

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

Oak Ridge Institute for Science and Education
Oak Ridge Associated Universities
Oak Ridge, Tennessee 37831-0117

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Quality Assurance Manual	ORISE/ESSAP
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Reviewed and

Approved by: Ann T. Payne (Original Signature on File) Date: 3/10/00
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Program Director

SECTION 1

ESSAP QUALITY ASSURANCE RESPONSIBILITIES

OVERVIEW

Introduction

Section 1 of this manual introduces the Quality Assurance plan for the Environmental Survey and Site Assessment Program (ESSAP) and outlines the specific responsibilities for Quality Assurance/Quality Control duties.

In this section

This section covers the following topics:

Topic	Page
Program Description	2
Purpose and Scope	2
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Responsibilities	3
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ESSAP QUALITY ASSURANCE RESPONSIBILITIES

Program description

The Environmental Survey and Site Assessment Program (ESSAP) of Oak Ridge Institute for Science and Education (ORISE) provides technical assistance to the U.S. Department of Energy (DOE) under contract DE-AC05-76OR00033 and to the 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 in the immediate vicinity. Other major activities include environmental assessments, 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 within a framework of policies and procedures which assure the validity and quality of the developed data.

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 is presented in the ESSAP Survey Procedures Manual and the Laboratory Procedures Manual.

References

The quality control procedures in this manual are based on:

- DOE Order 414.1A, Quality Assurance, September 29, 1999
- Quality Assurance Requirement for Nuclear Facility, Applications ASME, NQA-1, Quality Assurance Program Requirements for Nuclear Facilities, 1997
- ANSI/ASQC E4, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, 1994
- ORAU Policy and Procedure, Quality Assurance, GP-IPD-810
- ORAU Policy and Procedure, Excellence in Operations, GP-IPD-800

ESSAP QUALITY ASSURANCE RESPONSIBILITIES, Continued

Responsibilities The general organizational structure is shown in the figure on page 10. The table below lists the QA/QC duties for positions in ESSAP.

Position	QA/QC Duties
Program Director Associate Program Director	<ul style="list-style-type: none">• Establish policies & procedures;• Monitor training operations;• Monitor data collection, development, and management• Host, and if necessary, initiate external audits;• Review final survey reports prior to release; and• Authorize exceptions to the requirements of this manual.
Survey Projects	
Survey Projects Manager	<ul style="list-style-type: none">• Oversight of the Survey Procedures Manual;• Monitor survey quality control to ensure compliance and sound practice;• Review final survey reports prior to release;• Oversee training and certification for survey personnel; and• Oversee validation, including associated record keeping, for survey software.

ESSAP QUALITY ASSURANCE RESPONSIBILITIES, Continued

Position	QA/QC Duties
Site Coordinator Note: This role can be performed by Project Team Leaders, Assistant Project Team Leaders, or Field Survey Team Leaders	<ul style="list-style-type: none">• 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;• Assure documents and records for assigned projects are adequately controlled prior to archival;• Initiate requests for laboratory analysis; and• Prepare survey reports.
Field Survey Team Leaders	<ul style="list-style-type: none">• Train technicians to perform field duties;• 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.
HP Technicians	<ul style="list-style-type: none">• Perform peer reviews, as requested;• Provide input to Survey Projects Manager regarding work process improvements; and• Become generally familiar with Project Leader and Field Survey Team Leaders QA duties, and assist as assigned.

ESSAP QUALITY ASSURANCE RESPONSIBILITIES, Continued

Position	QA/QC Duties
Graphics Coordinator	<ul style="list-style-type: none">• Train others to perform graphics functions;• Coordinate with ORISE Information Systems Department to ensure maintenance of graphics hardware; and• Maintain electronic graphics files.
Technical Resources Group	
Laboratory Manager	<ul style="list-style-type: none">• Oversight of the Laboratory Procedures Manual;• Monitor laboratory quality control to ensure compliance and sound practice;• Oversee training and certification for laboratory personnel;• Provide (where applicable) the Purchasing Section with specifications for purchased equipment, services, materials, reagents, and chemicals;• Ensure inspections/tests of newly purchased items are completed to ensure established requirements are met;• Review developed laboratory data; including that received from contracted laboratories;• Review final survey reports prior to release;• Oversee validation, including associated record keeping, for laboratory software;• Oversee archival of samples;• Maintain and calibrate computer based equipment for radiometric measurements and maintain records for these activities;

ESSAP QUALITY ASSURANCE RESPONSIBILITIES, Continued

Position	QA/QC Duties
Laboratory Manager (continued)	<ul style="list-style-type: none">• Maintain and calibrate laboratory survey instruments;• Maintain files of traceable standard calibration documentation.• Initiate training and certification for laboratory staff, as required;• Oversee or perform laboratory quality control procedures including cross check analysis, duplicates, spikes, blanks, calibration, and daily analytical instrument checks;• Review laboratory data sheets;• Maintain files of original data sheets including undeveloped and developed data until archival is requested;• Maintain quality and quantity of laboratory supplies and chemicals;• Maintain laboratory equipment in operating condition;• Accept and maintain chain-of-custody of samples during analysis and archival;• Maintain 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.

ESSAP QUALITY ASSURANCE RESPONSIBILITIES, Continued

Position	QA/QC Duties
Count Room Coordinator	<ul style="list-style-type: none"> • Accept delegation of duties as assigned by the Laboratory Manager; and • Train technicians to perform instrument counting procedures.
Chemist and Senior Laboratory Technician	<ul style="list-style-type: none"> • Accept delegation of duties as assigned by the Laboratory Manager; • Train technicians to perform analytical procedures; and • Provide input regarding work process improvements.
Laboratory Technicians	<ul style="list-style-type: none"> • Become generally familiar with Chemist and Senior Technician QA duties, and assist as assigned; and • Provide input regarding work process improvements.
NOTE: The following group is not a part of the ESSAP program but is responsible for certain quality assurance functions. The Technical Resources Manager serves as the liaison with this group.	
Information Systems Department	<ul style="list-style-type: none"> • Maintain files of programs and flowsheets for internally generated software; • Maintain files of computer equipment records of repair and maintenance; and • Maintain original commercial software and software documentation for ESSAP.

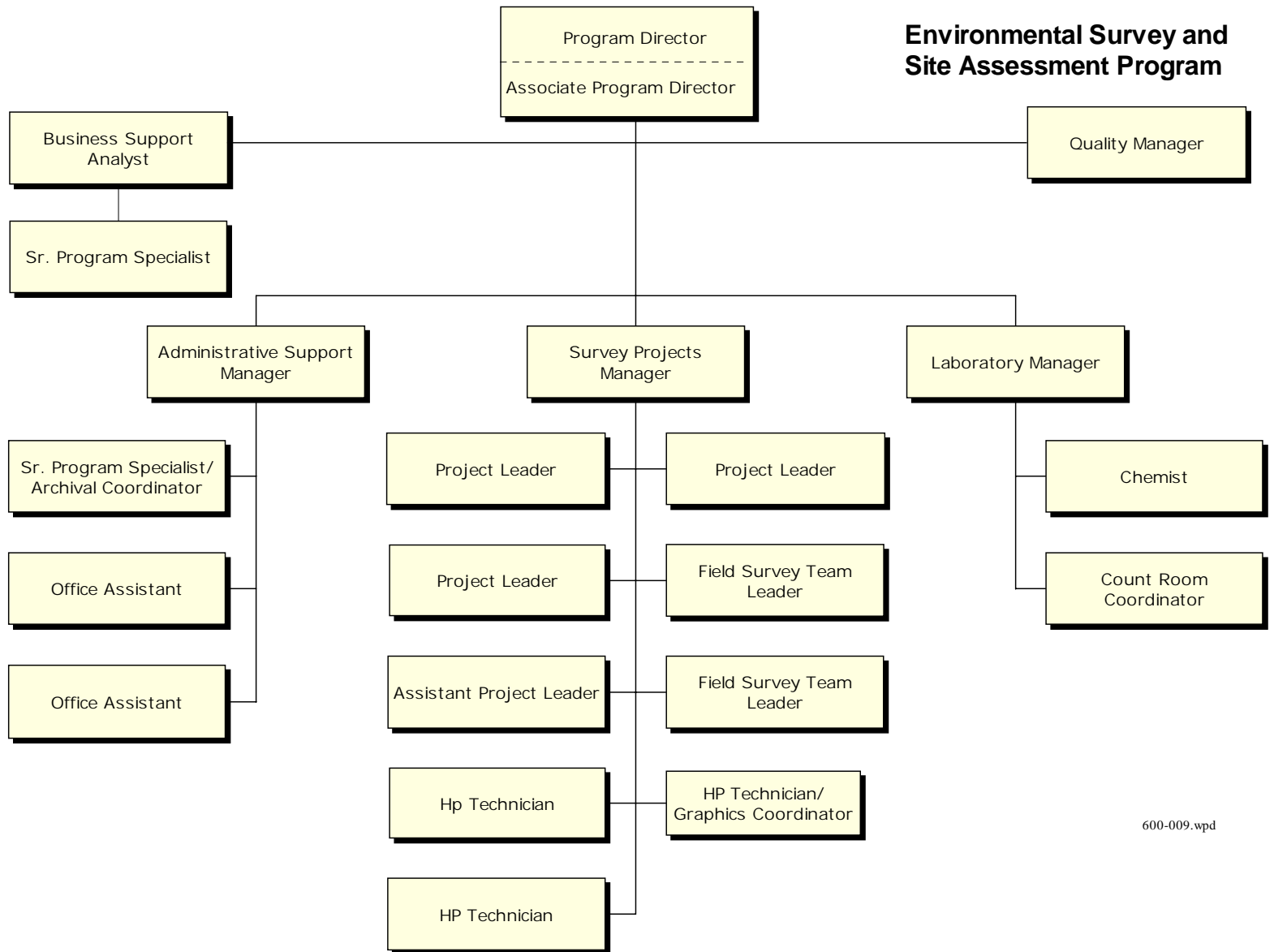
ESSAP QUALITY ASSURANCE RESPONSIBILITIES, Continued

Position	QA/QC Duties
Administrative Group	
Administrative Support/Quality Manager	<ul style="list-style-type: none">• Provide independent oversight for QA/QC pertaining to projects and laboratories;• Perform or oversee performance of project file reviews;• Reviews the QA/QC results from contracted laboratory services in conjunction with the Technical Resources Manager;• Oversight of the Quality Assurance Manual;• Oversee maintenance of the Quality Control, Audit, and nonconformance databases;• Oversee maintenance of ESSAP training and certification records;• Oversee ESSAP performance evaluation activities;• Coordinate vendor/provider assessments as deemed necessary by the Program Director;• Oversee the training and certification program for administrative personnel; and• Monitor administrative quality control activities to ensure compliance and sound practice.

ESSAP QUALITY ASSURANCE RESPONSIBILITIES, Continued

Position	QA/QC Duties
Senior Program Specialist	<ul style="list-style-type: none">• Perform peer reviews;• 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 Assistants	<ul style="list-style-type: none">• Perform peer reviews; and• Provide input regarding work process improvements.

Environmental Survey and Site Assessment Program



600-009.wpd

SECTION 2

PROCEDURES

OVERVIEW

Introduction

Procedures utilized by ESSAP are documented in manuals prepared for program-specific applications. Procedures are reviewed and approved by the appropriate Manager, Program Director or Associate Program Director, and Quality Manager prior to implementation.

In this section

This section covers the following topics:

Topic	Page
Procedure Development	2
Procedure Manuals	2
Distribution Control	3
Application of Procedures	3
Procedure Modifications	3
Special Procedures	3
Deviation from Procedures	4

PROCEDURES, Continued

Procedure development

Procedures are developed for activities conducted on a routine basis and considered to be critical to Program operations. Development is performed according to the following process:

- A manager assigns author responsibility for development of a specific procedure to a staff member.
- The manager reviews the draft procedure and provides comments to the author.
- The manager ensures that procedure testing is performed as necessary to confirm the accuracy and useability of the procedure steps.
- The author requests review by the Quality Manager.
- The Quality Manager reviews the procedure for content and confirms that all cross references to other manuals are in place and are accurate.
- A final procedure is formatted for inclusion into the appropriate manual and is prepared for approval.
- Procedures must be approved by the Manager of the activity, the Quality Manager, and the Program Director.
- The final procedure is provided to the Senior Program Specialist for controlled distribution.

Procedure manuals

Procedure manuals are reviewed annually and revised as necessary. Revisions are reviewed and approved by the appropriate manager, Quality Manager, and Program Director prior to implementation and inclusion in manuals. Procedures are documented in the following manuals:

- Laboratory Procedures Manual
- Survey Procedures Manual
- Quality Assurance Manual

PROCEDURES, Continued

Distribution control

ESSAP Personnel or agency representatives who use the information to plan, perform, or evaluate work, receive procedure manuals. Distribution is controlled by the Senior Program Specialist by way of unique number assignments and is tracked in a database. It is the assignee's responsibility to incorporate revisions when received and to return the signed receipt documentation form.

Application of procedures

The general procedures in the manuals are adapted for application through development of project specific survey plans, or statements of work. All survey plans and statements of work are reviewed and approved by the appropriate Manager, or Program Director.

Procedure modifications

- Inadequacies discovered in procedures must be communicated to the appropriate Manager immediately.
 - The Manager determines the need for an immediate deviation to the procedure. If a deviation is required it is handled as described below.
 - The cognizant Manager ensures that permanent procedure changes are incorporated into the controlled manual and submitted for review by the Quality Manager and Program Director.
 - Required procedures are approved by the cognizant Manager, the Quality Manager, and the Program Director.
-

Special procedures

For field or laboratory activities not covered by the manuals and survey plans, consensus or industry-wide procedures, such as those from EPA, EML, ASTM, ANSI, and other accepted standards organizations may be used. The use of such procedures must be approved by the manager responsible for the activity. Documentation must be included in the site file and provided to Quality Manager.

PROCEDURES, Continued

Deviation from procedures

The Program Director, Associate Program Director, Managers, or Site Coordinators may implement deviations from approved procedures, survey plans, or statements of work when necessary to meet agency requirements or to temporarily correct inadequacies identified during procedure use. Documentation of deviations must be included in each affected project file and contain the following information:

- project supervisors name;
- circumstances requiring the deviation;
- alternate approach and reason for choice;
- effective date(s) of deviation;
- approval of agency representative for deviations from survey plans which effect project scope; and
- approval for modification to statements of work should be obtained from the project contact.

SECTION 3

TRAINING AND CERTIFICATION

OVERVIEW

Introduction

The training and certification process is used to qualify personnel to perform procedures related to program activities.

In this section

This section covers the following topics:

Topic	Page
Definitions	2
On-the-Job Training	2
Training Responsibilities	3
Other Types of Training	5

TRAINING AND CERTIFICATION, Continued

Definitions

- Training for certification—instruction provided by a currently certified individual.
 - Certification—confirmation that training met all requirements as specified by this manual, and that the trainee is capable of performing a procedure independently.
 - Supervisor's review—notification to the supervisor that certification is completed.
 - Recertification—periodic update to previously received certification including performance of the procedure as well as instruction on new information and lessons learned.
 - Annual Training—instruction and recertification required annually will be performed within 365 days of initial certification. (A grace period of one month will be acceptable).
-

On-the-job training

Procedural training and certification needs are defined by Managers. Procedures are documented and approved prior to initial training. Checklists will be used to ensure consistent documentation. Each training session will be designed to ensure the employee is provided with the following:

- procedure purpose;
- job hazard analysis;
- correct application of procedure;
- associated safety hazards;
- related policies/procedures;
- conditions requiring supervisory approval before proceeding; and
- applicable quality control requirements.

Initial training and certification on a new procedure will be conducted by the staff member responsible for development of the procedure for program use. The developer will be designated as certified by the appropriate Manager, by virtue of past experience.

TRAINING AND CERTIFICATION, Continued

Training responsibilities

The following table lists responsibilities by position:

Position	Responsibility
Managers	<ul style="list-style-type: none">• training program oversight and approval of criteria;• identify procedures for which training and/or certification are required; and• designate trainers based on qualifications of prior certification and experience.
Trainers	<ul style="list-style-type: none">• must hold current certification; and• provide instruction using consistent methods;
Certification Staff	<ul style="list-style-type: none">• observe and document performance of trainee.
Laboratory Supervisor and Project Leaders	<ul style="list-style-type: none">• assist in identifying training needs;• initiate training and certification requests; and• review completed certifications.
Quality Manager	<ul style="list-style-type: none">• oversight of training and certification records.
Program Specialist	<ul style="list-style-type: none">• maintain training and certification records.
Administrative Trainee	<ul style="list-style-type: none">• read and discuss procedure with trainer;• observe and assist in performing procedure with a currently certified individual; and• independently perform procedure in presence of certifying staff member.

TRAINING AND CERTIFICATION, Continued

Position	Responsibility
Survey Trainee	<ul style="list-style-type: none">• read and discuss procedure with trainer;• observe and assist in performing procedure with a currently certified individual;• independently perform procedure in presence of certifying staff member; and• participate in annual recertification training.
Laboratory and Count Room Trainee	<ul style="list-style-type: none">• observe and assist in performing procedure with trainer;• successfully and independently complete an analysis by performing the procedure using a known standard;• achieve a value below the detection sensitivity of the procedure for the batch blank results;• for radiochemical analyses, achieve a result within 15% of the known activity;• discuss and be evaluated in theory and safety aspects specific to the procedure by the Laboratory Supervisor; and• participate in annual recertification training.

TRAINING AND CERTIFICATION, Continued

Other types of training

Training which is not “On-the-Job-Training” will be provided and tracked as follows:

ORISE Mandatory	<ul style="list-style-type: none">Scheduled and tracked by the Office of Human Resources (OHR).
Developmental	<ul style="list-style-type: none">Scheduled with supervisor’s approval.
Compliance/Regulatory	<ul style="list-style-type: none">Radiation worker, OSHA, First Aid, CPR, and Bloodborne Pathogen is scheduled and tracked by a Project Leader under the direction of the Survey Projects Manager.
Special Needs	<ul style="list-style-type: none">Specific training related to access at some field sites may be required and will be scheduled and tracked by the designated organization as the need arises.

SECTION 4

INSTRUMENT QUALITY CONTROL

OVERVIEW

Introduction

The identification, calibration frequencies, and responsibilities for instrumentation used in Program activities are provided in this section. Complete procedures for using Program instrumentation are documented in procedure manuals.

In this section

This section covers the following topics:

Topic	Page
Instrument Identification	2
Calibration Guidelines	2
Establishment of Background for Field Instrument Calibration	2
Operational Checks After Repairs	3
Laboratory Instrument Operational Checks	3
Laboratory Balance Operational Checks	3
Field Instrument Operational Checks	4
Calibration Frequency and Responsibilities	5

INSTRUMENTATION

Instrument identification

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

Calibration guidelines

- Calibration procedures will be performed according to the methods defined in the appropriate field or laboratory manuals.
- Calibrations shall be based on standards traceable to the National Institute of Standards and Technology (NIST). If NIST-traceable standards are not available, standards of an industry-recognized organization may be utilized.

Example: Uranium Standards from The New Brunswick Laboratory.

- Recalibration will be performed when control charts, extensive repairs, or relocation of instrumentation may invalidate earlier calibration data.
 - Calibration documentation will be reviewed and approved by the responsible manager or supervisor prior to the next use of the item.
 - Items sent to a manufacturer for calibration will have an operational check performed before usage to ensure no damage occurred during shipment.
-

Establishment of background for field instrument calibration.

- For each instrument, a series of 30 measurements is taken in an area representative of background conditions.
- The average, ± 2 and 3 standard deviations are calculated and recorded.
- A background measurement is performed prior to calibration and compared to the 2σ and 3σ acceptance limits.
- If the background is between the $\pm 2\sigma$ acceptance limits of the established instrument/detector control chart average background, the average value from the control chart is used for calibration.
- If the background value is between the 2σ and 3σ investigation limits, two or more background measurements are performed. If both counts are within the 2σ limits, the average value from the control chart is used for calibration.

INSTRUMENTATION, Continued

	<ul style="list-style-type: none">• If the initial background measurement is outside of the $\pm 3\sigma$ limits, three additional one minute background measurements are performed. If at least two out of the three additional measurements fall within the 2σ limits and the third measurement is less than the 3σ limit, the average value from the control chart is used for calibration.• If the above conditions are not met, then the instrument/detector combination must be removed from service until repairs can be made or the combination is evaluated for changes in instrument operational parameters or other factors. Establishment of a new control chart will then be required following any repair or modifications with the potential to affect the background range.
Operational checks after repairs	<ul style="list-style-type: none">• When repairs are performed that do not affect the instrument efficiency, the instrument may be returned to service after the operational criteria have been met. Repairs that may have altered the efficiency must be followed up with efficiency verification prior to placing the instrument/detector combination back in service.
Laboratory instrument operational checks	<ul style="list-style-type: none">• Operational checks of instruments will be performed prior to each day's use and the results placed on control charts or tables. Original data used to generate control charts will be organized and readily accessible.• Control charts are maintained for critical instrument parameters to provide a means of on-going process capability and stability.• Operational performance will be reviewed and recorded at least weekly for:<ul style="list-style-type: none">—completeness;—conformance with acceptance criteria; and—resolutions or corrective actions.
Laboratory balance operational checks	<ul style="list-style-type: none">• Operational checks of balances will be performed prior to each day's use and recorded in either paper or electronic logbooks.

INSTRUMENTATION, Continued

Field instrument operational checks

The consistent operation of portable instrument/detector combinations used for quantitative measurements is assessed during field activities by the performance of quality control measurements as described below:

- Instruments having results outside established ranges will be removed from service until the discrepancy can be resolved.
 - Data collected between the time valid QC measurements were obtained and when unacceptable results are obtained must be verified or designated as invalid.
 - Background measurements will be performed as follows:
 - Prior to beginning the performance of data measurements and/or scanning for the day;
 - Mid-way through the work day;
 - After completion of measurements and/or scanning for the day;
 - Any time detector contamination is suspected;
 - Any time instrument operation is in question; and
 - Result must fall within the background range established for the site.
 - Check-source measurements will be 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; and
- NOTE:** it is also recommended that check-source measurements be performed at mid-day when feasible.
- Result must fall within the check-source range established for the site.

INSTRUMENTATION, Continued

Calibration frequency and responsibilities

The following table depicts the calibration responsibilities for equipment and instrumentation:

Item	Calibration Frequency	Responsibility
Laboratory Instruments		
Alpha Spectrometers	When new, after repair, and when QC results indicate a need	Laboratory Manager
Gamma Spectrometer	When new, after repair, and when QC results indicate a need	Laboratory Manager
Low Background Alpha and Beta Counters	When new, after repair, and when QC results indicate a need	Laboratory Manager
Liquid Scintillation Counter	When new, after repair, and when QC results indicate a need	Laboratory Manager
Balances	Monthly - in house Annually - professional calibration service	Laboratory Manager
Field Survey Instruments		
Portable Radiological Survey Instruments	Prior to each site survey	Project Leaders
Portable Environmental Survey Instruments	Prior to each site survey	Project Leaders
Pressurized Ionization Chambers	Every 2 years	Laboratory Manager
Pulser	When new and annually thereafter	Laboratory Manager

SECTION 5

SAMPLE CHAIN-OF-CUSTODY

OVERVIEW

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.

In this section

This section covers the following topics:

Topic	Page
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

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.

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

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.
-

Security & transport

- Sample security seals may be placed on the container of samples to ensure container is tamper-proof. The number of the seal must be entered on the chain-of-custody form.
 - 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.
-

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 Relational Database (RDB).
- White copy of form is kept by the Laboratory manager; yellow copy is filed in the project file.

SAMPLE CHAIN-OF-CUSTODY, Continued

Sample archival & disposal

-
- 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.
-
- 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.
-

**ORISE/ESSAP
P.O. BOX 117
OAK RIDGE, TN 37830**

CHAIN-OF-CUSTODY RECORD

EMERGENCY CONTACTS
(865) 576-3561
(865) 241-3242

Site _____ **Sample Type** _____

Samplers_

Note: If more than one name is listed, circle the sample custodian.

[illegible]

Transport Method_____		Seal No._____	
1. Relinquished by:	Date	Time	*Received in good condition by:
2. Relinquished by:	Date	Time	*Received in good condition by:
3. Relinquished by:	Date	Time	*Received in good condition by:
4. Relinquished by:	Date	Time	*Received in good condition by:

*For sample received in unacceptable condition explain in "Remarks" column.

Distribution: Original to individual having custody
Copy filed in field data

SECTION 6

ANALYTICAL QUALITY CONTROL

Overview

Introduction

Quality control (QC) activities are intended to measure the performance of a work process against standards to verify adherence to defined requirements.

In this Section

This section covers the following topics:

Topic	Page
Radiophysical Analysis	2
Radiochemical Analysis	3
Sample Characterization	5
Control Charts	6
Outside Analytical Services	10

RADIOPHYSICAL ANALYSIS

General QC Requirements

- Quality control requirements for radiophysical analysis are presented in the following table.

Quality Control Activity	Frequency	Acceptance Criteria
Background: empty chamber count	Weekly	Within 3 σ of established limits for defined regions of interest and for full spectrum background
Reproducibility Check: count reference material of known activity	Daily	Within 3 σ of known

- 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.
- 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.

Out of control QC results

- Analyses for which quality control results do not meet these guidelines are evaluated by the laboratory staff in conjunction with the Associate Program Director or the Survey Projects Manager. 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 data sheets and project files.

Reporting data

- Analytical data for which quality control results meet these guidelines 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 Associate Program Director or the Survey Projects Manager will be reported.

RADIOCHEMICAL ANALYSIS

General QC Requirements

- 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.
- 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 as follows:
 - Batches consist of samples to be analyzed by the same procedure for a common set of parameters.
 - Batches may contain from 1-20 samples, based on the number of analyses requested, sample matrix, analytical parameters, and the level of QC required.
 - Each batch is assigned a unique identification 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 batch logbook or database.
- Batches will be handled as follows:
 - Analyze samples in a continuous, sequential manner; do not interrupt by processing samples from other batches. Analyze in the same area of the laboratory or facility.
 - Use the same lots of reagents.
- QC samples will be included in batches and evaluated as indicated in the following table:

RADIOCHEMICAL ANALYSIS, Continued

General QC requirements (continued)

Type	Frequency	Acceptance Criteria
Method Blank	One per batch	Established Process Control Limits
Standard	One per batch	1) Analysis value within 20 % of known value. Within 50% of known value for GAB. 2) Uncertainty is \leq 20% of the analysis value.
Chemical Recovery (Yield)	Per sample or at least 1 per batch	30 - 110%

- Definitions:
 - Method Blank - An analytical control, consisting of all reagents and internal standards, that is carried through the entire analytical procedure. The method blank is used to define the level of laboratory background and reagent contamination.
 - Control Standard - NIST traceable materials or other industry accepted standards and reference materials (e.g., NRM, TRM).

Out of control QC results

- Analyses for which quality control results do not meet these guidelines are evaluated by the laboratory staff in conjunction with the Associate Program Director or Survey Projects 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.

Reporting data

- Analytical data for which quality control results meet these guidelines 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 Associate Program Director or the Survey Projects Manager will be reported.

SAMPLE CHARACTERIZATION

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

- Definitions:

Matrix Spike (MS)—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. MS 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.

Replicate—Multiple analyses of an 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.

CONTROL CHARTS

General

- Control charts are maintained for critical laboratory quality control parameters to provide a means for evaluation of on-going process capability and stability.
 - Control charts will be maintained for the following parameters:
 - Count Instrument Backgrounds
 - Chemical Method Blanks
 - Reference Materials
 - Standards
 - Chemical Recovery (Yields)
-

Blanks

- Blanks and background values will be charted as actual values of total activity.
-

Reference materials, standards, & yields

- Radiochemical standards and yield results, regardless of matrix or concentration level, will be charted for specific analytical procedures as a ratio to the known value relative to 1.0.
-

CONTROL CHARTS, Continued

Establishing control charts

- Moving ranges are established using the following equations:

$$\text{Upper Control Limit (UCL}_R\text{)} = (D_4) \times (\bar{R})$$

$$D_4 = 3.268, \text{ for } n = 2$$

$$\text{Central Line (CL}_R\text{)} = \bar{R}$$

$$\text{Lower Control Limit (LCL}_R\text{)} = (D_3) \times (\bar{R})$$

$$D_3 = 0 \text{ for } n = 2$$

$$\bar{R} = \text{Average two point Range}$$

D_3 and D_4 are constants representing an estimate of the standard deviation; constants are provided in standard statistics texts.

Charts of Individual Values (QC Charts)

- Previously generated data are used to establish a chart of individual values allowing initial evaluation of process stability, ongoing evaluation of individual result acceptability, and ongoing evaluation of trends. These charts are generally referred to as QC charts.
- When 30 or more data points are available chart limits will be established as follows:

$$\text{Upper Control Limit (UCL)} = \bar{X} + 3\sigma$$

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

CONTROL CHARTS, Continued

Establishing control charts (continued)

$$\text{Lower Control Limit (LCL)} = \bar{X} - 3\sigma$$

\bar{X} = Average of individual points

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

- When fewer than 30 data points are available limits will be established using the following factors:

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

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

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

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

\bar{X} = Average of individual points

Where d_2 is a constant dependent on sample size. Constants are provided in standard statistics texts.

$$d_2 = 1.128, \text{ for } n = 2$$

- Evaluate the two-point moving range and QC chart to determine whether the process is in control. Points lying outside limits should be investigated.

CONTROL CHARTS, Continued

Establishing control charts (continued)

- If a special cause is identified, a decision is made as to whether the data point(s) truly represent the process. If they are not representative, remove the points from the data set and re-establish control limits using the remaining data.
 - If no special cause is identified the control limits are maintained.
-

Plotting routine data points

- Results are plotted on range and QC charts automatically or by manual entry prior to completion of data review by the Laboratory Manager.
-

Trend analysis

- Trend analysis of QC charts will be performed quarterly by the Quality Manager in conjunction with Laboratory Manager.
- The following conditions will require investigation by the Laboratory Manager:
 - Points outside the control limits
 - Seven consecutive points on the same side of the center line
 - Six or more consecutive points increasing or decreasing
 - Multiple points creating a sawtooth pattern
 - Clustering of points
 - Points hugging the control limits
- Investigation findings, along with follow-up recommendations, will be reported to the Program Director, Assistant Program Director, and Managers by the Laboratory Manager for review and input.
- Follow-up actions will be completed by the Laboratory Manager.
- The investigation and follow-up actions will be documented by the Laboratory Manager.
- Documentation items are considered quality assurance records and will be maintained by the Quality Manager.

OUTSIDE ANALYTICAL SERVICES

- When outside analytical laboratories are utilized, quality control samples are included at a rate consistent with the above requirements. QA/QC requirements, appropriate for the specific project data quality objectives, will be included in the purchase order.
- The Laboratory Manager and the Quality Manager will review the results of the outside analytical services to assure that specified QA/QC requirements have been met, and will document the findings of the review.

SECTION 7

DATA QUALITY CONTROL

Overview

Introduction

Data are collected in support of technical project evaluations. Documentation of such evaluations is summarized in the form of technical reports. Data management procedures are necessary to ensure quality standards are maintained.

In this section

Topic	Page
Data Quality Objectives	2
Data Review	2
Data Types	3
Data Correction	4
Data Validation	4
Data Approval	5

DATA QUALITY CONTROL, Continued

Data quality objectives

- Data must be recorded in a legible manner.
 - Data generation will allow for evaluation of minimum detectable concentrations at the 95% confidence level for analytical results.
 - Detection sensitivities are based on 3 plus 4.65 times the standard deviation of the background count.
 - The number of significant figures used for values included in reports will be representative of procedural limitations.
 - Total propagated uncertainties will be reported.
-

Data review

Data reviews evaluate data for the following:

- Accuracy of recording and transcription
- Procedure compliance
- Completeness
- Precision
- Accuracy of data processing
- Consistency of presentation

Any problems identified in the review process will be resolved prior to release of data for further use.

DATA TYPES

Type of Data	Definition of Data Type	Review Requirements	Comments
Raw Data	Measured values obtained from instrumentation or equipment, or transcription of values obtained from the other sources, e.g. NIST or data provided by other companies.	<ul style="list-style-type: none"> Reviewed by direct supervisor or designee for legibility, completeness, for technical appropriateness, and to determine if appropriate procedures were followed. reviewed prior to completion of a project and performed as soon after completion of a task as practical. document reviews by placing initials or signature and the date on the data sheet. 	
Processed Data	Data obtained from calculation performed either by hand or by using computer programs using raw data and established constants.	<u>Hand processed data</u> <ul style="list-style-type: none"> reviewed for completeness and accuracy by the direct supervisor or designee. a minimum of two hand calculations will be checked for each equation used. document reviews by placing initials or signature and the date on the data sheet. <u>Computer processed data</u> <ul style="list-style-type: none"> a minimum of two hand calculations will be checked for input values prior to release of the program for general use. documentation will consist of computer printouts and hand calculation sheets showing input parameters and results. document reviews by placing initials or signature and the date on the data review sheet. 	Equations not identified in approved procedures must be included in the documentation.
Transcribed Data	Transferring of data from one location to another, e.g. from field forms to tables or from written tables to typed tables.	<ul style="list-style-type: none"> transcribed data will be reviewed for accuracy by the direct supervisor or designee. a minimum of 10% of transcribed items will be checked. document reviews by placing initials or signature and the date on the data sheet. 	

DATA QUALITY CONTROL, Continued

Data correction

- Corrections are noted by striking a single line across the entry, entering the new data, then initialing and dating the correction. Data may not be obliterated using an eraser or white-out.
- Entire data sheets found to be incorrect will be labeled as such, along with date and initials of reviewer.

Data validation

Data validation is an assessment performed independently from the processing of data to:

- Trace and justify activities, analyses, and decisions to assure that all are defensible; and
- Compare a body of data to a set of performance objectives or data quality objectives.

Specific requirements are established for each statement of work. Minimum topics to be addressed are:

- Use of correct procedures;
- Training and certification of personnel;
- Acceptable equipment/instrumentation function within established parameters;
- Complete data reviews;
- Problem resolution;
- Complete documentation; and
- Deficiencies noted during the validation process will be handled according to the ESSAP nonconformance reporting procedure.

DATA QUALITY CONTROL, Continued

Data approval

Authorizations for release of information are required as follows:

- Laboratory Manager reviews data for approval prior to release from the laboratory.
- Final project reports are reviewed by the author, Survey Projects Manager, Laboratory Manager, Quality Manager and Program Director. The Program Director approves report distribution.

SECTION 8

DOCUMENT QUALITY CONTROL

Overview

Introduction

Project plans, reports, and other deliverables must be reviewed and released prior to issuance to the client.

In this section

Topic	Page
Responsibilities	2
Requirements for Reports, Project Plans, and Statements of Work	5
Requirements for General Correspondence	7
Internal Review Positions	8
Draft Report Review Flowchart	10
Final Report Review Flowchart	11

DOCUMENT QUALITY CONTROL

Responsibilities

The table below lists the responsibilities for each area of the review process.

Primary Responsibility/Backup	Duties
Associate Program Director Survey Projects Manager	<ul style="list-style-type: none">• Evaluate technical content, including clarity of presentation;• Determine if project goals were adequately conveyed/met; and• Approve dissemination of plan/report to customer.
Quality Manager/Program Director	<ul style="list-style-type: none">• Verify procedural compliance;• Verify accurate representation of data; and• Assess safety aspects.
Laboratory Manager	<ul style="list-style-type: none">• Evaluate laboratory technical content; and• Verify appropriate end use of laboratory data.
NOTE: Survey Projects Manager reviews are not required for laboratory-specific projects.	
Survey Projects Manager/Project Leader	<ul style="list-style-type: none">• Evaluate technical content, including clarity of presentation;• Evaluate procedural compliance; and• Determine if project goals were adequately conveyed/met.

DOCUMENT QUALITY CONTROL, Continued

Primary Responsibility/Backup	Duties
Office Assistants	<ul style="list-style-type: none">• Proof and compare data in report document (on PC) matches original hardcopy information provided for word processing;• Verify wording or questionable information with the author;• Format report following the standard process established;• Use spell checker and add program-specific terminology to checker for use in preparing reports;• Perform word processing peer reviews of the reports; and• Ensure reproduction services are as requested.
Graphics Coordinator	<ul style="list-style-type: none">• Use consistent approach in formatting illustrations;• Proof and compare data in figures/illustrations match hardcopy provided; and• Verify wording or questionable information with the author.
NOTE: Budgetary reviews apply only to project plans.	
Business Support Analyst	Verify budgetary information
Author	<ul style="list-style-type: none">• Ensure complete and accurate presentation of data;• Ensure completion of all required reviews; and

DOCUMENT QUALITY CONTROL, Continued

Primary Responsibility/Backup	Duties
Author (continued)	<ul style="list-style-type: none">• Ensure resolution of questions/comments prior to request for release of information.
NOTE: copy edit is coordinated by the Program Specialist/Administrative Assistant. Editors are selected from a pool of certified individuals.	
Copy Editor	<ul style="list-style-type: none">• Perform copy edit stressing mechanical elements such as capitalization, spelling, punctuation, grammar;• Evaluate document for consistency with the boilerplate;• Perform language edit to review the way ideas are expressed;• Verify references listed in text to those provided on reference page; and proper use of contract/account numbers and references; and• Evaluate design, format, and quality of final product.

DOCUMENT QUALITY CONTROL, Continued

NOTE: Flow charts are provided at the end of this section for specific draft and final report guidance.

Requirements for reports, project plans, and statements of work

Step	Performed By	Task
1	Author	Create draft.
2	Author	Submit to clerical “In Box” for word processing.
3	Office Assistants	Perform word processing.
4	Office Assistants	Perform word processing review using appropriate checklists and return to author.
5	Author/Office Assistants	Repeat steps 2-4 as necessary, until the document appears as the author thinks the customer should see it.
6	Author	Submit to Administrative Assistant for copy edit.
7	Senior Program Specialist	Identify available certified copy editor.
8	Copy Editor	Perform copy edit, complete copy edit checklist and return to author.
9	Author	Make revisions as deemed appropriate, submit to clerical “In Box” requesting internal review (provide names of reviewers).
10	Office Assistants	Make copies, attach a document review form, and distribute for review. See “Internal Review Positions” section.
11	Reviewers	Perform document review, provide comments to author.
12	Author	Perform comment resolution, submit to clerical “In Box” for revisions.

DOCUMENT QUALITY CONTROL, Continued

Step	Performed By	Task
13	Office Assistants	Perform word processing.
14	Office Assistants	Perform word processing review, return to author.
15	Author	Discuss with Survey Projects Manager or Associate Program Director for approval to release to customer.
16	Author	Submit to clerical "In Box" for distribution to customer.
17	Author	Perform resolution of customer comments. Submit to clerical "In Box" for word processing.
18	Office Assistants	Perform word processing.
19	Office Assistants	Perform word processing review using final report checklist, return to author.
20	Author	Submit to Administrative Assistant for copy edit.
21	Senior Program Specialist	Coordinate copy edit.
22	Copy Editor	Perform copy edit, return to author.
23	Author	Make final revisions, submit to clerical for final preparation and routing for final review and signature. See "Internal Review Positions" section.
24	Office Assistants	Perform final preparation. Attach a document review sheet and route for signature.
25	Office Assistants	Perform word processing review using Final Report checklist.

DOCUMENT QUALITY CONTROL, Continued

Step	Performed By	Task
26	Reviewers	Perform review, bring concerns to the attention of the author, sign and route. Return to clerical "In Box" last.
27	Office Assistants	Prepare document for reproduction.

**Requirements
for
general
correspondence**

Step	Performed By	Task
1	Author	Create draft.
2	Author	Submit to clerical "In Box" for word processing.
3	Office Assistants	Perform word processing.
4	Office Assistants	Perform word processing, review using appropriate checklists and return to author.
5	Author/Office Assistants	Repeat steps 2-4 as necessary.
6	Author	Submit to Administrative Assistant for copy edit.
7	Senior Program Specialist	Identify available certified copy editor.
8	Copy Editor	Perform copy edit, complete copy edit checklist and return to author.
9	Author	Make revisions as deemed appropriate, submit for internal review. See "Internal Review Position" section.
10	Reviewer	Perform document review, provide comments to author.

DOCUMENT QUALITY CONTROL, Continued

11	Author	Perform comment resolution, submit to clerical “In Box” for revisions and preparation of final version.
12	Office Assistants	Prepare final correspondence for signature and distribute.

**Internal
review
positions**

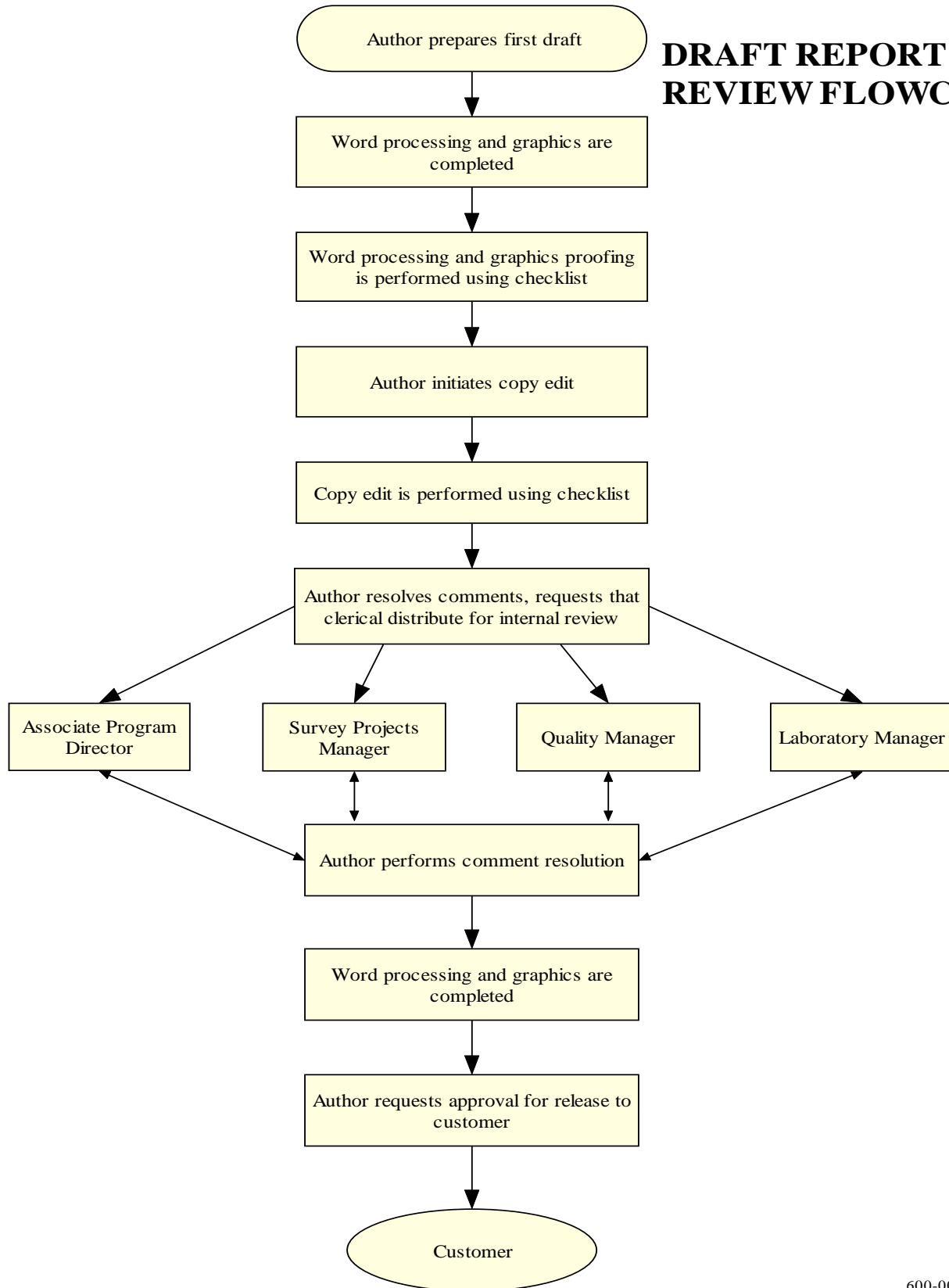
Internal document reviews will be performed by the following positions:

Draft Survey Reports:	Associate Program Director
	Survey Projects Manager
	Laboratory Manager
	Quality Manager
Final Survey Reports:	Program Director
	Associate Program Director
	Survey Projects Manager
	Laboratory Manager
	Quality Manager
Survey/Project Plans:	Associate Program Director and/or Survey Projects Manager
Comment Letters:	Associate Program Director and/or Survey Projects Manager
Laboratory Statements of Work:	Associate Program Director
	Laboratory Manager
Letter Reports—Survey:	Associate Program Director
	Survey Projects Manager
	Laboratory Manager
	Quality Manager

DOCUMENT QUALITY CONTROL, Continued

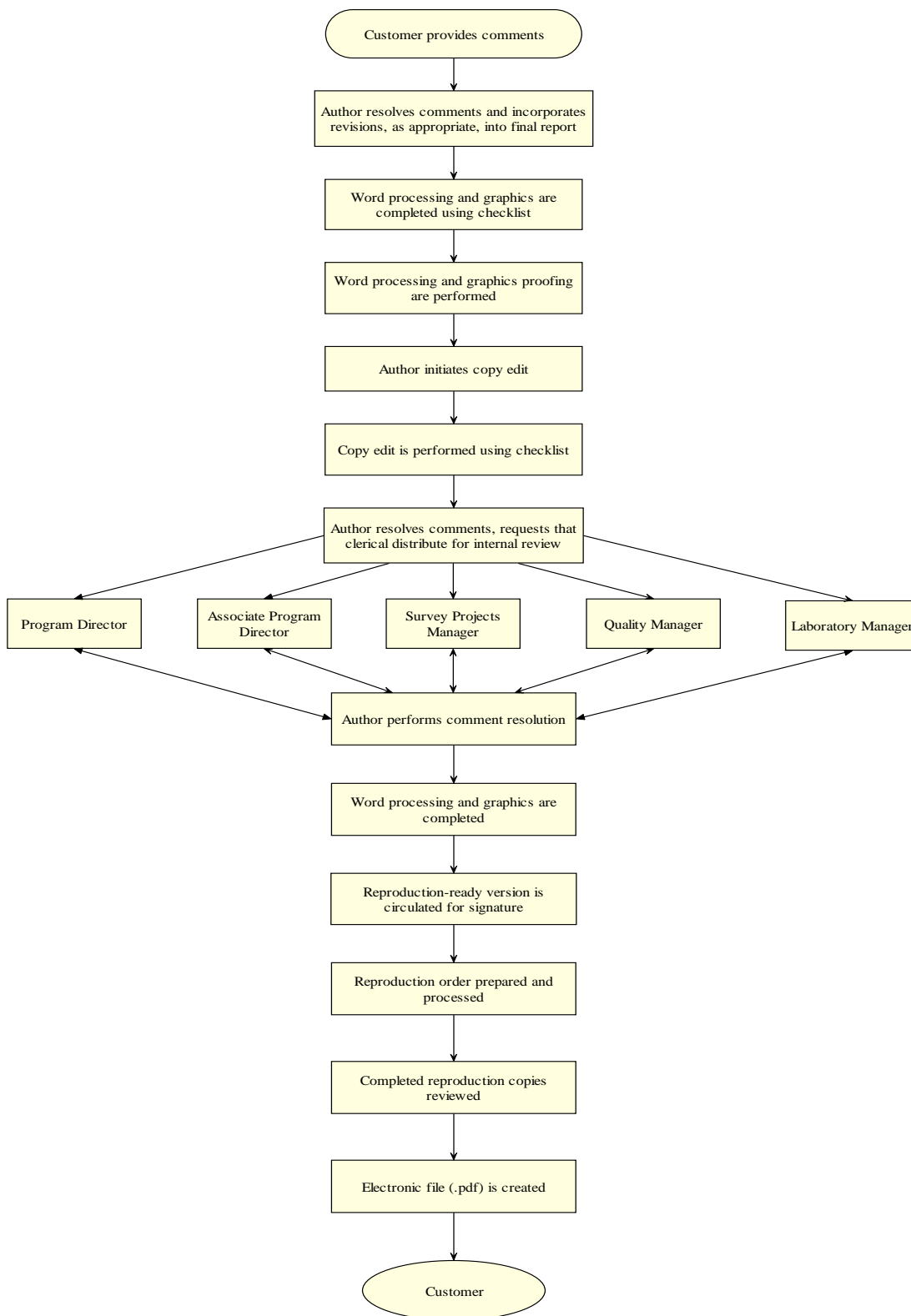
Letter Reports - Laboratory:	Associate Program Director
	Laboratory Manager
	Quality Manager
General Correspondence:	Cognizant Manager,
	OR Associate Program Director
	OR Program Director

DRAFT REPORT REVIEW FLOWCHART



600-007.sdr

FINAL REPORT REVIEW FLOWCHART



SECTION 9

NONCONFORMANCE SYSTEM

OVERVIEW

Introduction

A nonconformance (NC) is an item or process that does not meet established or expected requirements, or any occurrence that adversely affects the quality of products. Requirements are defined in ESSAP procedure manuals, however, manufacturer's specifications, worker experience, and industry standards may also be used to identify a condition adverse to quality.

In this section

Topic	Page
Responsibilities	2
Procedure	3
Electronic Nonconformance Database	6
Nonconformances Identified On Field Work Sites	6
Nonconformances Received from Other Organizations	7
Reporting Requirements	7
Nonconformance System Process Overview	8

NONCONFORMANCE SYSTEM

Responsibilities

The responsibilities for nonconformance reporting are provided in the following table:

Position	Nonconformance (NC) Responsibility
Managers	<ul style="list-style-type: none">• review the NC description in nonconformance reports (NCR) for clarity and completeness;• initiate “HOLD” tags, as necessary;• assist in root cause analysis, if necessary; and• assign responsibility for nonconformances, including desired completion date.
Quality Manager	<ul style="list-style-type: none">• review NCRs for clarity and completeness of all information;• determine appropriateness of NC designation;• assign NC tracking code;• recommend assignments and completion dates for NC resolution;• approve proposed corrective actions;• perform root cause analysis, if necessary;• determine need for follow-up testing of equipment, instruments, or procedures;• follow up on corrective actions and verify completion of NC items;• ensure database entry is performed;• issue quarterly reports; and• conduct training when deemed necessary.

NONCONFORMANCE SYSTEM, Continued

Position	Nonconformance (NC) Responsibility
Assignee	<ul style="list-style-type: none">• accept responsibility for NC items, as assigned;• determine probable cause of NC items;• assist in root cause analysis, if necessary;• submit a proposed corrective action plan to the Quality Manager;• complete approved corrective action plans; and• report completion of the corrective action plan to the Quality Manager.
All Employees	<ul style="list-style-type: none">• identify nonconformances;• assist in root cause analyses as requested; and• assist in performing corrective actions, as required.

Refer to the flowchart on page 9 of this section.

Procedure

Step	Action
1	Identify nonconformance and submit information to Manager.
2	Manager reviews the information for clarity and completeness of the description and forwards to the Quality Manager. The Quality Manager enters the information into the database.
3	Manager determines the need for placement of a "HOLD" tag. If a hold tag is necessary, the Manager informs the Quality Manager who enters the date into the database.

NONCONFORMANCE SYSTEM, Continued

Step	Action																				
3 (continued)	<p>HOLD tag is placed if:</p> <p>Continued operation of related equipment or instrumentation could cause harm to personnel or property</p> <p>Continued operation could cause recurrence of the nonconformance.</p> <p>NOTE: Tag may not be removed until the Quality Manager verifies closure of the nonconformance.</p>																				
4	Quality Manager enters review date and hold tag information into database.																				
5	<p>Quality Manager assigns a tracking code using the following designations:</p> <table> <thead> <tr> <th><u>Program Groups</u></th><th><u>Categories</u></th></tr> </thead> <tbody> <tr> <td>R-Radiochemical</td><td>1-Program</td></tr> <tr> <td>C-Counting</td><td>2-Training and Qualification</td></tr> <tr> <td>F-Field Projects</td><td>3-Quality Improvement</td></tr> <tr> <td>A-Administrative</td><td>4-Documents and Records</td></tr> <tr> <td></td><td>5-Work Processes</td></tr> <tr> <td></td><td>6-Design</td></tr> <tr> <td></td><td>7-Procurement</td></tr> <tr> <td></td><td>8-Inspection and Acceptance Testing</td></tr> <tr> <td></td><td>9-Management Assessment</td></tr> </tbody> </table>	<u>Program Groups</u>	<u>Categories</u>	R-Radiochemical	1-Program	C-Counting	2-Training and Qualification	F-Field Projects	3-Quality Improvement	A-Administrative	4-Documents and Records		5-Work Processes		6-Design		7-Procurement		8-Inspection and Acceptance Testing		9-Management Assessment
<u>Program Groups</u>	<u>Categories</u>																				
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	5-Work Processes																				
	6-Design																				
	7-Procurement																				
	8-Inspection and Acceptance Testing																				
	9-Management Assessment																				

NONCONFORMANCE SYSTEM, Continued

Step	Action				
5 (continued)	<table><tr><td><u>Program Groups</u> (continued)</td><td><u>Categories</u> (continued)</td></tr><tr><td colspan="2">10-Independent Assessment</td></tr></table>	<u>Program Groups</u> (continued)	<u>Categories</u> (continued)	10-Independent Assessment	
<u>Program Groups</u> (continued)	<u>Categories</u> (continued)				
10-Independent Assessment					
6	Quality Manager enters code and item number into database.				
7	Manager assigns responsibility for the nonconformance and notifies the Quality Manager who enters the assignment into the database.				
8	If a probable cause is evident, the assignee notifies the Quality Manager.				
9	Assignee submits the recommended corrective action plan and proposed completion date to the Quality Manager.				
10	<p>Quality Manager reviews the corrective action plan to ensure that the root cause will be fully addressed, possibility of recurrence will be minimized, and testing required as evidence of complete resolution is included in the plan.</p> <p>If plan is accepted:</p> <p>Quality Manager enters "Accepted" into the "Corrective Action Plan" field indicating approval.</p> <p>If plan is unacceptable:</p> <p>Quality Manager requests a revised corrective action plan from the assignee.</p>				
11	Assignee completes the corrective action plan items, notifying the Quality Manager of status as information becomes available.				

NONCONFORMANCE SYSTEM, Continued

Step	Action
12	Quality Manager ensures status update information is entered into the tracking database.
13	When corrective action items have been completed the assignee notifies the Quality Manager.
14	Quality Manager verifies successful completion, marks the item closed on the form and in the database, and notifies the Manager.

Electronic Nonconformance Database

- Nonconformance reporting is documented in an electronic database.
 - The Quality Manager has overall responsibility for maintenance of the Nonconformance Database.
-

Nonconformances identified on field work sites

- Nonconformances affecting the outcome of activities on field sites should be corrected prior to completion of on-site activities.
- The site coordinator determines probable cause, corrective action, and any retesting requirements necessary to assure that completion of corrective actions has been successful.
- Quality Manager is contacted as necessary to assist with resolution of concerns.
- Nonconformance report is submitted to Quality Manager upon return to ESSAP.
- Quality Manager will assign tracking code and enter information in the tracking database.

NONCONFORMANCE SYSTEM, Continued

**Nonconformances
received from
other
organizations**

- Nonconformances received from other organizations concerning ESSAP activities will be forwarded to the Quality Manager for handling according to the same procedure.
-

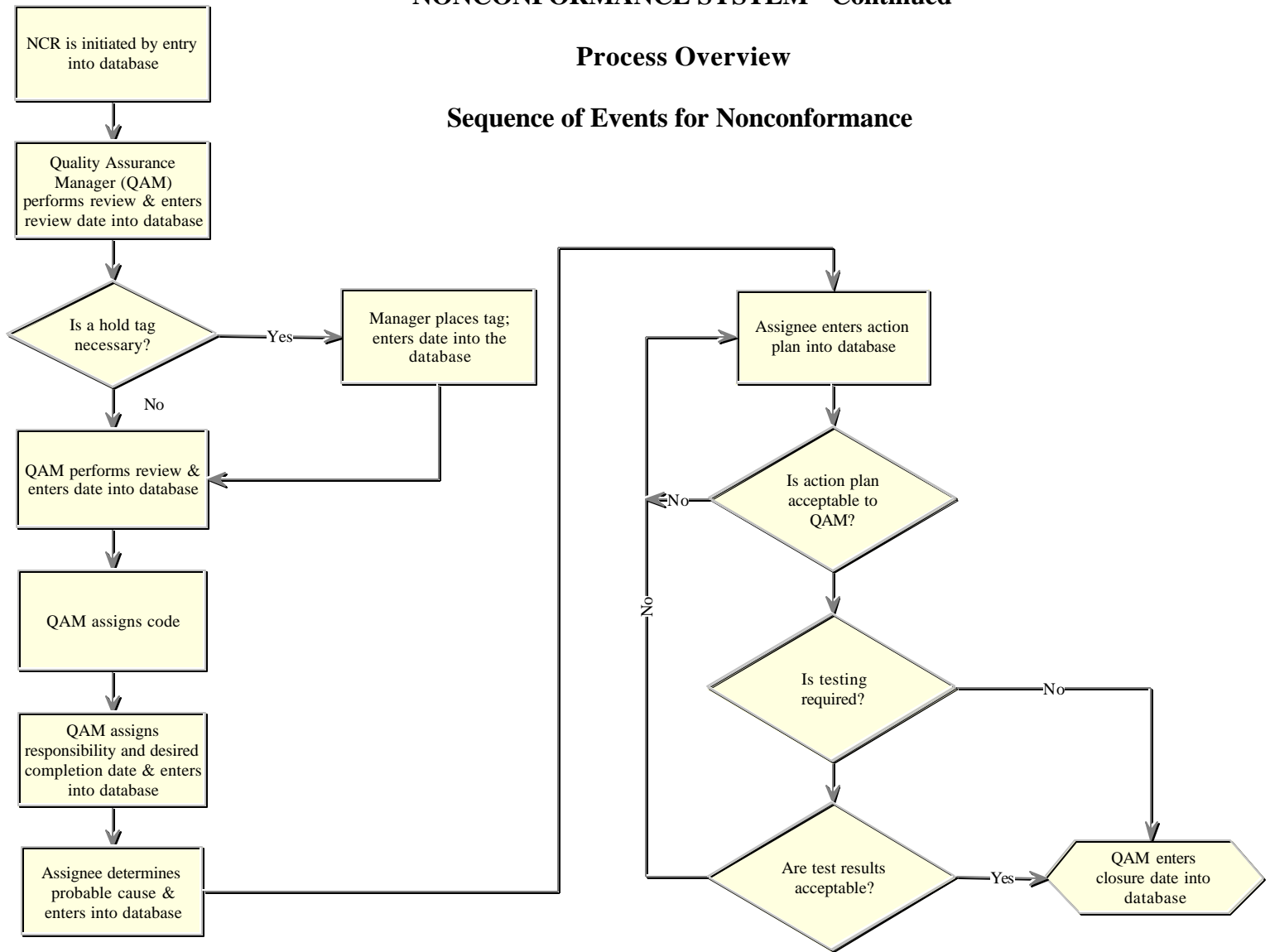
**Reporting
requirements**

- The Quality Manager will provide quarterly summary reports to Managers, the Assistant Program Director, and Program Director. Quarterly reports will include an evaluation for potential trends in nonconformances.
 - Nonconformance information will be provided to customers as necessary to ensure project requirements are met, or on request.
-

NONCONFORMANCE SYSTEM - Continued

Process Overview

Sequence of Events for Nonconformance



SECTION 10

SERVICE ORGANIZATION SUPPORT

OVERVIEW

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.

In this section

Topic	Page
Facility Services	2
Procurement Services	2
Shipping, Handling, and Storage Services	3

CRITICAL RECORD HANDLING AND STORAGE, Continued

Facility services

- Facility design and maintenance are coordinated with the Facilities Management Section in compliance with government regulations approved by the Safety and Environmental Protection Department.
- 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 Safety and Environmental Protection Department 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 Safety and Environmental Protection Department.

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.

CRITICAL RECORD HANDLING AND STORAGE, Continued

Shipping, handling, and storage services

- Shipping, handling, and storage of items is coordinated with the Safety and Environmental Protection Department and the Facilities and Transportation Department.
- Specific handling and storage requirements for equipment, instrumentation and supplies are identified in appropriate ESSAP or Safety and Environmental Protection Department 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

OVERVIEW

Introduction

ESSAP maintains all documentary materials, termed "critical records." Critical Records are defined as 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.

In this section

This section covers the following topics:

Topic	Page
Responsibility and Ownership	2
Record Completion Standards	2
Field Records	3
Document Requirements at Field Sites	4
Document Transport	4
Scarboro Building Record Control	5
Laboratory Records	6
Laboratory Record Locations	6
Quality Assurance Records	7
Archival of Records	7
Disposal	8
Check Out/Check In	8
Lost Items	8
Miscellaneous	8
Borrowed Records	9
ESSAP Request for Record Archival Form	10

CRITICAL RECORD HANDLING AND STORAGE, Continued

Responsibility and ownership

- The cognizant project supervisor determines the critical nature of records.
 - Original field and laboratory data are the property of the funding organization.
 - If they require these original materials, copies will be retained for ESSAP files.
 - Manager will determine when limited access is required for electronic or hard copy files or folders.
-

Records completion standards

- Critical Records will be legibly written in ink. **NOTE:** drawings and maps may first be drawn in pencil but must be made permanent by tracing in ink or producing a photocopy prior to the addition of data to the page.
- Photocopies must be marked as "originals".
- Critical Records must be dated and signed to be valid.
- Data in critical records shall not be obliterated by erasing or using white-out. Incorrect entries shall be corrected by striking a single line across the entry. The correction shall be entered, initialed and dated.
- Changes to column headings or requested information on record forms that are inappropriate for specific situations must be modified to meet the requirements of the task.
- If information requested on a form or in a formatted logbook is not applicable, the appropriate space or columns must be marked as such by noting "NA" or by crossing through them as an indication that such information was not applicable, rather than having possibly been forgotten.

CRITICAL RECORD HANDLING AND STORAGE, Continued

Field records

-
- Critical field records include, but are not limited to:
 - Requests for Technical Assistance (RFTA);
 - Survey plans;
 - Survey plan approval forms;
 - Site logbooks;
 - Field data sheets;
 - Calibration data sheets;
 - Daily check-out sheets;
 - Field drawings;
 - Chain-of-custody (yellow carbon copy) forms;
 - Field certification documentation;
 - Source certification sheets;
 - Computer files for tracking calibration frequency.
 - Original instrument calibration and maintenance records are kept in the instrument room files at all times until such time as archival is requested.
 - Field Site logbooks must contain the following information:
 - Full name of the site
 - Project tracking number(s)
 - Funding Agency
 - Site contact name and phone number
 - Agency representative name and phone number
 - Directions to the site
 - Brief description of project goal
 - Date of Entry
 - Signature of individual completing the entry
 - Preliminary site visit information; when applicable
 - List of personnel on site, e.g. ESSAP, agency representatives
 - Work hours
 - Designated site supervisor if different than specified in the survey plan

CRITICAL RECORD HANDLING AND STORAGE, Continued

Field records

(continued)

- Sample screening plan
- Health and safety issues
- Weather conditions (for outside surveys)
- Site conditions which adversely affect survey performance, personnel safety
- Summary of the days survey activities
- Deviations to plan or procedures, reason for deviations, affect on overall survey outcome, concurrence given by funding agency
- Number and types of samples collected, sample numbers used

Document requirements at field sites

- The initiator is responsible for a record until a task is complete. The site coordinator is responsible for completed field records and for reviewing all data for accuracy and completeness before on-site activities are concluded.
- When not in use, records and/or the site file will be kept in the possession of the site coordinator, a container that can be sealed or locked such as a zero case, portable file or vehicle.
- Upon completion, field records will be placed in the site file and are the responsibility of the site coordinator.
- The site coordinator will document the review by dating and initialing, or signing each data sheet. Documentation may also be accomplished by a site logbook entry including a summary of the data reviewed, the signature of the reviewer and the review date.

Document transport

- Upon completion of on-site activities, records are transported to Scarboro building either in the possession of the site coordinator or his/her designee or by a traceable method of shipment.

If possible, critical records should be transported in the possession of program personnel. If items are shipped, documentation of the shipment must be included in the site file.

CRITICAL RECORD HANDLING AND STORAGE, Continued

Scarboro building control

Site coordinator initiates inventory of critical records and enters information on record inventory sheet. Record inventory sheet is maintained in project file.

The Scarboro Building remains locked at all times. Active files in the facility are the responsibility of the site coordinator or their designee while in use.

CRITICAL RECORD HANDLING AND STORAGE, Continued

Laboratory records

Critical laboratory records include, but are not limited to:

- Statements of Work
- Lab analysis sheets
- Laboratory training certification
- Analytical standard certification documentation
- Certification documents for standard weight sets
- Lab survey documentation
- Balance logs
- Batch logs
- Chain-of-custody (white original) forms
- Instrument calibration and operational check records
- Computer disks/tapes
- Computer files for tracking calibration frequency

Laboratory record locations

Category	Record	Location
General	Original Records While work is ongoing	Possession of initiator
	Upon completion of task	Chemist's office.
Analytical Instrument and Balances	Control charts and logs of current daily instrument operational checks.	With instrument.
	Completed control charts, calibration, and maintenance records.	Laboratory Manager's files.
	Survey instrument calibration and maintenance records.	Instrument room files.
Standards	Certification documentation for analytical standards.	Laboratory Manager's files.
	Certification documentation for standard weight sites.	Laboratory Manager's files.

CRITICAL RECORD HANDLING AND STORAGE, Continued

Category	Record	Location
Chain-of-Custody	Original Chain-of-Custody	Chemist's office.
Spectra	Spectra Records from Alpha and Gamma Spectrometers	Laboratory Manager's Office

Quality assurance records

- Critical QA records include but are not limited to:
 - On-the-job training files
 - Audit reports and follow-up documentation
 - Performance evaluation results and associated documentation
 - Records for the current and previous calendar year are maintained in the Quality Managers Office. Less current information is archived.
-

Archival of records

- Critical project records including any pertinent clerical files, will be archived for permanent storage within three months of final product release to the funding agency, i.e. the final report or final analytical results.
- Critical records will be retained for a minimum of seven years past the date of the final project report. The retention time for a particular record will be determined based on the status of activities associated with the project.
- A "Request for Archival" form shall be submitted to the Archival Coordinator (see Figure pages 9 & 10).
- The Archival Coordinator will verify the contents of the site file based on the inventory list on the form and acknowledge receipt of the file by signing the form. Record information will be entered into the electronic database.
- When archival is complete, the "Request for Archival" form will be signed and dated by the Archival Coordinator.
- File storage locations (file cabinet number and drawer number) will be noted on the form and then filed in alphabetical order by site name and are kept in a binder in the archive room.

CRITICAL RECORD HANDLING AND STORAGE, Continued

Archival of records (continued)

- Records will be stored in the Scarboro Facility in an access controlled area constructed to meet DOE, NRC and ORISE records storage requirements.
 - Supplements to archived files will be handled in the same manner as original files.
-

Disposal

- Disposal of records is under the authority of the Program Director or the Associate Program Director only and requires the approval of the funding agency for the individual project.
-

Check out/ check in

- Removal of material from the archive files for any reason should be accomplished through the Archival Coordinator. A logbook is kept identifying the site title, the material removed, date removed, individual responsible for the material while it is out, and the date it is returned to the file. The Archival Coordinator will acknowledge the removal and return of all material by initialing each date.
-

Lost items

- Report lost items to the Site Coordinator.

If possible, lost items should be replaced or restored. If this is not feasible, an attempt should be made to add documentation to the file that describes the item and summarizes the lost information based on other available information.

A record of the loss will be added to the project logbook.

Miscellaneous

- Certification and training records are kept by the Quality Manager in individual personnel files.
- Chain-of-custody records must be handled according to Section 5.
- Laboratory standard certificates will be filed and stored in the appropriate (radiochemical or non-radiochemical) Laboratory Supervisors office.

CRITICAL RECORD HANDLING AND STORAGE, Continued

Miscellaneous (continued)

- Field instrument calibration source certificates are filed and stored in the instrument room files.
 - Critical records not associated with a specific project will be archived for permanent storage at the request of the cognizant supervisor.
-

Borrowed records

- Critical records generated by other organizations that will be in ESSAP's possession for a limited time will be handled as follows:
- The inventory must be verified upon receipt and again prior to returning the shipment to the owner. The individual responsible for verifying the inventory will sign and date the inventory list.
- A copy of the inventory list, indicating that both verifications have occurred, will be included in the site 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: _____

ESSAP Task: _____

Funding Org.: _____ Project No.: _____ Task Number: _____

Project Supervisor: _____ Status: _____

Project Contact(s)/Phone: _____

Survey Date Started: _____ Survey Date Completed: _____

Contaminants: _____

Sites for Cross Reference: _____

Final Report(s): _____

Release Guidelines: _____

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: _____	
Archival Complete: _____		
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 Measurements	<input type="checkbox"/> PIC Tracking Form
<input type="checkbox"/> Borehole Logging & Sampling	<input type="checkbox"/> PIC Calibration Curve
<input type="checkbox"/> Calibration Data - Alpha/Beta	<input type="checkbox"/> PIC Field Check Out 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	<input type="checkbox"/> Sample Log Book Copies
<input type="checkbox"/> Drawings	<input type="checkbox"/> Stack Velocity Worksheet
<input type="checkbox"/> Electronic Calibration Record	<input type="checkbox"/> Stack Sampling Rate Worksheet
<input type="checkbox"/> ESSAP Report (Draft or Final)*	<input type="checkbox"/> Stack Sampling Record
<input type="checkbox"/> ESSAP Correspondence	<input type="checkbox"/> Surface Activity Survey
<input type="checkbox"/> Exposure Rate Measurements and Samples	<input type="checkbox"/> Survey Plan*
<input type="checkbox"/> Exposure Rate Calibration Data	<input type="checkbox"/> Systematic/Random Surface Measurements
<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	

*Required

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

SECTION 12

PERFORMANCE ASSESSMENT

OVERVIEW

Introduction

Assessments of ESSAP activities are performed to ensure continuing adequacy and effectiveness toward meeting customer project objectives.

In this section

This section covers the following topics:

Topic	Page
Project File Reviews	2
Laboratory Performance Evaluation	2
Independent Audits	3
Audit Follow-up	3

PERFORMANCE ASSESSMENT, Continued

Project file reviews

- Areas/tasks critical to project success have been identified.
 - Once basic project work has been completed, a project file review (PFR) is conducted.
 - A checklist is used to ensure all critical tasks are reviewed.
 - Items that do not meet requirements are referred to the Survey Projects Manager and/or the Laboratory Manager for resolution.
 - All items not meeting requirements will be addressed prior to release of final deliverable to the customer.
 - A minimum of twenty-five percent of project files will be reviewed.
 - Projects will be chosen for review according to the sequence in which project tracking numbers are established. Reviews will also be performed when requested by customers.
 - Documentation of reviews will be maintained with the project file and in a central QA file.
-

Laboratory performance evaluation

- The ESSAP laboratory participates in the following performance evaluation (PE) programs:
 - Department of Energy Environmental Measurements Laboratory (EML)
 - Department of Energy Mixed Analyte Performance Evaluation Program (MAPEP)
 - Department of Energy Radiological and Environmental Science Laboratory (RESL) Intercomparison
 - National Institute of Standards and Technology Radiochemistry Intercomparison Program
 - NIST Radiochemistry Intercomparison Program
- Analysis of performance evaluation samples is given highest priority in laboratory schedules.
- Performance evaluation sample types are chosen to correspond with the media and nuclides routinely processed by the ESSAP laboratory.

PERFORMANCE ASSESSMENT, Continued

Laboratory performance evaluation (continued)

- Results that do not fall within the limits defined as acceptable by the evaluation program report will be investigated at the earliest possible time. Such circumstances will constitute a nonconformance. 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.
- Documentation of re-analysis and evaluations of results will be included in the nonconformance file.
- Results within acceptable limits as defined by the performance evaluation report but in warning ranges may be re-analyzed at the discretion of the Laboratory Manager, or the direction of the Program Director.
- Performance evaluation program results will be tracked on control charts. The ratio of ESSAP results/known values will be charted along with the total propagated error of the ratio, when error values are made available by the evaluation program.
- Summary reports will be provided to customers on request.
- The Quality Manager maintains all PE files including an electronic database.

Independent audits

- Independent audits may occur at any time by contracting organizations.
- If an independent audit has not occurred over a two year period one will be initiated by invitation.

Audit follow-up

- Response to assessment/audit findings will be initiated in a timely manner.
- Findings will be tracked through completion, as defined by corrective action requirements.
- Records of audits, findings, and closures will be kept in the Quality Manager's office or record archival.