

**QUALITY ASSURANCE MANUAL  
FOR THE  
ENVIRONMENTAL SURVEY AND SITE ASSESSMENT PROGRAM**

Oak Ridge Institute for Science and Education  
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## SECTION 1

### ESSAP PROGRAM DESCRIPTION AND QUALITY ASSURANCE RESPONSIBILITIES

#### 1.0 PURPOSE

Specific responsibilities for quality assurance and quality control duties are outlined in this section.

#### 2.0 PROGRAM DESCRIPTION

The Environmental Survey and Site Assessment Program (ESSAP) of the Oak Ridge Institute for Science and Education (ORISE) provides technical assistance under a contract with the U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC) and other federal agencies under interagency agreements. ORISE and its programs are operated by Oak Ridge Associated Universities (ORAU) through a contract with DOE. Sites surveyed under this program are primarily those where residual contamination from previous operations may pose a potential risk to the environment or to the health and safety of those occupying the site, presently or in the future. Other major activities include environmental assessments, instrument evaluations, training related to decommissioning survey activities, effluent sampling and monitoring, special laboratory analyses, program appraisals and document reviews, consulting on environment-related topics, and technical assistance for guideline development. Performance of activities is managed according to procedures designed to assure validity of developed data and technical determinations.

#### 3.0 PURPOSE AND SCOPE

The purpose of this manual is to provide Program policy and oversight for the maintenance of quality assurance (QA) and quality control (QC) within ESSAP. This manual describes administrative systems, as well as specific quality control procedures, which apply to all functional groups in ESSAP. The methodology for performance of particular field and laboratory activities and the associated Integrated Safety Management requirements are presented in the ESSAP Survey Procedures Manual and the Laboratory Procedures Manual.

#### 4.0 REFERENCES

The quality control procedures in this manual are based on:

- DOE Order 414.1B, Quality Assurance
- 10 CFR 830.120, Quality Assurance Requirements

- ASME NQA-1, Quality Assurance Program Requirements for Nuclear Facilities
- Quality Assurance Manual for Office of Nuclear Material Safety and Safeguards
- ORAU Policy and Procedure, Quality Assurance, GP-810

## 5.0 RESPONSIBILITIES

The general organizational structure is shown in the figure at the end of this section. Responsibilities for specific positions in ESSAP are listed below.

### Program Director

- ✓ Establish procedures;
- ✓ Monitor training operations;
- ✓ Monitor data collection, development, and management;
- ✓ Host, and if necessary, initiate external audits;
- ✓ Review technical documents for special projects; and
- ✓ Authorize exceptions to the requirements of this manual.

### All employees

- ✓ Perform work safely and responsibly with emphasis on personal safety and the safety of coworkers, the public, and the environment;
- ✓ Adhere to all quality control requirements;
- ✓ Attend required training;
- ✓ Be continually alert for potential hazards; and
- ✓ Report all potential hazards.

### All managers

- ✓ Ensure hazards are assessed prior to commencement of work.
- ✓ Determine physical and fiscal resources needed for projects to ensure safe operations can be carried out.
- ✓ Ensure employees are up-to-date in all required training and certification.
- ✓ Perform quarterly walk-through inspections.
- ✓ Follow all identified safety concerns through resolution.
- ✓ Review all available safety information and reports related to their operations.
- ✓ Discuss safety issues in staff meetings.

## **Survey Projects Group**

### Survey Projects Manager

- ✓ Oversee the Survey Procedures Manual;
- ✓ Monitor quality control of technical information and data to ensure compliance and sound practice;
- ✓ Review and approve survey reports prior to release;
- ✓ Provide (where applicable) the Purchasing Department with specifications for purchased equipment, and services;
- ✓ Establish training and certification content specific to survey activities; and
- ✓ Oversee software validation, including associated record keeping.

### Site Coordinator

Note: This role can be performed by any member designated as ORISE's representative and on-site supervisor, as determined by the Director or a Technical Manager.

- ✓ Oversee performance of field quality control procedures including calibration and daily instrument checks;
- ✓ Perform field record review;
- ✓ Oversee preparation of sample chain-of-custody documentation;
- ✓ Ensure document and records for assigned projects are adequately controlled prior to archival;
- ✓ Initiate requests for laboratory analysis;
- ✓ Ensure data are accurately reported; and
- ✓ Monitor safety conditions on the work site and report any potential safety concern to the Survey Projects Manager and site contact.

### Health Physics Project Leader

- ✓ Ensure adherence to procedural requirements for assigned survey projects;
- ✓ Confirm training and certification requirements are met for each survey project;
- ✓ Perform pre-project hazard analysis and develop project specific health and safety plans, when applicable, in conjunction with ES&H office and the Survey Projects Manager;
- ✓ Monitor work practices on survey sites and follow-up on any identified safety concern;
- ✓ Ensure adherence to quality control requirements associated with assigned projects;
- ✓ Ensure complete documentation of project activities; and
- ✓ Ensure accurate presentation of data and technical determinations in reports.

### Field Survey Team Leader

- ✓ Train technicians to perform field activities;
- ✓ Maintain instrument calibration sheets in central files;
- ✓ Perform field quality control procedures including calibration and daily instrument checks;
- ✓ Prepare chain-of-custody documentation in the field; and
- ✓ Accept delegation of duties as assigned by the Survey Projects Manager.

### Health Physics Technician

- ✓ Complete all required site-specific training;
- ✓ Adhere to all procedural and specific quality control requirements;
- ✓ Provide input to Survey Projects Manager regarding work process improvements; and become generally familiar with Site Coordinator and Field Survey Team Leader QA duties, and assist as assigned.

### Graphics Coordinator

- ✓ Train others to perform graphics functions;
- ✓ Coordinate with ORISE Information Systems Department to ensure maintenance of graphics hardware; and
- ✓ Maintain electronic graphics files.

## **Laboratory Group**

### Laboratory Manager

- ✓ Oversee the Laboratory Procedures Manual;
- ✓ Oversee modifications and maintenance of the ESSAP Database System;
- ✓ Monitor laboratory quality control to ensure compliance and sound practice;
- ✓ Establish training and certification content specific to laboratory activities;
- ✓ Provide (where applicable) the Purchasing Department with specifications for purchased equipment, services, materials, reagents, and chemicals;
- ✓ Ensure inspections/tests of newly purchased items are completed to meet established requirements;
- ✓ Review developed laboratory data, including that received from contracted laboratories;
- ✓ Review reports that include laboratory data, prior to release;
- ✓ Approve release of laboratory reports;
- ✓ Oversee validation, including associated record keeping, for laboratory software;
- ✓ Oversee interim and final disposition of samples;
- ✓ Maintain and calibrate computer based equipment for radiometric measurements and maintain records for these activities;

- ✓ Maintain and calibrate laboratory survey instruments;
- ✓ Maintain files of traceable standard calibration documentation;
- ✓ Oversee laboratory quality control procedures;
- ✓ Review laboratory data sheets;
- ✓ Maintain files of original data sheets including undeveloped and developed data until archival is requested or until data from a field survey are turned over to the individual responsible for the project.
- ✓ Oversee maintenance of quality and quantity of laboratory supplies and chemicals;
- ✓ Oversee maintenance of laboratory equipment in operating condition;
- ✓ Accept and maintain chain-of-custody of samples during analysis and archival;
- ✓ Oversee a program for checking and documenting reagent water quality;
- ✓ Maintain records of laboratory standard certification documentation; and
- ✓ Perform and/or oversee inspections/tests of newly purchased items to ensure that established requirements are met.

#### Senior Chemist

- ✓ Act on behalf of the Laboratory Manager in his absence;
- ✓ Train other staff members to perform analytical procedures; and
- ✓ Provide input regarding work process improvements.

#### Count Room Coordinator

- ✓ Accept delegation of duties as assigned by the Laboratory Manager;
- ✓ Train other staff members to perform instrument counting procedures;
- ✓ Maintain the calibration and operational checkout documentation for the count room instrumentation;
- ✓ Provide input regarding work process improvements.

#### Chemist and Laboratory Technician

- ✓ Become generally familiar with Senior Chemist QA duties and assist as assigned; and
- ✓ Provide input regarding work process improvements.

### **Health Physics and Technical Projects Group**

#### Health Physics and Technical Projects Manager

- ✓ Monitor quality control of technical information and data to ensure compliance and sound practice;
- ✓ Review reports prior to release;

- ✓ Provide (where applicable) the Purchasing Department with specifications for purchased equipment, and services;
- ✓ Establish training and certification content specific to areas of responsibility; and
- ✓ Oversee software validation, including associated record keeping.

#### Health Physics Project Leader

- ✓ Ensure adherence to procedural requirements for assigned projects;
- ✓ Confirm training and certification requirements are met for each project;
- ✓ Perform pre-project hazard analyses and develop project specific health and safety plans, when applicable, in conjunction with ES&H office and the Health Physics and Technical Projects Manager;
- ✓ Monitor work practices during assigned projects and follow-up on any identified safety concern;
- ✓ Ensure adherence to quality control requirements associated with assigned projects;
- ✓ Ensure complete documentation of project activities; and
- ✓ Ensure accurate presentation of data and technical determinations in reports.

#### Field Survey Team Leader

- ✓ Train technicians to perform field activities;
- ✓ Maintain instrument calibration sheets in central files;
- ✓ Perform field quality control procedures including calibration and daily instrument checks;
- ✓ Prepare chain-of-custody documentation in the field; and
- ✓ Accept delegation of duties as assigned by the Health Physics and Technical Projects Manager.

### **Administrative Group**

#### Quality and Administrative Support Manager

- ✓ Provide independent oversight for QA/QC pertaining to Survey Projects, Health Physics and Technical Projects, and Laboratory activities;
- ✓ Review and provide concurrence for release of reports that must meet Survey and/or Laboratory Procedures Manual requirements;
- ✓ Perform or oversee performance of project file reviews;
- ✓ Oversee archival of critical records;
- ✓ Review the QA/QC results from contracted laboratory services in conjunction with the Laboratory Manager;
- ✓ Oversee the Quality Assurance Manual;
- ✓ Ensure required data entry to the Quality Control, Audit, and Nonconformance data tracking systems;
- ✓ Oversee maintenance of the ESSAP training and certification records;

- ✓ Ensure complete documentation of performance evaluation activities;
- ✓ Coordinate vendor/provider assessments as deemed necessary by the Program Director;
- ✓ Oversee the training for administrative personnel; and
- ✓ Monitor administrative quality control activities to ensure compliance and sound practice.

#### Senior Program Specialist

- ✓ Perform peer reviews of other clerical staff work;
- ✓ Perform archival of critical program records;
- ✓ Perform distribution of controlled documents;
- ✓ Maintain ESSAP worker qualification training and certification records; and
- ✓ Provide input regarding work process improvements.

#### Program Specialists and Office Assistant

- ✓ Perform peer reviews of other clerical staff work; and
- ✓ Provide input regarding work process improvements.

### **Support Services**

Business Operations support groups within ORAU/ORISE are responsible for certain quality assurance functions for ESSAP.

#### Information Systems Department

The Laboratory Manager serves as the liaison with this group.

- ✓ Maintain files of programs and flow sheets for internally generated software;
- ✓ Maintain files of computer equipment records of repair and maintenance; and
- ✓ Maintain original commercial software and software documentation for ESSAP; and
- ✓ Maintain files of computer equipment records of repair and maintenance.

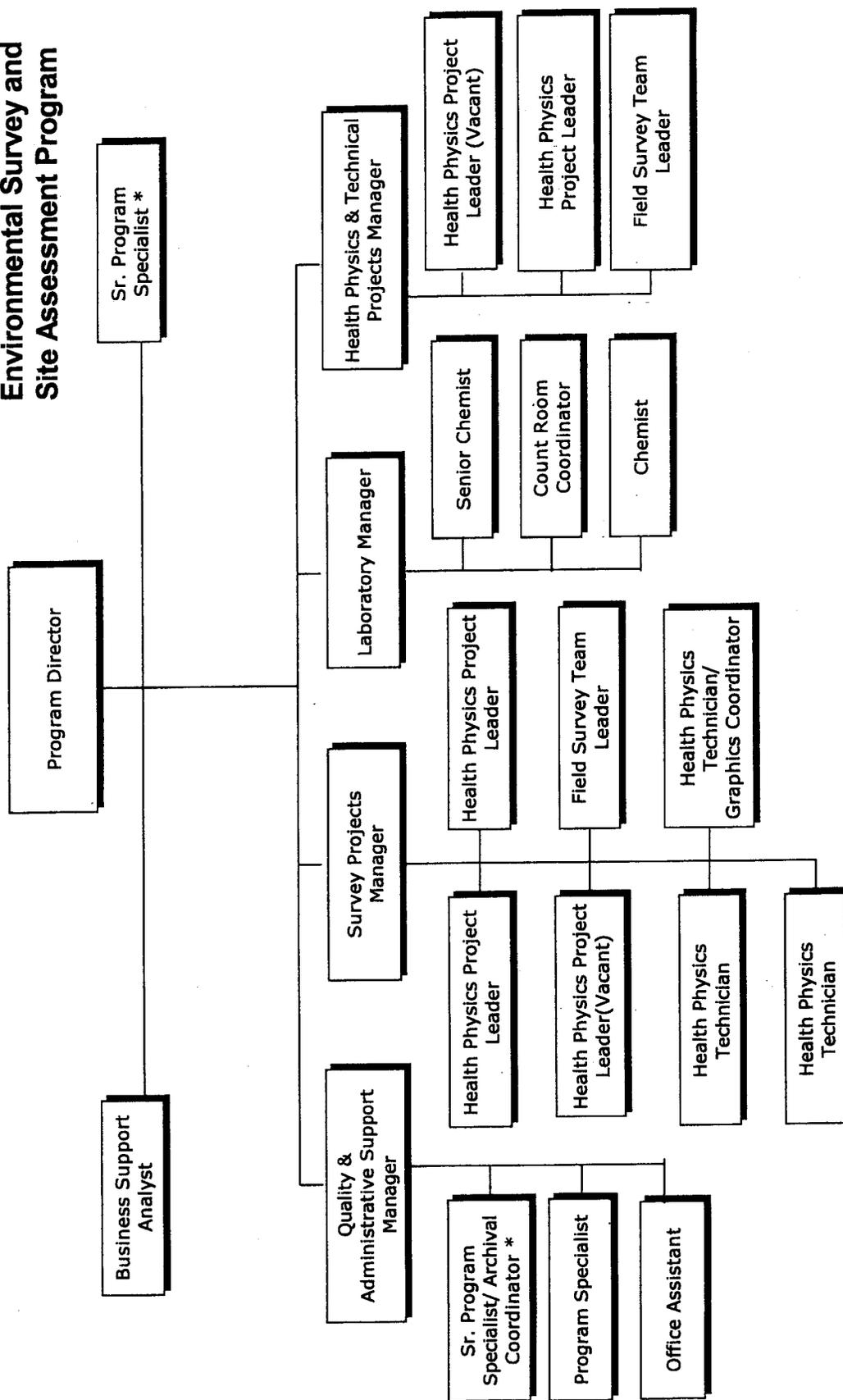
#### Procurement Department

Assist with purchasing of items and services to ensure safety and quality requirements are met.

#### Environmental Safety and Health office

Provide support with the review of job hazards and monitoring, Job Hazard Analysis development, and with the development of project specific health and safety plans.

# Environmental Survey and Site Assessment Program



\* Dual role

## SECTION 2

### PROCEDURES

#### 1.0 PURPOSE

Procedures are established and maintained for activities requiring the application of standard and approved methods to ensure regulatory requirements are met, to document technical sufficiency of the approach, and to ensure effective and efficient processes are used. Procedures utilized by ESSAP are documented in manuals prepared for program-specific applications. The procedures are applied through the development of project specific survey plans or statements of work. If approved procedures will not meet project needs, special procedure requirements will be identified in the work plan, if applicable, and documented in the project file. Special procedures are termed “Nonroutine” and are not expected to be generally applicable to other projects, or are not expected to be used frequently. The need for a new or revised procedure may be determined as a result of the completion of a Pre-Job Hazard Checklist or Integrated Safety Management Plan for New or Modified Work.

#### 2.0 RESPONSIBILITIES

##### Director

- ✓ Review procedures and approve them for implementation.

##### Survey Projects Manager, Health Physics and Technical Projects Manager, and Laboratory Manager

- ✓ Identify the need for a new or revised procedure.
- ✓ Serve as author or assign a staff member to serve as author for new or revised procedures and the associated Job Hazard Analyses.
- ✓ Ensure procedures address all regulatory requirements and applicable industry standards.
- ✓ Ensure procedure testing is performed and documented, as necessary, to confirm the accuracy and usability of procedure steps.
- ✓ Provide procedure testing and comment resolution documentation to the Quality Manager.
- ✓ Approve procedures for implementation.
- ✓ Determine whether Nonroutine procedures will be included in a manual.
- ✓ The Survey Projects Manager reviews the Survey Procedures Manual at least annually and initiates updates as necessary.

- ✓ The Laboratory Manager reviews the Laboratory Procedures Manual at least annually and initiates updates as necessary.

#### Quality Manager

- ✓ Review all procedures to ensure cross references between manuals are maintained and QA requirements have been met.
- ✓ Review the Quality Assurance Manual at least annually and update it as necessary.
- ✓ Approve Quality Assurance procedures for implementation.
- ✓ Maintain tracking information for manual revisions, files of original procedure versions, comment resolution documentation, and procedure approval documentation.

#### Administrative Assistant

- ✓ Perform procedure distribution.
- ✓ Track controlled manual/procedure distribution.

#### All staff members

- ✓ Complete required actions as defined on procedure distribution memos.
- ✓ Communicate procedure inadequacies and suggestions for improvement to the cognizant Manager.

### **3.0 DEFINITIONS**

Nonroutine procedures: Procedures that are expected to be used infrequently

Procedures: Documents that specify or describe how critical activities are performed.

### **4.0 PROCEDURE**

#### 4.1 Procedure Manuals

4.1.1 Procedures are documented and maintained as part of the following manuals:

- ✓ Survey Procedures Manual
- ✓ Laboratory Procedures Manual

✓ Quality Assurance Manual

Nonroutine procedures are incorporated into manuals at the discretion of the cognizant manager.

- 4.1.2 All ESSAP staff are notified of procedure revisions for all three manuals.
- 4.1.3 Controlled procedure manuals are issued to ESSAP staff members, as applicable, according to their work assignments. Hard copy procedure revisions are distributed to all individuals assigned controlled manuals. Staff members who must plan, perform, or evaluate work procedures where web access is not available or feasible are required to maintain a hard copy controlled manual. Staff members who must access procedures for reference only or who have web access where they are performing work may access procedures on the web site. Any staff member may request hard copy procedures. Non-staff members will be referred to the web for procedures at the following address: <http://www.ora.gov/essap>.
- 4.1.4 The Quality Assurance Manual applies to all ESSAP activities. Staff members may elect to maintain a hard copy manual or access the web site for the current version.
- 4.1.5 All Survey Projects and Health Physics and Technical Projects staff members, and any other staff members whose job assignments require them to perform survey procedures, are required to maintain a hard copy of the Survey Procedures Manual. Other staff members may elect to maintain a hard copy manual or access the current version on the web.
- 4.1.6 All Laboratory staff members, and any other staff members whose job assignments require them to perform laboratory procedures, are required to maintain a hard copy of the Laboratory Procedures Manual. Other staff members may elect to maintain a hard copy manual or access the current version on the web.
- 4.1.7 A unique number is assigned by the Administrative Assistant to each hard copy manual for tracking purposes.
- 4.1.8 It is the assignee's responsibility to incorporate revisions when received.
- 4.1.9 Procedure manuals are reviewed annually by the cognizant manager and revised as necessary.

4.1.10 Tracking of annual reviews and revisions is maintained by the Quality Manager.

## 4.2 Procedure Development

4.2.1 A manager identifies, or approves of, the need for a new procedure or the revision of a current procedure. The manager then serves as the author or assigns a staff member as author for development of the procedure and the associated Job Hazard Analysis (JHA), as applicable.

4.2.2 The author develops the new or revised procedure draft. The following components are included in each procedure, as applicable:

- ✓ Descriptive title;
- ✓ Current revision number and the effective date;
- ✓ Statement of purpose;
- ✓ Scope or principle of the method;
- ✓ References;
- ✓ Precautions;
- ✓ Step-by-step instructions;
- ✓ Limits of detection; and
- ✓ Reporting and record requirements.

4.2.3 The author determines whether a JHA covering the activity exists or must be developed. If a JHA for the work does not exist, the manager will ensure that staff members who will carry out the procedure are involved in JHA development.

4.2.4 The author performs and documents procedure testing and/or verification of results.

4.2.5 The cognizant manager ensures that:

- ✓ Appropriate references are included;
- ✓ Procedure testing is performed and documented, as necessary, to confirm the accuracy and usability of the procedure steps; and
- ✓ JHA has been approved by the ES&H office.

4.2.6 The author requests clerical formatting for procedures that will be included in a manual.

4.2.7 For Nonroutine procedures, the manager determines whether the procedure should be incorporated into a procedure manual. If a

Nonroutine procedure is not incorporated into a manual it will be maintained as a critical record in the project file. A cover sheet will be prepared documenting completion of reviews and applicability for a specific project, task, or time period.

- 4.2.8 The author requests review by the cognizant manager, Quality Manager, and Director. Reviews will include evaluation of editorial and technical accuracy. Review comments will be documented by each reviewer. The author will document the resolution of comments and provide documentation to the Quality Manager to maintain as a critical record.
- 4.2.9 The cognizant manager and the Director approve procedures for implementation. The Quality Manager provides concurrence approval for the Survey and Laboratory Procedures Manuals. Implementation approval is documented on the manual Table of Contents or on the cover page of a Nonroutine procedure that will not be incorporated into a procedure manual.
- 4.2.10 Final procedures and Nonroutine procedures to be included in a procedure manual are provided to the Administrative Assistant for controlled distribution (See Section 4.4). The Administrative Assistant ensures that the final electronic version of the procedure and the updated Table of Contents are saved in the correct electronic and hard copy folders and posted to the web site. Nonroutine procedures that will not be included in the manual are saved as a hard copy in the project file.
- 4.2.11 Inadequacies discovered in procedures must be communicated to the cognizant manager immediately.
- 4.2.12 The Director, manager, or Site Coordinator determines the need for an immediate deviation to a procedure. If a deviation is required it is handled as described in Section 4.5.

#### 4.3 Procedure Training

- 4.3.1 The procedure author is considered to be trained and certified by virtue of his/her role in procedure development. Documentation of the author's training and proficiency testing will be maintained in the training files.

4.3.2 Procedure training will require one of the following:

- ✓ Reading the procedure and JHA and discussing any questions with the author or cognizant manager. Completion will be documented in the employee training files.
- ✓ Reading the procedure and JHA and attendance in a training session. Completion will be documented in the employee training files.
- ✓ Reading the procedure and JHA, attendance in a training session, and certification by proficiency testing. Completion will be documented in the employee training files.

4.3.3 The manager determines the level of training required, whether proficiency testing will be required, and which staff members are required to participate in training and proficiency testing for each procedure.

4.3.4 Staff members will complete training before they perform work using the procedure.

4.3.5 For specific training or proficiency testing requirements see Quality Assurance Manual Section 3.

#### 4.4 Controlled Distribution and Implementation of Procedures

4.4.1 Procedures are implemented after they have been approved and training has been completed.

4.4.2 Procedure distribution is controlled by the Administrative Assistant.

4.4.3 Procedures will be issued in total. For procedures included in a manual, the Table of Contents for each manual serves as the record of procedures approved for use, including the implementation date.

4.4.4 The Quality Manager maintains a list of historical procedure revisions. Historical copies of procedures included in manuals are maintained as both hard copy and electronic files.

4.4.5 The Administrative Assistant maintains a list of individuals receiving controlled manuals, the date assigned, and the manual number.

4.4.6 Hard copy procedure revisions are distributed to all individuals assigned a controlled manual.

4.4.7 New procedures and procedure revisions will be distributed using a memo stating the following requirements:

- ✓ Update hard copies of controlled manuals;
- ✓ Read the procedure and JHA;
- ✓ Perform training as specified; and
- ✓ Document completion of procedure review training and/or proficiency testing in the ESSAP Database.

#### 4.5 Deviations from Procedures

4.5.1 The Director, Managers, or Site Coordinators may implement deviations from approved procedures when necessary to meet customer requirements or to temporarily correct inadequacies identified during procedure use.

4.5.2 Documentation of procedure deviations must be included in each affected project file and contain the following information:

- ✓ Project supervisor's name;
- ✓ Circumstances requiring the deviation;
- ✓ Alternate approach and reason for choice; and
- ✓ Effective date(s) of deviation.

Procedure deviations will also be noted in final project deliverables.

4.5.3 The cognizant manager will determine whether a deviation is one that should be adopted for general use and incorporated into a procedure manual.

## SECTION 3

### TRAINING

#### 1.0 PURPOSE

Training is provided to ensure that employees develop and maintain the skills needed to perform their duties and responsibilities.

#### 2.0 RESPONSIBILITIES

##### Survey Projects Manager, Health Physics and Technical Projects Manager, and Laboratory Manager

- ✓ Serve as the author for procedures or assign the responsibility for procedure development and testing;
- ✓ Identify procedures for which training, proficiency testing, refresher training, and recertification are required;
- ✓ Identify staff members required to complete training and proficiency testing;
- ✓ Approve proficiency testing criteria; and
- ✓ Ensure training documentation is up-to-date.

##### Trainer

- ✓ Serve as procedure developer or show knowledge and/or proficiency of the procedure requirements;
- ✓ Observe and document proficiency certification; and
- ✓ Document that training and/or proficiency testing was provided.

##### Administrative Assistant

- ✓ Maintain training and certification records; and
- ✓ Assist with entry of training documentation into the ESSAP Database.

##### All staff

- ✓ Complete training and proficiency testing as directed; and
- ✓ Enter training documentation into the ESSAP Database.

### 3.0 DEFINITIONS

Certification: Documentation indicating completion of training and/or proficiency testing.

Developmental Training: Training that is not required but is performed to enhance the individuals professional development and may be part of the Individual Performance Plan.

On-the-job Training: Training related to ESSAP controlled procedures, provided by ESSAP staff members.

Proficiency testing: Demonstration of the ability to perform procedure steps independently and meet specified criteria for results. Procedures for which proficiency testing is required, and acceptance criteria are identified by the cognizant Manager.

Recertification: Periodic update to previous proficiency testing to ensure skill level is maintained and instruction on new information and lessons learned related to the procedure are shared. Recertification is required annually, within a year and one month of the previous certification.

Refresher training: Periodic update to previous training which does not include proficiency testing.

Training: Instruction regarding a new or revised procedure provided by the procedure author or another individual who has demonstrated proficiency.

### 4.0 PROCEDURE

#### 4.1 ORAU/ORISE Mandatory Training

ORAU/ORISE mandatory training is scheduled and tracked by the Office of Human Resources.

#### 4.2 Compliance/Regulatory Training

Compliance training is required for specific job assignments and can include the following:

- ✓ Radiation Worker Training
- ✓ OSHA HAZWOPER Training
- ✓ First Aid Training
- ✓ CPR Training

- ✓ Bloodborne Pathogen Training
- ✓ Site Specific Health and Safety Training
- ✓ Respirator Training

Human Resources maintains “Required Training” forms for all employees and tracks compliance training. ESSAP maintains a listing of completion dates for convenience.

#### 4.3 ESSAP Procedure Training

- 4.3.1 Training requirements are determined by the cognizant manager for the procedure.
- 4.3.2 Training must be completed before a procedure is performed for direct project work activities.
- 4.3.3 Training types and documentation requirements:

##### Reading and understanding procedures

- ✓ Required for all new and revised procedures;
- ✓ Some procedures or procedure revisions require only reading the procedure and requesting clarification from the author for the individual to be able to implement the procedure requirements.
- ✓ Documentation of completion is maintained in the employee training files.

##### Procedure training

- ✓ The cognizant Manager determines which procedures require training ~~is~~ and which staff members are required to complete training.
- ✓ The procedure author, or another person who has demonstrated knowledge of the procedure, provides training. The author’s certification is approved by the supervisor by virtue of the knowledge gained during procedure development and testing.
- ✓ Documentation of completion is maintained in the employee training files.
- ✓ The need for refresher training, and the content, is determined by the cognizant manager.

### Proficiency testing

- ✓ The cognizant manager determines which procedures require proficiency testing and which staff members are required to complete proficiency testing.
- ✓ The procedure author, or another person who has demonstrated knowledge of the procedure, provides training. The trainer's certification is approved by the supervisor by virtue of the knowledge gained during procedure development and testing.
- ✓ Recertification of proficiency testing must be updated annually for all staff responsible for performing the procedure.
- ✓ Documentation of completion is maintained in the employee training files.

#### 4.4 Developmental Training

Developmental training is scheduled with the cognizant manager's approval.

## SECTION 4

### INSTRUMENT QUALITY CONTROL

#### 1.0 PURPOSE

The identification, calibration frequencies, and responsibilities for instrumentation are provided in this section. Complete procedures for calibration, operational check out, and use are documented in the ESSAP Survey and Laboratory Procedures Manuals.

#### 2.0 RESPONSIBILITIES

##### Survey Projects and Laboratory Managers

- ✓ Identify parameters to be measured.
- ✓ Establish acceptable performance criteria.
- ✓ Ensure documentation is maintained

##### Survey and Laboratory Staff

- ✓ Record performance data and compare it to established criteria.
- ✓ Field Site Coordinators are responsible for assuring implementation of these requirements on survey sites.

##### Quality Manager

- ✓ Perform reviews of performance documentation and work with managers to initiate corrective actions, as appropriate.

#### 3.0 INSTRUMENT IDENTIFICATION

New equipment and instrumentation items are uniquely identified upon receipt to allow for independent traceability.

#### 4.0 CALIBRATION AND OPERATIONAL CHECK STANDARD REQUIREMENTS

Calibrations are based on standards traceable to the National Institute of Standards and Technology (NIST). If NIST-traceable standards are unavailable or prohibitively expensive, standards of an industry-recognized organization may be used. An example of an acceptable replacement would be uranium standards from the New Brunswick Laboratory.

## 5.0 CALIBRATION AND OPERATIONAL CHECKOUT REQUIREMENTS

### 5.1 Survey Instrumentation Calibration and Checkout

- 5.1.1 The Survey Projects Manager establishes operational parameters to be monitored for survey instrumentation, and determines appropriate methods and frequencies for monitoring.
- 5.1.2 Calibration procedures are performed according to the methods defined in the ESSAP Survey Procedures Manual.
- 5.1.3 Items sent to a manufacturer for calibration have an operational check performed before usage to ensure no damage occurred during shipment.
- 5.1.4 Field instrumentation calibration is performed prior to initiating surveys at a new site, or every six months when used at a single site, and following any substantial repair. The PIC is the only exception; it is calibrated by the manufacturer every two years and after repairs.
- 5.1.5 When operational check-out conditions are not met survey instrument/detector combinations are removed from service until the discrepancy can be resolved.
- 5.1.6 Data collected between the time valid QC measurements were obtained and when unacceptable results are obtained are verified or designated as invalid.
- 5.1.7 Calibration documentation is reviewed and approved by the Survey Projects Manager or supervisor prior to the next use of the instrument.
- 5.1.8 Background measurements must fall within the background range established for the site and are performed as follows:
  - ✓ Prior to beginning the performance of data measurements and/or scanning for the day;
  - ✓ Midway through the work day;
  - ✓ After completion of measurements and/or scanning for the day;
  - ✓ Any time detector contamination is suspected; and
  - ✓ Any time instrument operation is in question
- 5.1.9 Check source measurements must fall within the check-source range established for the site and are performed as follows:

- ✓ Prior to beginning the performance of data measurements and/or scanning for the day
- ✓ After completion of measurements and/or scanning for the day
- ✓ Any time instrument operation is in question
- ✓ At mid-day, when feasible

## 5.2 Laboratory Count Instrumentation Calibration and Checkout

### 5.2.1 Applicable instrumentation

Alpha Spectrometer  
Gamma Spectrometer  
Low Background Alpha and Beta Counter  
Liquid Scintillation Counter

### 5.2.2 Calibration of Laboratory Instrumentation

5.2.2.1 The Laboratory Manager establishes operational parameters to be monitored for laboratory instrumentation, and determines appropriate methods and frequencies for monitoring.

5.2.2.2 Calibration procedures are performed according to the methods defined in the ESSAP Laboratory Procedures Manual.

5.2.2.3 Calibration documentation is reviewed and approved by the Laboratory Manager prior to the next use of the instrument.

5.2.2.4 Items sent to a manufacturer for calibration have an operational check performed before usage to ensure no damage occurred during shipment.

5.2.2.5 Initial calibration of instrumentation is performed as part of the set up.

5.2.2.6 Recalibration of laboratory instrumentation is performed when control charts, extensive repairs, or relocation of instrumentation may invalidate earlier calibration data.

### 5.2.3 Operational Checks of Laboratory Instrumentation

#### 5.2.3.1 Operational Check Types

### Background count

A background count is acquired by counting the empty chamber.

- ✓ Background counts are performed weekly.
- ✓ Results must be within 3 sigma of established limits for defined regions of interest and for full spectrum background.

### Reproducibility Check

A reproducibility check is performed by counting reference material.

- ✓ Reference materials are prepared using primary or secondary standards traceable to NIST.
- ✓ Reproducibility checks are performed daily prior to counting samples.
- ✓ Results must be within 3 sigma of the known.

### Quench Indicating Parameter

Quench Indicating Parameter (QIP) is a value used to express the level of reduction in the scintillation intensity seen by the photomultiplier tubes of the counter due to the presence of materials interfering with the production or detection of light.

- ✓ QIP is used for liquid scintillation counting.
- ✓ QIP is determined for each sample.
- ✓ Results must fall within 20% for all non DOE analyses
- ✓ Results must fall within 5% for DOE analyses

5.2.3.2 Background or reproducibility counts which do not meet the acceptance criteria are repeated and evaluated. Repairs or corrections to the system are performed, as necessary, until acceptable results are obtained and calibration parameters are either verified or re-established.

5.2.3.3 Results of operational checks of instruments are placed on control charts or tables. Original data values used to generate control charts are organized and readily available.

5.2.3.4 Charts are generated automatically by the instrument software.

5.2.3.5 Analyses for which operational check results do not meet the guidelines required by this procedure are evaluated by the Laboratory Manager in conjunction with the Project Manager, if applicable. Information such as data end use and sample matrix characteristics are used to determine whether reanalysis is necessary. In all such cases explanatory comments are added to the project file.

5.2.3.6 Analytical data for which operational check results meet the requirements of this procedure are considered acceptable for use in project reports. When re-analysis of samples is performed all analytical results determined to be technically sound by the Laboratory Manager will be reported.

5.2.4 When operational check-out conditions are not met the operational checks must be rerun successfully two times in succession, or the instrument will be taken out of service until the problem is resolved.

5.2.5 Control charts are maintained for critical instrument parameters to provide a means of evaluating on-going process capability and stability. Charts are generated by the instrument software.

5.2.6 Operational performance is reviewed by the Laboratory Manager and recorded at least weekly for completeness, conformance with acceptance criteria, undesirable trends, and resolution or corrective actions.

### 5.3 Laboratory Balance Calibration and Checkout

5.3.1 Balances are calibrated monthly in-house according to the requirements specified in the Laboratory Procedures Manual and annually by a calibration service.

5.3.2 Operational checks of balances are performed prior to each day's use and recorded in either paper or electronic logbooks.

### 5.4 Laboratory pH Meter Calibration and Checkout

The pH meter is calibrated in-house before use in sample analysis or before reagent preparation requiring specific pH tolerances. Calibration is performed according to the requirements specified in the Laboratory Procedures Manual.

## SECTION 5

### SAMPLE CHAIN-OF-CUSTODY

#### OVERVIEW

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##### **Introduction**

Sample accountability and integrity is maintained by use of chain-of-custody procedures. Sample custody documentation is initiated upon collection or receipt of the samples by the program and continues until the samples are consumed in analysis, transferred to another organization, or disposed of properly.

An acceptable chain-of-custody is maintained when the sample is under direct surveillance; kept in a tamper-free container; or is within a controlled access facility.

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##### **In this section**

This section covers the following topics:

<b>Topic</b>	<b>Page</b>
Samples Collected by Other Organizations	2
Initiation of Sample Custody	2
Transfer of Custody	2
Sample Security & Transport	3
Laboratory Sample Custody	3
Sample Archival & Disposal	4
Chain-of-Custody Record	5

## SAMPLE CHAIN-OF-CUSTODY, Continued

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**Samples collected by other organizations**

Samples collected by other organizations that are provided to field personnel will have chain-of-custody initiated for them by the individual receiving the samples. When the organization has an established chain-of-custody in place, a copy of the form will be attached to the ESSAP form.

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**Initiation of sample custody**

- Chain-of-custody forms must be prepared daily.
  - A sample collector assumes responsibility as custodian and initiates a chain-of-custody form in duplicate.
  - Samples collected by other organizations that are provided to field personnel will have chain-of-custody initiated for them by the individual receiving the samples. When the organization has an established chain-of-custody in place, a copy of the form will be attached to the ESSAP form.
  - The sample(s) must be under direct surveillance of the sample custodian, secured in a locked vehicle or building, or in a tamper-proof container.
  - Each sample may be listed on the form separately; or a group of samples having common characteristics from a single site may be recorded as a single entry using a sample identification number range.
  - Samples of more than one matrix may be listed on a form if the samples can be packed and transported in the same container without risk to sample integrity.
  - If an item is not applicable “NA” is entered.
- 

**Transfer of custody**

- Sample custody is transferred by the custodian signing the “relinquished by” block and the receiver signing the “received in good condition by” block.

## SAMPLE CHAIN-OF-CUSTODY, Continued

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### Transfer of custody (continued)

- Samples are inspected prior to custody transfer to determine any evidence of tampering. Evidence of tampering and/or any deviations must be explained in the “remarks” section of the form. If sample integrity is questionable for any reason, a nonconformance report will be initiated, including, as part of the corrective action plan, determination of the effect on the usefulness of the analytical data.

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### Sample security & transport

- Sample security seals may be placed on the container of samples to ensure container is tamper-proof.
- Containers with security seals do not have to remain in a secured area but precautions should be taken to restrict access to the samples by authorized individuals.
- The original (white copy) of the chain-of-custody form must contain all signatures and other pertinent records regarding custody. Therefore, the original is retained in the possession of the individual who has custody at any specific time.
- As long as sample remains in custody of the collector, both copies of the chain-of-custody form are to accompany the samples.
- When shipping samples, the yellow copy of the chain-of-custody is sealed in the container with the samples and the white copy is maintained by the custodian. In cases where the custodian will not return to the laboratory prior to deadlines for sample analysis, the white copy must be signed and mailed to the ESSAP Laboratory Supervisor.

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### Laboratory sample custody

A member of the laboratory staff will:

- Inspect sample container and contents for tampering; compare to original chain-of-custody form; note any deficiencies in the remarks column; and sign form to accept custody.
- Enter sample information into the ESSAP Database System.
- White copy of form is kept by the Laboratory manager; yellow copy is filed in the project file.

## **SAMPLE CHAIN-OF-CUSTODY, Continued**

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### **Laboratory sample custody (continued)**

- During analysis, the samples will remain in a locked building during working hours and in a locked room in the building during non-working hours.
  - The Laboratory Manager is responsible for ensuring chain-of-custody.
- 

### **Sample archival & disposal**

- Samples are considered active until disposed of, consumed, transferred, or destroyed
  - Archived samples are stored in a locked building with limited access.
  - Sample disposal must be approved by the agency.
-



## SECTION 6

### ANALYTICAL QUALITY CONTROL

#### 1.0 PURPOSE

Analytical Quality Control (QC) Activities are intended to measure the performance of the analytical chemical processes against standards to verify adherence to defined requirements.

#### 2.0 REFERENCES

Advanced Topics in Statistical Process Control, D. J. Wheeler, 1995

#### 3.0 RESPONSIBILITIES

##### Laboratory Manager

- ✓ Identify parameters to be routinely measured.
- ✓ Establish acceptable performance criteria for operating parameters.
- ✓ Review quality control performance data for each batch.
- ✓ Review process control data quarterly.
- ✓ Review the results of outside analytical services.

##### Quality Manager

- T Perform reviews of performance documentation, document findings, and track follow-up.
- T Review process control data quarterly, in conjunction with the Laboratory Manager.

##### Laboratory staff members

- T Record quality control performance data and compare to established criteria.
- T Report all unacceptable quality control results to the Laboratory Manager.

#### 4.0 QUALITY CONTROL REQUIREMENTS FOR CHEMICAL ANALYSIS

##### 4.1 Quality of Standards

- ✓ Unless noted otherwise, chemicals used for reagent preparation are, at a minimum, American Chemical Society reagent grade.
- ✓ Quality control samples are prepared using primary or secondary standards

traceable to the National Institute of Standards and Technology (NIST) or industry accepted reference material.

#### 4.2 Sample Flow

Samples flow through chemical procedures in batches. Batches are used to monitor sample flow and ensure quality control. Upon receipt of a Laboratory Work Request, the batches are established and analyzed as follows:

- T Batches consist of samples to be analyzed by the same procedure for a common set of parameters.
- T Batches may contain from 1 to 20 samples, based on the number of analyses requested, sample matrix, analytical parameters, and the level of quality control required.
- T Each batch is assigned a unique identification (ID) number. This number is the next sequential number in the batch logbook or database. The ID number for the batch, sample identification, and associated QC samples, are recorded in the ESSAP database.
- T Batches are analyzed in a continuous, sequential manner; processing of samples is not interrupted by processing of samples from other batches.
- T Samples in the same batch are analyzed in the same area of the laboratory or facility.
- T The same reagent lots are used for all samples in a batch.

#### 4.3 Batch Quality Control

Samples are included in batches and evaluated as indicated below:

##### Method Blank

A method blank is an analytical control consisting of all reagents and internal standards that is carried through the entire analytical procedure. The result used for quality control evaluation includes the instrument background. The method blank is used to define the level of laboratory background and reagent contamination.

- T One method blank is run per batch.
- T The gross counts per minute must be at or below the upper process control limit.

##### Laboratory Control Standards

A Laboratory Control Standard (LCS) is a NIST traceable material or other industry accepted standard or reference material (e.g., NRM, TRM).

- T One LCS is run per batch.
- T The measured value must be within 50% of the known value for gross alpha/beta and for nonroutine procedures.
- T The measured value must be within 20% of the known value for routine procedures.

#### Chemical Recovery/Yield (Including BMO analyses)

The Chemical Recovery/Yield is a measurement of the fraction or percent of analyte present at the completion of the procedure.

- T One Chemical Recovery/Yield determination is performed per sample - or at a minimum one per batch for all analytical procedures except tritium by distillation.
- T The recovery/yield must be between 30 and 110% for isotopic analyses.
- T The recovery/yield must be between 40 and 110% for stable isotopes.

#### 4.4 Unacceptable Quality Control Results

Analyses for which quality control results do not meet the requirements stated in this procedure are evaluated by the Laboratory Manager. Information such as data end use and sample matrix characteristics are used to determine whether re-analysis is necessary. In all such cases, explanatory comments are added to the data sheets and project files.

#### 4.5 Acceptable Results

Analytical data for which quality control results meet the requirements stated in this procedure are considered acceptable for use in project reports. When re-analysis of samples is performed, all analytical results determined to be technically sound by the Laboratory Manager in conjunction with the Director and/or the cognizant manager will be reported.

#### 4.6 Process Control Charts

4.6.1 Process control charts are maintained for the following critical laboratory quality control parameters to provide a means for evaluation of on-going process capability and stability.

- T Method Blanks are charted as the gross counts per minute of total activity.
- T Laboratory Control Standards are charted as a ratio of the

measured value to the known value.

T Chemical recovery/Yields are charted as a ratio of the measured value to the known value.

#### 4.6.2 Establishing process control charts

4.6.2.1 Process control charts are created by using previously generated data, considered representative of the process, to establish a chart of individual values. Data points that are known to be unrepresentative of the process are not used for the calculation of control limits. Process control charts allow:

T Initial evaluation of process stability

T Ongoing evaluation of process variation

4.6.2.2 Charts of individual values are created using the following equations to establish the chart limits:

$$\text{Upper Control Limit (UCL}_x) = \bar{X} + 3 \left( \frac{\bar{R}}{d_2} \right)$$

$$\text{Central Line (CL}_x) = \bar{X}$$

$$\text{Lower Control Limit (LCL}_x) = \bar{X} - 3 \left( \frac{\bar{R}}{d_2} \right)$$

$$\frac{\bar{R}}{d_2} = \text{estimate of sigma}$$

$$\bar{X} = \text{Average of individual points}$$

$$\bar{R} = \text{Average of all two point moving ranges}$$

$d_2$  = a constant dependent on sample size. Constants are provided in standard statistics texts.

For  $n = 2$ ,  $d_2 = 1.128$ .

4.6.2.3 Evaluate the chart to determine whether the process is in control.

- ✓ Points lying outside the limits are investigated.
- ✓ If a special cause for an outlying point is identified, the data point is evaluated to determine whether or not it represents the process. If it is not representative, the point is removed from the data set and control limits are re-established using the

- remaining data.
- ✓ If no special cause is identified the control limits are maintained.

#### 4.6.3 Plotting Routine Data Points

Data points are plotted on control charts automatically or by manual entry after data review by the Laboratory Manager has been completed.

#### 4.6.4 Trend Analysis

4.6.4.1 Trend analysis of Laboratory Control Standards, Method Blanks, and Chemical Recoveries is performed quarterly by the Laboratory and Quality Managers. Results are documented in the Process Control Database.

4.6.4.2 The following conditions require investigation by the Laboratory Manager:

- T Occurrence of a point outside the three standard deviation control limit.
- T Eight successive values falling on the same side of the central line.
- T Persistent negative results.
- T Any time a recurring pattern is observed.

4.6.4.3 Limits are re-established only when the data set used to establish the current limits is determined to be inhomogeneous.

4.6.4.4 Follow-up actions are completed by the Laboratory Manager or Quality Manager.

#### 4.7 Sample Characterization

In cases where sample characterization is desired, matrix spike samples and/or replicate samples may also be analyzed.

- ✓ A **matrix spike** is an aliquot of a matrix fortified (spiked) with known quantities of specific compounds and subjected to the entire analytical procedure in order to indicate the appropriateness of the method for the matrix by measuring recovery. Matrix spike results are evaluated based on, at a minimum, the combination of standard control chart limits and sample variability. Sample variability is assigned a value of 20% if unknown.

- ✓ **Replicates** are multiple analyses of a homogenized sample. For nondestructive analysis a replicate may be the entire sample reanalyzed. Results will be used to calculate mean and standard deviation to delineate sample homogeneity. These values will be used in conjunction with total uncertainties to evaluate sample homogeneity.

#### 4.8 Outside Analytical Services

- 4.8.1 When outside analytical laboratories are utilized, quality control samples are included, or required to be included by the vendor, at a rate consistent with the above requirements. QA/QC requirements, appropriate for the specific project data quality objectives, are included in the purchase order.
- 4.8.2 The Laboratory Manager reviews the results of the outside analytical services to assure that specified QA/QC requirements have been met, and will resolve any discrepancies. Documentation of the review is maintained in the project file.

## SECTION 7

### DATA QUALITY CONTROL

#### 1.0 PURPOSE

Data collected in support of technical projects must be reviewed for completeness and accuracy, and to ensure that data treatments are technically sound and meet the project/task objectives. Data management procedures are described to establish the minimum controls necessary to maintain data quality.

#### 2.0 RESPONSIBILITIES

##### Director

- ✓ Approve standardized ESSAP data calculation and presentation approaches.

##### Technical Managers

- ✓ Approve technical approach to project specific data determinations;
- ✓ Perform data validation to ensure data meet project requirements; and
- ✓ Approve release of final data.

##### All Staff

- ✓ Record data accurately and in a legible manner; and
- ✓ Perform reviews of data generated by other staff members.

##### Project Leader

- ✓ Ensure that data generation conforms to approved procedures and project requirements; and
- ✓ Ensure that data review is performed.

##### Quality Manager

- ✓ Confirm completion of data reviews; and
- ✓ Perform verification to confirm data were generated according to approved procedures and were accurately reported as documented in the project file.

#### 3.0 DEFINITIONS

Data Validation: The act of confirming that data meet the project requirements.

Data Verification: The act of confirming data were generated according to approved procedures and reported accurately.

Processed Data: Data obtained from calculations performed using raw data. Calculations can be performed either by hand or by using computer programs.

Raw Data: Measured values recorded from instrumentation or equipment, or data obtained from other sources, such as NIST or other companies.

Transcribed Data: Data that is transferred from one location to another, for example transfer from field record forms to tables or from one electronic file to another, or transfer of the contents of an entire database to a new database.

## 4.0 PROCEDURES

### 4.1 General Data Quality Requirements

- ✓ Data must be recorded in a legible manner.
- ✓ Data must be protected from loss or destruction. Paper and electronic records of data are protected according to QA Manual Section 11 requirements.
- ✓ Data generation will allow for evaluation of minimum detectable concentrations at the 95% confidence level for analytical results.
- ✓ The number of significant figures used for values included in reports will be representative of procedural limitations.

### 4.2 Raw Data

4.2.1 Review of raw data is performed prior to processing or reporting of the data, and as soon after completion of a task as practical, to ensure errors are identified early in the process when potential for corrections is greatest. Data generated in the field is reviewed prior to leaving the field site.

4.2.2 Review of raw data is performed by the Site Coordinator for data generated in the field, by the Laboratory Manager for data generated in the laboratory, and by the Project Manager for other technical projects.

Reviews of raw data include evaluation of:

- ✓ Legibility
- ✓ Completeness

- ✓ Technical appropriateness
- ✓ Procedural compliance

4.2.3 Data reviews are documented by placing initials, or signature, and the review date on the data sheet.

#### 4.3 Processed Data

##### 4.3.1 Hand Processed Data

4.3.1.1 Hand processed data is reviewed by a technically qualified person not involved with the initial processing or collection of the raw data.

4.3.1.2 At least two hand calculations are replicated for each equation used.

4.3.1.3 Reviews are documented by placing initial, or signature, and the date on the record.

##### 4.3.2 Computer Processed Data

4.3.2.1 Equations created in electronic spreadsheets or programs are checked by a technically qualified person not involved with the initial processing prior to release of the spreadsheet or computer program for generation of reportable data.

4.3.2.2 Accuracy of automated equations is confirmed by replication of each equation by hand calculation. Confirmation of accurate automated application of the equation to multiple cells/destinations is performed by randomly selecting a minimum of ten percent of the cells/locations and ensuring that the correct equation was applied.

4.3.2.3 Documentation will consist of computer printouts and/or hand calculation sheets showing input parameters and results. Equations not identified in approved procedures must be included in the documentation.

4.3.2.4 Reviews are documented by placing initials, or signature, and the date on the review record.

#### 4.4 Transcribed Data

- 4.4.1 Transcribed data will be reviewed for accuracy by a technically qualified person not involved with the initial processing.
- 4.4.2 A minimum of ten percent of transcribed items will be checked for accuracy.
- 4.4.3 Reviews are documented by placing initials, or signature, and the date on the data review sheet, or by entering the name of the reviewer and date of review into an electronic log.

#### 4.5 Data Corrections

- 4.5.1 Data may not be obliterated using an eraser or white-out or by deletion of the data from electronic files serving as critical records, as defined in QA Manual Section 11.
- 4.5.2 Corrections to data in paper form are documented by striking a single line across the entry, entering the new data, then initialing and dating the correction.
- 4.5.3 Corrections to electronic data must be documented in an electronic change log linked to the electronic data file in a traceable manner, or in another location designated on the electronic data display.

#### 4.6 Data Record Review

- 4.6.1 Reviews of data records are performed as soon as possible after completion of the data entry. For field survey data, reviews are completed by the Site Coordinator prior to leaving the work site. For other data, reviews are completed prior to incorporation into external reports or prior to release of data for internal use by other groups. Reviews include evaluation of the following:
  - ✓ Accuracy of recording and transcription
  - ✓ Procedure compliance
  - ✓ Completeness
  - ✓ Accuracy of data processing
  - ✓ Consistency of presentation
- 4.6.2 Problems identified in the review process will be resolved prior to release of data for further use.

#### 4.7 Data Verification

4.7.1 The Project Leader is responsible for confirming that reported data conforms to the requirements of the procedure manuals and to any additional uniquely established project requirements.

4.7.2 The Quality Manager is responsible for confirming that generated data has been reviewed, and reported data values match raw or processed data as documented in the project file.

#### 4.8 Data Validation and Approval

The cognizant manager is responsible for confirming that data meets the project requirements, and for approving data to be released outside of ESSAP. The Laboratory Manager is responsible for approving release of laboratory data for further internal processing.

#### 4.9 Measurement Uncertainty

##### 4.9.1 Single Analytical Values

Total Propagated Uncertainties (TPU) will be reported for all analytical values, except smear count results. TPUs will be calculated according to the following equation:

$$2\sigma TPU = C \cdot 1.96 \sqrt{\frac{G+B}{(G-B)^2} + RE^2 + RY^2 + RQ^2} = pCi/unit$$

Where:

- B = Detector background counts
- C = Concentration
- G = Gross sample counts
- RE = 1  $\sigma$  relative uncertainty of the efficiency
- RQ = 1  $\sigma$  relative uncertainty of the quantity
- RY = 1  $\sigma$  relative uncertainty of the yield

##### 4.9.2 Repeated Analytical Measurements

Uncertainty for the average of repeated analytical measurements will be calculated according to the following equation:

$$2\sigma TPU = 1.96 \left( \frac{\sqrt{TPU_1^2 + TPU_2^2 \dots + TPU_n^2}}{n} \right) = pCi/unit$$

Where:            n = Total number of repeated measurements  
                       TPU<sub>n</sub> = Total propagated uncertainty of each measurement

#### 4.9.3 Field Measurement Values

Uncertainties will not be reported for field survey instrument measurements.

#### 4.9.4 Spatially Variable Data

For averages of data collected from spatially distributed locations, the standard deviation will be reported. Standard deviation will be calculated according to the following equation:

$$\sqrt{\frac{1}{n-1} \sum (x_i - \bar{x})^2}$$

Where:            n = Total number of measurements  
                       x = Individual measurement

### 4.10 Reporting Data

4.10.1 Average Minimum Detectable Concentrations (MDC) will be reported. MDC will be calculated according to the following equations.

For the Laboratory:

$$MDC = \frac{3 + 4.65 \sqrt{B}}{T * E * Y * Q}$$

Where:            B = Detector background counts  
                       E = Counting efficiency  
                       Q = Sample quantity  
                       T = Count time in minutes  
                       Y = Tracer yield

For survey instrument measurements:

$$MDC = \frac{3 + 4.65 \sqrt{B}}{T * \epsilon_{tot} * G}$$

Where: B = Background (total counts) in a time interval

$$\epsilon_{\text{tot}} = \text{total efficiency} = \frac{\text{counts}}{\text{disintegration}} = \epsilon_i * \epsilon_s$$

$$G = \text{Geometry} = \frac{\text{physical detector area (cm}^2\text{)}}{100}$$

T = Count time (min) to be used for field measurements

#### 4.10.2 Negative data will be reported

#### 4.10.3 Significant Figures

The number of significant figures used for values included in reports will be representative of procedural limitations. The following guidelines will be applied unless special project considerations are identified and documented in the project file.

Analytical data in the MDC range will be reported no more accurately than:

- ✓ Gamma Spectrometry: two significant figures for the TPU and rounding the value to the same number of places.
- ✓ Gross Alpha and Beta: two significant figures.
- ✓ Alpha Spectrometry: Data values in the MDC range will be reported to the hundredths place. Values larger than the MDC range will be reported using two significant figures for the TPU and rounding the value to the same number of places.
- ✓ Other wet chemistry: two significant figures for the TPU and rounding the value to the same number of places.

Values larger than the MDC range will be reported using two significant figures for the TPU and rounding the value to the same number of places.

Field survey measurements will be reported using no more than two significant figures.

## SECTION 8

### DOCUMENT QUALITY CONTROL

#### 1.0 PURPOSE

Project reports, project plans, proposals, contract documents, and other deliverables must be reviewed and approved for release prior to issuance to the client to ensure accuracy and completeness of the information, and adherence to all project and quality assurance requirements.

#### 2.0 RESPONSIBILITIES

##### Director

- ✓ Approve Project level contracting documents;
- ✓ Review technical documents for special projects; and
- ✓ May act in place of any Manager or Project Leader.

##### Survey Projects Manager, Health Physics and Technical Projects Manager, and Laboratory Manager

- ✓ Approve release of reports;
- ✓ Confirm that Integrated Safety Management requirements were documented for the project;
- ✓ Evaluate documentation of procedural compliance;
- ✓ Evaluate technical content of documents, including clarity of presentation, reasonableness, consistency and completeness of data;
- ✓ Determine if project goals were adequately met and conveyed to the reader;
- ✓ Approve release of Task level work plans and general correspondence to the customer; and
- ✓ May serve as Project Leader.

##### Quality Manager

- ✓ Verify documentation of procedural compliance;
- ✓ Ensure final data verification is performed and documented; and
- ✓ Perform project file review of quality control requirements.

##### Project Leader

- ✓ Has responsibility for the project; may hold the title of Project Leader, Manager, or Director;
- ✓ Ensure complete and accurate presentation of data;
- ✓ Ensure data transcription and calculation reviews are performed and documented;

- ✓ Ensure correction of deficiencies identified during the review process and resolution of comments prior to requesting approval for release to the customer; and
- ✓ Ensure completion and documentation of report reviews and approvals.

#### Author

Note: Any staff member may serve as the Author.

- ✓ Coordinate the assembly of the text, figures, and tables as applicable; and
- ✓ Work with other technical staff to determine appropriate presentation of information.

#### Site Coordinator

- ✓ Approve release of data during field surveys at the request of the customer;
- ✓ Ensure that all quality control requirements have been completed prior to release of the data; and
- ✓ Communicate with the Project Leader or Survey Projects Manager to resolve any concerns about data prior to release.

#### Administrative Assistant

Ensure that the following processes are completed:

- ✓ Report is formatted following the ESSAP standard process;
- ✓ Spell check has been run and any unrecognized technical terms have been verified with the Author;
- ✓ Clerical word processing has been proofed;
- ✓ The final document version is saved according to the ESSAP file management system;
- ✓ Reproduction services are as requested; and
- ✓ Final deliverables are converted to PDF and saved according to the ESSAP file management system.

#### Graphics Coordinator

- ✓ Use consistent approach in formatting illustrations; and
- ✓ Ensure data in figures match raw information provided.

#### Business Support Analyst

- ✓ Provide budgetary information for project plans, proposals, and other contracting documents.

### **3.0 DEFINITIONS**

Comment letter: A letter summarizing technical comments resulting from the review of documents submitted by other organizations.

Communication letters: Letters regarding general project or task activities.

Draft report: Report presenting descriptions of project work, summaries of collected and analyzed data, and when requested, technical conclusions. Any type of report can be prepared as a draft version prior to final report preparation. Draft reports may be prepared at the request of the customer to allow for customer input before the report is finalized. Draft reports developed for the purpose of soliciting customer comments are issued only after all technical and quality reviews have been completed, and approval and concurrence for release has been documented.

Final report: Report presenting descriptions of project work, summaries of collected and analyzed data and, when requested by the customer, technical conclusions. Final reports are issued only after all technical and quality reviews completed, and approval and concurrence for release has been documented.

Full report: Report prepared according to the ESSAP standard report format, generally including a signature page, a Table of Contents, a page defining abbreviations and acronyms, and appendices discussing procedures, instrumentation, and equipment. A full report is distributed as a hard copy report.

Letter report: Report presenting project results in letter format generally containing no more than two pages of text and having no subheadings. Enclosures such as data tables or figures may be included, but should be minimized. Electronic transfer of letter reports by email will be used when necessary to satisfy contract requirements

Preliminary data: Data provided prior to issuance of a draft or final report to meet a customer's request that may not have been through complete review and verification. This does not include electronic data transfer of laboratory results, as required in the NRC contract.

Project level contract document: Statements of work, project plans, proposals for new work, and other contracting documents which will establish new work based on new Project level funding. Specifications for project work and cost estimates are included in these documents.

Restricted Release Data Form: A standardized form created to capture specific data and other information from a short duration survey.

Task level contract document: Statements of work, project plans, survey plans, proposals for new work, and other contracting documents which will establish new work based on existing Project funding. Specifications for project work and cost estimates are included in these documents.

Technical concept report: Report presenting the results from technical research or other work, new technical concepts, or interpretations of technical material generated by other organizations. Results included in Technical Concept Reports are not those generated from the performance of procedures as set forth in ESSAP Field Survey or Laboratory Manuals. Examples of technical concept reports are comment letters, dose assessment summaries, or instrument evaluation summaries.

Technical Management Team: Includes the Director, Survey Projects Manager, Health Physics and Technical Projects Manager, and the Laboratory Manager.

#### **4.0 RELEASE OF PRELIMINARY DATA OR CONCLUSIONS**

- 4.1 Author prepares email text including preliminary information as requested by the customer and disclaimers stating that quality reviews have not been completed.
- 4.2 When data are to be included, Author ensures data transcription and calculations have been reviewed and are correct, based on the information available at the time, and sends email to manager.
- 4.3 Manager reviews all information to be provided to the customer (text and data) and sends an email to the Author approving release of the information to the customer.
- 4.4 Author issues information by email to the customer and saves copies of the approval email and the email to the customer in the project file.

#### **5.0 PROJECT OR TASK RELATED LETTERS AND OTHER CORRESPONDENCE**

Note: This includes hard copy or electronic comment letters and weekly/monthly customer status reports.

- 5.1 Author prepares draft.
- 5.2 Manager reviews draft and provides comments to the Author.
- 5.3 Author resolves comments.
- 5.4 Author submits the document to the Administrative Assistant, if necessary, for preparation of the final version.
- 5.5 Author indicates acceptance by signing the letter or initiating an email.
- 5.6 A member of the Technical Management Team signifies acceptance by initialing in the distribution approval block on a hard copy letter, or in an

email message to the Author.

## **6.0 CONTRACT DOCUMENTS**

- 6.1 Author prepares draft.
- 6.2 Business Support Analyst prepares cost information and provides it to the Author for incorporation.
- 6.3 Manager reviews draft. If the Author is a Manager, the review will be performed by another Manager, the Director, or the Associate Director.
- 6.4 Author resolves comments.
- 6.5 Business Support Analyst reviews presentation of cost information in Project level contracts.
- 6.6 Task level contract documents
  - 6.6.1 Author indicates acceptance by signing letter or memo.
  - 6.6.2 Manager signifies acceptance by initialing in the distribution block of the letter or memo, for external distribution of Task level documents.
- 6.7 Project level contract documents
  - 6.7.1 Director signs the cover letter or memo documenting approval for external distribution of Project level documents.
  - 6.7.2 Manager signifies acceptance by initialing in the distribution block of the letter or memo.

## **7.0 TRANSFER OF DATA IN THE FIELD (INCLUDES RESTRICTED RELEASE DATA FORMS)**

- 7.1 Site Coordinator communicates with the Project Leader or Survey Projects Manager to resolve any concerns prior to data transfer.
- 7.2 Site Coordinator prepares form, signs indicating review of data was completed, and provides a copy of the form to the site contact.

## **8.0 TECHNICAL CONCEPT REPORTS**

- 8.1 Author prepares draft text, figures, and tables, as applicable.
- 8.2 Author confers with other technical staff as necessary to ensure that the

report is complete and meets all project and quality assurance requirements.

- 8.3 Author provides draft report to cognizant manager for review. When laboratory data are included, review by the Laboratory Manager is required. When any collected or generated data are included, review by the Quality Manager is required. Comments are documented on the *Report Review Form*.
- 8.4 Author resolves comments and documents resolution on the *Report Review Form*.
- 8.5 Author submits the report to the Administrative Assistant to prepare it for external distribution.
- 8.6 Author indicates acceptance by signing the cover letter.
- 8.7 A Technical Management Team member signifies approval for distribution by initialing in the distribution approval /concurrence blocks of the cover letter. Concurrence by the Laboratory Manager is required when laboratory data are included. When collected or generated data are included, concurrence by the Quality Manager is required. Additional concurrence may be required depending on assigned project responsibilities.
- 8.8 Administrative Assistant ensures that the Author's name and the approval initials are entered into the final electronic version and that it is converted to PDF.
- 8.9 Project Leader maintains the *Report Review Form* and any other documentation of comment resolution in the project file.

## **9.0 LETTER REPORTS**

- 9.1 Author prepares draft text and any figures and/or tables.
- 9.2 Author submits the draft text to the Administrative Assistant for formatting and incorporation of tables and figures, as necessary.
- 9.3 Author confers with other technical staff as necessary to ensure that the report is complete and meets all project and quality assurance requirements.
- 9.4 Author provides the draft report to the cognizant Manager for review. When the report includes laboratory data, review by the Laboratory

Manager is required. When collected or generated data are included, review by the Quality Manager is required.

- 9.5 Review comments will be documented on the *Report Review Form* or in Email messages.
- 9.6 Author resolves comments and documents resolution on the *Report Review Form* or on copies of emailed comments.
- 9.7 A Technical Management Team member signifies approval for release by initialing in the distribution approval/concurrence block of the cover letter. Concurrence by the Laboratory Manager is required when laboratory data are included. Concurrence by the Quality Manager is required when collected or generated data are included. Additional concurrence may be required depending on assigned project responsibilities.
- 9.8 Author submits the report to the Administrative Assistant to prepare it for external distribution.
- 9.9 Administrative Assistant ensures that the Author's name and the approval initials are entered into the final electronic version and that it is converted to PDF.
- 9.10 Project Leader maintains the *Report Review Form* and any other documentation of comment resolution in the project file.

## **10.0 FULL REPORTS**

- 10.1 Draft full reports
  - 10.1.1 Author prepares draft text and requests preparation of any figures and tables.
  - 10.1.2 Author confers with other technical staff as necessary to ensure that the report is complete and meets all project and quality assurance requirements.
  - 10.1.3 Author submits the draft text to the Administrative Assistant for formatting and incorporation of tables and figures, as necessary.
  - 10.1.4 Author requests hard copy distribution for internal review by the cognizant manager, the Quality Manager, and when the report includes laboratory data, the Laboratory Manager. Review results are documented on the *Report Review Form*.

- 10.1.5 Author resolves comments, documents resolution on the *Report Review Form*, and requests approval for distribution.
  - 10.1.6 A Technical Management Team member approves the report for distribution and documents approval by initialing in the distribution concurrence block of the cover letter.
  - 10.1.7 Author submits the report to the Administrative Assistant to prepare it for external distribution.
  - 10.1.8 Administrative Assistant provides the report to the Quality Manager for verification of quality control requirements, which is documented by initialing in the distribution concurrence block of the cover letter.
  - 10.1.9 The Administrative Assistant ensures that the document and cover letter are converted to PDF.
  - 10.1.10 Project Leader maintains the *Report Review Form* or other documentation of comment resolution in the project file.
- 10.2 Final full reports
- 10.2.1 Author incorporates or otherwise resolves external comments.
  - 10.2.2 Author submits the final text to the Administrative Assistant for formatting and incorporation of tables and figures, as necessary.
  - 10.2.3 Author confers with other technical staff as necessary to ensure that it is complete and meets all project and quality assurance requirements.
  - 10.2.4 Author signs the report approval page and requests documentation of approval for release by the cognizant manager and documentation of concurrence for release by the Project Leader, Laboratory Manager, and Quality Manager, as applicable. All approval and concurrence signatures will be documented on the report approval page. Any final comments are summarized, along with documentation of resolution, on the *Report Review Form*.
  - 10.2.5 Author resolves final comments and documents resolution on the *Report Review Form*.
  - 10.2.6 Author submits the report to the Administrative Assistant to

prepare the final report for external distribution.

- 10.2.7 Administrative Assistant provides the report to the Quality Manager, just prior to release of the report to the customer, for Quality Control verification. Quality Manager signs the signature page when any remaining quality issues have been resolved.
- 10.2.8 Administrative Assistant ensures that the approval names and dates are entered into the final electronic version and that the document including the cover letter is converted to PDF.
- 10.2.9 Project Leader maintains the *Report Review Form* or other documentation of comment resolution in the project file.

## **11.0 MINIMUM REQUIREMENTS FOR REPORTING DATA**

All documents in which data values are reported will include the following:

- ✓ ORISE laboratory identification
- ✓ Requestor identification
- ✓ Applicable approval concurrence information
- ✓ References to approved procedures
- ✓ Analytical results with uncertainty limits

## **12.0 DOCUMENTATION OF REPORT REVIEW AND APPROVAL**

The Project Leader will ensure that documentation of substantial review comments is included in the project file on the *Report Review Form* or other paper copy method. Documentation of spelling, grammar, and punctuation comments is not required.





## SECTION 9 PERFORMANCE ASSESSMENT

### 1. PURPOSE

Assessments of ESSAP activities are performed to ensure continuing adequacy and effectiveness of procedures and equipment in order to meet customer project objectives and good work practice expectations. Compliance with applicable regulations and customer specifications, and opportunities for general process improvement, are evaluated through the processes set forth in this section. Operational requirements are defined in ESSAP procedure manuals; however, manufacturer's specifications, work experience, and industry standards may also be used to identify conditions adverse to quality and quality improvement actions.

### 2. RESPONSIBILITIES

#### Director

- ✓ Approve annual management assessment plan.
- ✓ Approve audit corrective action plans.

#### Group Managers

- ✓ Take part in evaluations of quality improvement actions.
- ✓ Ensure follow-up for improvement actions through closure.
- ✓ Oversee corrective action plan follow-up.
- ✓ Initiate "Hold" or "Stop Work" status for equipment, instrumentation, or processes as necessary.

#### Quality Manager

- ✓ Ensure completion and documentation of project file reviews.
- ✓ Maintain files for performance evaluation programs.
- ✓ Draft the annual management assessment plan.
- ✓ Manage the nonconformance system.
- ✓ Assist with evaluations of all quality improvement actions.
- ✓ Ensure database entry of corrective action status is performed.
- ✓ Issue quarterly reports of corrective action status to the Director and Managers.

#### All Staff

- ✓ Notify the cognizant Manager, the Quality Manager, or the Director of any conditions adverse to quality.
- ✓ Initiate "Stop Work" status for any unsafe working condition.

- ✓ Assist with follow-up to correct conditions adverse to quality and complete quality improvement actions.
- ✓ Complete corrective action plans as assigned.
- ✓ Report completion of corrective action plans to the Quality Manager.

### 3. DEFINITIONS

Condition Adverse to Quality: Any situation that could lead to a nonconformance or unsafe condition.

Corrective Action Plan: Plan summarizing the actions to be taken to either 1) correct a nonconformance, eliminate the cause and, whenever possible, to prevent its recurrence or 2) to improve a condition adverse to quality.

External Audit: A systematic, independent, and documented process used to determine the effective implementation of the quality system.

Informal Work Process Assessment: Assessment performed informally at any time by any staff member during the course of day-to-day work activities.

Laboratory Performance Evaluation: Laboratory analysis of blind samples provided by an external organization.

Management Assessment: Annual assessment performed by the RSAT Director and the RSAT Group Managers to evaluate operations with the focus of improvement in organizational performance, safety, meeting customer expectations, and identification of barriers that hinder improved performance.

Nonconformance: Product or service which does not conform to customer requirements, procedure requirements, or normal good practice.

Project File Review: A formal review of the documentation contained in a project file that is performed by the Quality Manager or other staff member not involved in the direct work activities of that project.

Quality Improvement Action: An activity initiated to improve a process or product.

### 4. INTERNAL ASSESSMENTS

#### 4.1. Informal Work Process Assessments

- 4.1.1. During day-to-day operations staff members are encouraged to identify situations that pose the potential for a condition adverse to quality, nonconformance, or an opportunity for quality improvement. Any

situation where an item, service, or process appears to be unsafe, or does not meet established requirements or expectations for good work practices, is immediately called to the attention of the Manager. Suggestions for quality improvement of work processes are discussed with supervisors or managers at the earliest possible time.

- 4.1.2. Nonconformances, conditions adverse to quality, and quality improvement actions from informal work process assessments are documented in the ESSAP Database.
- 4.1.3. All staff members are encouraged to identify items or processes that may be adverse to quality. Conditions with the potential to cause harm to people or property are discontinued immediately. All staff members have the authority to stop work due to unsafe conditions.
- 4.1.4. The staff member identifying a nonconformance or condition adverse to quality notifies the cognizant manager and enters a description of the situation, the date, and their name into the ESSAP Database.
- 4.1.5. The manager assigns responsibility for follow-up to a staff member and notifies the Quality Manager who enters the assignment into the ESSAP Database. See Section 6 of this procedure for follow-up requirements.
- 4.1.6. Nonconformances or conditions adverse to quality that are identified on a field work site are reported to the Site Coordinator and handled according to the following steps.
  - 4.1.6.1. The Site Coordinator determines probable cause, corrective action, removal of instrumentation or equipment from service, or retesting requirements necessary to assure successful resolution of the situation and to prevent recurrence on the work site in question. This information is documented in the project logbook and constitutes the corrective action plan.
  - 4.1.6.2. For nonconformances or conditions adverse to quality affecting data and other survey information that can only be resolved while on site, the corrective action plan must be successfully completed during the field survey.
  - 4.1.6.3. The Site Coordinator is responsible for working with the field survey team to carry out the corrective action plan and for verification of corrective action plan completion on the field site.
  - 4.1.6.4. The Site Coordinator notifies the Manager and Quality Manager, as necessary, if assistance is needed to determine the appropriate

corrective action plan or complete the corrective action plan requirements.

- 4.1.6.5. The information about the situation is entered into the ESSAP Database according to the requirements of Section 6 upon return from the field site.
- 4.1.6.6. The Manager and Quality Manager review the information and determine whether any additional follow-up actions are necessary. The Quality Manager assigns a tracking code and ensures that the ESSAP Database entries are complete.

#### 4.2. Project File Reviews

- 4.2.1. A minimum of twenty-five percent of project files will be reviewed.
- 4.2.2. The Quality Manager is responsible for ensuring Project File Reviews are completed.
- 4.2.3. A checklist is used to ensure all critical quality control requirements are reviewed.
- 4.2.4. Items that do not meet requirements are considered nonconformances and are entered into the ESSAP Database by the Quality Manager.
- 4.2.5. Items are referred to the staff member assigned responsibility for general management of the project. Follow-up is performed according to Section 6 of this procedure.
- 4.2.6. Items not meeting requirements will be addressed prior to release of the final deliverable to the customer.
- 4.2.7. Documentation of Project File Reviews will be maintained with the project file.

#### 4.3. Management Assessments

- 4.3.1. Management Assessments will be performed annually after the fiscal year financial account closing is completed.
- 4.3.2. The Director and Managers will not delegate responsibility for Management Assessments.
- 4.3.3. Management Assessments will follow a standard plan developed and maintained by the Quality Manager and approved by the RSAT Director.

4.3.4. Management Assessments will seek information to evaluate:

- ✓ Progress toward strategic goals and objectives
- ✓ Adequacy and implementation of management programs
- ✓ Safety of work environments
- ✓ Product and service quality
- ✓ Regulatory and contractual compliance

4.3.5. Quality improvement actions identified as part of Management Assessments, including the assignee for each item, will be entered into the ESSAP Database by the Quality Manager.

4.3.6. Section 6 of this procedure will be used to track each action through completion.

4.3.7. A summary report will be distributed to ESSAP and PTP staff.

## **5. EXTERNAL ASSESSMENTS**

### **5.1. Laboratory Performance Evaluation**

5.1.1. The ESSAP laboratory participates in the following performance evaluation (PE) programs:

- ✓ Department of Energy Mixed Analyte Performance Evaluation Program (MAPEP)
- ✓ Department of Energy Radiological and Environmental Science Laboratory (RESL) Intercomparison Test Program (ITP)

5.1.2. Performance evaluation sample types are chosen to correspond with the media and radionuclides routinely processed by the ESSAP laboratory.

5.1.3. Analysis of performance evaluation samples is given the highest priority in laboratory schedules.

5.1.4. The Laboratory Manager initiates a paper file when the samples are received.

5.1.5. All performance evaluation results are verified for transcription accuracy prior to submission.

5.1.6. Results that do not fall within the limits defined as acceptable by the evaluation program will be considered nonconformances, entered into the ESSAP Database, and investigated at the earliest possible time. See Section 6 of this procedure for follow-up requirements.

- 5.1.7. If enough of the original material is available the analysis will be performed again, if not, a NIST traceable standard will be used. In either case the results will be evaluated in an effort to identify the reason for the outlier.
- 5.1.8. Documentation of the re-analysis and evaluations of results will be included in the paper file.
- 5.1.9. Results within acceptable limits as defined by the performance evaluation report but in the warning range may be re-analyzed at the discretion of the Laboratory Manager.
- 5.1.10. Performance evaluation results are entered into a spreadsheet for easier tracking and evaluation. The ratio of ESSAP results to the known values will be charted. The total propagated uncertainty of the ratio will be included on the chart when uncertainty values are provided by the evaluation program.
- 5.1.11. The Quality Manager maintains all paper performance evaluation files or ensures they are archived.

## 5.2. Laboratory Traceability Program

The ESSAP laboratory participates in the National Institute of Standards and Technology Radiochemistry Intercomparison Program. This program provides low-level radiochemistry traceability testing to meet the voluntary guidance defined in related ANSI standards. It also provides another avenue for sharing technical experience to help improve laboratory performance.

## 5.3. External Audits

- 5.3.1. External audits may be initiated at any time by customers.
- 5.3.2. If an external audit has not occurred over a two year period one will be contracted.
- 5.3.3. On receipt of the audit report the Quality Manager will work with the cognizant Managers to draft corrective action plans for all audit findings and observations. The corrective action plans will include:
  - ✓ Correction of errors when possible.
  - ✓ Actions to minimize possibility of recurrence.
  
  - ✓ Any testing required to provide evidence of complete resolution.
  - ✓ Completion dates for each item.

- 5.3.4. The Director will approve the corrective action plans and submit them to the audit team leader.
- 5.3.5. Once corrective action plan approval is received from the customer, or other audit group, work begins on the corrective action plan requirements.
- 5.3.6. The Quality Manager enters the findings, observations, and corrective action plans into the tracking system.
- 5.3.7. Assignees provide status information to the Quality Manager as work progresses.
- 5.3.8. After the assignee reports that an item has been completed, the Quality Manager verifies completion of the requirements and enters the information into the tracking system.
- 5.3.9. The audit team leader and the customer are notified when the corrective action plan requirements for the findings and observations have been completed.
- 5.3.10. Section 6 provides the steps for ESSAP Database tracking of items through completion.
- 5.3.11. Paper records of audits, findings, and closures will be kept in the Quality Manager's office or in record archival.
- 5.3.12. Audit status will be reported quarterly, at a minimum, to the Director and Managers. See Section 6 of this procedure.

## **6. TRACKING AND FOLLOW-UP**

- 6.1. Tracking and follow-up of all nonconformances, conditions adverse to quality, and quality improvement activities are performed using the ESSAP Database.
- 6.2. Response to assessment items or audit findings will be initiated in a timely manner. Response deadlines set by external audit groups will be met or, if approved by the Director, new deadlines will be negotiated.
- 6.3. Items and findings will be tracked through completion using the ESSAP Database.
  - 6.3.1. The Manager determines the need for a "Hold" tag for equipment or instrumentation, or a "Stop Work" for processes that must not be used until the nonconformance is resolved.

6.3.1.1. A “Hold” tag is placed if:

- ✓ Continued operation of related equipment or instrumentation could cause harm to personnel or property.
- ✓ Continued operation could cause recurrence of the concern.

6.3.1.2. A “Hold” tag may not be removed until the Quality Manager verifies closure of the nonconformance.

6.3.2. The Quality Manager enters the review date and “Hold” tag information, if applicable, into the tracking database.

6.3.3. The Quality Manager assigns a tracking code to the item using the following designations:

Assignment of a program group designation:

- R – Radiochemical
- C- Counting
- F – Field Survey Projects
- H – Health Physics and Technical Projects
- A – Administrative

Categories:

- 1 – Program
- 2 – Training and Qualification
- 3 – Quality Improvement
- 4 – Documents and Records
- 5 – Work Processes
- 6 – Design
- 7 – Procurement
- 8 – Inspection and Acceptance Testing
- 9 – Management Assessment
- 10 – Independent Assessment

For example, a report concerning a procurement administrative process would receive the code A7.

6.3.4. The Quality Manager enters the code and item number into the tracking system.

6.3.5. The assignee investigates the situation, prepares a corrective action plan, determines a proposed completion date, and enters the information into the ESSAP Database.

- 6.3.6. The Quality Manager reviews the corrective action plan to ensure the following elements are included in the plan:
- ✓ A thorough evaluation of the situation to determine probable cause.
  - ✓ Identification of the need for additional technical expertise for the evaluation from outside ESSAP.
  - ✓ Correction of the error, when possible.
  - ✓ Notification to the customer if project quality has been compromised.
  - ✓ Actions to minimize the possibility of recurrence
  - ✓ Testing required as evidence of complete resolution.
- 6.3.7. The Quality Manager works with the assignee to enhance the plan, if necessary, and notifies assignee when final plan is approved.
- 6.3.8. Assignee completes the corrective action plan requirements, notifying the Quality Manager of status.
- 6.3.9. The Quality Manager maintains updated status in the tracking system.
- 6.3.10. The Quality Manager verifies successful completion of the corrective action plan, marks the item as closed in the tracking system, and notifies the assignee and the Manager.

## **7. PERFORMANCE ASSESSMENT SUMMARIES**

- 7.1. The Quality Manager will provide quarterly reports to the Director and other Managers summarizing performance assessment actions.
- 7.2. Status reports will include:
- ✓ Description of new performance assessment actions identified during the quarter for nonconformances, conditions adverse to quality, and quality improvement actions.
  - ✓ Status of corrective action plans for open items.
  - ✓ Summary of closed items.
  - ✓ Trend evaluation.

## SECTION 10

### SERVICE ORGANIZATION SUPPORT

#### OVERVIEW

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**Introduction**

The quality assurance/quality control system is affected by internal and external influences. These include service organizations that are important to the quality control process and are monitored by the Quality Manager on a continuous basis.

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**In this section**

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Shipping, Handling, and Storage Services	3

## SERVICE ORGANIZATION SUPPORT, Continued

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### Facility services

- Facility design and maintenance are coordinated with the Facilities Management Section in compliance with government regulations approved by the Environment, Safety and Health office.
- New facility design and maintenance of facilities are handled by work orders listing specifications.
- ESSAP develops conceptual plans and identifies the quality requirements for facilities and equipment, and works with the Facilities and Transportation Department and the Environment, Safety and Health office to develop specifications.
- Plans and drawings are developed and related critical documents are maintained by the Facilities Management Section.
- Actions to ensure compliance with government regulations for safety and health are either mandated or approved by the Environment, Safety and Health office.

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### Procurement services

- Items identified for purchase are coordinated with the Procurement Group in the Financial Operations Department.
- ESSAP provides descriptions of items or services along with specifications, health and safety considerations, and quality requirements.
- The ORISE Financial Operations Department is responsible for procurement processing and compliance with all applicable regulations.
- ESSAP is responsible for assessment/inspection of items or services and payment approval.
- Control of original documents relating to this process is the responsibility of the Financial Operations Department.

## **SERVICE ORGANIZATION SUPPORT, Continued**

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### **Shipping, handling, and storage services**

- Shipping, handling, and storage of items is coordinated with the Environment, Safety and Health office and the Facilities and Transportation Department.
- Specific handling and storage requirements for equipment, instrumentation and supplies are identified in appropriate ESSAP or Environment, Safety and Health office policies or procedures. The Facilities and Transportation Department is responsible for compliance with all applicable regulations for shipping and receiving of items. ESSAP staff may initiate some shipping paperwork, however all shipments must be approved and initiated by the Facilities and Transportation Department.

## SECTION 11 CRITICAL RECORD HANDLING AND STORAGE

### 1.0 PURPOSE

Records documenting ESSAP work activities must be protected from tampering, destruction, or loss and must be stored in a retrievable manner to ensure that a defensible data trail is maintained.

### 2.0 RESPONSIBILITIES

#### All Staff Members

- ✓ Protect original records during use.

#### Site Coordinator

- ✓ Protect completed records.
- ✓ Enter critical record inventory into the project logbook.
- ✓ Review records before leaving the worksite.
- ✓ Ensure safe transport of records to Scarboro.

#### Project Leader

- ✓ Determine the critical nature of records.
- ✓ Protect completed records.

#### Managers

- ✓ Determine project specific record security requirements.
- ✓ Determine when limited access to records is required.
- ✓ Ensure compliance with any project specific record requirements.

#### Quality Manager

- ✓ Oversee the ESSAP record archival process.

## Senior Program Specialist/Archival Coordinator

- ✓ Ensure that project files are archived on request and that the archive location is entered into the ESSAP database.
- ✓ Ensure that file contents are verified and scanned.
- ✓ Ensure that the critical records in submitted project files are scanned and saved in the appropriate electronic folder.

### **3.0 DEFINITIONS**

Active Records: Recorded data or information that has not yet been archived and is in use for report preparation or other project needs.

Archived Records: Records that have been entered into the record archive system and assigned a location in the archive area.

Critical Records: Those records, or documents, containing original data that would be difficult, if not impossible, to replace. For comparison, non-critical records are of a support nature and are easily replaced; such as reports from other organizations or topographical maps.

Procedure Training/Certification Records: Records documenting training and certification provided by ESSAP staff, for ESSAP staff.

Worker Qualification Records: Records documenting training or evaluations that are required by law or by ORAU/ORISE requirements. Examples include physicals, respirator fit training and testing, Radiation Worker Training, Hazardous Waste Operations Site Worker training.

### **4.0 GENERAL**

- 4.1 Original records related to direct project/task work activities are the property of the agency or other organization funding the work.
- 4.2 Record security requirements are determined by the manager prior to the start of work activities.
- 4.3 The manager will determine when access to electronic and/or hard copy files must be limited, and will ensure that adequate protection methods are established and maintained.
- 4.4 Records are retained for a minimum of seven years, unless otherwise specified by the customer.

## **5.0 RECORD COMPLETION STANDARDS**

- 5.1 Records will be legibly written in ink.
- 5.2 Records must be dated and initialed or signed to be valid.
- 5.3 Information in records will not be obliterated by erasing or using white-out, or by deletion from electronic files serving as critical records.
- 5.4 Corrections to paper records will be documented by striking a single line across the entry, entering the new information, then initialing and dating the correction. Corrections to electronic records must be documented in an electronic change log linked to the electronic record in a traceable manner, or in another location designated on the electronic data display.
- 5.5 Pages of bound logbooks used as critical records will be numbered. Skipped pages will be marked as such.

## **6.0 FIELD RECORDS**

- 6.1 Critical field records include, but are not limited to:
  - ✓ Request for Technical Assistance (RFTA) or statements of work
  - ✓ Essential project communication
  - ✓ Survey plan
  - ✓ Survey Plan Approval Form (SPAF)
  - ✓ Project logbook
  - ✓ Field data forms
  - ✓ Instrument calibration data forms
  - ✓ Daily instrument operational check-out forms
  - ✓ Field drawings
  - ✓ Chain-of-custody forms
  - ✓ In-house training certification documentation
  - ✓ Source certification certificates
  - ✓ Document review and data verification documentation
  - ✓ Documentation of special technical determinations
  - ✓ Final deliverable
- 6.2 Project logbooks must contain the following information, as applicable:
  - ✓ Full name of the field survey site, when applicable
  - ✓ Project and Task numbers
  - ✓ Funding agency
  - ✓ Site contact information
  - ✓ Agency representative contact information

- ✓ Directions to the site
- ✓ Date of entry
- ✓ Designated Site Coordinator
- ✓ Signature of individual completing an entry
- ✓ List of ESSAP personnel, agency representatives, and other groups working with us on site
- ✓ Work hours
- ✓ Sample screening plan
- ✓ Health and safety issues
- ✓ Site conditions which adversely affect survey performance
- ✓ Summary of activities each day
- ✓ Deviations to plan or procedures, reasons for deviations, concurrence given by funding agency
- ✓ Number and types of samples collected and sample numbers used
- ✓ Page numbers

### 6.3 Field Survey Record Requirements

- 6.3.1 Original instrument calibration and maintenance records are kept in the instrument room files at all times until such time as archival is requested.
- 6.3.2 The initiator of a field record is responsible for the record until a task is complete.
- 6.3.3 The Site Coordinator is responsible for completed field records.
- 6.3.4 When not in use, records will be kept in the possession of the Site Coordinator or in a secure location such as a locked zero case or vehicle to prevent loss or tampering.
- 6.3.5 The Site Coordinator will enter an inventory of critical records into the project logbook prior to leaving the field site.
- 6.3.6 The Site Coordinator will review all data in critical records prior to leaving the survey site according to the requirements of Quality Assurance manual Section 7.
- 6.3.7 The Site Coordinator will ensure that records are transported to Scarboro either in the possession of an ESSAP staff member or by a traceable method of shipment.
- 6.3.8 The Site Coordinator will transfer the records to the Project Leader upon return to the Scarboro facility.

6.3.9 The Scarboro buildings remain locked at all times. Active files in use in one of the buildings are the responsibility of the Project Leader. When field records are needed by other staff members, the Project Leader will issue copies of records and maintain responsibility for the originals.

## 7.0 LABORATORY RECORDS

7.1 Critical laboratory records include, but are not limited to:

- ✓ Analytical standard certification documentation
- ✓ Balance logs
- ✓ Batch logs
- ✓ Certification documents for standard weight sets
- ✓ Instrument calibration and operational check records
- ✓ Chain-of-custody (white original) forms for all samples
- ✓ Chain-of-custody (yellow copy) for sample analysis that does not involve field survey activities
- ✓ Computer disks/tapes
- ✓ Laboratory survey documentation
- ✓ Laboratory training certification
- ✓ Statements of work
- ✓ Essential project communication
- ✓ Analysis Assignment Form
- ✓ Lab Data Sheet
- ✓ Concentration and Uncertainty Report
- ✓ Report review and data verification documentation
- ✓ Documentation of special technical determinations.
- ✓ Final deliverable

7.2 Laboratory Record Requirements

7.2.1 Project records

7.2.1.1 Original records are the responsibility of the initiator.

7.2.1.2 Upon completion of a task the associated records are placed in the project file.

7.2.1.3 Active laboratory project files are maintained in the laboratory file room.

7.2.2 Analytical Instrument and Balance Records

7.2.2.1 Control charts and logs of current daily instrument operational checks are maintained with the instrument or in the Count Laboratory files.

7.2.2.2 Completed control charts, calibration, and maintenance records are maintained in the Count Laboratory files.

7.2.2.3 Survey instrument calibration records are maintained in the instrument room files.

7.2.2.4 Instrument maintenance records are maintained in the Count Laboratory files.

### 7.2.3 Standards

7.2.3.1 Certification documentation for analytical standards is maintained in the laboratory file room.

7.2.3.2 Certification documentation for standard weight sets is maintained in the laboratory file room.

7.2.4 Chain-of-custody originals are maintained in the laboratory file room.

## 8.0 TECHNICAL PROJECT RECORDS

8.1 Critical technical project records include but are not limited to:

- ✓ Contract information
- ✓ Essential project communication
- ✓ Background information, such as meeting notes or reference information
- ✓ Log of work activities
- ✓ Original data generated by ESSAP
- ✓ Report review and data verification documentation
- ✓ Documentation of special technical determinations.
- ✓ Final deliverable

8.2 Technical Project Record Requirements

8.2.1 Original records are the responsibility of the initiator.

8.2.2 Upon completion of a task the associated records are placed in the project file.

8.2.3 The Project Leader is responsible for security of records for the duration of the project, until archival is requested.

## **9.0 QUALITY ASSURANCE RECORDS**

9.1 Critical Quality Assurance records include but are not limited to:

- ✓ On-the-job and worker qualification training files
- ✓ Audit reports and follow-up documentation
- ✓ Performance Evaluation program documentation
- ✓ Procedure review comments
- ✓ Original versions of controlled procedures
- ✓ Log of controlled procedure changes
- ✓ Documentation of controlled procedure updates by staff

9.2 Record Locations

9.2.1 Training files are maintained in suite 111.

9.2.2 Audit records are maintained in the Quality Manager's office.

9.2.3 Records of Performance Evaluation activities for the current fiscal year are maintained in the Quality Manager's office. Less current information is archived.

9.2.4 Original versions of controlled procedures and procedure review comments are maintained in the archive area

9.2.5 The log of controlled procedure changes is maintained in the Quality Manager's office.

9.2.6 Documentation of controlled procedure manual numbers and distribution of controlled procedure updates are maintained in the Archival Coordinator's office.

## **10.0 RECORD ARCHIVAL**

10.1 General

10.1.1 Critical project records, including any pertinent clerical files, will be archived for permanent storage within three months of the final product release to the customer.

10.1.2 Critical records will be maintained for a minimum of seven years past the date of the final project report, unless we are directed to do otherwise by the customer.

## 10.2 Procedure for record archival

10.2.1 A “Request for Archival” form will be submitted to the Archival Coordinator (see Figure pages 8 and 9)

10.2.2 The Archival Coordinator will verify the contents of the project file based on the inventory list on the form and acknowledge receipt of the file by signing the form.

10.2.3 The Archival Coordinator will ensure that the file contents are scanned into an electronic file labeled according to the task number.

10.2.4 The Archival Coordinator will assign an archive cabinet and drawer location to the file, enter the location on the “Request for Archival” form, and ensure that all pertinent information is entered into the ESSAP Database.

10.2.5 When archival is complete, the Archival Coordinator will sign and date the “Request for Archival” form and include it in the project file.

10.2.6 The archival area will be maintained as a controlled access area.

## 10.3 Archived Record Check Out

Removal of material from the archive files for any reason should be accomplished through the Archival Coordinator. An “Out” card is placed in the location from which the record(s) were removed indicating what was removed, the date, and the name of the individual who will have responsibility for the record(s) while they are checked out.

## 11.0 RECORD DISPOSAL

Disposal of records requires the approval of the funding agency or customer and the Program Director.

## **12.0 LOST RECORDS**

- 12.1 Lost records are reported to the cognizant manager and the Quality Manager.
- 12.2 A nonconformance will be initiated for loss of critical records.
- 12.3 Documentation of the lost records will be included in the project file.

**ESSAP REQUEST FOR RECORD ARCHIVAL (FRONT)**

Requested By: \_\_\_\_\_ Date Submitted: \_\_\_\_\_

Is This An Addition To An Existing File? Yes \_\_\_\_\_ No \_\_\_\_\_

Site/Project Title: \_\_\_\_\_

City/State/Zip: \_\_\_\_\_

Funding Org.: \_\_\_\_\_ Project No.: \_\_\_\_\_ Task Number: \_\_\_\_\_

Project Supervisor: \_\_\_\_\_ Status: \_\_\_\_\_

Project Contact(s)/Phone: \_\_\_\_\_

Survey Date Started: \_\_\_\_\_ Survey Date Completed: \_\_\_\_\_

Sites for Cross Reference: \_\_\_\_\_

Final Report(s): \_\_\_\_\_

Remarks: \_\_\_\_\_

Central Office File Relinquished By: \_\_\_\_\_ Date: \_\_\_\_\_

Laboratory File Relinquished By: \_\_\_\_\_ Date: \_\_\_\_\_

Calibration File Relinquished By: \_\_\_\_\_ Date: \_\_\_\_\_

Inventory Complete and Legible: _____ Name: _____ Date: _____
Received By: _____ Name: _____ Date: _____
Inventory Complete and Legible: _____ Name: _____ Date: _____ File Location: _____

## ESSAP REQUEST FOR RECORD ARCHIVAL (BACK)

### FIELD DATA INVENTORY SHEET

- |  |  |
|--|--|
| <input type="checkbox"/> Activity Survey Record                          | <input type="checkbox"/> Logbook   |
| <input type="checkbox"/> Air Sampling Sheet                              | <input type="checkbox"/> Maps, Blueprints                                  |
| <input type="checkbox"/> Area Scan & Radiation Level Survey              | <input type="checkbox"/> Miscellaneous Sample Record Form                  |
| <input type="checkbox"/> Biased Surface Soil Samples/Gamma Measurements  | <input type="checkbox"/> PIC Calibration Curve                             |
| <input type="checkbox"/> Borehole Logging & Sampling                     | <input type="checkbox"/> PIC/Bicron Micro-Rem Meter Field Check Out Form   |
| <input type="checkbox"/> Calibration Data - Alpha/Beta                   | <input type="checkbox"/> PIC/Bicron Micro-Rem Meter Tracking Form          |
| <input type="checkbox"/> Chain-of-Custody Record (yellow copy)           | <input type="checkbox"/> Pictures  |
| <input type="checkbox"/> Construction Material Background Determinations | <input type="checkbox"/> Rotameter Calibration                             |
| <input type="checkbox"/> Cross Calibration Form                          | <input type="checkbox"/> Stack Velocity Worksheet                          |
| <input type="checkbox"/> Drawings  | <input type="checkbox"/> Stack Sampling Rate Worksheet                     |
| <input type="checkbox"/> Electronic Calibration Record                   | <input type="checkbox"/> Stack Sampling Record                             |
| <input type="checkbox"/> ESSAP Report (Draft or Final)                   | <input type="checkbox"/> Surface Activity Survey                           |
| <input type="checkbox"/> ESSAP Correspondence                            | <input type="checkbox"/> Survey Plan                                       |
| <input type="checkbox"/> Exposure Rate Measurements and Soil Samples     | <input type="checkbox"/> Systematic/Random Soil Samples/Gamma Measurements |
| <input type="checkbox"/> Exposure Rate Calibration Data                  | <input type="checkbox"/> Tape Calibration Form                             |
| <input type="checkbox"/> Instrument Oper. Check Out                      | <input type="checkbox"/> Vehicle Survey Sheet                              |
| <input type="checkbox"/> Interior Exposure Rate Measurements             | <input type="checkbox"/> Vehicle Checklist                                 |
| <input type="checkbox"/> Lab Work Request                                |  |

### LAB DATA INVENTORY SHEET

- |   |   |
|---|---|
| <input type="checkbox"/> Alpha Spec [ ] U [ ] Pu [ ] Am [ ] Th  | <input type="checkbox"/> Other                      |
| <input type="checkbox"/> Ashing Log                             | <input type="checkbox"/> PCB                        |
| <input type="checkbox"/> Carbon-14                              | <input type="checkbox"/> Pesticides                 |
| <input type="checkbox"/> Correspondence                         | <input type="checkbox"/> Polonium                   |
| <input type="checkbox"/> Gamma Spec (See Counting Room Manager) | <input type="checkbox"/> Radium [ ] 226 [ ] 228     |
| <input type="checkbox"/> Gross Alpha/Beta                       | <input type="checkbox"/> Radon                      |
| <input type="checkbox"/> H3                                     | <input type="checkbox"/> Smears                     |
| <input type="checkbox"/> Iodine                                 | <input type="checkbox"/> Strontium [ ] 89/90 [ ] 90 |
| <input type="checkbox"/> Mercury                                | <input type="checkbox"/> Tc-99                      |
| <input type="checkbox"/> Neutron Activation                     | <input type="checkbox"/> Tritium                    |
| <input type="checkbox"/> Nickel-63                              | <input type="checkbox"/> X-Ray Fluorescence         |