Frequency	Method
^{3}H	HTO and tritiated compounds	>100 mCi at one time	Within 4 to 72 hours following use	urinalysis
^{14}C	Monoxide	>50 Ci[3]	Within 24 to 72 hours following use	urinalysis
	Dioxide	> 5 Ci[3]		
	Compounds	> 50 mCi[3]		
^{35}S	vapor	>250 mCi[3]	Within 24 to 72 hours following use	urinalysis
^{125}I, ^{131}I	Volatile	>1 mCi open room or bench >10 mCi in fume hood >100 mCi in glove box	Within 24 to 72 hours following use	Thyroid count
	Bound to nonvolatile agent	>10 mCi open room or bench >100 mCi in fume hood >1000 mCi in glove box		

Public Dose

NRC regulations (10 CFR 20.1302) require demonstration of compliance to the 100 millirem (mrem) annual dose limit to the public. In addition, 10 CFR 20.1101(d) establishes a constraint on air emissions such that the individual member of the public likely to receive the highest dose shall not be expected to receive a total effective dose equivalent from air emissions in excess of 10 mrem per year.

Aptuit will demonstrate compliance with the public dose limit and the constraint on air emissions on an annual basis using methods described in NRC regulatory guidance documents. These methods may include calculation or measurement of emissions. In addition, Aptuit will establish and maintain levels for gaseous and liquid effluents ALARA.

IX. PROCEDURES FOR WORKING WITH RADIOACTIVE MATERIALS

Standard Laboratory Practices

[2]The quantities also apply to the cumulative amount handled during a one month period.
[3] Based on handling 25 times the ALI at one time or cumulative over 1 month.

The following standard laboratory practices will be followed for work with radioactive materials in the absence of procedures for specific operations and/or areas. Specific procedures that are developed shall be sufficient to maintain exposures ALARA. Specific procedures shall be approved by the RSC.

a) The areas and equipment within a laboratory where radioactive materials are used should be clearly marked, (i.e., with radioactive material warning tape at the work site) or labeled.

b) Secondary containment and/or absorbent paper should be used with radioactive materials that have the potential to cause contamination. After the completion of an experiment, the paper will be removed for appropriate disposal (i.e. disposal as radioactive waste if it is contaminated).

c) After completion of the experiment and removal of potentially contaminated disposable material (e.g. absorbent paper), the area will be surveyed for possible radioactive contamination using appropriate survey procedures (e.g. a Geiger counter equipped with a pancake-probe (PGM) for ^{14}C, a thin-window scintillation crystal for ^{125}I, or by collecting and counting wipe samples for ^{3}H). The results of the survey will be documented on the Survey Log (Attachment C).

d) If contamination is found on surfaces or equipment greater than the limits in Table 3, decontamination must be performed and the area resurveyed after decontamination.

e) Glassware that may have been in contact with radioactive material must be appropriately labeled and decontaminated or discarded in the radioactive waste at the completion of the experiment.

f) Disposable gloves must be worn when handling radioactive materials or wiping areas.

g) Laboratory coats must be worn at all times when using radioactive materials and should not be worn outside the radioisotope laboratory area.

h) Mouth pipeting is strictly prohibited in all laboratories.

i) Smoking, eating, drinking, and applying makeup or contact lenses is prohibited in all areas where radioisotopes are used or stored.

j) Applications that use volatile radioisotopes or are likely to produce aerosols will be restricted to approved enclosed areas, i.e., fume hoods, metabolism cages, or biobubbles. Volatile radioisotopes should not be used in a biological safety cabinet without prior approval by the RSO.

k) Gloves must be removed and discarded prior to handling uncontaminated items, such as drawer pulls, telephones, door handles, Geiger counters, etc.

l) All solid radioactive waste will be double bagged and placed in **Clearly Labeled Containers.** Also, liquid waste will be stored in appropriate **Clearly Labeled Containers.**

m) The need for shielding and/or remote handling devices must be determined prior to the start of a project. Consult with the RSO for guidance on shielding or remote handling devices.

n) After completion of work with radioactive materials (with the exception of ^{3}H), personnel must frisk with an appropriate instrument (e.g. PGM or thin NaI) for possible contamination prior to leaving the laboratory.

o) All employees must wash their hands prior to leaving the laboratory.

p) The Survey Log will be filled out after completion of contamination surveys. The Survey Log must be sent to the RSO at the end of each month.

q) Employees shall use the principles of time, distance and shielding wherever possible to keep external doses ALARA.

Procedures for work with radioactive materials may be revised only if:

a) The changes are reviewed and approved by the RSC;

b) The affected staff is provided training in the revised procedures prior to implementation;

c) The changes are in compliance with NRC regulations and the license; and

d) The changes do not degrade the effectiveness of the program.

Radiological Areas and Posting

Radiological area definitions and posting/labeling requirements throughout Aptuit facilities will be as described in 10 CFR 20.1003 and 10 CFR 20, Subpart J--Precautionary Procedures. All personnel permitted unescorted access to the radiologically restricted areas of the facilities are trained in recognition of posting/labeling during radiation safety training.

NRC Form 3, "Notice to Employees", shall be posted in prominent locations where it may be seen by those engaging in licensed activities. The "Notice to Employees" form will include a notice stating that “Copies of the regulations in 10 CFR 19 and 20; the license, license conditions, or documents incorporated into the license by reference, and amendments thereto; and operating procedures applicable to licensed activities are available from the RSO.”

Authorized Facilities

No laboratory or area at Aptuit will be used for the storage or use of radioactive materials without review by the RSC and prior approval of the NRC. Facilities and equipment must be sufficient to ensure the safe use of the isotopes, quantities, and activities planned. All research and development laboratories used for radioactive materials conform to minimum standards that include impervious lab bench tops and laboratory ventilation with one pass air. Fume hoods or other containment will be available as needed. Laboratory flooring is constructed for easy decontamination, i.e. either made of impervious material or is designed for easy removal of small sections.

In evaluating areas for use or storage of radioisotopes, the RSC will consider the isotopes, quantities and procedures to be used and the administrative and engineering controls needed to work safely with the materials.

Approved laboratories will be conspicuously identified by distinctive signs supplied by the RSO. These signs will bear the standard radiation symbol and appropriate wording as required by regulation (see **Radiological Areas and Posting**). Any specific entry requirements or restrictions will be posted (e.g. Shoe covers and lab coats required for entry, Authorized Personnel Only, etc.) at the entrance to laboratories and areas approved for radioactive material use or storage. These signs will not be affixed or removed from any area without the permission of the RSO.

Once a laboratory or area has been approved for radioactive material use it becomes subject to the survey requirements found in **Radiation Safety Surveys** of this RPP. If the use of a laboratory for radioactive materials is to be terminated, prompt notification of the RSO is required. Area and equipment surveys may be required by the RSO prior to an area being decommissioned as a radioisotope use or storage area as described in **Contamination Surveys**. Contamination limits for areas and equipment are found in Table 3.

Radiation Monitoring Instruments

Aptuit will maintain an adequate number of calibrated instruments for the types and levels of radiation present.

Table 2 - Radiation detection instruments available at Aptuit

Type of Instrument	Radiation Detected	Sensitivity Range	Window Thickness	USE
Survey meter with pancake G-M detector (PGM)	beta, gamma	X.1, X1, X10 0-5K cpm or 0-5 mR/hr	1.7 +/-.03 mg/cm²	Contamination surveys

Type of Instrument	Radiation Detected	Sensitivity Range	Window Thickness	USE
Alarm Ratemeter with PGM	Beta , gamma	0 - 500 cpm, X1, X10, X100, X1k	1.7 +/-.03 mg/cm²	Personnel contamination monitoring
Inspector (G-M)	beta, gamma	0-300K cpm .001-1000 mR/hr	1.5-2.0 mg/cm²	Contamination surveys
Liquid Scintillation Counter	beta	NA	NA	Removable contamination, waste and product assays
Ion chamber or microR meter	gamma	0 – 5000 mR/hr	NA	Exposure rate, package surveys
Low energy gamma detector	Low energy gamma	0 - 500 cpm X1, X10, X100, X1000	18.4 mg/cm²	I-125 surveys
Large area gas proportional detector	Alpha, beta	X1, X10, X100, X1000 0 - 500 cpm,	0.4 – 0.8 mg/cm²	Contamination surveys

Portable survey instruments are calibrated annually or after repair by persons authorized by the NRC, an Agreement State, or a licensing State to perform that service. Calibration records are maintained in the radiation safety files. Fixed laboratory instruments used for analysis of samples are checked for satisfactory performance pursuant to vendor instruction manuals.

Instruments used for radiation detection/measurement may be upgraded as necessary at the discretion of the RSO.

Radiation Safety Surveys

Aptuit will perform radiation safety surveys that are sufficient in scope to assess the radiation hazards to workers and the public. These surveys will consist of dose-rate and contamination surveys, as appropriate, in and adjacent to locations where radioactive materials are used or stored. The RSO will determine the types, locations and frequency of radiation safety surveys in accordance with current guidance documents (e.g. NUREG-1556, Vol. 7, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope). The RSO maintains records of radiation safety surveys. General guidelines for performing surveys are presented below.

Dose-rate Surveys

Dose-rate surveys may be performed in areas where external exposure hazards are present. In general, dose-rate surveys should be performed if radiation levels

could result in doses in excess of 500 mrem per year or where the dose rate in the area could exceed 2.5 mrem per hour. The frequency of dose-rate surveys will depend on the type, quantity and use of radioactive materials, as well as the controls that are in place to protect workers and members of the public from external exposure to radiation.

Contamination Surveys

Contamination surveys are performed to evaluate radioactive contamination that could be present on building surfaces, fixtures, laboratory furniture, equipment and personnel. Contamination surveys may consist of measurements of total contamination by direct reading instruments and/or removable contamination by wipe survey.

Routine contamination surveys are performed in and adjacent to areas where radioactive materials are used or stored. The RSO will determine the type, locations, and frequency of routine surveys depending on the radionuclides, quantities and type of use. Wipe tests will be performed in the immediate areas of benches, hoods, doors, equipment, etc. where radioactive material is handled. Storage areas, waste disposal areas, floors, and other locations where inadvertent contamination is likely to occur will also be wiped. Sufficient wipes will be collected to provide an accurate profile of the area.

Guidelines for the frequency for performing routine contamination surveys are below.

- Weekly routine surveys will be performed in and adjacent to radiosynthesis areas and monthly in R&D areas.

- Users will perform daily surveys in radiosynthesis areas and at project completion in R&D areas.

Results will be recorded on the Survey Log. If contamination is found on surfaces or equipment greater than the limits in Table 3, the user responsible for the laboratory will carry out corrective measures as recommended by the RSO. The area will be resurveyed after decontamination. If decontamination is not possible, the area shall be clearly marked and the RSO notified.

Sealed sources, such as the ^{63}Ni foils contained in electron capture detector of gas chromatographs, will be tested for leakage at the interval specified in the license.

Contamination Limits

Acceptable surface contamination limits for equipment and for building surfaces are found in Table 3. Contamination found in unrestricted areas should be promptly decontaminated to background levels. If background levels are not achievable then the contamination level must not exceed the limits in Table 3.

Potentially contaminated facilities and equipment must be decontaminated to levels below those in Table 3 to be acceptable for unrestricted release. In

addition, contamination levels should be reduced to ALARA prior to release. Facilities that are to be decommissioned and removed from the NRC license must meet the requirements of 10 CFR 20, Subpart E--Radiological Criteria for License Termination.

Table 3 - Acceptable Surface Contamination Levels (based on NUREG-1556, Vol. 11)

Nuclide	Average[a, b]	Maximum[a, c]	Removable[a, d]
^{3}H, ^{14}C, ^{32}P, ^{35}S	5,000 dpm/100 cm^2	15,000 dpm/100 cm^2	1,000 dpm/100 cm^2
^{131}I	1,000 dpm/100 cm^2	3,000 dpm/100 cm^2	200 dpm/100 cm^2
^{125}I	100 dpm/100 cm^2	300 dpm/100 cm^2	20 dpm/100 cm^2

[a] As used in this table, dpm (disintegration per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation. For example for ^{14}C, using published efficiency for a PGM detector (5%) with a 15 cm^2 probe and a background count rate of 40 cpm, it is possible to detect <5000 dpm/100 cm^2 with the probe stationary and <13,000 dpm/100 cm^2 while scanning. Under these conditions, a reading of 2X background is approximately 5000 dpm/100 cm^2.
[b] Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.
[c] The maximum contamination level applies to an area of not more than 100 cm^2.
[d] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

Airborne Radioactivity Surveys

Air sampling and/or monitoring is performed based on the potential for release of significant quantities of airborne radioactive materials into the workplace. The need for and type of air monitoring is determined on a case-by-case basis using current guidance documents.[4]

Emergency Procedures

In the event of an accident involving the release of significant quantities of radioactive material, the objectives of all remedial actions are:

a) Minimizing personal exposure to radioactive materials, including surface contamination, absorption through the skin, ingestion, inhalation, or through any wounds.

[4] Current guidance as of this RPP revision include Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992, and NUREG-1400, "Air Sampling in the Workplace," dated September 1993.

b) Removing any radioactive contamination on personnel.

c) Preventing the spread of contamination from the area of the accident.

d) Decontamination and clean up of the spilled material.

Personnel Decontamination

The following procedures should be followed if contamination is detected on an individual, his/her clothing, or belongings.

a) The individual who detects the contamination should immediately advise his coworkers, supervisor, and the RSO.

b) Any contaminated clothing must be removed before determining the level of skin contamination.

c) Contaminated areas of the skin must be washed thoroughly with copious amounts of water, being careful not to abrade skin. Any area of the body found to have significantly higher levels of contamination will be initially spot cleaned with soap and water to prevent the spread of contamination. Care should be taken to ensure that localized contamination is not spread to other areas during the washing process. Hands should be washed with soap and water with special attention to the areas between fingers and around fingernails.

d) All affected areas will be monitored after washing. The above procedures will be repeated if monitoring indicates the presence of skin contamination.

e) If the radiation is still excessive, more powerful decontamination procedures will be initiated after consultation with the RSO and Health Services.

ALL incidents involving personnel contamination must be reported to Health Services and the RSO.

Minor Spills

Most spills in the laboratory will involve only minor quantities of radioactivity (microcurie to millicurie quantities). In these cases, the person responsible for the spill will follow the procedure outlined below:

a) Notify persons in the area that a spill has occurred.

b) Wash hands if they are contaminated as a result of the accident. Put on disposable gloves to prevent contamination of the hands.

c) Cover liquid spill with absorbent material to limit the spread of contamination. If solids are spilled, dampen the paper and then cover the spill.

d) Notify maintenance to shut off ventilation equipment if airborne contamination is suspected. This can be done by calling Security at extension 1500.

e) Mark off contaminated area and restrict traffic to the area.

f) Do not allow anyone to leave contaminated area without first being monitored to be sure they are not contaminated.

g) Notify the RSO of the incident.

h) Start decontamination procedures as soon as possible. Cleaning agents normally used in the lab should be adequate. Start at the periphery of the contaminated area and work inward, systematically reducing the contaminated area.

i) Place all contaminated disposal materials into doubled, plastic bags for disposal.

j) Assign a person equipped with an appropriate survey meter to follow the work and to watch for the accidental spread of contamination. Survey the area around the spill and check hands, clothing, and shoes for contamination.

Major Spills or Releases

a) In the event of fire, explosion or other incident resulting in a major release of airborne radioactivity, all affected personnel in the immediate area will be notified to evacuate. After reaching a safe location, report the event by calling Security at extension 1500. The RSO will be notified by Security.

b) Notify the laboratory supervisor.

c) Block off or isolate the incident area.

d) Notify maintenance to shut off ventilation equipment. Radioactive hoods with isolated exhaust systems and equipped with exhaust filters can remain in operation.

e) Survey all persons involved in the emergency. Follow decontamination procedures for any personnel found to be contaminated.

f) Survey the area to determine protective devices needed for decontamination.

g) Decontamination will be conducted under the direction of the RSO.

h) A detailed report of any incident involving radioactive materials will be prepared by the laboratory supervisor using the site accident report form. An

incident investigation will be conducted under the direction of the RSO to identify causes and take corrective actions to prevent recurrence.

After-Hours Incidents Involving Radioactive Materials

In the event that radioactive material is spilled or found leaking after-hours, the following steps will be taken:

a) Security will immediately notified to block or close off the area involved to prevent the spread of contamination.

b) The RSO and the employee responsible for that lab will be contacted by Security.

c) No attempt to clean up the spill will be made by unauthorized personnel. The RSO and the authorized user will be responsible for defining decontamination procedures.

X. WASTE MANAGEMENT

Authorized users are responsible for the initial identification and segregation of waste.

The packaging, storage and disposal of radioactive waste will be conducted under the supervision of the RSO and/or the Environmental Specialist. The user will label all waste for pick-up with the following information:

a) Radioisotope
b) Total activity in appropriate units (e.g. microcuries, millicuries, curies, etc.)
c) Authorized user's name

Waste that does not contain this information will not be picked up and the user will be notified.

Current waste streams and disposal methods are described below. However, waste streams and/or disposal options may change and the disposal methods may be revised if:

a) The changes are reviewed and approved by the RSC;
b) The affected staff is provided training in the revised methods prior to implementation;
c) The changes are in compliance with NRC regulations and the license.

Disposal guidelines are contained in Attachment D.

Waste Types

Solid Waste

Dry solid waste, such as gloves, paper towels, dry test tubes, etc., are collected in plastic bags or metal cans which are kept in hoods. Activity assigned to the bag or should agree with that on the close-out sheets. When these bags or cans are full they are placed into appropriate, lined containers for pick-up. **NOTE: No free liquids or tubes with liquids can be placed into this container!** ^{3}H, ^{14}C, and short lived isotopes ($T_{1/2} \leq 120$ days) are segregated from all other isotopes. The log form is completed indicating radioactive material and activity added.

Liquid Waste

The RSO and/or Environmental Specialist should be contacted for pick-up of liquid waste. Upon pouring the waste into the container, the user will assign an activity based on assay or through process knowledge and keep a running total of the waste input until the container is full or otherwise ready for disposal. Liquid wastes generated at Aptuit falls into several categories with each having specific disposal options.

Liquid Scintillation Media (LSM)**:** This includes biodegradable, nonhazardous LSM and flammable LSM. LSM is further classified for disposal based on the concentration of ^{3}H and ^{14}C. LSM containing ≤ 0.05 μCi ^{3}H or ^{14}C per gram of medium may be disposed without regard to the radioactive content. LSM that is flammable or that contains ≥ 0.05 μCi of ^{3}H or ^{14}C per gram of medium is collected in a DOT–approved, 55 gallon steel drum with 4 mil plastic liner in alternating 6 inch layers of vials and vermiculite. LSM that is nonhazardous and contains ≤ 0.05 μCi of ^{3}H or ^{14}C per gram of medium are collected in a DOT-approved, 55-gallon drum with a plastic liner. The LSM must be clearly identified as to classification.

Tritiated Water: ^{3}H water waste (tritiated water) may be solidified with Portland cement or other solidification agents for disposal.

Aqueous Liquid Waste: Water-based radioactive wastes (with the exception of tritiated water) will be transferred to the RSO and/or Environmental Specialist for proper disposal.

Non-aqueous Liquid Waste**:** EPA listed liquids containing radioisotopes will be accumulated in appropriate containers depending on the waste characteristics. The waste may be segregated by isotope and by waste type (e.g. ^{3}H pump oil) as directed by the RSO and/or Environmental Specialist. When the waste container is full it is then transferred for proper disposal.

Other Radioactive Wastes

Contact the RSO or the Environmental Specialist for information on collection of waste streams not identified above.

Waste Disposal

Decay-in-Storage

a) Waste material with a physical half-life of less than 120 days may be held for decay-in-storage before being disposed of as non-radioactive waste. Each isotope must be collected separately.

b) All material held for decay-in-storage will be allowed to decay a minimum of 10 half-lives.

c) Prior to disposal, radioactivity will be monitored with an appropriate survey meter to ensure activity at container surface is indistinguishable from background radiation levels. All radiation labels will be removed or defaced prior to disposal. Dry waste can be placed into medical waste containers.

Accumulation of Wastes for Transfer to Off-Site Disposal Facility or Extended Interim Storage Pending Off-Site Disposal

a) Contaminated wastes and LSM with isotopes with physical half life $\geq$ 120 days, are accumulated in suitably marked waste containers and stored in the radioactive waste storage area.

b) Records are maintained for each disposal drum showing the category of material, the isotope(s), and total activity.

Disposal by Release into Sanitary Sewerage Systems

Sanitary Sewer discharge will only be done by the RSO (or designee). Sink disposal logs will be maintained. The date, initials, radioactive material, and quantity disposed (in appropriate units such as μCi), must be recorded at the time of any sink disposal.

Attachment A

APTUIT, INC.

BACKGROUND AND EXPERIENCE HANDLING RADIOACTIVE MATERIALS

Please print or type:

Name: _____ ID:_____ SSN:_____ DOB:_____
Gender: _____ Department: _____ Cost Center: _____
Job Title: _____Supervisor:_____
Extension: _____ Mail Stop: _____ Email: _____

Please list training received in radioactive materials handling and/or protection:

Topic	Location	Duration	Formal or On-the-Job?

Please list your experience working with radioactive materials:

Radionucleide	Amount (mCi)	Chemical or Physical Form	Procedure or Technique*

Please list radionuclides you plan on working with and the procedures which will be used:

Radionuclide	Amount (mCi)	Chemical or Physical Form	Procedure or Technique*

*General category of experiment (e.g., RIA, DNA sequencing, etc.)

Signature: _____ Date:_____

Radiation Safety Use Only

Reviewed by: _____ Date: _____

Attachment B

FORM LETTER FOR DECLARING PREGNANCY

This form letter is provided for your convenience. To make your written declaration of pregnancy, you may fill in the blanks in this form letter or you may write your own letter.

DECLARATION OF PREGNANCY

To: Radiation Safety Officer

Health Services

_____ (Immediate supervisor)

In accordance with the NRC regulation at 10 CFR 20.1208, "Dose to an Embryo/Fetus," I am declaring that I am pregnant. I believe I became pregnant in _____(month and year).

I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 0.5 rem (unless that dose has already been exceeded between the time of conception and submitting this letter). I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

_____,
(Your signature)

_____,
(Your name printed)

_____,
(Date)

Attachment C

SURVEY LOG

MONTH/YEAR: _____ LAB No. _____

DATE	ISOTOPE USED	METER ID	METER (CPM)	WIPES (DPM)	USER	AREA

Post in Laboratory. Send to RSO at the end of the month.

Attachment D

DISPOSAL GUIDELINES FOR RADIOACTIVE MATERIALS

To track isotope usage and disposal, waste disposal logs will be posted on all containers used to dispose of radioactive material. Isotope users are responsible for recording:

1. The date waste was added to the container.
2. The initials of the person disposing of the waste.
3. The isotope(s) and the material disposed of.
4. The activity of the waste (in μCi, mCi, or Ci) disposed of at each location.

Amounts of waste can be estimated by the following procedures:

DRAIN DISPOSAL: If the binding percentage of a radioassay is known, the total bound radioactivity can be subtracted from the total isotope used. For example, in a binding assay where 10% of the isotope is bound to the substrate, 90% of the total isotope added is disposed of by an appropriate means. If 10 μCi of isotope are added, 9 μCi remain unbound and are disposed of into the waste container.

SCINTILLATION VIALS: To estimate the activity in scintillation vials in μCi, use the following conversion equation:

$$\frac{(\text{CPM} \div \text{Efficiency}) \times \text{Number of Vials}}{2.22 \times 10^6}$$

CPM = average counts per minute of vials
Efficiency = efficiency of counter (used to convert CPM to DPM)

If 96 vials with an average of 12000 CPM on a counter with 40% efficiency, the conversion to μCi is shown below.

$$((12000 \div 0.40) \times 96) \div 2.22 \times 10^6 = 1.3\ \mu\text{Ci}$$

NOTE – Vials containing more than 0.05 μCi/g are regulated and must be segregated into a separate drum. A vial containing 0.05μCi/g in 10-mL of scintillation fluid will have a count of approximately 1,111,000 DPM. A vial containing 0.05 μCi/g in 5-mL of scintillation fluid will have a count of approximately 555,000 DPM. Contact the RSO prior to generating large quantities of vials containing >0.05 μCi/g.

AQUEOUS LIQUIDS: A log of liquid radioactive waste must be kept for each container or jug. The log may be attached to or associated with the jug. Information to be included on the log includes: location of jug, name of radioactive material & isotope, activity of waste, and the initials of the person adding the waste.